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DEPARTMENT OF TREASURY

Office of the Comptroller of the Currency

12 CFR Part 3

[Docket ID OCC–2014–0025]

RIN 1557–AD88

FEDERAL RESERVE SYSTEM

12 CFR Part 217

[Regulation Q; Docket No. R–1502]

RIN 7100–AE 24

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Part 324

RIN 3064–AE12

Regulatory Capital Rules: Regulatory Capital, Final Revisions Applicable to Banking Organizations Subject to the Advanced Approaches Risk-Based Capital Rule

AGENCIES: Office of the Comptroller of the Currency, Treasury; the Board of Governors of the Federal Reserve System; and the Federal Deposit Insurance Corporation.

ACTION: Final rule.

SUMMARY: The Office of the Comptroller of the Currency (OCC), the Board of Governors of the Federal Reserve System (Board), and the Federal Deposit Insurance Corporation (FDIC) are adopting a final rule to clarify, correct, and update aspects of the regulatory capital framework applicable to certain large, internationally active banking organizations. The revisions correct technical and typographical errors and clarify certain requirements of the advanced approaches risk-based capital rule based on observations made by the agencies during the parallel run review process of advanced approaches banking organizations. The corrections also enhance consistency of the agencies' advanced approaches risk-based capital rule with relevant international standards. The agencies proposed these changes in a notice of proposed rulemaking that was published in the **Federal Register** on December 18, 2014. The agencies are now adopting the proposed rule as final with some additional clarifications and amendments.

DATES: This rule is effective on October 1, 2015.

FOR FURTHER INFORMATION CONTACT:

OCC: Margot Schwadron, Senior Risk Expert (202) 649–6982; or Mark Ginsberg, Principal Risk Expert (202) 649–6983, Capital Policy; or Kevin Korzeniewski, Senior Attorney, Legislative and Regulatory Activities Division, (202) 649–5490, for persons who are deaf or hard of hearing, TTY, (202) 649–5597, Office of the Comptroller of the Currency, 400 7th Street SW., Washington, DC 20219.

Board: Constance M. Horsley, Assistant Director, (202) 452–5239; Juan Climent, Manager, (202) 872–7546; Andrew Willis, Supervisory Financial Analyst, (202) 912–4323, Matthew McQueeney, Senior Financial Analyst, (202) 425–2942, or Justyna Milewski, Senior Financial Analyst, (202) 452–3607, Capital and Regulatory Policy, Division of Banking Supervision and Regulation; or Christine Graham, Counsel (202) 452–3005; or David W. Alexander, Counsel (202) 452–2877, Legal Division, Board of Governors of the Federal Reserve System, 20th and C Streets NW., Washington, DC 20551. For the hearing impaired only, Telecommunication Device for the Deaf (TDD), (202) 263–4869.

FDIC: Bobby R. Bean, Associate Director, *bbean@fdic.gov*; Ryan Billingsley, Chief, Capital Policy Section, *rbillingsley@fdic.gov*; or Benedetto Bosco, Capital Markets Policy Analyst, *bbosco@fdic.gov*; Capital Markets Branch, Division of Risk Management Supervision, (202) 898–6888; or Michael Phillips, Counsel, *mphillips@fdic.gov*; Rachel Ackmann, Senior Attorney, *rackmann@fdic.gov*; Supervision Branch, Legal Division, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429.

SUPPLEMENTARY INFORMATION:

I. Background

In 2013, the Office of the Comptroller of the Currency (OCC), the Board of Governors of the Federal Reserve System (Board), and the Federal Deposit Insurance Corporation (FDIC) (collectively, the agencies) comprehensively revised and strengthened the capital requirements applicable to banking organizations [1] (regulatory capital framework).[2] Among other changes, the regulatory capital framework revised elements of the advanced approaches risk-based capital rule (advanced approaches rule) now located at subpart E of the agencies' revised regulatory capital framework.[3]

The advanced approaches rule applies to large, internationally active banking organizations, generally those with $250 billion or more in total consolidated assets or $10 billion or more in total on-balance sheet foreign exposure, depository institution subsidiaries of those banking organizations that use the advanced approaches rule, and banking organizations that elect to use the advanced approaches rule (advanced approaches banking organizations).[4] Before an advanced approaches banking organization may use the advanced approaches rule to determine its risk-based capital requirements, it must conduct a satisfactory parallel run.[5] After the primary Federal supervisor determines that the banking organization fully complies with all the qualification requirements, has conducted a satisfactory parallel run, and has an adequate process to ensure ongoing compliance, the banking

[1] The term *banking organizations* includes national banks, state member banks, state nonmember banks, savings associations, and top-tier bank holding companies domiciled in the United States not subject to the Board's Small Bank Holding Company Policy Statement (12 CFR part 225, appendix C), as well as top-tier savings and loan holding companies domiciled in the United States, except for certain savings and loan holding companies that are substantially engaged in insurance underwriting or commercial activities.

[2] The Board and the OCC issued a joint final rule on October 11, 2013 (78 FR 62018) and the FDIC issued a substantially identical interim final rule on September 10, 2013 (78 FR 55340). In April 2014, the FDIC adopted the interim final rule as a final rule with no substantive changes. 79 FR 20754 (April 14, 2014).

[3] 12 CFR part 3 (OCC), 12 CFR part 217 (Board), and 12 CFR part 324 (FDIC).

[4] 12 CFR 3.100(b)(1) (OCC), 12 CFR 217.100(b)(1) (Board), and 12 CFR 324.100(b)(1) (FDIC).

[5] 12 CFR 3.121(c) (OCC), 12 CFR 217.121(c) (Board), and 12 CFR 324.121(c) (FDIC).

organization will be required to use the advanced approaches rule to calculate its risk-based capital requirements.[6]

An advanced approaches banking organization that is required to calculate its risk-based capital requirements under the advanced approaches rule also must determine its risk-based capital requirements under the standardized approach in subpart D of the agencies' regulatory capital framework.[7] In accordance with section 171 of the Dodd-Frank Act, the lower ratio (*i.e.,* the more binding ratio) for each risk-based capital requirement is the ratio the banking organization must use for regulatory capital purposes.

II. Proposed Rule and Summary of Comments

In December 2014, the agencies invited comment on a notice of proposed rulemaking designed to clarify, correct, and update aspects of the regulatory capital framework applicable to advanced approaches banking organizations (proposed rule).[8] The proposed revisions were largely driven by observations made by the agencies during the parallel run review process of advanced approaches banking organizations, and included corrections to typographical and technical errors, clarifications and updates in light of revisions to other rules. The proposed revisions were also intended to enhance consistency of the agencies' advanced approaches rule with relevant international standards.[9] The proposed amendments affect only those provisions of the revised capital framework that apply to advanced approaches banking organizations.

The agencies received two comment letters on the proposed revisions—one from a financial services trade association, and another from a public advocacy nonprofit organization. The financial services trade association suggested that several of the proposed changes also be applied to the standardized approach. Both commenters expressed views on the proposed treatment of cleared transactions. The financial services trade association suggested that the agencies expand the proposed treatment, while the public advocacy nonprofit organization suggested that the proposed treatment was too generous. In addition, the public advocacy nonprofit organization disagreed with the proposed exemption for cleared transactions from the higher capital charge applicable to large nettings sets.

III. Overview of the Final Rule

1. Definitions and Applicability

A. Definition of Residential Mortgage Exposure

The proposed rule would have revised the definition of *residential mortgage exposure* in section 2 of the regulatory capital framework to clarify that an advanced approaches banking organization must manage qualifying exposures as part of a segment of exposures with homogenous risk characteristics, and not on an individual basis, for purposes of classifying an exposure as a residential mortgage exposure under the advanced approaches rule. This clarification was consistent with the agencies' intent in adopting the proposed definition of residential mortgage exposure, and with the requirement that an advanced approaches banking organization have an internal system that groups retail exposures into the appropriate retail exposure subcategory and that groups the retail exposures in each retail exposure subcategory into separate segments with homogenous risk characteristics.[10] The agencies did not receive any comments on this part of the proposed rule and are adopting it as final, with a technical edit to correct a grammatical error.

B. Calculation of Total On-Balance Sheet Foreign Exposure

As mentioned above, the advanced approaches rule generally applies to a banking organization with $250 billion or more in total consolidated assets or $10 billion or more in on-balance sheet foreign exposure. The proposed rule would have updated the method of calculating on-balance sheet foreign exposure to reference the current line items on the regulatory reporting forms. The agencies did not receive any comments on this part of the proposed rule and are adopting it as final, with a technical edit to update a reference to the Federal Financial Institutions Examination Council (FFIEC) 009 Report instead of referencing the Call Report.

2. Disclosure Requirements

A. Disclosure Requirements for Advanced Approaches Banking Organizations

Section 173 of the regulatory capital framework requires advanced approaches banking organizations that have completed the parallel run process to provide qualitative and quantitative disclosures relating to their capital requirements. The proposed rule would have clarified two items related to disclosure requirements in the advanced approaches rule.

First, the proposed rule would have clarified that an advanced approaches banking organization would be required to disclose information related to external ratings in Table 6 to section 173 only if it considered external ratings in its internal ratings approach. An advanced approaches banking organization that did not use or consider external ratings would not be required to make such a disclosure.

Second, the proposed rule would have updated the disclosure requirement related to securitization exposures in Table 9 to reflect the treatment of credit-enhancing interest only strips (CEIOs) and after-tax gain-on-sale resulting from a securitization. Specifically, CEIOs that do not constitute after-tax gain-on-sale would be risk-weighted at 1,250 percent, and an after-tax gain-on-sale resulting from a securitization would be deducted from common equity tier 1 capital, rather than from tier 1 capital. The agencies did not receive any comments on this part of the proposed rule and are adopting it as final.

B. Application and Disclosure of the Supplementary Leverage Ratio

Advanced approaches banking organizations are subject to the supplementary leverage ratio.[11] The agencies proposed to clarify that the supplementary leverage ratio would apply to an advanced approaches banking organization, regardless of whether it had completed its parallel run process. The supplementary leverage ratio described in section 10(c)(4) would begin to apply to a banking organization immediately following the quarter in which the banking organization becomes subject to the advanced approaches rule pursuant to section 100(b)(1) of the advanced approaches rule.

In addition, the agencies proposed to clarify the disclosure requirements

[6] 12 CFR 3.121(d) (OCC), 12 CFR 217.121(d) (Board), and 12 CFR 324.121(d) (FDIC).

[7] *See* 12 CFR part 3.10(c) (OCC); 12 CFR part 217.10(c) (Board); and 12 CFR part 324.10(c) (FDIC).

[8] *See* 79 FR 75455 (Dec. 18, 2014).

[9] *See* International Convergence of Capital Measurement and Capital Standards: A Revised Framework,'' (June 2006) *http://www.bis.org/publ/bcbs128.htm.*

[10] *See* 12 CFR 3.122(b)(3) (OCC), 12 CFR 217.122(b)(3) (Board), and 12 CFR 324.122(b)(3) (FDIC).

[11] *See* section 10(c)(4)(ii) of the regulatory capital framework and 79 FR 57725 (Sept. 26, 2014) (2014 SLR rule).

applicable to advanced approaches banking organizations.[12] The proposed rule clarified that advanced approaches banking organizations, not just top-tier banking organizations, would be required to publicly disclose the supplementary leverage ratio and the components thereof (that is, tier 1 capital and total leverage exposure) on a quarterly basis. A banking organization that qualified as an advanced approaches banking organization before January 1, 2015, would be required to provide these disclosures, beginning with the first quarter in 2015, while a banking organization that qualified as an advanced approaches banking organization on or after January 1, 2015, would be subject to the disclosures beginning with the calendar quarter immediately following the calendar quarter in which the banking organization became an advanced approaches banking organization. For example, a banking organization that becomes subject to the advanced approaches rule as of year-end 2015 would begin disclosing its supplementary leverage ratio and components thereof as of March 31, 2016.

In addition to the disclosure requirements above, the proposed rule clarified that all top-tier[13] advanced approaches banking organizations, regardless of their parallel run status, would be required to publicly disclose the quantitative information described in Table 13 in section 173 of the advanced approaches rule[14] for twelve consecutive quarters or a shorter period, as applicable, beginning on January 1, 2015. For example, a top-tier banking organization that became an advanced approaches banking organization prior to January 1, 2015 (therefore subject to the supplementary leverage ratio disclosure requirements beginning January 1, 2015), and remains the top-tier banking organization, would publicly disclose supplementary leverage ratio data for one quarter in the first quarterly disclosure of 2015, two quarters in the second quarterly disclosure of 2015, and so on, disclosing twelve quarters of supplementary leverage ratio data in the quarterly disclosures for the fourth quarter of 2017. The agencies did not receive comments on this part of the proposed rule, and are finalizing it as proposed.

3. Risk Weights for Cleared Transactions

A. Risk Weights for Certain Client Cleared Transactions

The agencies proposed to revise the advanced approaches rule for clearing member banking organizations' exposures to a central counterparty (CCP) where the clearing member does not guarantee the performance of the CCP to the clearing member client. Under the advanced approaches rule, a clearing member banking organization is required to assign a two percent risk weight to the trade exposure amount for a cleared transaction with a qualifying CCP (QCCP), and a risk weight applicable to the CCP under section 32 of the regulatory capital framework for a cleared transaction with a CCP that is not a QCCP. This risk weight is applied when the banking organization is acting as a financial intermediary on behalf of its clearing member client.

The proposed rule would have permitted clearing member banking organizations to assign a zero percent risk weight under the advanced approaches rule to the trade exposure amount of a cleared transaction that arises when a clearing member banking organization does not guarantee the performance of the CCP and has no payment obligation to the clearing member client in the event of a CCP default. The proposed treatment would align the risk-based capital requirements for client-cleared transactions with the treatment under the agencies' 2014 SLR rule.

Both commenters provided views on this provision. The public advocacy nonprofit organization suggested that the agencies not finalize the zero percent risk weight, arguing that it underestimates the clearing member's risk to a CCP default. Conversely, the financial services trade association suggested that the agencies expand the zero percent risk weight to transactions cleared on behalf of clients that would not meet the eligibility criteria in sections 3(a)(3) and (3)(a)(4) of the regulatory capital framework for a cleared transaction, to the extent that the clearing member does not guarantee the performance of the CCP and has no payment obligation to the clearing member client in the event of a CCP default.

The agencies believe that requiring the clearing member banking organization to include in risk-weighted assets a trade exposure amount for the client-cleared transactions could overstate the clearing member's risk where the clearing member is not contractually obligated to perform on the transaction to its client in the event of a CCP failure. Furthermore, the public advocacy nonprofit commenter's concerns are partially addressed by the additional capital requirement for a clearing member banking organization's exposure to the default fund of a CCP, which considers its capitalization and risk profile, and the nature of its default fund. With respect to the financial services trade association's suggestion to make an exception from the requirements in sections 3(a)(3) and 3(a)(4) of the regulatory capital framework, it is not clear that the risks in transactions where the clearing member advanced approaches banking organization does not guarantee the performance of the CCP are negligible. Thus, the agencies are finalizing the changes to the risk weight for certain client-cleared transactions as proposed.

The financial services trade association also noted that the proposed changes should apply to the standardized approach contained in subpart D of the regulatory capital framework. However, the agencies did not seek comment on revisions to the provisions in the standardized approach, and banking organizations subject to the standardized approach but not to the advanced approaches rule may not have had sufficient notice of the change. Therefore, the agencies are not adopting the change requested by the commenter, but will consider the suggested change in the context of future proposed rulemakings.

B. Margin Period of Risk in the Internal Models Methodology (IMM)

The regulatory capital framework increases the margin period of risk in the IMM for large netting sets, netting sets involving illiquid collateral or over-the-counter (OTC) derivatives that cannot easily be replaced, or netting sets with more than two margin disputes with the counterparty over the previous two quarters that lasted more than the margin period of risk.[15] In the proposed rule, the agencies proposed to clarify that a cleared transaction would be exempt from the higher margin period of risk solely due to the fact that it is part of a large netting set (*i.e.*, a netting set that exceeds 5,000 trades at any time during the previous quarter). A cleared transaction would be subject to the higher margin period of risk if the netting set contained illiquid collateral,

[12] Section 172(d) was added to the regulatory capital framework as part of the 2014 SLR rule.

[13] Disclosure requirements in section 173 of the advanced approaches rule apply only to banking organizations that are not a consolidated subsidiary of a BHC, covered SLHC, or depository institution that is subject to these disclosure requirements or a subsidiary of a non-U.S. banking organization that is subject to comparable public disclosure requirements in its home jurisdiction.

[14] Table 13 in section 173 of the advanced approaches rule was adopted by the agencies in the 2014 SLR rule.

[15] Section 132(d)(5)(iii)(B).

derivatives that could not easily be replaced, or the banking organization had more than two margin disputes with the counterparty over the previous two quarters that lasted more than the margin period of risk.

The public advocacy nonprofit commenter raised concerns about the exemption of cleared transactions that are part of a large netting set from the twenty business day margin-period-of-risk requirement. However, in the agencies' view, the fact that cleared transactions are part of a large netting set should not automatically subject them to a higher capital requirement. In order for trades to meet the regulatory capital framework's definition of cleared transaction, they must involve a CCP, which facilitates trades between counterparties and has a proven record of being able to efficiently process a large volume of transactions. Furthermore, most types of cleared transactions must meet the operational criteria in section 3(a) of the regulatory capital framework, including the portability requirement in section 3(a)(4). These factors sufficiently mitigate the risk to warrant not applying an increased margin-period-of-risk for a netting set of cleared transactions solely because of the size of the netting set. In addition, this change promotes international regulatory consistency by aligning the advanced approaches rule with international standards regarding the requirements for netting sets containing 5,000 or more cleared transactions. Thus, the agencies are finalizing the changes to the margin period of risk in the IMM as proposed.

C. Collateral Posted by a Clearing Member Client Banking Organization and a Clearing Member Banking Organization

The agencies proposed to correct a cross-reference related to the calculation of exposure for cleared transactions for clearing member banking organizations and for clearing member client banking organizations in section 133 of the regulatory capital framework. Prior to the proposed change, the provisions for measuring the risk-weighted asset amount for posted collateral cross-referenced only to section 131 of the regulatory capital framework, which contained the provisions for risk-weighting wholesale and retail exposures.[16] Because collateral may be in the form of a securitization exposure, equity exposure, or a covered position, the proposed change would have replaced the cross-reference to section 131 with a cross-reference to subparts E and F.

The agencies did not receive any comments on this proposed revision to the advanced approaches rule, and are adopting it as final. Notably, the financial services trade association commenter noted that the proposed clarifications should be applied to the standardized approach and suggested that the agencies make a corresponding change to section 35 in subpart D of the regulatory capital framework. However, the agencies did not seek comment on revisions to the standardized approach, and non-advanced approaches banking organizations subject to the standardized approach may not have had sufficient notice of the change. Therefore, the agencies are not adopting the change requested by the commenter, but will consider the suggested change in the context of future proposed rulemakings.

4. Risk Weights for Derivatives

A. Exposure at Default Adjustment for Recognized Credit Valuation Adjustment (CVA)

In calculating risk weights for derivative contracts, banking organizations may use the IMM if they receive approval from their primary Federal supervisor, or they may use the current exposure methodology (CEM). In calculating exposure at default (EAD) for derivative contracts under the IMM, a banking organization may reduce EAD by the CVA that the banking organization has recognized in the fair value of derivative contracts reported on its balance sheet. This adjustment reflects the fair value adjustment for counterparty credit risk in the valuation of the netting set. Under the regulatory capital framework, a banking organization could not make a similar adjustment under the CEM.

In the proposed rule, the agencies proposed to adjust the CEM (section 132(c)(1)) to permit an advanced approaches banking organization to reduce the EAD by the recognized CVA on the balance sheet. The agencies noted that, for purposes of calculating standardized total risk-weighted assets as required under section 10 of the regulatory capital framework, advanced approaches banking organizations would not be permitted to reduce the EAD calculated according to the CEM. The agencies did not receive comment on this proposed revision to the advanced approaches rule and are adopting it as final, with an update in section 132(c)(1) to remove a reference to section 132(d) and a technical edit in section 132(c)(2) to also permit an adjustment to EAD by the recognized CVA for OTC derivatives subject to a qualifying master netting agreement.

One commenter proposed that the agencies make a corresponding change to the standardized approach and permit banking organizations to reduce the EAD amount for derivative contracts by recognized CVA. The commenter argued that the current treatment under the standardized approach double counts the impact of CVA, and noted that the adjustment to the standardized approach would more closely align the regulatory capital framework with international standards. However, the agencies did not seek comment on revisions to the provisions in the standardized approach, and non-advanced approaches banking organizations subject to the standardized approach may not have had sufficient notice of the change. Therefore, the agencies are not adopting the change requested by the commenter, but will consider the suggested change in the context of future proposed rulemakings.

B. Fair Value of Liabilities due to Changes in the Banking Organization's Own Credit Risk

Section 22 of the regulatory capital framework requires a banking organization to adjust its common equity tier 1 capital for changes in the fair value of liabilities due to changes in the banking organization's own credit risk. The agencies proposed to clarify that, for derivative liabilities, an advanced approaches banking organization would deduct the difference between its credit spread premium and the risk-free rate as part of this adjustment, and not in addition to this adjustment.

The agencies did not receive any comments on this part of the proposed rule and are adopting it as final.

5. Requirements and Mechanics Applicable to Banking Organizations That Use the Advanced Approaches Rule

In February 2014 and in March 2015, the OCC and the Board granted permission to a number of advanced approaches banking organizations to begin calculating their risk-based capital requirements under the advanced approaches rule.[17] During the parallel

[16] *See* sections 133(b)(4)(ii) and 133(c)(4)(ii) (rules applicable to clearing member client banking organizations and clearing member banking organizations, respectively).

[17] Board Press Releases: *http://www.federalreserve.gov/newsevents/press/bcreg/20140221a.htm, http://www.federalreserve.gov/newsevents/press/bcreg/20150331a.htm*; OCC Press releases: *http://www.occ.gov/news-issuances/news-releases/2014/nr-ia-2014-21.html, http://*

run evaluation process for advanced approaches banking organizations that are calculating their risk-based capital requirements under the advanced approaches rule, the agencies concluded that several areas of the advanced approaches rule should be revised to (1) clarify the requirements and mechanics for calculating risk-weighted assets under the advanced approaches rule and (2) promote international consistency by more clearly aligning the U.S. regulations with international standards.

Sections 122 and 131 of the regulatory capital framework set forth the qualification requirements for the internal ratings-based approach (IRB) for advanced approaches banking organizations and describe the mechanics for calculating risk-weighted assets for wholesale and retail exposures under the advanced approaches rule. When the agencies initially adopted the advanced approaches rule in 2007,[18] they incorporated these elements into the supervisory review process rather than into the advanced approaches rule. However, the agencies believe that certain elements of sections 122 and 131 of the regulatory capital framework should be clarified to ensure that advanced approaches banking organizations appropriately: (1) Obtain and consider all relevant and material information to estimate probability of default (PD), loss given default (LGD), and EAD; (2) quantify risk parameters for wholesale and retail exposures; and (3) establish internal requirements for collateral and risk management processes.

Accordingly, in the proposed rule, the agencies proposed incorporating new rule text to add specificity and enhance transparency regarding the IRB process and the mechanics used to calculate total wholesale and retail risk-weighted assets. More specifically, the proposed rule would have amended sections 122 and 131 of the regulatory capital framework to clarify requirements associated with: (1) The frequency for reviewing risk rating systems, (2) the independence of the systems' development, design, and implementation, (3) time horizons for default and loss data when estimating risk parameters, (4) changes in advanced approaches banking organizations' lending, payment processing, and account monitoring practices, (5) the use of all relevant available data for assigning risk ratings, and (6) the need for internal requirements for collateral management and risk management processes. These proposed modifications are consistent with the current overarching principles in sections 122 and 131 of the regulatory capital framework under which advanced approaches banking organizations must have an internal risk rating and segmentation system that accurately and reliably differentiates among degrees of credit risk for wholesale and retail exposures, and must have a comprehensive risk-parameter quantification process that produces accurate, timely, and reliable risk-parameter estimates. The agencies emphasize that the revisions were intended to clarify, but not change, existing requirements. In fact, many of these clarifications in subpart E of the regulatory capital framework are included in agency supervisory guidance and examination materials. Therefore, because they demonstrated that they comply with the existing requirements, advanced approaches banking organizations that have already exited parallel run demonstrated that they met the proposed requirements upon exit. The agencies did not receive any comments on this part of the proposed rule and are adopting the changes as final, with a technical edit to the rule text in section 122(c)(2)(v)(11) to include language that was included in the regulatory capital framework but inadvertently omitted from the proposed revisions.

6. Technical Corrections

In addition to the revisions discussed above, the agencies proposed to make the following technical corrections:

- In section 131(e)(3)(vi), the rule would have been revised to reference section 22(d) and not section 22(a)(7);
- In Table 1 of section 132, the reference in the column heading would have been corrected to state that ''Non-sovereign issuers risk weight under this section (in percent)'' and ''Sovereign issuers risk weight under this section (in percent)'' are found in section 32.
- In section 132(d)(7)(iv)(B), the agencies would have revised the rule to reference section 132(b)(2) and not section 131(b)(2);
- In section 132(d)(9)(ii), the agencies would have revised the rule to reference section 132(e)(6) and not section 132(e)(3);
- In section 133(b)(3)(i)(B), the agencies would have revised the rule to reference section 133(b)(3)(i)(A) and not section 132(b)(3)(i)(A); and
- In section 136(e)(2)(i) and 136(e)(2)(ii), the agencies would have revised the rule to reference section 136(e)(1) and (e)(2) and not section 135(e)(1) and (e)(2).

No comments were received on the above proposed technical corrections. The agencies are finalizing these changes as proposed and are correcting an additional internal cross-reference error in section 132 that was identified after the publication of the proposed rule. Specifically, the agencies are amending section 132(d)(2)(iv)(C) to replace the reference to paragraph (d)(5) with the correct reference to paragraph (d)(6).

In addition, the FDIC has added a clarification of its prior **Federal Register** instructions regarding the regulatory capital framework. In its amendatory rule text, the FDIC is clarifying for **Federal Register** publication purposes a certain paragraph of its prompt corrective action (PCA) rules in 12 CFR 324.403(b). The FDIC has provided this clarification to ensure that its PCA rules, as published in the **Federal Register**, are identical to the current PCA rules of the Board and the OCC.

IV. Regulatory Analyses

A. Paperwork Reduction Act (PRA)

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

B. Regulatory Flexibility Act Analysis

OCC: The Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* (RFA), requires an agency, in connection with a final rule, to prepare a Final Regulatory Flexibility Analysis describing the impact of the final rule on small entities, or to certify that the final rule would not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, the Small Business Administration (SBA) defines small entities as those with $550 million or less in assets for commercial banks and savings institutions, and $38.5 million or less in assets for trust companies.

As described in the **SUPPLEMENTARY INFORMATION** section of the preamble, the final rule would apply only to advanced approaches banking organizations. No OCC-supervised advanced approaches banking organization qualifies as a small

www.occ.gov/news-issuances/news-releases/2015/nr-ia-2015-47.html.

[18] 72 FR 69288 (December 7, 2007).

entity as defined by the SBA. Therefore, the OCC certifies that the final rule will not have a significant economic impact on a substantial number of OCC-supervised small entities.

FDIC: The RFA requires an agency, in connection with a notice of final rulemaking, to prepare a Final Regulatory Flexibility Act analysis describing the impact of the rule on small entities (defined by the SBA for purposes of the RFA to include banking entities with total assets of $550 million or less) or to certify that the final rule will not have a significant economic impact on a substantial number of small entities.

Using the SBA's size standards, as of March 31, 2015, the FDIC supervised 3,407 small entities. As described in the **SUPPLEMENTARY INFORMATION** section of the preamble, however, the final rule applies only to advanced approaches banking organizations. *Advanced approaches banking organization* is defined to include a state nonmember bank or a state savings association that has, or is a subsidiary of, a bank holding company or savings and loan holding company that has total consolidated assets of $250 billion or more, total consolidated on-balance sheet foreign exposure of $10 billion or more, or that has elected to use the advanced approaches framework. As of March 31, 2015, based on a $550 million threshold, zero (out of 3,119) small state nonmember banks and zero (out of 288) small state savings associations were under the advanced approaches rule. Therefore, the FDIC does not believe that the final rule results in a significant economic impact on a substantial number of small entities under its supervisory jurisdiction.

The FDIC certifies that the final rule does not have a significant economic impact on a substantial number of small FDIC-supervised institutions.

Board: The Board is providing a final regulatory flexibility analysis with respect to this final rule. As discussed above, this final rule would clarify, correct, and update aspects of the agencies' regulatory capital framework applicable to banking organizations that are subject to the advanced approaches rule. The revisions are largely driven by observations made by the agencies during the parallel run review process of advanced approaches banking organizations as well as a recent assessment of the regulatory capital framework.

Under regulations issued by the SBA, a small entity includes a depository institution, bank holding company, or savings and loan holding company with total assets of $550 million or less (a small banking organization).[19] As of March 31, 2015, there were approximately 631 small state member banks. As of December 31, 2014, there were approximately 3,833 small bank holding companies and 271 small savings and loan holding companies.

The final rule applies only to advanced approaches banking organizations, which, generally, are banking organizations with total consolidated assets of $250 billion or more, that have total consolidated on-balance sheet foreign exposure of $10 billion or more, are a subsidiary of an advanced approaches depository institution, or that elect to use the advanced approaches rule. Currently, no small top-tier bank holding company, top-tier savings and loan holding company, or state member bank is an advanced approaches banking organization, so there would be no additional projected compliance requirements imposed on small bank holding companies, savings and loan holding companies, or state member banks. The Board expects that any small bank holding company, savings and loan holding company, or state member bank that would be covered by this final rule would rely on its parent banking organization for compliance and would not bear additional costs.

The Board is aware of no other Federal rules that duplicate, overlap, or conflict with the final rule. The Board believes that the final rule will not have a significant economic impact on small banking organizations supervised by the Board and therefore believes that there are no significant alternatives to the final rule that would reduce the economic impact on small banking organizations supervised by the Board.

C. OCC Unfunded Mandates Reform Act of 1995 Determination

The OCC analyzed the final rule under the factors set forth in the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1532). Under this analysis, the OCC considered whether the final rule includes a Federal mandate that may result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more in any one year ($143 million adjusted for inflation).

The final rule includes clarifications, corrections, and updates for certain aspects of the agencies' regulatory capital framework applicable to national banks and Federal savings associations subject to the OCC's advanced approaches rule.

Because the final rule is designed to clarify, correct, and update existing rules, and does not introduce any new requirements, the OCC has determined that it would not result in expenditures by State, local, and Tribal governments, or by the private sector, of $143 million or more.

D. Plain Language

Section 722 of the Gramm-Leach-Bliley Act requires the Federal banking agencies to use plain language in all proposed and final rules published after January 1, 2000. The agencies have sought to present the final rule in a simple and straightforward manner, and did not receive any comments on the use of plain language.

List of Subjects

12 CFR Part 3

Administrative practice and procedure, Capital, National banks, Reporting and recordkeeping requirements, Risk.

12 CFR Part 217

Administrative practice and procedure, Banks, Banking, Capital, Federal Reserve System, Holding companies, Reporting and recordkeeping requirements, Securities.

12 CFR Part 324

Administrative practice and procedure, Banks, Banking, Capital Adequacy, Reporting and recordkeeping requirements, Savings associations, State non-member banks.

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

12 CFR Chapter I

Authority and Issuance

For the reasons set forth in the common preamble and under the authority of 12 U.S.C. 93a, 1462, 1462a, 1463, 1464, 3907, 3909, 1831o, and 5412(b)(2)(B), the Office of the Comptroller of the Currency amends part 3 of chapter I of title 12, Code of Federal Regulations as follows:

PART 3—CAPITAL ADEQUACY STANDARDS

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

Authority: 12 U.S.C. 93a, 161, 1462, 1462a, 1463, 1464, 1818, 1828(n), 1828 note, 1831n note, 1835, 3907, 3909, and 5412(b)(2)(B).

[19] *See* 13 CFR 121.201. Effective July 14, 2014, the Small Business Administration revised the size standards for banking organizations to $550 million in assets from $500 million in assets. 79 FR 33647 (June 12, 2014).

■ 2. Section 3.2 is amended by revising the definition of ''Residential mortgage exposure'' to read as follows:

§ 3.2 Definitions.

* * * * *

Residential mortgage exposure means an exposure (other than a securitization exposure, equity exposure, statutory multifamily mortgage, or presold construction loan):

(1)(i) That is primarily secured by a first or subsequent lien on one-to-four family residential property; or

(ii) With an original and outstanding amount of $1 million or less that is primarily secured by a first or subsequent lien on residential property that is not one-to-four family; and

(2) For purposes of calculating capital requirements under subpart E of this part, managed as part of a segment of exposures with homogeneous risk characteristics and not on an individual-exposure basis.

* * * * *

■ 3. Section 3.10 is amended by revising paragraph (c) introductory text to read as follows:

§ 3.10 Minimum capital requirements.

* * * * *

(c) *Advanced approaches capital ratio calculations.* An advanced approaches national bank or Federal savings association that has completed the parallel run process and received notification from the OCC pursuant to § 3.121(d) must determine its regulatory capital ratios as described in paragraphs (c)(1) through (3) of this section. An advanced approaches national bank or Federal savings association must determine its supplementary leverage ratio in accordance with paragraph (c)(4) of this section, beginning with the calendar quarter immediately following the quarter in which the national bank or Federal savings association meets any of the criteria in § 3.100(b)(1).

* * * * *

■ 4. Section 3.22 is amended by revising paragraph (b)(1)(iii) to read as follows:

§ 3.22 Regulatory capital adjustments and deductions.

* * * * *

(b) * * *

(1) * * *

(iii) A national bank or Federal savings association must deduct any net gain and add any net loss related to changes in the fair value of liabilities that are due to changes in the national bank's or Federal savings association's own credit risk. An advanced approaches national bank or Federal savings association must deduct the difference between its credit spread premium and the risk-free rate for derivatives that are liabilities as part of this adjustment.

* * * * *

■ 5. Section 3.100 is amended by revising paragraph (b)(1)(ii) to read as follows:

§ 3.100 Purpose, applicability, and principle of conservatism.

* * * * *

(b) * * *

(1) * * *

(ii) Has consolidated total on-balance sheet foreign exposure on its most recent year-end Federal Financial Institutions Examination Council (FFIEC) 009 Report equal to $10 billion or more (where total on-balance sheet foreign exposure equals total foreign countries cross-border claims on an ultimate-risk basis, plus total foreign countries claims on local residents on an ultimate-risk basis, plus total foreign countries fair value of foreign exchange and derivative products), calculated in accordance with the FFIEC 009 Country Exposure Report;

* * * * *

■ 6. Section 3.122 is amended by:

■ a. Revising paragraphs (a)(3) and (b)(1);

■ b. Adding paragraph (b)(2)(iii);

■ c. Revising paragraphs (b)(3) and (5) and (c)(1), (2), (5), and (6);

■ d. Redesignating paragraphs (c)(9) and (10) as paragraphs (c)(10) and (11), revising newly redesignated paragraphs (c)(10) and (11), and adding a new paragraph (c)(9); and

■ e. Revising paragraph (i)(5).

The revisions and additions read as follows:

§ 3.122 Qualification requirements.

(a) * * *

(3) Each national bank or Federal savings association must have an appropriate infrastructure with risk measurement and management processes that meet the qualification requirements of this section and are appropriate given the national bank's or Federal savings association's size and level of complexity. Regardless of whether the systems and models that generate the risk parameters necessary for calculating a national bank's or Federal savings association's risk-based capital requirements are located at any affiliate of the national bank or Federal savings association, the national bank or Federal savings association itself must ensure that the risk parameters and reference data used to determine its risk-based capital requirements are representative of long run experience with respect to its own credit risk and operational risk exposures.

(b) *Risk rating and segmentation systems for wholesale and retail exposures.* (1)(i) A national bank or Federal savings association must have an internal risk rating and segmentation system that accurately, reliably, and meaningfully differentiates among degrees of credit risk for the national bank's or Federal savings association's wholesale and retail exposures. When assigning an internal risk rating, a national bank or Federal savings association may consider a third-party assessment of credit risk, provided that the national bank's or Federal savings association's internal risk rating assignment does not rely solely on the external assessment.

(ii) If a national bank or Federal savings association uses multiple rating or segmentation systems, the national bank's or Federal savings association's rationale for assigning an obligor or exposure to a particular system must be documented and applied in a manner that best reflects the obligor's or exposure's level of risk. A national bank or Federal savings association must not inappropriately allocate obligors or exposures across systems to minimize regulatory capital requirements.

(iii) In assigning ratings to wholesale obligors and exposures, including loss severity ratings grades to wholesale exposures, and assigning retail exposures to retail segments, a national bank or Federal savings association must use all relevant and material information and ensure that the information is current.

(iv) When assigning an obligor to a PD rating or retail exposure to a PD segment, a national bank or Federal savings association must assess the obligor or retail borrower's ability and willingness to contractually perform, taking a conservative view of projected information.

(2) * * *

(iii) A national bank or Federal savings association must have an effective process to obtain and update in a timely manner relevant and material information on obligor and exposure characteristics that affect PD, LGD and EAD.

(3) For retail exposures:

(i) A national bank or Federal savings association must have an internal system that groups retail exposures into the appropriate retail exposure subcategory and groups the retail exposures in each retail exposure subcategory into separate segments with homogeneous risk characteristics that provide a meaningful differentiation of risk. The national bank's or Federal

savings association's system must identify and group in separate segments by subcategories exposures identified in § 3.131(c)(2)(ii) and (iii).

(ii) A national bank or Federal savings association must have an internal system that captures all relevant exposure risk characteristics, including borrower credit score, product and collateral types, as well as exposure delinquencies, and must consider cross-collateral provisions, where present.

(iii) The national bank or Federal savings association must review and, if appropriate, update assignments of individual retail exposures to segments and the loss characteristics and delinquency status of each identified risk segment. These reviews must occur whenever the national bank or Federal savings association receives new material information, but generally no less frequently than quarterly, and, in all cases, at least annually.

* * * * *

(5) The national bank's or Federal savings association's internal risk rating system for wholesale exposures must provide for the review and update (as appropriate) of each obligor rating and (if applicable) each loss severity rating whenever the national bank or Federal savings association obtains relevant and material information on the obligor or exposure that affects PD, LGD and EAD, but no less frequently than annually.

(c) *Quantification of risk parameters for wholesale and retail exposures.* (1) The national bank or Federal savings association must have a comprehensive risk parameter quantification process that produces accurate, timely, and reliable estimates of the risk parameters on a consistent basis for the national bank's or Federal savings association's wholesale and retail exposures.

(2) A national bank's or Federal savings association's estimates of PD, LGD, and EAD must incorporate all relevant, material, and available data that is reflective of the national bank's or Federal savings association's actual wholesale and retail exposures and of sufficient quality to support the determination of risk-based capital requirements for the exposures. In particular, the population of exposures in the data used for estimation purposes, the lending standards in use when the data were generated, and other relevant characteristics, should closely match or be comparable to the national bank's or Federal savings association's exposures and standards. In addition, a national bank or Federal savings association must:

(i) Demonstrate that its estimates are representative of long run experience, including periods of economic downturn conditions, whether internal or external data are used;

(ii) Take into account any changes in lending practice or the process for pursuing recoveries over the observation period;

(iii) Promptly reflect technical advances, new data, and other information as they become available;

(iv) Demonstrate that the data used to estimate risk parameters support the accuracy and robustness of those estimates; and

(v) Demonstrate that its estimation technique performs well in out-of-sample tests whenever possible.

* * * * *

(5) The national bank or Federal savings association must be able to demonstrate which variables have been found to be statistically significant with regard to EAD. The national bank's or Federal savings association's EAD estimates must reflect its specific policies and strategies with regard to account management, including account monitoring and payment processing, and its ability and willingness to prevent further drawdowns in circumstances short of payment default. The national bank or Federal savings association must have adequate systems and procedures in place to monitor current outstanding amounts against committed lines, and changes in outstanding amounts per obligor and obligor rating grade and per retail segment. The national bank or Federal savings association must be able to monitor outstanding amounts on a daily basis.

(6) At a minimum, PD estimates for wholesale obligors and retail segments must be based on at least five years of default data. LGD estimates for wholesale exposures must be based on at least seven years of loss severity data, and LGD estimates for retail segments must be based on at least five years of loss severity data. EAD estimates for wholesale exposures must be based on at least seven years of exposure amount data, and EAD estimates for retail segments must be based on at least five years of exposure amount data. If the national bank or Federal savings association has relevant and material reference data that span a longer period of time than the minimum time periods specified above, the national bank or Federal savings association must incorporate such data in its estimates, provided that it does not place undue weight on periods of favorable or benign economic conditions relative to periods of economic downturn conditions.

* * * * *

(9) If a national bank or Federal savings association uses internal data obtained prior to becoming subject to this subpart E or external data to arrive at PD, LGD, or EAD estimates, the national bank or Federal savings association must demonstrate to the OCC that the national bank or Federal savings association has made appropriate adjustments if necessary to be consistent with the definition of default in § 3.101. Internal data obtained after the national bank or Federal savings association becomes subject to this subpart E must be consistent with the definition of default in § 3.101.

(10) The national bank or Federal savings association must review and update (as appropriate) its risk parameters and its risk parameter quantification process at least annually.

(11) The national bank or Federal savings association must, at least annually, conduct a comprehensive review and analysis of reference data to determine relevance of the reference data to the national bank's or Federal savings association's exposures, quality of reference data to support PD, LGD, and EAD estimates, and consistency of reference data to the definition of default in § 3.101.

* * * * *

(i) * * *

(5) The national bank or Federal savings association must have an internal audit function or equivalent function that is independent of business-line management that at least annually:

(i) Reviews the national bank's or Federal savings association's advanced systems and associated operations, including the operations of its credit function and estimations of PD, LGD, and EAD;

(ii) Assesses the effectiveness of the controls supporting the national bank's or Federal savings association's advanced systems; and

(iii) Documents and reports its findings to the national bank's or Federal savings association's board of directors (or a committee thereof).

* * * * *

■ 7. Section 3.131 is amended by:

■ a. Revising paragraphs (d)(5)(ii) and (iii); and

■ b. In paragraph (e)(3)(vi), removing ''§ 3.22(a)(7)'' and adding ''§ 3.22(d)'' in its place.

The revisions read as follows:

§ 3.131 Mechanics for calculating total wholesale and retail risk-weighted assets.

* * * * *

(d) * * *

(5) * * *

(ii) A national bank or Federal savings association may take into account the risk reducing effects of guarantees and credit derivatives in support of retail exposures in a segment when quantifying the PD and LGD of the segment. In doing so, a national bank or Federal savings association must consider all relevant available information.

(iii) Except as provided in paragraph (d)(6) of this section, a national bank or Federal savings association may take into account the risk reducing effects of collateral in support of a wholesale exposure when quantifying the LGD of the exposure, and may take into account the risk reducing effects of collateral in support of retail exposures when quantifying the PD and LGD of the segment. In order to do so, a national bank or Federal savings association must have established internal requirements for collateral management, legal certainty, and risk management processes.

* * * * *

■ 8. Section 3.132 is amended by:
■ a. In Table 1 to § 3.132, removing ''this section'' and adding ''§ 3.32'' in its place, wherever it appears;
■ b. Revising paragraphs (c)(1), (c)(2) and (d)(5)(iii)(B);
■ c. In paragraph (d)(2)(iv)(C), removing ''(d)(5)'' and adding ''(d)(6)'' in its place;
■ d. In paragraph (d)(7)(iv)(B), removing ''§ 3.131(b)(2)'' and adding ''§ 3.132(b)(2)'' in its place; and
■ d. In paragraph (d)(9)(ii), removing ''paragraph (e)(3)'' and adding ''paragraph (e)(6)'' in its place.

The revisions read as follows:

§ 3.132 Counterparty credit risk of repo-style transactions, eligible margin loans, and OTC derivative contracts.

* * * * *

(c) *EAD for OTC derivative contracts*—(1) *OTC derivative contracts not subject to a qualifying master netting agreement.* A national bank or Federal savings association must determine the EAD for an OTC derivative contract that is not subject to a qualifying master netting agreement using the current exposure methodology in paragraph (c)(5) of this section or using the internal models methodology described in paragraph (d) of this section. A national bank or Federal savings association may reduce the EAD calculated according to paragraph (c)(5) of this section by the credit valuation adjustment that the national bank or Federal savings association has recognized in its balance sheet valuation of any OTC derivative contracts in the netting set. For purposes of this paragraph (c)(1), the credit valuation adjustment does not include any adjustments to common equity tier 1 capital attributable to changes in the fair value of the national bank's or Federal savings association's liabilities that are due to changes in its own credit risk since the inception of the transaction with the counterparty.

(2) *OTC derivative contracts subject to a qualifying master netting agreement.* A national bank or Federal savings association must determine the EAD for multiple OTC derivative contracts that are subject to a qualifying master netting agreement using the current exposure methodology in paragraph (c)(6) of this section or using the internal models methodology described in paragraph (d) of this section. A national bank or Federal savings association may reduce the EAD calculated according to paragraph (c)(6) of this section by the credit valuation adjustment that the national bank or Federal savings association has recognized in its balance sheet valuation of any OTC derivative contracts in the netting set. For purposes of this paragraph (c)(2), the credit valuation adjustment does not include any adjustments to common equity tier 1 capital attributable to changes in the fair value of the national bank's or Federal savings association's liabilities that are due to changes in its own credit risk since the inception of the transaction with the counterparty.

* * * * *

(d) * * *
(5) * * *
(iii) * * *

(B) Twenty business days if the number of trades in a netting set exceeds 5,000 at any time during the previous quarter (except if the national bank or Federal savings association is calculating EAD for a cleared transaction under § 3.133) or contains one or more trades involving illiquid collateral or any derivative contract that cannot be easily replaced. If over the two previous quarters more than two margin disputes on a netting set have occurred that lasted more than the margin period of risk, then the national bank or Federal savings association must use a margin period of risk for that netting set that is at least two times the minimum margin period of risk for that netting set. If the periodicity of the receipt of collateral is N-days, the minimum margin period of risk is the minimum margin period of risk under this paragraph (d) plus N minus 1. This period should be extended to cover any impediments to prompt re-hedging of any market risk.

* * * * *

■ 9. Section 3.133 is amended by:
■ a. In paragraph (b)(3)(i)(B) removing ''§ 3.132(b)(3)(i)(A)'' and adding paragraph (b)(3)(i)(A) of this section'' in its place;
■ b. In paragraph (b)(4)(ii) removing ''§ 3.131'' and adding ''subparts E or F of this part, as applicable'' in its place;
■ c. Adding paragraph (c)(3)(iii); and
■ d. In paragraph (c)(4)(ii) removing ''§ 3.131'' and adding ''subparts E or F of this part, as applicable'' in its place.

The addition reads as follows:

§ 3.133 Cleared transactions.

* * * * *

(c) * * *
(3) * * *

(iii) Notwithstanding paragraphs (c)(3)(i) and (ii) of this section, a clearing member national bank or Federal savings association may apply a risk weight of 0 percent to the trade exposure amount for a cleared transaction with a CCP where the clearing member national bank or Federal savings association is acting as a financial intermediary on behalf of a clearing member client, the transaction offsets another transaction that satisfies the requirements set forth in § 3.3(a), and the clearing member national bank or Federal savings association is not obligated to reimburse the clearing member client in the event of the CCP default.

* * * * *

§ 3.136 [Amended]

■ 10. Section 3.136 is amended by:
■ a. In paragraph (e)(2)(i), removing ''§ 3.135(e)(1) and (e)(2)'' and adding ''paragraphs (e)(1) and (2) of this section'' in its place: And
■ b. In paragraph (e)(2)(ii), removing ''§§ 3.135(e)(1) and (e)(2)'' and adding ''paragraphs (e)(1) and (2) of this section'' in its place.

■ 11. Section 3.172 is amended by revising paragraph (d) to read as follows:

§ 3.172 Disclosure requirements.

* * * * *

(d)(1) A national bank or Federal savings association that meets any of the criteria in § 3.100(b)(1) before January 1, 2015, must publicly disclose each quarter its supplementary leverage ratio and the components thereof (that is, tier 1 capital and total leverage exposure) as calculated under subpart B of this part, beginning with the first quarter in 2015. This disclosure requirement applies without regard to whether the national bank or Federal savings association has completed the parallel run process and received notification from the OCC pursuant to § 3.121(d).

(2) A national bank or Federal savings association that meets any of the criteria

in § 3.100(b)(1) on or after January 1, 2015, must publicly disclose each quarter its supplementary leverage ratio and the components thereof (that is, tier 1 capital and total leverage exposure) as calculated under subpart B of this part beginning with the calendar quarter immediately following the quarter in which the national bank or Federal savings association becomes an advanced approaches national bank or Federal savings association. This disclosure requirement applies without regard to whether the national bank or Federal savings association has completed the parallel run process and has received notification from the OCC pursuant to § 3.121(d).

■ 12. Section 3.173 is amended by:

■ a. Redesignating paragraph (a) introductory text as paragraph (a)(1) and revising newly redesignated paragraph (a)(1);

■ b. Adding paragraphs (a)(2) and (a)(3);

■ c. Revising the entry for (a)(1) in Table 6 to § 3.173; and

■ d. Revising the entry for (i)(2) in Table 9 to § 3.173.

The revisions and additions read as follows:

§ 3.173 Disclosures by certain advanced approaches national banks or Federal savings associations.

(a)(1) An advanced approaches national bank or Federal savings association described in § 3.172(b) must make the disclosures described in Tables 1 through 12 to § 3.173.

(2) An advanced approaches national bank or Federal savings association that is required to publicly disclose its supplementary leverage ratio pursuant to § 3.172(d) must make the disclosures required under Table 13 to § 3.173, unless the national bank or Federal savings association is a consolidated subsidiary of a bank holding company, savings and loan holding company, or depository institution that is subject to these disclosures requirements or a subsidiary of a non-U.S. banking organization that is subject to comparable public disclosure requirements in its home jurisdiction.

(3) The disclosures described in Tables 1 through 12 to § 3.173 must be made publicly available for twelve consecutive quarters beginning on January 1, 2014, or a shorter period, as applicable, for the quarters after the national bank or Federal savings association has completed the parallel run process and received notification from the OCC pursuant to § 3.121(d). The disclosures described in Table 13 to § 3.173 must be made publicly available for twelve consecutive quarters beginning on January 1, 2015, or a shorter period, as applicable, for the quarters after the national bank or Federal savings association becomes subject to the disclosure of the supplementary leverage ratio pursuant to § 3.172(d) and § 3.173(a)(2).

* * * * *

TABLE 6 TO § 3.173—CREDIT RISK: DISCLOSURES FOR PORTFOLIOS SUBJECT TO IRB RISK-BASED CAPITAL FORMULA

Qualitative disclosures	(a)	* * *
		(1) Structure of internal rating systems and if the national bank or Federal savings association considers external ratings, the relation between internal and external ratings;
*	*	* * * * *

* * * * *

TABLE 9 TO § 3.173—SECURITIZATION

*	*	*	* * * * *
Quantitative Disclosures			
*	*	*	* * * * *
		(i)	* * *
			(2) Aggregate amount disclosed separately by type of underlying exposure in the pool of any:
			(i) After-tax gain-on-sale on a securitization that has been deducted from common equity tier 1 capital: And
			(ii) Credit-enhancing interest-only strip that is assigned a 1,250 percent risk weight.
*	*	*	* * * * *

* * * * *

FEDERAL RESERVE SYSTEM

12 CFR CHAPTER II

Authority and Issuance

For the reasons set forth in the common preamble, part 217 of chapter II of title 12 of the Code of Federal Regulations is amended as follows:

PART 217—CAPITAL ADEQUACY OF BANK HOLDING COMPANIES, SAVINGS AND LOAN HOLDING COMPANIES, AND STATE MEMBER BANKS (REGULATION Q)

■ 13. The authority citation for part 217 continues to read as follows:

Authority: 12 U.S.C. 248(a), 321–338a, 481–486, 1462a, 1467a, 1818, 1828, 1831n, 1831o, 1831p–l, 1831w, 1835, 1844(b), 1851, 3904, 3906–3909, 4808, 5365, 5368, 5371.

■ 14. Section 217.2 is amended by revising the definition of ''Residential mortgage exposure'' to read as follows:

§ 217.2 Definitions.

* * * * *

Residential mortgage exposure means an exposure (other than a securitization exposure, equity exposure, statutory multifamily mortgage, or presold construction loan):

(1)(i) That is primarily secured by a first or subsequent lien on one-to-four family residential property; or

(ii) With an original and outstanding amount of $1 million or less that is primarily secured by a first or subsequent lien on residential property that is not one-to-four family; and

(2) For purposes of calculating capital requirements under subpart E of this part, managed as part of a segment of exposures with homogeneous risk characteristics and not on an individual-exposure basis.

* * * * *

■ 15. Section 217.10 is amended by revising paragraph (c) introductory text to read as follows:

§ 217.10 Minimum capital requirements.

* * * * *

(c) *Advanced approaches capital ratio calculations.* An advanced approaches Board-regulated institution that has completed the parallel run process and received notification from the Board pursuant to § 217.121(d) must determine its regulatory capital ratios as described in paragraphs (c)(1) through (3) of this section. An advanced approaches Board-regulated institution must determine its supplementary leverage ratio in accordance with paragraph (c)(4) of this section, beginning with the calendar quarter immediately following the quarter in which the Board-regulated institution meets any of the criteria in § 217.100(b)(1).

* * * * *

■ 16. Section 217.22 is amended by revising paragraph (b)(1)(iii) to read as follows:

§ 217.22 Regulatory capital adjustments and deductions.

* * * * *

(b) * * *

(1) * * *

(iii) A Board-regulated institution must deduct any net gain and add any net loss related to changes in the fair value of liabilities that are due to changes in the Board-regulated institution's own credit risk. An advanced approaches Board-regulated institution must deduct the difference between its credit spread premium and the risk-free rate for derivatives that are liabilities as part of this adjustment.

* * * * *

■ 17. Section 217.100 is amended by revising paragraphs (b)(1)(i)(*B*)(2) and (b)(1)(ii)(*B*) to read as follows:

§ 217.100 Purpose, applicability, and principle of conservatism.

* * * * *

(b) * * *

(1) * * *

(i) * * *

(*B*) * * *

(2) Has consolidated total on-balance sheet foreign exposure on its most recent year-end Federal Financial Institutions Examination Council (FFIEC) 009 Report equal to $10 billion or more (where total on-balance sheet foreign exposure equals total foreign countries cross-border claims on an ultimate-risk basis, plus total foreign countries claims on local residents on an ultimate-risk basis, plus total foreign countries fair value of foreign exchange and derivative products), calculated in accordance with the FFIEC 009 Country Exposure Report;

* * * * *

(ii) * * *

(*B*) Has consolidated total on-balance sheet foreign exposure on its most recent year-end Federal Financial Institutions Examination Council (FFIEC) 009 Report equal to $10 billion or more (where total on-balance sheet foreign exposure equals total foreign countries cross-border claims on an ultimate-risk basis, plus total foreign countries claims on local residents on an ultimate-risk basis, plus total foreign countries fair value of foreign exchange and derivative products), calculated in accordance with the FFIEC 009 Country Exposure Report;

* * * * *

■ 18. Section 217.122 is amended by:

■ a. Revising paragraphs (a)(3) and (b)(1);

■ b. Adding paragraph (b)(2)(iii);

■ c. Revising paragraphs (b)(3) and (5) and (c)(1), (2), (5), and (6);

■ d. Redesignating paragraphs (c)(9) and (10) as paragraphs (c)(10) and (11), revising newly redesignated paragraphs (c)(10) and (11), and adding a new paragraph (c)(9); and

■ e. Revising paragraph (i)(5).

The revisions and additions read as follows:

§ 217.122 Qualification requirements.

(a) * * *

(3) Each Board-regulated institution must have an appropriate infrastructure with risk measurement and management processes that meet the qualification requirements of this section and are appropriate given the Board-regulated institution's size and level of complexity. Regardless of whether the systems and models that generate the risk parameters necessary for calculating a Board-regulated institution's risk-based capital requirements are located at any affiliate of the Board-regulated institution, the Board-regulated institution itself must ensure that the risk parameters and reference data used to determine its risk-based capital requirements are representative of long run experience with respect to its own credit risk and operational risk exposures.

(b) *Risk rating and segmentation systems for wholesale and retail exposures.* (1)(i) A Board-regulated institution must have an internal risk rating and segmentation system that accurately, reliably, and meaningfully differentiates among degrees of credit risk for the Board-regulated institution's wholesale and retail exposures. When assigning an internal risk rating, a Board-regulated institution may consider a third-party assessment of credit risk, provided that the Board-regulated institution's internal risk rating assignment does not rely solely on the external assessment.

(ii) If a Board-regulated institution uses multiple rating or segmentation systems, the Board-regulated institution's rationale for assigning an obligor or exposure to a particular system must be documented and applied in a manner that best reflects the obligor or exposure's level of risk. A Board-regulated institution must not inappropriately allocate obligors or exposures across systems to minimize regulatory capital requirements.

(iii) In assigning ratings to wholesale obligors and exposures, including loss severity ratings grades to wholesale exposures, and assigning retail exposures to retail segments, a Board-regulated institution must use all relevant and material information and ensure that the information is current.

(iv) When assigning an obligor to a PD rating or retail exposure to a PD segment, a Board-regulated institution must assess the obligor or retail borrower's ability and willingness to contractually perform, taking a conservative view of projected information.

(2) * * *

(iii) A Board-regulated institution must have an effective process to obtain and update in a timely manner relevant and material information on obligor and exposure characteristics that affect PD, LGD and EAD.

(3) For retail exposures:

(i) A Board-regulated institution must have an internal system that groups retail exposures into the appropriate retail exposure subcategory and groups the retail exposures in each retail exposure subcategory into separate segments with homogeneous risk characteristics that provide a meaningful differentiation of risk. The Board-regulated institution's system must identify and group in separate

segments by subcategories exposures identified in § 217.131(c)(2)(ii) and (iii).

(ii) A Board-regulated institution must have an internal system that captures all relevant exposure risk characteristics, including borrower credit score, product and collateral types, as well as exposure delinquencies, and must consider cross-collateral provisions, where present.

(iii) The Board-regulated institution must review and, if appropriate, update assignments of individual retail exposures to segments and the loss characteristics and delinquency status of each identified risk segment. These reviews must occur whenever the Board-regulated institution receives new material information, but generally no less frequently than quarterly, and, in all cases, at least annually.

* * * * *

(5) The Board-regulated institution's internal risk rating system for wholesale exposures must provide for the review and update (as appropriate) of each obligor rating and (if applicable) each loss severity rating whenever the Board-regulated institution obtains relevant and material information on the obligor or exposure that affects PD, LGD and EAD, but no less frequently than annually.

(c) *Quantification of risk parameters for wholesale and retail exposures.* (1) The Board-regulated institution must have a comprehensive risk parameter quantification process that produces accurate, timely, and reliable estimates of the risk parameters on a consistent basis for the Board-regulated institution's wholesale and retail exposures.

(2) A Board-regulated institution's estimates of PD, LGD, and EAD must incorporate all relevant, material, and available data that is reflective of the Board-regulated institution's actual wholesale and retail exposures and of sufficient quality to support the determination of risk-based capital requirements for the exposures. In particular, the population of exposures in the data used for estimation purposes, the lending standards in use when the data were generated, and other relevant characteristics, should closely match or be comparable to the Board-regulated institution's exposures and standards. In addition, a Board-regulated institution must:

(i) Demonstrate that its estimates are representative of long run experience, including periods of economic downturn conditions, whether internal or external data are used;

(ii) Take into account any changes in lending practice or the process for pursuing recoveries over the observation period;

(iii) Promptly reflect technical advances, new data, and other information as they become available;

(iv) Demonstrate that the data used to estimate risk parameters support the accuracy and robustness of those estimates; and

(v) Demonstrate that its estimation technique performs well in out-of-sample tests whenever possible.

* * * * *

(5) The Board-regulated institution must be able to demonstrate which variables have been found to be statistically significant with regard to EAD. The Board-regulated institution's EAD estimates must reflect its specific policies and strategies with regard to account management, including account monitoring and payment processing, and its ability and willingness to prevent further drawdowns in circumstances short of payment default. The Board-regulated institution must have adequate systems and procedures in place to monitor current outstanding amounts against committed lines, and changes in outstanding amounts per obligor and obligor rating grade and per retail segment. The Board-regulated institution must be able to monitor outstanding amounts on a daily basis.

(6) At a minimum, PD estimates for wholesale obligors and retail segments must be based on at least five years of default data. LGD estimates for wholesale exposures must be based on at least seven years of loss severity data, and LGD estimates for retail segments must be based on at least five years of loss severity data. EAD estimates for wholesale exposures must be based on at least seven years of exposure amount data, and EAD estimates for retail segments must be based on at least five years of exposure amount data. If the Board-regulated institution has relevant and material reference data that span a longer period of time than the minimum time periods specified above, the Board-regulated institution must incorporate such data in its estimates, provided that it does not place undue weight on periods of favorable or benign economic conditions relative to periods of economic downturn conditions.

* * * * *

(9) If a Board-regulated institution uses internal data obtained prior to becoming subject to this subpart E or external data to arrive at PD, LGD, or EAD estimates, the Board-regulated institution must demonstrate to the Board that the Board-regulated institution has made appropriate adjustments if necessary to be consistent with the definition of default in § 217.101. Internal data obtained after the Board-regulated institution becomes subject to this subpart E must be consistent with the definition of default in § 217.101.

(10) The Board-regulated institution must review and update (as appropriate) its risk parameters and its risk parameter quantification process at least annually.

(11) The Board-regulated institution must, at least annually, conduct a comprehensive review and analysis of reference data to determine relevance of the reference data to the Board-regulated institution's exposures, quality of reference data to support PD, LGD, and EAD estimates, and consistency of reference data to the definition of default in § 217.101.

* * * * *

(i) * * *

(5) The Board-regulated institution must have an internal audit function or equivalent function that is independent of business-line management that at least annually:

(i) Reviews the Board-regulated institution's advanced systems and associated operations, including the operations of its credit function and estimations of PD, LGD, and EAD;

(ii) Assesses the effectiveness of the controls supporting the Board-regulated institution's advanced systems; and

(iii) Documents and reports its findings to the Board-regulated institution's board of directors (or a committee thereof).

* * * * *

■ 19. Section 217.131 is amended by:

■ a. Revising paragraphs (d)(5)(ii) and (iii); and

■ b. In paragraph (e)(3)(vi), removing ''§ 217.22(a)(7)'' and adding ''§ 217.22(d)'' in its place.

The revisions read as follows:

§ 217.131 Mechanics for calculating total wholesale and retail risk-weighted assets.

* * * * *

(d) * * *

(5) * * *

(ii) A Board-regulated institution may take into account the risk reducing effects of guarantees and credit derivatives in support of retail exposures in a segment when quantifying the PD and LGD of the segment. In doing so, a Board-regulated institution must consider all relevant available information.

(iii) Except as provided in paragraph (d)(6) of this section, a Board-regulated institution may take into account the risk reducing effects of collateral in support of a wholesale exposure when quantifying the LGD of the exposure, and may take into account the risk

reducing effects of collateral in support of retail exposures when quantifying the PD and LGD of the segment. In order to do so, a Board-regulated institution must have established internal requirements for collateral management, legal certainty, and risk management processes.

* * * * *

■ 20. Section 217.132 is amended by:
■ a. In Table 1 to § 217.132, removing ''this section'' and adding ''§ 217.32'' in its place, wherever it appears;
■ b. Revising paragraphs (c)(1), (c)(2) and (d)(5)(iii)(B);
■ c. In paragraph (d)(2)(iv)(C), removing ''(d)(5)'' and adding ''(d)(6)'' in its place;
■ d. In paragraph (d)(7)(iv)(B), removing ''§ 217.131(b)(2)'' and adding ''§ 217.132(b)(2)'' in its place; and
■ e. In paragraph (d)(9)(ii), removing ''paragraph (e)(3)'' and adding ''paragraph (e)(6)'' in its place. The revisions read as follows:

§ 217.132 Counterparty credit risk of repo-style transactions, eligible margin loans, and OTC derivative contracts.

* * * * *

(c) *EAD for OTC derivative contracts*—(1) *OTC derivative contracts not subject to a qualifying master netting agreement.* A Board-regulated institution must determine the EAD for an OTC derivative contract that is not subject to a qualifying master netting agreement using the current exposure methodology in paragraph (c)(5) of this section or using the internal models methodology described in paragraph (d) of this section. A Board-regulated institution may reduce the EAD calculated according to paragraph (c)(5) of this section by the credit valuation adjustment that the Board-regulated institution has recognized in its balance sheet valuation of any OTC derivative contracts in the netting set. For purposes of this paragraph (c)(1), the credit valuation adjustment does not include any adjustments to common equity tier 1 capital attributable to changes in the fair value of the Board-regulated institution's liabilities that are due to changes in its own credit risk since the inception of the transaction with the counterparty.

(2) *OTC derivative contracts subject to a qualifying master netting agreement.* A Board-regulated institution must determine the EAD for multiple OTC derivative contracts that are subject to a qualifying master netting agreement using the current exposure methodology in paragraph (c)(6) of this section or using the internal models methodology described in paragraph (d) of this section. A Board-regulated institution may reduce the EAD calculated according to paragraph (c)(6) of this section by the credit valuation adjustment that the Board-regulated institution has recognized in its balance sheet valuation of any OTC derivative contracts in the netting set. For purposes of this paragraph (c)(2), the credit valuation adjustment does not include any adjustments to common equity tier 1 capital attributable to changes in the fair value of the Board-regulated institution's liabilities that are due to changes in its own credit risk since the inception of the transaction with the counterparty.

* * * * *

(d) * * *

(5) * * *

(iii) * * *

(B) Twenty business days if the number of trades in a netting set exceeds 5,000 at any time during the previous quarter (except if the Board-regulated institution is calculating EAD for a cleared transaction under § 217.133) or contains one or more trades involving illiquid collateral or any derivative contract that cannot be easily replaced. If over the two previous quarters more than two margin disputes on a netting set have occurred that lasted more than the margin period of risk, then the Board-regulated institution must use a margin period of risk for that netting set that is at least two times the minimum margin period of risk for that netting set. If the periodicity of the receipt of collateral is N-days, the minimum margin period of risk is the minimum margin period of risk under this paragraph (d) plus N minus 1. This period should be extended to cover any impediments to prompt re-hedging of any market risk.

* * * * *

■ 21. Section 217.133 is amended by:
■ a. In paragraph (b)(3)(i)(B) removing ''§ 217.132(b)(3)(i)(A)'' and adding paragraph (b)(3)(i)(A) of this section'' in its place;
■ b. In paragraph (b)(4)(ii) removing ''§ 217.131'' and adding ''subparts E or F of this part, as applicable'' in its place;
■ c. Adding paragraph (c)(3)(iii); and
■ d. In paragraph (c)(4)(ii) removing ''§ 217.131'' and adding ''subparts E or F of this part, as applicable'' in its place.

The addition read as follows:

§ 217.133 Cleared transactions.

* * * * *

(c) * * *

(3) * * *

(iii) Notwithstanding paragraphs (c)(3)(i) and (ii) of this section, a clearing member Board-regulated institution may apply a risk weight of 0 percent to the trade exposure amount for a cleared transaction with a CCP where the clearing member Board-regulated institution is acting as a financial intermediary on behalf of a clearing member client, the transaction offsets another transaction that satisfies the requirements set forth in § 217.3(a), and the clearing member Board-regulated institution is not obligated to reimburse the clearing member client in the event of the CCP default.

* * * * *

§ 217.136 [Amended]

■ 22. Section 217.136 is amended by:
■ a. In paragraph (e)(2)(i), removing ''§ 217.135(e)(1) and (e)(2)'' and adding ''paragraphs (e)(1) and (2) of this section'' in its place; and
■ b. In paragraph (e)(2)(ii), removing ''§§ 217.135(e)(1) and (e)(2)'' and adding ''paragraphs (e)(1) and (2) of this section'' in its place.

■ 23. Section 217.172 is amended by revising paragraph (d) to read as follows:

§ 217.172 Disclosure requirements.

* * * * *

(d)(1) A Board-regulated institution that meets any of the criteria in § 217.100(b)(1) before January 1, 2015, must publicly disclose each quarter its supplementary leverage ratio and the components thereof (that is, tier 1 capital and total leverage exposure) as calculated under subpart B of this part, beginning with the first quarter in 2015. This disclosure requirement applies without regard to whether the Board-regulated institution has completed the parallel run process and received notification from the Board pursuant to § 217.121(d).

(2) A Board-regulated institution that meets any of the criteria in § 217.100(b)(1) on or after January 1, 2015, must publicly disclose each quarter its supplementary leverage ratio and the components thereof (that is, tier 1 capital and total leverage exposure) as calculated under subpart B of this part beginning with the calendar quarter immediately following the quarter in which the Board-regulated institution becomes an advanced approaches Board-regulated institution. This disclosure requirement applies without regard to whether the Board-regulated institution has completed the parallel run process and has received notification from the Board pursuant to § 217.121(d).

■ 24. Section 217.173 is amended by:
■ a. Designating paragraph (a) introductory text as paragraph (a)(1) and revising newly redesignated paragraph (a)(1);

■ b. Adding paragraphs (a)(2) and (3);
■ c. Revising the entry for (a)(1) in Table 6 to § 217.173; and
■ d. Revising the entry for (i)(2) in Table 9 to § 217.173.

The revisions and additions read as follows:

§ 217.173 Disclosures by certain advanced approaches Board-regulated institutions.

(a)(1) An advanced approaches Board-regulated institution described in § 217.172(b) must make the disclosures described in Tables 1 through 12 to § 217.173.

(2) An advanced approaches Board-regulated institution that is required to publicly disclose its supplementary leverage ratio pursuant to § 217.172(d) must make the disclosures required under Table 13 to § 217.173, unless the Board-regulated institution is a consolidated subsidiary of a bank holding company, savings and loan holding company, or depository institution that is subject to these disclosures requirements or a subsidiary of a non-U.S. banking organization that is subject to comparable public disclosure requirements in its home jurisdiction.

(3) The disclosures described in Tables 1 through 12 to § 217.173 must be made publicly available for twelve consecutive quarters beginning on January 1, 2014, or a shorter period, as applicable, for the quarters after the Board-regulated institution has completed the parallel run process and received notification from the Board pursuant to § 217.121(d). The disclosures described in Table 13 to § 217.173 must be made publicly available for twelve consecutive quarters beginning on January 1, 2015, or a shorter period, as applicable, for the quarters after the Board-regulated institution becomes subject to the disclosure of the supplementary leverage ratio pursuant to § 217.172(d) and § 217.173(a)(2).

* * * * *

TABLE 6 TO § 217.173—CREDIT RISK: DISCLOSURES FOR PORTFOLIOS SUBJECT TO IRB RISK-BASED CAPITAL FORMULA

Qualitative disclosures	(a)	* * *
		(1) Structure of internal rating systems and if the Board-regulated institution considers external ratings, the relation between internal and external ratings;
*	*	* * * * *

* * * * *

TABLE 9 TO § 217.173—SECURITIZATION

*	*	*	* * * * *
Quantitative disclosures.			
*	*	*	* * * * *
		(i)	* * *
			(2) Aggregate amount disclosed separately by type of underlying exposure in the pool of any: (i) After-tax gain-on-sale on a securitization that has been deducted from common equity tier 1 capital; and (ii) Credit-enhancing interest-only strip that is assigned a 1,250 percent risk weight.
*	*	*	* * * * *

* * * * *

FEDERAL DEPOSIT INSURANCE CORPORATION

12 CFR Chapter III

Authority and Issuance

For the reasons stated in the preamble, the Federal Deposit Insurance Corporation amends part 324 of chapter III of Title 12, Code of Federal Regulations as follows:

PART 324—CAPITAL ADEQUACY

■ 25. The authority citation for part 324 continues to read as follows:

Authority: 12 U.S.C. 1815(a), 1815(b), 1816, 1818(a), 1818(b), 1818(c), 1818(t), 1819(Tenth), 1828(c), 1828(d), 1828(i), 1828(n), 1828(o), 1831o, 1835, 3907, 3909, 4808; 5371; 5412; Pub. L. 102–233, 105 Stat. 1761, 1789, 1790 (12 U.S.C. 1831n note); Pub. L. 102–242, 105 Stat. 2236, 2355, as amended by Pub. L. 103–325, 108 Stat. 2160, 2233 (12 U.S.C. 1828 note); Pub. L. 102–242, 105 Stat. 2236, 2386, as amended by Pub. L. 102–550, 106 Stat. 3672, 4089 (12 U.S.C. 1828 note); Pub. L. 111–203, 124 Stat. 1376, 1887 (15 U.S.C. 78o–7 note).

■ 26. Section 324.2 is amended by revising the definition of ''Residential mortgage exposure'' to read as follows:

§ 324.2 Definitions.

* * * * *

Residential mortgage exposure means an exposure (other than a securitization exposure, equity exposure, statutory multifamily mortgage, or presold construction loan):

(1)(i) That is primarily secured by a first or subsequent lien on one-to-four family residential property; or

(ii) With an original and outstanding amount of $1 million or less that is primarily secured by a first or subsequent lien on residential property that is not one-to-four family; and

(2) For purposes of calculating capital requirements under subpart E of this part, managed as part of a segment of exposures with homogeneous risk characteristics and not on an individual-exposure basis.

* * * * *

■ 27. Section 324.10 is amended by revising paragraph (c) introductory text to read as follows:

§ 324.10 Minimum capital requirements.

* * * * *

(c) *Advanced approaches capital ratio calculations.* An advanced approaches FDIC-supervised institution that has

completed the parallel run process and received notification from the FDIC pursuant to § 324.121(d) must determine its regulatory capital ratios as described in paragraphs (c)(1) through (3) of this section. An advanced approaches FDIC-supervised institution must determine its supplementary leverage ratio in accordance with paragraph (c)(4) of this section, beginning with the calendar quarter immediately following the quarter in which the FDIC-supervised institution meets any of the criteria in § 324.100(b)(1).

* * * * *

■ 28. Section 324.22 is amended by revising paragraph (b)(1)(iii) to read as follows:

§ 324.22 Regulatory capital adjustments and deductions.

* * * * *

(b) * * *

(1) * * *

(iii) An FDIC-supervised institution must deduct any net gain and add any net loss related to changes in the fair value of liabilities that are due to changes in the FDIC-supervised institution's own credit risk. An advanced approaches FDIC-supervised institution must deduct the difference between its credit spread premium and the risk-free rate for derivatives that are liabilities as part of this adjustment.

* * * * *

■ 29. Section 324.100 is amended by revising paragraph (b)(1)(ii) to read as follows:

§ 324.100 Purpose, applicability, and principle of conservatism.

* * * * *

(b) * * *

(1) * * *

(ii) Has consolidated total on-balance sheet foreign exposure on its most recent year-end Federal Financial Institutions Examination Council (FFIEC) 009 Report equal to $10 billion or more (where total on-balance sheet foreign exposure equals total foreign countries cross-border claims on an ultimate-risk basis, plus total foreign countries claims on local residents on an ultimate-risk basis, plus total foreign countries fair value of foreign exchange and derivative products), calculated in accordance with the FFIEC 009 Country Exposure Report;

* * * * *

■ 30. Section 324.122 is amended by:

■ a. Revising paragraphs (a)(3) and (b)(1);

■ b. Adding paragraph (b)(2)(iii);

■ c. Revising paragraphs (b)(3) and (5), and (c)(1), (2), (5), and (6);

■ d. Redesignating paragraphs (c)(9) and (c)(10) as paragraphs (c)(10) and (c)(11), revising newly redesignated paragraphs (c)(10) and (c)(11), and adding a new paragraph (c)(9); and

■ e. Revising paragraph (i)(5).

The revisions and additions read as follows:

§ 324.122 Qualification requirements.

(a) * * *

(3) Each FDIC-supervised institution must have an appropriate infrastructure with risk measurement and management processes that meet the qualification requirements of this section and are appropriate given the FDIC-supervised institution's size and level of complexity. Regardless of whether the systems and models that generate the risk parameters necessary for calculating an FDIC-supervised institution's risk-based capital requirements are located at any affiliate of the FDIC-supervised institution, the FDIC-supervised institution itself must ensure that the risk parameters and reference data used to determine its risk-based capital requirements are representative of long run experience with respect to its own credit risk and operational risk exposures.

(b) *Risk rating and segmentation systems for wholesale and retail exposures.* (1)(i) An FDIC-supervised institution must have an internal risk rating and segmentation system that accurately, reliably, and meaningfully differentiates among degrees of credit risk for the FDIC-supervised institution's wholesale and retail exposures. When assigning an internal risk rating, an FDIC-supervised institution may consider a third-party assessment of credit risk, provided that the FDIC-supervised institution's internal risk rating assignment does not rely solely on the external assessment.

(ii) If an FDIC-supervised institution uses multiple rating or segmentation systems, the FDIC-supervised institution's rationale for assigning an obligor or exposure to a particular system must be documented and applied in a manner that best reflects the obligor or exposure's level of risk. An FDIC-supervised institution must not inappropriately allocate obligors or exposures across systems to minimize regulatory capital requirements.

(iii) In assigning ratings to wholesale obligors and exposures, including loss severity ratings grades to wholesale exposures, and assigning retail exposures to retail segments, an FDIC-supervised institution must use all relevant and material information and ensure that the information is current.

(iv) When assigning an obligor to a PD rating or retail exposure to a PD segment, an FDIC-supervised institution must assess the obligor or retail borrower's ability and willingness to contractually perform, taking a conservative view of projected information.

(2) * * *

(iii) An FDIC-supervised institution must have an effective process to obtain and update in a timely manner relevant and material information on obligor and exposure characteristics that affect PD, LGD and EAD.

(3) For retail exposures:

(i) An FDIC-supervised institution must have an internal system that groups retail exposures into the appropriate retail exposure subcategory and groups the retail exposures in each retail exposure subcategory into separate segments with homogeneous risk characteristics that provide a meaningful differentiation of risk. The FDIC-supervised institution's system must identify and group in separate segments by subcategories exposures identified in § 324.131(c)(2)(ii) and (iii).

(ii) An FDIC-supervised institution must have an internal system that captures all relevant exposure risk characteristics, including borrower credit score, product and collateral types, as well as exposure delinquencies, and must consider cross-collateral provisions, where present.

(iii) The FDIC-supervised institution must review and, if appropriate, update assignments of individual retail exposures to segments and the loss characteristics and delinquency status of each identified risk segment. These reviews must occur whenever the FDIC-supervised institution receives new material information, but generally no less frequently than quarterly, and, in all cases, at least annually.

* * * * *

(5) The FDIC-supervised institution's internal risk rating system for wholesale exposures must provide for the review and update (as appropriate) of each obligor rating and (if applicable) each loss severity rating whenever the FDIC-supervised institution obtains relevant and material information on the obligor or exposure that affects PD, LGD and EAD, but no less frequently than annually.

(c) *Quantification of risk parameters for wholesale and retail exposures.* (1) The FDIC-supervised institution must have a comprehensive risk parameter quantification process that produces accurate, timely, and reliable estimates of the risk parameters on a consistent basis for the FDIC-supervised institution's wholesale and retail exposures.

(2) An FDIC-supervised institution's estimates of PD, LGD, and EAD must

incorporate all relevant, material, and available data that is reflective of the FDIC-supervised institution's actual wholesale and retail exposures and of sufficient quality to support the determination of risk-based capital requirements for the exposures. In particular, the population of exposures in the data used for estimation purposes, the lending standards in use when the data were generated, and other relevant characteristics, should closely match or be comparable to the FDIC-supervised institution's exposures and standards. In addition, an FDIC-supervised institution must:

(i) Demonstrate that its estimates are representative of long run experience, including periods of economic downturn conditions, whether internal or external data are used;

(ii) Take into account any changes in lending practice or the process for pursuing recoveries over the observation period;

(iii) Promptly reflect technical advances, new data, and other information as they become available;

(iv) Demonstrate that the data used to estimate risk parameters support the accuracy and robustness of those estimates; and

(v) Demonstrate that its estimation technique performs well in out-of-sample tests whenever possible.

* * * * *

(5) The FDIC-supervised institution must be able to demonstrate which variables have been found to be statistically significant with regard to EAD. The FDIC-supervised institution's EAD estimates must reflect its specific policies and strategies with regard to account management, including account monitoring and payment processing, and its ability and willingness to prevent further drawdowns in circumstances short of payment default. The FDIC-supervised institution must have adequate systems and procedures in place to monitor current outstanding amounts against committed lines, and changes in outstanding amounts per obligor and obligor rating grade and per retail segment. The FDIC-supervised institution must be able to monitor outstanding amounts on a daily basis.

(6) At a minimum, PD estimates for wholesale obligors and retail segments must be based on at least five years of default data. LGD estimates for wholesale exposures must be based on at least seven years of loss severity data, and LGD estimates for retail segments must be based on at least five years of loss severity data. EAD estimates for wholesale exposures must be based on at least seven years of exposure amount data, and EAD estimates for retail segments must be based on at least five years of exposure amount data. If the FDIC-supervised institution has relevant and material reference data that span a longer period of time than the minimum time periods specified above, the FDIC-supervised institution must incorporate such data in its estimates, provided that it does not place undue weight on periods of favorable or benign economic conditions relative to periods of economic downturn conditions.

* * * * *

(9) If an FDIC-supervised institution uses internal data obtained prior to becoming subject to this subpart E or external data to arrive at PD, LGD, or EAD estimates, the FDIC-supervised institution must demonstrate to the FDIC that the FDIC-supervised institution has made appropriate adjustments if necessary to be consistent with the definition of default in § 324.101. Internal data obtained after the FDIC-supervised institution becomes subject to this subpart E must be consistent with the definition of default in § 324.101.

(10) The FDIC-supervised institution must review and update (as appropriate) its risk parameters and its risk parameter quantification process at least annually.

(11) The FDIC-supervised institution must, at least annually, conduct a comprehensive review and analysis of reference data to determine relevance of the reference data to the FDIC-supervised institution's exposures, quality of reference data to support PD, LGD, and EAD estimates, and consistency of reference data to the definition of default in § 324.101.

* * * * *

(i) * * *

(5) The FDIC-supervised institution must have an internal audit function or equivalent function that is independent of business-line management that at least annually:

(i) Reviews the FDIC-supervised institution's advanced systems and associated operations, including the operations of its credit function and estimations of PD, LGD, and EAD;

(ii) Assesses the effectiveness of the controls supporting the FDIC-supervised institution's advanced systems; and

(iii) Documents and reports its findings to the FDIC-supervised institution's board of directors (or a committee thereof).

* * * * *

■ 31. Section 324.131 is amended by:

■ a. Revising paragraphs (d)(5)(ii) and (iii); and

■ b. In paragraph (e)(3)(vi), removing ''§ 324.22(a)(7)'' and adding ''§ 324.22(d)'' in its place.

The revisions read as follows:

§ 324.131 Mechanics for calculating total wholesale and retail risk-weighted assets.

* * * * *

(d) * * *

(5) * * *

(ii) An FDIC-supervised institution may take into account the risk reducing effects of guarantees and credit derivatives in support of retail exposures in a segment when quantifying the PD and LGD of the segment. In doing so, an FDIC-supervised institution must consider all relevant available information.

(iii) Except as provided in paragraph (d)(6) of this section, an FDIC-supervised institution may take into account the risk reducing effects of collateral in support of a wholesale exposure when quantifying the LGD of the exposure, and may take into account the risk reducing effects of collateral in support of retail exposures when quantifying the PD and LGD of the segment. In order to do so, an FDIC-supervised institution must have established internal requirements for collateral management, legal certainty, and risk management processes.

* * * * *

■ 32. Section 324.132 is amended by:

■ a. In Table 1 to § 324.132, removing ''this section'' and adding ''§ 324.32'' in its place, wherever it appears;

■ b. Revising paragraphs (c)(1), (c)(2) and (d)(5)(iii)(B);

■ c. In paragraph (d)(2)(iv)(C), removing ''(d)(5)'' and adding ''(d)(6)'' in its place;

■ d. In paragraph (d)(7)(iv)(B), removing ''§ 324.131(b)(2)'' and adding ''§ 324.132(b)(2)'' in its place; and

■ e. In paragraph (d)(9)(ii), removing ''paragraph (e)(3)'' and adding ''paragraph (e)(6)'' in its place.

The revisions read as follows:

§ 324.132 Counterparty credit risk of repo-style transactions, eligible margin loans, and OTC derivative contracts.

* * * * *

(c) *EAD for OTC derivative contracts—(1) OTC derivative contracts not subject to a qualifying master netting agreement.* An FDIC-supervised institution must determine the EAD for an OTC derivative contract that is not subject to a qualifying master netting agreement using the current exposure methodology in paragraph (c)(5) of this section or using the internal models methodology described in paragraph (d) of this section. An FDIC-supervised institution may reduce the EAD calculated according to paragraph (c)(5)

of this section by the credit valuation adjustment that the FDIC-supervised institution has recognized in its balance sheet valuation of any OTC derivative contracts in the netting set. For purposes of this paragraph (c)(1), the credit valuation adjustment does not include any adjustments to common equity tier 1 capital attributable to changes in the fair value of the FDIC-supervised institution's liabilities that are due to changes in its own credit risk since the inception of the transaction with the counterparty.

(2) *OTC derivative contracts subject to a qualifying master netting agreement.* An FDIC-supervised institution must determine the EAD for multiple OTC derivative contracts that are subject to a qualifying master netting agreement using the current exposure methodology in paragraph (c)(6) of this section or using the internal models methodology described in paragraph (d) of this section. An FDIC-supervised institution may reduce the EAD calculated according to paragraph (c)(6) of this section by the credit valuation adjustment that the FDIC-supervised institution has recognized in its balance sheet valuation of any OTC derivative contracts in the netting set. For purposes of this paragraph (c)(2), the credit valuation adjustment does not include any adjustments to common equity tier 1 capital attributable to changes in the fair value of the FDIC-supervised institution's liabilities that are due to changes in its own credit risk since the inception of the transaction with the counterparty.

* * * * *

(d) * * *

(5) * * *

(iii) * * *

(B) Twenty business days if the number of trades in a netting set exceeds 5,000 at any time during the previous quarter (except if the FDIC-supervised institution is calculating EAD for a cleared transaction under § 324.133) or contains one or more trades involving illiquid collateral or any derivative contract that cannot be easily replaced. If over the two previous quarters more than two margin disputes on a netting set have occurred that lasted more than the margin period of risk, then the FDIC-supervised institution must use a margin period of risk for that netting set that is at least two times the minimum margin period of risk for that netting set. If the periodicity of the receipt of collateral is N-days, the minimum margin period of risk is the minimum margin period of risk under this paragraph (d) plus N minus 1. This period should be extended to cover any impediments to prompt re-hedging of any market risk.

* * * * *

■ 33. Section 324.133 is amended by:

■ a. In paragraph (b)(3)(i)(B), removing ''§ 324.132(b)(3)(i)(A)'' and adding ''paragraph (b)(3)(i)(A) of this section'' in its place;

■ b. In paragraph (b)(4)(ii) removing ''§ 324.131'' and adding ''subparts E or F of this part, as applicable'' in its place;

■ c. Adding paragraph (c)(3)(iii); and

■ d. In paragraph (c)(4)(ii) removing ''§ 324.131'' and adding ''subparts E or F of this part, as applicable'' in its place.

The additions read as follows:

§ 324.133 Cleared transactions.

* * * * *

(c) * * *

(3) * * *

(iii) Notwithstanding paragraphs (c)(3)(i) and (ii) of this section, a clearing member FDIC-supervised institution may apply a risk weight of 0 percent to the trade exposure amount for a cleared transaction with a CCP where the clearing member FDIC-supervised institution is acting as a financial intermediary on behalf of a clearing member client, the transaction offsets another transaction that satisfies the requirements set forth in § 324.3(a), and the clearing member FDIC-supervised institution is not obligated to reimburse the clearing member client in the event of the CCP default.

* * * * *

■ 34. Section 324.136 is amended by,

■ a. In paragraph (e)(2)(i) removing ''§ 324.135(e)(1) and (e)(2)'' and adding paragraphs (e)(1) and (e)(2) of this section'' in its place; and

■ b. In paragraph (e)(2)(ii) removing ''§§ 324.135(e)(1) and (e)(2)'' and adding paragraphs (e)(1) and (e)(2)'' of this section in its place.

■ 35. Section 324.172 is amended by revising paragraph (d) to read as follows:

§ 324.172 Disclosure requirements.

* * * * *

(d)(1) An FDIC-supervised institution that meets any of the criteria in § 324.100(b)(1) before January 1, 2015, must publicly disclose each quarter its supplementary leverage ratio and the components thereof (that is, tier 1 capital and total leverage exposure) as calculated under subpart B of this part, beginning with the first quarter in 2015. This disclosure requirement applies without regard to whether the FDIC-supervised institution has completed the parallel run process and received notification from the FDIC pursuant to § 324.121(d).

(2) An FDIC-supervised institution that meets any of the criteria in § 324.100(b)(1) on or after January 1, 2015, must publicly disclose each quarter its supplementary leverage ratio and the components thereof (that is, tier 1 capital and total leverage exposure) as calculated under subpart B of this part beginning with the calendar quarter immediately following the quarter in which the FDIC-supervised institution becomes an advanced approaches FDIC-supervised institution. This disclosure requirement applies without regard to whether the FDIC-supervised institution has completed the parallel run process and has received notification from the FDIC pursuant to § 324.121(d).

■ 36. Section 324.173 is amended by:

■ a. Designating paragraph (a) as paragraph (a)(1) and revising newly redesignated paragraph (a)(1);

■ b. Adding paragraphs (a)(2) and (3);

■ c. Revising the entry for (a)(1) in Table 6 to § 324.173; and

■ d. Revising the entry for (i)(2) in Table 9 in § 324.173.

The revisions and additions read as follows:

§ 324.173 Disclosures by certain advanced approaches FDIC-supervised institutions.

(a)(1) An advanced approaches FDIC-supervised institution described in § 324.172(b) must make the disclosures described in Tables 1 through 12 to § 324.173.

(2) An advanced approaches FDIC-supervised institution that is required to publicly disclose its supplementary leverage ratio pursuant to § 324.172(d) must make the disclosures required under Table 13 to § 324.173, unless the FDIC-supervised institution is a consolidated subsidiary of a bank holding company, savings and loan holding company, or depository institution that is subject to these disclosures requirements or a subsidiary of a non-U.S. banking organization that is subject to comparable public disclosure requirements in its home jurisdiction.

(3) The disclosures described in Tables 1 through 12 to § 324.173 must be made publicly available for twelve consecutive quarters beginning on January 1, 2014, or a shorter period, as applicable, for the quarters after the FDIC-supervised institution has completed the parallel run process and received notification from the FDIC pursuant to § 324.121(d). The disclosures described in Table 13 to § 324.173 must be made publicly available for twelve consecutive quarters beginning on January 1, 2015, or a shorter period, as applicable, for the quarters after the FDIC-supervised

institution becomes subject to the disclosure of the supplementary leverage ratio pursuant to § 324.172(d) and § 324.173(a)(2).

* * * * *

TABLE 6 TO § 324.173—CREDIT RISK: DISCLOSURES FOR PORTFOLIOS SUBJECT TO IRB RISK-BASED CAPITAL FORMULA

Qualitative disclosures	(a)	* * *
		(1) Structure of internal rating systems and if the FDIC-supervised institution considers external ratings, the relation between internal and external ratings;
*	*	* * * * *

* * * * *

TABLE 9 TO § 324.173—SECURITIZATION

*	*	* * * * *
Quantitative Disclosures.		
*	*	* * * * *
	(i)	* * *
		(2) Aggregate amount disclosed separately by type of underlying exposure in the pool of any: (i) After-tax gain-on-sale on a securitization that has been deducted from common equity tier 1 capital; and (ii) Credit-enhancing interest-only strip that is assigned a 1,250 percent risk weight.
*	*	* * * * *

* * * * *

■ 37. Section 324.403(b) is revised to read as follows:

§ 324.403 Capital measures and capital category definitions.

* * *

(b) *Capital categories.* For purposes of section 38 of the FDI Act and this subpart, an FDIC-supervised institution shall be deemed to be:

(1) ''Well capitalized'' if it:

(i) Has a total risk-based capital ratio of 10.0 percent or greater; and

(ii) Has a Tier 1 risk-based capital ratio of 8.0 percent or greater; and

(iii) Has a common equity tier 1 capital ratio of 6.5 percent or greater; and

(iv) Has a leverage ratio of 5.0 percent or greater;

(v) Is not subject to any written agreement, order, capital directive, or prompt corrective action directive issued by the FDIC pursuant to section 8 of the FDI Act (12 U.S.C. 1818), the International Lending Supervision Act of 1983 (12 U.S.C. 3907), or the Home Owners' Loan Act (12 U.S.C. 1464(t)(6)(A)(ii)), or section 38 of the FDI Act (12 U.S.C. 1831o), or any regulation thereunder, to meet and maintain a specific capital level for any capital measure; and

(vi) Beginning on January 1, 2018 and thereafter, an FDIC-supervised institution that is a subsidiary of a covered BHC will be deemed to be well capitalized if the FDIC-supervised institution satisfies paragraphs (b)(1)(i) through (v) of this section and has a supplementary leverage ratio of 6.0 percent or greater. For purposes of this paragraph, a covered BHC means a U.S. top-tier bank holding company with more than $700 billion in total assets as reported on the company's most recent Consolidated Financial Statement for Bank Holding Companies (FR Y–9C) or more than $10 trillion in assets under custody as reported on the company's most recent Banking Organization Systemic Risk Report (FR Y–15).

* * * * *

Dated: June 16, 2015.

Thomas J. Curry,

Comptroller of the Currency.

By order of the Board of Governors of the Federal Reserve System, June 15, 2015.

Robert deV. Frierson,

Secretary of the Board.

Dated at Washington, DC, this 16th day of June, 2015.

By order of the Board of Directors.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2015–15748 Filed 7–14–15; 8:45 am]

BILLING CODE

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 702

[Docket No. 140501396–5463–02]

RIN 0694–AG17

U.S. Industrial Base Surveys Pursuant to the Defense Production Act of 1950

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: This rule sets forth the policies and procedures of the Bureau of Industry and Security (BIS) for conducting surveys to obtain information in order to perform industry studies assessing the U.S. industrial base to support the national defense pursuant to the Defense Production Act of 1950, as amended. Specifically, this rule provides a description of BIS's authority to issue surveys; the purpose for the surveys and the manner in which such surveys are developed; the confidential treatment of submitted information; and the penalties for non-compliance with surveys. This rule is intended to facilitate compliance with surveys, thereby resulting in stronger and more complete assessments of the U.S. industrial base.

DATES: This rule is effective August 14, 2015.

FOR FURTHER INFORMATION CONTACT: Jason Bolton, Trade and Industry Analyst, Office of Technology Evaluation, phone: 202–482–5936 email: *jason.bolton@bis.doc.gov* or Brad Botwin, Director, Industrial Base Studies, Office of Technology Evaluation, phone: 202–482–4060 email: *brad.botwin@bis.doc.gov*.

SUPPLEMENTARY INFORMATION:

Background

Pursuant to authorities under section 705 of the Defense Production Act of 1950 as amended (DPA) (50 U.S.C. app. 2155) and § 104 of Executive Order 13603 of March 16, 2012 (National Defense Resources Preparedness, 77 FR 16651, 3 CFR, 2012 Comp., p. 225), the Bureau of Industry and Security (BIS) conducts studies that assess the capabilities of the U.S. industrial base to support the national defense. To produce these studies, BIS may issue surveys to collect detailed information related to the health and competitiveness of the U.S. industrial base from government sources and private individuals or organizations.

BIS published a proposed rule addressing its authority to conduct the studies, the authority to issue surveys to gather data in support of the studies, the purpose of the surveys and the manner in which such surveys are developed, the confidential treatment of submitted information, and the penalties for non-compliance with surveys (*see* 80 FR 11350, March 3, 2015). BIS received two comments on the proposed rule and is not making any changes to the final rule text in response to those comments. This final rule makes no substantive change to the proposed rule.

Public Comments and BIS's Response

BIS received two comments on the proposed rule. They are reproduced in their entireties along with BIS's responses below.

Comment 1.

''The Defense Production Act of 1950 was enacted so that [the] [P]resident could (1) require business[es] to sign contracts deemed necessary for defense, (2) allow the [P]resident to create mechanisms that would allow the allocation of goods and services to support defense and (3) allow the [P]resident to control civilian economy so that scare resource are available for defense. This Act was used during for the Cold War, and could be labeled as outdated and unnecessary. Under this act, the [P]resident and his staff is given a lot of power over the economy. I disagree with the BIS that there should be some sort of supervision over this act. From what I have researched I have found one use of the Act in 2011, where the Government seized equipment from telecommunications companies for criminal charges. One incident should not raise alarm of possible fraud or misuse. Although I wish that all sections of the government could be monitored more, I know that the money spent on the oversight of this Act could be spent more effectively elsewhere.''

Response: Section 705 of the Defense Production Act of 1950 (50 U.S.C. app. 2155), authorizes the President to, among other things, ''require such reports and the keeping of such records by, make such inspection of the books, records, and other writings, premises or property of, and take the sworn testimony of, and administer oaths and affirmations to, any person as may be necessary or appropriate, in his discretion, to the enforcement or the administration of this Act and the regulations or orders issued thereunder.'' In 2003, an amendment to that Act made clear that such ''authority . . . includes the authority to obtain information in order to perform industry studies assessing the capabilities of the United States industrial base to support the national defense.'' This rule is designed to set forth policies and procedures to facilitate the accurate and timely completion of surveys issued by BIS to collect data for these studies. Whether or not the Act is outdated and unnecessary is a decision for Congress, and is not something to be addressed in this regulation. This regulation is solely intended to clearly implement the provisions of Section 705 of the DPA.

Additionally, BIS does not engage in ''supervision over this act.'' The studies that BIS conducts under the DPA are for the purpose of assessing the capabilities of the United States industrial base to support the national defense. BIS does not seize property under the DPA in connection with criminal charges and the proposed rule makes no mention of seizure authority.

Accordingly, BIS is making no changes to the proposed rule in response to this comment.

Comment 2.

''The corporation does not posses [sic] the rights of citizenship within U.S. borders, privileges or immunity clause ensures this within The Constitution of the United States of America. Societal roles force us to consider the implications surrounding predictive analytics based in Logic while the National Identity is a consensus being manufactured through a rational theory exercise in speculative risk. Insurers effectively are prohibited from utilizing coercion due to the McCarran Ferguson Act, however significant concerns exist with regard to the applicability of industry influence with-out the force of Anti-trust regulations to secure American values toward equality. A proposal to reduce the unnecessary burdens establishing this future of regulation, suggests the McCarran Ferguson Act may be applied to the Gramm Leech Bliley Act as a measured and proportionate Logic introduced to the irrational manufacture of consent.

Response: The proposed rule and this final rule are entirely unrelated to the rights of citizenship as they may or may not apply to corporations, the privileges and immunities clause of the Constitution of the United States, the regulation of insurers, anti-trust law, the Gramm Leech Bliley Act, or the McCarran Ferguson Act. The proposed rule and this final rule address surveys issued by BIS to collect data for studies assessing the capabilities of the United States industrial base to support the national defense, consistent with the authorities set forth in section 705 of the Defense Production Act of 1950.

As this comment is unrelated to the BIS activities this rule addresses, BIS is making no changes to the final rule in response to this comment.

General Description of the Rule

This rule sets forth procedures intended to facilitate the accurate and timely completion of surveys issued by BIS to collect data for these studies. This rule sets forth in a single part of the Code of Federal Regulations the information about BIS's authority to conduct the studies, the authority to issue surveys to gather data in support of the studies, the purpose of the surveys and the manner in which such surveys are developed, the confidential treatment of submitted information, and the penalties for non-compliance with surveys.

Additionally, this rule explains BIS's procedures for verifying that the scope and purpose of the surveys are well defined, and assures that the surveys do not solicit data that duplicates adequate and authoritative data that is available to BIS from any federal or other responsible agency. A survey may require the submission of information similar or identical to information possessed by another federal agency but that is not available to BIS.

Based on requests it receives from U.S. Government agencies, BIS produces studies to develop findings and policy recommendations for the purpose of improving the competitiveness of specific domestic industries and technologies critical to meeting national defense and essential civilian requirements. These studies may require surveys to collect relevant data and assessments of that data and other information available to BIS.

BIS, in cooperation with the requesting agency, selects the persons to be surveyed based on the likelihood that they will have information relevant to a

study. That likelihood is related to the person's association with the industry sector, material, product, service or technology that is the subject of the study. That association may be based on factors such as the person's role in directly or indirectly providing, producing, distributing, utilizing, procuring, researching, developing, consulting or advising on, the industry sector, material, product, service or technology that is the subject of the study.

Whether a person's association with the industry sector, material, product, service or technology being assessed is proximate or remote does not determine whether that person's association is sufficient for inclusion in the survey. For example, information about a supplier of raw materials or components that is several transactions removed from the production of the product that is the subject of a study may be relevant to assessing the capabilities of the U.S. industrial base to supply the product to support the national defense. In such a situation, the supplier would be included in the survey. The nature of the person from whom the information is sought also does not determine whether that person's association with the industry sector, material, product, service or technology at issue is sufficient for inclusion in the survey. Surveys may require information from businesses organized for profit, non-profit organizations, academic institutions and government agencies.

To be useful, a study must be comprehensive, accurate and focused on the relevant industry sector, material, product, service or technology. Therefore, surveys may require information about employment, research and development, sources of supply, manufacturing processes, customers, business strategy, finances and other factors affecting the industry's health and competitiveness. To properly focus the survey on the industry sector, material, product, service or technology being assessed, BIS may request information about a corporation as a whole or information about one or more specified units or individual activities of that corporation. The DPA provides both a civil remedy and criminal penalties that may be used when recipients of surveys do not supply the information sought.

BIS deems the information supplied in response to survey requests to be confidential and is prohibited by law from publishing or disclosing such information unless the Under Secretary for Industry and Security determines that withholding the information is contrary to the interest of the national defense. The authority to make this determination, which section 705(d) of the DPA gives to the President, has been delegated to relevant agencies, including the Secretary of Commerce, by § 802 of Executive Order 13603. The Secretary of Commerce re -delegated this authority to the Under Secretary for Industry and Security. The DPA provides criminal penalties for any person who willfully violates its prohibition on publication or disclosure.

Section by Section Description of the Rule

This rule creates a new part in Title 15, Chapter VII, Subchapter A of the Code of Federal Regulations to be designated as 15 CFR part 702. This new part is devoted exclusively to BIS's collection of information under section 705 of the DPA (50 U.S.C. app. 2155). Placing the new part in Subchapter A promotes an orderly and logical regulatory structure because all other regulations implementing BIS authorities related to the DPA are contained in that subchapter.

Section 702.1

Section 702.1 sets forth a general description of BIS's authority to collect information needed to complete the surveys. The survey responses assist BIS in determining the capabilities of the industrial base to support the national defense and to develop policy recommendations to improve both the international competitiveness of specific domestic industries and their ability to meet national defense needs.

Section 702.2

Section 702.2 implements the requirement found in section 705 of the DPA (50 U.S.C. app. 2155(a)) to publish regulations by requiring BIS personnel of appropriate competence and authority to ensure that before a survey is sent to any person for completion; 1) the scope and purpose of a survey have been established, 2) the scope and purpose are consistent with BIS's authorities under the DPA, and 3) the data requested by the survey does not duplicate adequate and authoritative data available to BIS from a federal or other authoritative source. A survey may require information that is similar or identical to information possessed by other federal agencies but not available to BIS. The section does not limit the factors that may be considered in deciding whether to conduct a survey nor does it modify or replace the requirements of the Paperwork Reduction Act. In addition, all surveys are reviewed by BIS and by the Office of Management and Budget (OMB) pursuant to the Paperwork Reduction Act before they are distributed. The OMB review process provides additional assurance that surveys are designed to collect only information deemed necessary to meet the scope and purpose of a study.

Section 702.3

Section 702.3 addresses the confidentiality requirements imposed by section 705(d) of the DPA (50 U.S.C. app. 2155(d)) and, in accordance with that section, provides two procedures by which the restrictions on disclosure in section 705(d) would be invoked. First, consistent with its current practice, BIS would deem all information submitted in response to a survey to be confidential. Second, a person submitting a response to a survey may request confidential treatment of the information submitted. Although the second procedure is likely to be redundant of the first, the statute prohibits disclosure if either the government deems the information to be confidential or if the person furnishing the information requests confidential treatment. BIS concludes that both procedures should be included in the regulations to be consistent with the statute. Additionally, § 702.3 notes that confidential information shall not be published or disclosed unless the Under Secretary for Industry and Security determines that withholding the information is contrary to the interest of the national defense. The statutory authority of the President to make this determination has been delegated to the Under Secretary for Industry and Security. This section also repeats the penalties that the statute authorizes for persons convicted of willfully violating the prohibition on disclosure.

Section 702.4

Section 702.4 requires timely, complete and adequate responses to surveys. Specifically, the section requires that survey responses be returned to BIS within the time frame stated on the initial distribution letter or other request for information. The section treats a response as ''inadequate'' if it provides information that is not responsive to the questions asked or if it provides aggregated information when specific information was requested.

Section 702.4 sets forth the criteria by which BIS may grant either an exemption from complying with the survey requirement or an extension of time to comply. The grounds for granting an exemption or an extension are limited and generally result when

BIS concludes that the survey recipient lacks information deemed relevant to the survey or when compliance with the requirement would be unduly burdensome.

Section 702.4 makes clear that the deadline for complying with a survey is not suspended by submitting a request for an exemption or extension of time to comply.

Finally, § 702.4 provides that BIS may return responses that are incomplete or inadequate and specify a due date for a complete and adequate response.

Section 702.5

Section 702.5 sets forth the consequences of failure to comply with a survey or other request for information. These consequences are established by section 705(a) and (c) of the DPA (50 U.S.C. app. 2155(a) and (c)). If a person does not comply with a survey, BIS may serve a subpoena upon that person to compel compliance. If the person still does not comply, the government may apply to the U.S. district court in any district in which the person is found, resides or transacts business for an order requiring such person to comply. The district court has authority to punish any failure to comply with the order as contempt of court. Persons who are convicted of willfully failing to comply with a survey or other request for information may be fined not more than $10,000 or imprisoned for not more than one year, or both.

Section 702.6

Section 702.6 defines certain terms used in part 702.

The word ''confidential'' is defined in terms of section 705(d) of the DPA, thereby distinguishing its use in this rule from its use in connection with the classification of information for national security purposes as set forth in Executive Order 13526 of December 29, 2009, Classified National Security Information (75 FR 707; 3 CFR, 2010 Comp., p. 298).

The definition of the term ''person'' is based on the definition of ''person'' in section 702 of the DPA (50 U.S.C. app. 2152) with some additions. The DPA definition reads: ''The term 'person' includes an individual, corporation, partnership, association, or any other organized group of persons, or legal successor or representative thereof, or any State or local government or agency thereof.'' Use of the word ''includes'' in the statutory definition implies that the list following that word is not exhaustive. BIS concludes that the use of ''includes'' indicates that Congress recognized that the agency implementing the DPA would need discretion to identify the types of entities that would likely possess information relevant to the subject of each industrial base assessment to ensure a comprehensive collection of information.

This rule adds ''The Government of the United States, of the District of Columbia, of any commonwealth, territory or possession of the United States, or any department, agency or commission thereof.'' BIS has concluded that inclusion of the additional entities is within its authority under the DPA because the DPA definition prefaces the list of entities with the word ''includes,'' and because inclusion of the additional entities is necessary to achieve the purpose of the statute.

Based on prior studies, BIS has observed that the U.S. Government makes a significant contribution to the industrial base, whether in research, technology development, testing, manufacturing, repair and overhaul, or trade development. As a result, the U.S. Government is a significant source of information regarding the industrial base. Similarly, it is plausible that the District of Columbia, commonwealths of the United States and other territories and agencies can be survey respondents, and therefore have been included to ensure the completeness of a survey sample and corresponding assessment.

The regulatory definition also makes clear that the term ''corporation, partnership, association, or any other organized group of persons'' is not limited to commercial, for-profit enterprises or publicly traded corporations.

The definitions of the terms ''initial distribution letter'' and ''survey'' each describe a document used in the data collection process. The definitions describe those documents based on the way they are used in current BIS practice.

Supplement No. 1 to Part 702

Supplement No. 1 to part 702 provides information that BIS believes would be helpful to persons who receive a survey. This information includes both a description of the survey and a glossary of terms.

Differences Between This Final Rule and the Proposed Rule

The definition of ''initial distribution letter'' in § 702.6 in the proposed rule contained a sentence that read ''[t]he letter also provides BIS contact information.'' In this final rule, the word ''provides'' has been replaced with the word ''includes'' for precision. This final rule also corrects a typographical error that appeared in Supplement No.1 to Part 702, introductory text, second sentence in the proposed rule. The phrase that read: ''. . . is purely in example . . .'' has been corrected to read ''. . . is purely an example . . . .'' There are no other differences in regulatory text between this final rule and the proposed rule.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 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, and other advantages; distributive impacts; and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has been determined not to be a ''significant regulatory action,'' significant, as that term is defined in Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et. seq.*) unless that collection of information displays a currently valid OMB control number. This rule does not contain a collection of information that is subject to the Paperwork Reduction Act. This rule sets forth procedures related to BIS's administration of surveys pursuant to § 705 of the DPA (50 U.S.C. app. 2155). Individual surveys that are subject to the Paperwork Reduction Act will display a currently valid OMB control number.

3. This rule does not contain policies with Federalism implications as that term is defined in Executive Order 13132.

4. The Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 *et seq.,* generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to the notice and comment rulemaking requirements under the Administrative Procedure Act (5 U.S.C. 553) or any other statute. However, under § 605(b) of the RFA, if the head of an agency certifies that a rule will not have a significant impact on a substantial number of small entities, the RFA does not require the agency to prepare a regulatory flexibility

analysis. Pursuant to § 605(b), the Chief Counsel for Regulation, Department of Commerce, submitted a memorandum to the Chief Counsel for Advocacy, Small Business Administration, certifying that the proposed rule, if promulgated, will not have a significant impact on a substantial number of small entities. The proposed rule set forth the rationale for that certification. BIS received no comments on that rationale and is making no substantive changes to it. The rationale for that certification is as follows.

Impact

This rule sets forth, in a single part of the Code of Federal Regulations, the Department of Commerce's authority under § 705 of the DPA ''to obtain information in order to perform industry studies assessing the capabilities of the United States industrial base to support the national defense.'' Since the mid-1980s, BIS and its predecessor organizations within the Department of Commerce have conducted such studies and required survey responses based on the statute. Section 705 of the DPA authorizes the collection of the information. The statute also authorizes the issuance of subpoenas for the information and authorizes the United States district courts to issue orders compelling compliance with such subpoenas. It also provides criminal penalties for failure to comply with the government's requests for information. This final rule will not require any person to supply information that the person would not be required to provide pursuant to the statute.

This final rule requires that surveys issued by BIS pursuant to § 705 be responded to by the deadline set forth in the survey. The rule incorporates BIS's existing internal policies and standards for the granting of both an extension of time to comply with the requirement and exemptions from compliance. To the extent that publication of these policies and standards in the Code of Federal Regulations could be construed as a change in the burden on small entities or any other entities, the publication would have to be deemed as a reduction in burden because it facilitates access to the standards by all parties.

This final rule also sets forth the statutory standards for treating information submitted in response to a survey as confidential. It reiterates the statutory penalties for failure to comply with a survey and for unauthorized release of information that § 705 requires to be treated as confidential.

This rule adopts the statutory definition of ''person'' but also adds ''[t]he Government of the United States, of the District of Columbia, of any commonwealth, territory or possession of the United States, or any department, agency or commission thereof'' to the definition. The term ''person'' is used in the statute and in this final rule to represent those to whom the requirements of the statute and this final rule apply. BIS has historically interpreted the statute to apply to units of the U.S. Government (including the District of Columbia Government and the governments of the territories and possessions) and does not view this as a substantive change. For purposes of this certification, the addition is immaterial because the government bodies that will be added to the statutory definition by this final rule are not small entities under the definition provided in the Small Business Regulatory Enforcement Fairness Act of 1996.

Number of Small Entities

Surveys are one-time exercises used to assess the state and/or capabilities of a particular industry sector or technology. Entities are selected for participation based on their role in, or relationship to, the industry sector or technology being assessed. Information obtained during the course of any one assessment may be relevant to determining whether the current entity supplying that information is a small entity. However, the composition of survey respondents varies dramatically between industry studies due to the complexity of each industry sector or technology being assessed. Consequently, BIS is unable to draw from existing data to estimate the number of small businesses participating in future collections. Accordingly, BIS is unable to determine the number of small entities that may be affected by this final rule.

Conclusion

Although BIS cannot predict the exact number of small entities that will be participating in any one survey, this rule will not impose a significant burden on any such small entities because it will not require any impacted entity to perform any action that it is not already required to perform pursuant to section 705 of the DPA.

List of Subjects in Part 702

Business and industry, Confidential business information, Employment, Penalties, National defense, Research, Science and technology.

Accordingly, the National Security Industrial Base Regulations (15 CFR Chapter VII, Subchapter A) are amended by adding Part 702 to read as follows:

Subchapter A—National Security Industrial Base Regulations

PART 702—INDUSTRIAL BASE SURVEYS—DATA COLLECTIONS

Sec.
702.1 Introduction.
702.2 Scope and purpose of surveys—avoiding duplicative requests for information.
702.3 Confidential information.
702.4 Requirement to comply with surveys or other requests for information.
702.5 Consequences of failure to comply.
702.6 Definitions.

Supplement No. 1 to Part 702—General Survey Information

Authority: 50 U.S.C. app. 2061 *et seq.;* E.O. 13603, 77 FR 16651, 3 CFR, 2012 Comp., p. 225.

§ 702.1 Introduction.

In accordance with 50 U.S.C. app. 2155, the Bureau of Industry and Security (BIS) may obtain such information from, require such reports and the keeping of such records by, make an inspection of the books, records, and other writings, premises or property of, take the sworn testimony of and administer oaths and affirmations to, any person as may be necessary or appropriate, in its discretion, to the enforcement or the administration of its authorities and responsibilities under the Defense Production Act of 1950 as amended (DPA) and any regulations or orders issued thereunder. BIS's authorities under the DPA (50 U.S.C. app. 2061 *et seq.*) include authority to collect data via surveys to perform industry studies assessing the capabilities of the United States industrial base to support the national defense and develop policy recommendations to improve both the international competitiveness of specific domestic industries and their ability to meet national defense program needs.

§ 702.2 Scope and purpose of surveys—avoiding duplicative requests for information.

(a) BIS will not send any survey to any person for completion unless the scope and purpose of the survey have been established, that scope and purpose are consistent with BIS's authorities under the DPA, and the data requested by the survey does not duplicate adequate and authoritative data already available to BIS from a Federal or other authoritative source.

(b) BIS personnel of appropriate competence and authority will ensure that the requirements of paragraph (a) of this section are met.

(c) This section shall not be construed as limiting the criteria that BIS may consider in determining whether to proceed with a survey. This paragraph shall not be construed as replacing or in any way modifying the requirements of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

§ 702.3 Confidential information.

This section implements section 705(d) of the DPA.

(a) BIS deems all information submitted in response to a survey issued pursuant to this part to be confidential.

(b) Any person submitting information in response to a survey issued pursuant to this part may request confidential treatment of that information.

(c) The President's authority under the DPA to protect confidential information has been delegated to the Under Secretary for Industry and Security. The information described in paragraphs (a) and (b) of this section shall not be published or disclosed unless the Under Secretary for Industry and Security determines that the withholding thereof is contrary to the interest of the national defense.

(d) Any person convicted of willfully violating the prohibition in paragraph (c) of this section may be fined not more than $10,000 or imprisoned for not more than one year, or both.

§ 702.4 Requirement to comply with surveys or other requests for information.

(a) *Requirement to comply.* Every person who receives a survey or other request for information issued pursuant to this part must submit a complete and adequate response to BIS within the time frame stated on the initial distribution letter or other request for information. Survey response information that does not adhere to the survey question criteria or that contains only aggregate information in place of specified information will be treated as inadequate and therefore noncompliant. BIS may exempt persons from this requirement for the reasons in paragraph (b) of this section, or grant extensions of time to comply as set forth in paragraph (c) of this section. Submitting a request to BIS for an exemption or an extension of time for completion does not suspend the initial deadline required by BIS (or any extended deadline subsequently granted by BIS). Thus, persons who request an exemption or extension of time are advised to proceed as if the response is required by the deadline until advised otherwise by BIS.

(b) *Grounds for exemption.* (1) An exemption from the requirements of this section may be granted if the person receiving the survey or other request for information:

(i) Has no physical presence in the United States of any kind;

(ii) Does not provide, produce, distribute, utilize, procure, research, develop, consult or advise on, or have any other direct or indirect association with the materials, products, services or technology that are within the scope of the survey;

(iii) Has ceased business operations more than 12 months prior to receipt of the survey;

(iv) Has been in business for less than one year; or

(v) BIS determines that extenuating circumstances exist that make responding impractical.

(2) BIS may also grant an exemption if, based on the totality of the circumstances, it concludes that compliance would be impractical and/or that requiring compliance would be unduly time intensive.

(3) Existence of a pre-existing private non-disclosure agreement or information sharing agreement between a person and another party (*e.g.,* customers, suppliers, etc.), does not exempt a person from the obligation to comply with and complete a survey. The authority to conduct the survey and comply with the survey is derived from the DPA, and that statutory obligation to comply supersedes any private agreement.

(c) *Extensions of time to complete.* A person who receives a survey or other request for information may request an extension of time to submit the complete response to BIS. BIS may grant such an extension of time, if, in its judgment, circumstances are such that additional time reasonably is needed, the extension would not jeopardize timely completion of BIS's overall analysis, and the person is making reasonable progress towards completing the survey or response to the other request for information. Generally, extensions will be for no more than two weeks. A person who receives a survey or other request for information may request successive extensions if the person believes that it continues to have a legitimate need for additional time to complete the survey. BIS will not grant extensions that would jeopardize the performance and timely completion of its industrial base assessments.

(d) *Procedure for requesting exemptions or extensions of time.* Requests for exemptions or extensions of time must be made to BIS at the telephone number, email address or BIS physical address provided in the initial distribution letter for a survey or in the other request for information. A request for an exemption must provide factual information and documentation that are adequate for BIS to determine that one or more of the criteria stated in paragraph (b) or (c) of this section are met.

(e) *Responses that are incomplete or inadequate.* BIS may return responses that are incomplete or inadequate to the person for prompt completion. BIS will specify the required period of time permitted for completion and submission of the revised survey.

§ 702.5 Consequences of failure to comply.

(a) *Civil.* If any person fails to comply with the requirements of § 702.4, BIS may issue a subpoena requiring that person to submit the information called for in the survey. In the case of contumacy or refusal to obey such a subpoena, the U.S. Government may apply for an order by the United States district court in a district where that person resides or transacts business that would compel the person to submit the completed survey.

(b) *Criminal.* In accordance with 50 U.S.C. app. 2155, any person who willfully fails to comply with § 702.4, may, upon conviction, be fined not more than $10,000 or imprisoned not more than one year, or both.

§ 702.6 Definitions.

The definitions in this section apply throughout this part.

Confidential. A description of information that is subject to the disclosure prohibitions of the DPA (50 U.S.C. app. 2155(d)).

Initial distribution letter. A letter that BIS sends to a person that has been identified by the U.S. Government as a supplier or customer of materials, products or services used for activities of the industry that is the focus of a survey. The letter describes the survey's primary objectives, how survey results will assist the U.S. Government, and the confidential treatment of the information submitted. The letter also includes BIS contact information.

Person. The term ''person'' includes:

(1) An individual, corporation, partnership, association, or any other organized group of persons, or legal successor or representative thereof;

(2) Any State or local government or agency thereof;

(3) The Government of the United States, of the District of Columbia, of any commonwealth, territory or possession of the United States, or any department, agency or commission thereof.

Note to the definition of ''person.'' Paragraph (1) of this definition is not

limited to commercial or for-profit organizations. For example, the term ''any other organized group of persons'' may encompass labor unions, academic institutions, charitable organizations or any group of persons who are organized in some manner. The term corporation is not limited to publicly traded corporations or corporations that exist for the purpose of making a profit.

Survey. A questionnaire or other request for information that collects detailed information and data to support both the assessment of a particular industrial sector or technology and the development of a corresponding study.

Supplement No. 1 to Part 702—General Survey Information

This supplement provides general information about surveys and the content of the typical survey. The content of this supplement is purely an example of a typical survey, and in no way limits the content that may appear in a specific Bureau of Industry and Security (BIS)-issued survey. Procedures and content vary from survey to survey, and as such, there is no set template to follow. Nonetheless, BIS is offering this information as a basic guide to some elements of a survey.

Survey Structure

Most surveys include the following sections: Cover Page; Table of Contents; General Instructions; Glossary of Terms; Organizational Information, and sector-specific sections.

—The cover page typically includes the title of the survey, its scope, an explanation of the legal requirement to comply, the burden estimate for compliance with the survey, the Office of Management and Budget (OMB) control number, and the survey date of expiration.

—The General Instructions section normally includes process steps necessary for a person's survey submittal. These include but are not limited to instructions for survey completion, survey support staff point-of-contact information, the name and address of the presiding BIS official, and instructions for both survey certification and submittal.

—The Glossary of Terms section explains terms contained in the survey. Terms contained in the survey may be unique to the subject matter of the industry assessment, and therefore may change in meaning from survey to survey. Therefore, it is important to follow the specific instructions and defined terms contained in the specific survey you receive, regardless of any previous survey you might have completed.

—The Organization Information section requests information related to the person in receipt of the survey, including address information, the source level of response (*e.g.,* facility, business unit, division, corporate consolidated, etc.), point of contact details, and other pertinent contact information.

The survey is generally organized in a question and answer format and is presented on an electronic survey system. Each survey is specially tailored to collect the specific information requested. Therefore, specific detailed information is what should be submitted in response to a survey requesting such information.

—For example, if we ask for a listing of your customers that order widget A, your response should not be a listing of your entire customer base. Only the information pertaining to customers' ordering widget A is responsive to that kind of question.

Also note that your reply to a survey request is compulsory, unless you meet the criteria for exemption set forth in the body of the regulation. Therefore, any non-disclosure agreements or similar agreements you may have with your customers or clients are not applicable to a survey's request for information. Compliance with the survey is required by the DPA. Accordingly, compliance with that statutory requirement is paramount to any private agreement you have with your customers or other parties.

In addition to the aforementioned sections, each survey contains sections tailored to the specific scope of the study, including but not limited to Facility Locations, Products and Services, Inventories, Suppliers and Customers, Challenges and Organizational Outlook, Employment, Operations, Financial Statements, Sales, Research and Development, and Capital Expenditures.

Examples of survey terms.

Certification: A section of the survey in which a person (an authorizing official) certifies that the information supplied in response to the survey is complete and correct, to the best of the person's knowledge.

Facility: A building or the minimum complex of buildings or parts of buildings in which a person operates to serve a particular function, producing revenue and incurring costs for the person. A facility may produce an item of tangible or intangible property or may perform a service. It may encompass a floor or group of floors within a building, a single building, or a group of buildings or structures. Often, a facility is a group of related locations at which employees work, together constituting a profit-and-loss center for the person, and it may be identified by a unique Dun and Bradstreet number.

Sole source: An organization that is the only source for the supply of parts, components, materials, or services. No alternative U.S. or non-U.S. based supplier exists other than the current supplier.

Survey template: The data collection instrument supplied by BIS to persons by which survey information is recorded and submitted to BIS. The survey is generally organized in a question and answer format and is presented on an electronic survey system.

Supplier: An entity from which your organization obtains inputs. A supplier may be another firm with which you have a contractual relationship, or it may be another facility owned by the same parent organization. The inputs may be materials, products or services.

Dated: July 10, 2015.

Kevin J. Wolf,

Assistant Secretary for Export Administration.

[FR Doc. 2015–17388 Filed 7–14–15; 8:45 am]

BILLING CODE 3510–33–P

SECURITIES AND EXCHANGE COMMISSION

17 CFR Part 200

[Release No. 34–75388; File No. S7–07–14]

RIN 3235–AL58

Freedom of Information Act Regulations: Fee Schedule, Addition of Appeals Time Frame, and Miscellaneous Administrative Changes

AGENCY: Securities and Exchange Commission.

ACTION: Final rule.

SUMMARY: The Securities and Exchange Commission (''Commission'') is adopting amendments to its regulations under the Freedom of Information Act (''FOIA'') to allow the Commission to collect fees that reflect its actual costs, add an appeals time frame that will create a more practical and systematic administrative process and clarify other issues in the regulations.

DATES: *Effective Date:* August 14, 2015.

FOR FURTHER INFORMATION CONTACT: John Livornese, FOIA/PA Officer, Office of FOIA Services, (202) 551–3831; Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–5041.

SUPPLEMENTARY INFORMATION: The Commission is adopting amendments to

its FOIA regulations at 17 CFR 200.80 and 17 CFR 200.80e.

I. Introduction

On June 20, 2014 the Commission proposed amendments to its regulations under the Freedom of Information Act.[1] The proposed amendments would amend the Commission's FOIA fee schedule for searching and reviewing records; establish an appeals time frame; allow for submission of appeals by additional methods; and allow the Commission's Office of FOIA Services to issue responses to FOIA requests indicating that no records were located. The proposing release requested comment on all aspects of the proposal.

The Commission received three comments regarding the proposed amendments to its regulations under the Freedom of Information Act.[2] One commenter wholly supported the Commission's amendment of the regulations related to its FOIA fee schedule. The other two commenters disagreed with the proposed time frame for FOIA appeals, and one also objected to the proposed fee amendments. The comments are discussed in more detail below. In adopting this final rule, the Commission has reviewed and considered all of the comments received.

II. Discussion of the Final Rules

As discussed in further detail below, the Commission is adopting the rules largely as proposed, with the exception of the provision concerning the FOIA appeals time frame, which has been revised in response to comments received.

A. Changes to Fee Regulations

The fees the Commission charges for searching, reviewing, and duplicating records pursuant to FOIA requests are currently set forth in 17 CFR 200.80e, Appendix E—Schedule of fees for records services. The Commission is updating the fee schedule for searching and reviewing records in accordance with Uniform Freedom of Information Act Fee Schedule and Guidelines promulgated by the Office of Management and Budget.[3]

The OMB Guidelines, pursuant to the Freedom of Information Reform Act of 1986, require that each agency's fees be based upon its ''direct reasonable operating costs of providing FOIA services.'' [4] The guidelines state that ''[a]gencies should charge fees that recoup the full allowable direct costs they incur.'' [5] Direct costs include ''the salary of the employee performing work (the basic rate of pay for the employee plus 16 percent of that rate to cover benefits).'' [6] OMB recognized that costs would necessarily vary from agency to agency and directed that each agency promulgate regulations specifying the charges for search, review, and duplication. The OMB Guidelines state that ''agencies should charge at the salary rate[s] [*i.e.* basic pay plus 16 percent] of the employee[s] making the search'' or, ''where a homogeneous class of personnel is used exclusively . . . agencies may establish an average rate for the range of grades typically involved.'' [7]

The Commission's current regulation contains set rates for FOIA request search and review activities: $16/hour for grade 11 and below; and $28/hour for grade 12 and above. The Commission proposed to revise this regulation to reflect the formula contained in the OMB Guidelines (basic pay plus 16 percent) rather than setting forth a fixed price. The proposal would establish a representative rate for each of the three different groups of grades typically involved: Personnel in grades SK–8 or below; personnel in grades SK–9 to SK–13; and personnel in grades SK–14 or above.[8] The Commission's Web site will contain current rates for search and review fees for each class. The rates will be updated as salaries change and will be determined by using the formula in the regulation. For the current calendar year, the fees would be assessed as follows: SK–8 or below: $29/hour; SK–9 to 13: $61/hour; and SK–14 or above: $89/hour.[9] The proposed regulation would allow the Commission to charge FOIA requesters in quarter-hour increments at the rates established by reference to the OMB Guidelines.[10] The Commission also proposed to remove the first sentence of 17 CFR 200.80(e)(1) which provides that up to one half hour of staff time devoted to searching for and reviewing Commission records will be provided without charge.

One commenter asserted, without providing any data, that increasing FOIA fees would make it more difficult for individuals to obtain information from the SEC and will ''put the FOIA process out of reach of the average citizen.'' [11] All changes to the Commission's FOIA fee schedule are in conformity with the FOIA and guidance set forth by the Office of Management and Budget. The OMB Guidelines, pursuant to the Freedom of Information Reform Act of 1986, require that each agency's fees be based upon its ''direct reasonable operating costs of providing FOIA services.'' The Commission has not increased its fees for processing FOIA requests in over 20 years, despite increased costs to the agency.

Under the proposal, fees would not be charged under either the FOIA or the Privacy Act where the costs of collecting and processing the fee are likely to equal or exceed the amount of the fee or where the requester has met the requirements for a statutory fee waiver. The new language is based upon that of 5 U.S.C. 552(a)(4)(A)(iv) (providing that no fee may be charged if the fee exceeds the costs of collecting and processing the fee). No comments addressed this provision, and the Commission is adopting the amendments as proposed. Currently, the cost of the average fee collection activity is $20, so no fee will be charged of $20 or less.

One commenter also recommended that the Commission allow documents to be released generally without any charge or at a reduced charge at its discretion and/or if disclosure of the information is in the public interest

[1] *See Freedom of Information Act Regulations: Fee Schedule, Addition of Appeal Time Frame and Miscellaneous Administrative Changes,* Release No. 34–72440 (June 20, 2014), 79 FR 36443 (June 27, 2014).

[2] *See* letter from Sheldon Mark Patnett (July 14, 2014) (the Patnett letter); letter from the National Archives and Records Administration's Office of Government Information Services (July 28, 2014) (the OGIS letter), and letter from David K. Colapinto of Kohn, Kohn & Colapinto, LLP (July 28, 2014) (the Colapinto letter).

[3] *See* 52 FR 10011 (March 27, 1987).

[4] *Id.* at 10015.

[5] *Id.* at 10018.

[6] *Id.* at 10017.

[7] *Id.* at 10018.

[8] In the proposing release, while the preamble set forth these three groupings, the draft rule text erroneously listed the groupings as: Grades SK–9 or below; Grades SK–10 to SK–14; and Grades SK–15 or above. That was a typographical error and was inconsistent with the text of the preamble of the proposal. Only one commenter addressed the specific amount of the fees, and in making its comment, that commenter used the correct grouping as stated in the preamble of the proposing release.

[9] The SK–8 and below rate is estimated using the maximum and minimum annual salary of a Washington, DC-based SK–6 staffer. For 2014 this is [($41,619 + $63,307)/2][1/2087 hours per year][1.16 OMB markup factor] = $29 per hour. Similarly, the SK–9 through SK–13 category is estimated by using the maximum and minimum annual salary of a Washington, DC-based SK–12 staffer, who typically does most of the work of a FOIA request. For 2014 this is [($82,037 + $138,211)/2][1/2087 hours/year][1.16 OMB markup factor] = $61/hour. Finally, the SK–14 and above category is estimated by using the maximum and minimum salary of a Washington, DC-based SK–15 supervisor. For 2014 this is [($118,743 + $200,033)/2][1/2087 hours per year][1.16 OMB markup factor] = $89/hour.

[10] As per the OMB Guidelines, fees for searches of computerized records will continue to be based on the actual cost to the Commission which includes machine and operator time. 17 CFR 200.80(e)(9)(i).

[11] *See* Colapinto letter.

because it is likely to contribute significantly to public understanding of the operations or activities of the government and is not primarily in the commercial interest of the requester.[12] 17 CFR 200.80(e)(4)(i) allows the Commission's Office of Freedom of Information and Privacy Act [Services] to waive or reduce search, review, and duplication fees if: (1) Disclosure of the requested records is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government; and (2) Disclosure is not primarily in the commercial interest of the requester. Thus, much of what the commenter suggested is already allowed by existing rules. Possible changes to that section, including allowing for purely discretionary waivers or reduction of fees as suggested by the commenter, are not the subject of this rulemaking. This portion of the rule will be adopted as proposed.

B. Changes to FOIA Appeals Time Frames

The FOIA requires federal agencies to notify requesters of their right to appeal any adverse determination. 5 U.S.C. 552(a)(6)(A)(i). Although the FOIA does not require agencies to establish an appeals time frame, neither does it preclude them from doing so. The Commission proposed to establish an appeals time frame of 30 days in order to allow more efficient and improved appeals processing by the Commission's Office of the General Counsel. Under the proposal, an appeal from an adverse decision ''must be received within thirty (30) calendar days of the date of the adverse decision.'' The proposing release noted that the implementation of a 30 day appeals time frame is consistent with the practices of a number of other federal agencies. Commission staff has reviewed the practices at twenty-two separate federal agencies. Of these, ten have a FOIA appeals time frame of 30 days, one has a 30 business day time frame, one has a 35 day time frame, two have a 45 day time frame, seven have a 60 day time frame and one has a 90 day time frame.[13]

Two comment letters opposed the 30 day time frame. One suggested that the Commission consider allowing a 60 day time frame for appeals.[14] The sole reason offered was the commenter's observation that mail screening by Federal agencies can slow the amount of time it takes appeals to reach their destination. Another commenter similarly objected to the imposition of a 30 day time frame in which to file an appeal as too short and asserted that it ''does not afford individuals (such as whistleblowers and individual investors) sufficient time to find legal representation or to file a substantive appeal.'' [15] The commenter also noted that the likelihood of missing the 30 day deadline ''is high.''

In response to these concerns, the Office of FOIA Services staff referred to the above-referenced review of the FOIA appeals procedures at twenty-two federal agencies. It was noted that over half of those agencies have appeals time frames longer than 30 days. To permit FOIA requesters ample opportunity to fully address any complex issues related to their appeal, the Commission has determined to adopt a 90 day time frame for filing an appeal. The longer time frame should also obviate any concerns about delays resulting from mail screening. The 90 day time frame being adopted today is among the longest of those identified at other federal agencies. Accordingly, the Commission believes that an appeals time frame of 90 days is appropriate.

C. Submission of FOIA Appeals by Email and Facsimile

The Commission proposed to revise 17 CFR 200.80(d)(6)(ii) to allow appeals to be submitted by facsimile or email as well as through the mail. No commenter addressed this issue, and the Commission is adopting it as proposed.

D. Responses to FOIA Requests Indicating No Records Could Be Located

The Commission proposed to amend 17 CFR 200.80(d)(5)(i) by adding a sentence to provide for responses to FOIA requests that indicate that no responsive records were located.[16] This proposed amendment would make clear that a possible response to a FOIA request is that no responsive records could be located. No commenter addressed this issue, and the new sentence would be adopted as proposed.

III. Economic Analysis

The Commission is sensitive to the economic effects, including the costs and benefits, that result from its rules, and Section 23(a)(2) of the Exchange Act requires the Commission, in making rules pursuant to any provision of the Exchange Act, to consider among other matters the impact any such rule would have on competition.

As the Commission explained in the proposal, the rules are intended to help align the Commission's fees related to FOIA requests with its direct reasonable operating costs of providing FOIA services and to allow more efficient processing of requests. In the proposal, the Commission explained that although the Commission believed that the proposed rules were unlikely to have a significant impact on the economy, the proposed rules would benefit the Commission and the public. In particular, compared to the baseline, which includes the current fee structure outlined above, the Commission believed that the proposed rules would permit the Commission to charge fees that more closely reflect the direct costs the Commission incurs to provide FOIA services. Additionally, as the Commission explained, the proposed rules would provide increased flexibility to FOIA requesters by expressly permitting appeals by email and facsimile and would also improve efficiency in the appeal process by establishing a time frame for FOIA appeals that, in light of potential alternatives, is consistent with the practice of other federal agencies.

The Commission also recognized in the proposal that the proposed rules may impose costs. Specifically, the Commission explained that the proposed rules may impose additional costs on individuals who wish to obtain access to Commission records and may impose a burden on requesters who would be required to appeal a decision within 30 days. The Commission noted, however, that those costs would be insignificant. Additionally, the Commission noted that the proposed rules would not burden competition and that the Commission believed that any potential burden on competition imposed by the proposed rules would be appropriate in furtherance of purposes of the Exchange Act.

The Commission requested comment on all aspects of the benefits and costs of the proposal, including any anticipated impacts on competition. No commenter addressed the economic analysis contained in the proposal, although, as discussed above, one commenter noted that the proposed rules would increase costs for FOIA requesters. After reviewing the comments, the Commission continues to believe that the rules will result in the economic effects described in the proposal and notes that the 90 day appeal time frame will likely impose

[12] *See* OGIS letter.

[13] Independent financial agencies comparable to the SEC (CFTC and FTC) have 30 calendar day appeals time frames. The FDIC has a 30 business day appeals time frame.

[14] *See* OGIS letter.

[15] *See* Colapinto letter.

[16] The draft amended rule text of 17 CFR 200.80(d)(5)(i) published in the proposed rule inadvertently omitted the penultimate sentence from existing paragraph (d)(5)(i). That language is included in amendatory text of this final rule.

less of a burden on requesters compared to the proposed 30 day time frame. In addition, the Commission continues to believe that the rules will have a minimal economic effect and that any potential burden on competition imposed by the amended rules would be appropriate in furtherance of purposes of the Exchange Act.

IV. Regulatory Flexibility Act Certification

Pursuant to Section 605(b) of the Regulatory Flexibility Act,[17] the Commission certified that, when adopted, the amendments to 17 CFR 200.80 would not have a significant economic impact on a substantial number of small entities. This certification, including our basis for the certification, was included in the proposing release. The Commission solicited comments on the appropriateness of its certification, but received none. The Commission is adopting the final rules as proposed. Accordingly, there have been no changes to the proposal that would alter the basis upon which the certification was made.

V. Other Administrative Law Matters

These amendments do not contain any collection of information requirement as defined by the Paperwork Reduction Act of 1995, as amended.[18]

VI. Statutory Authority and Text of Rule Amendments

The amendments contained herein have been made under the authority set forth in 5 U.S.C. 552 and 15 U.S.C. 78d–1.

List of Subjects in 17 CFR Part 200

Administrative practice and procedure, Freedom of information.

Text of Amendments

For the reasons stated in the preamble, title 17, chapter II of the Code of Federal Regulations is amended as follows:

PART 200—ORGANIZATION; CONDUCT AND ETHICS; AND INFORMATION AND REQUESTS

Subpart D—Information and Requests

■ 1. The authority citation for part 200, subpart D, is revised to read, in part, as follows:

Authority: 5 U.S.C. 552, as amended, 15 U.S.C. 77f(d), 77s, 77ggg(a), 77sss, 78m(F)(3), 78w, 80a–37, 80a–44(a), 80a–44(b), 80b–10(a), and 80b–11, unless otherwise noted.

* * * * *

■ 2. Amend § 200.80 by:

■ a. Revising paragraphs (d)(5)(i), (d)(6)(i) and (ii), and (e) introductory text; and

■ b. Removing the first sentence of paragraph (e)(1).

The revisions read as follows:

§ 200.80 Commission records and information.

* * * * *

(d) * * *

(5) *Initial determination; multi-track processing, and denials*—(i) *Time within which to respond.* When a request complies with the procedures in this section for requesting records under the Freedom of Information Act, a response shall be sent within 20 business days from the date the Office of FOIA Services receives the request, except as described in paragraphs (d)(5)(ii) and (iii) of this section. If that Office has identified the requested records, the response shall state that the records are being withheld, in whole or in part, under a specific exemption or are being released. If that Office cannot locate any requested records, the response shall advise the requester accordingly.

* * * * *

(6) * * *

(i) *Time limits and content of appeal.* Appeals shall be clearly and prominently identified at the top of the first page with the legend ''Freedom of Information Act Appeal'' and shall provide the assigned request number. Copies of the request and the SEC's response, if any, should be included with the appeal. If an appeal is from an adverse decision, it must be received within ninety (90) calendar days of the date of the adverse decision. If only a portion of the decision is appealed, the requester must specify which part of the decision is being appealed. An appeal from an adverse decision should also identify the name of the deciding official, the date of the decision, and the precise subject matter of the appeal. An appeal is not perfected until the SEC receives the information identified in this paragraph (d)(6)(i).

(ii) *How to file and address a written appeal.* The appeal must be sent to both the General Counsel and the Office of FOIA Services at 100 F Street NE., Washington, DC 20549. The SEC accepts facsimiles (faxes) and emails as written FOIA appeals. Information regarding where to fax or email a FOIA appeal is available on the SEC's FOIA home page on the Commission's Web site at *http://www.sec.gov/foia.shtml.* A legible return address must be included with the FOIA appeal. The requester may also include other contact information, such as a telephone number and/or an email address.

* * * * *

(e) *Fees for records services.* Information pertaining to search and review services, including locating, reviewing, and making records available, attestations and copying, appears in appendix E to this subpart, § 200.80e. A schedule of fees is located at the Commission's Web site at *http://www.sec.gov/foia/feesche.htm.*

* * * * *

■ 3. Amend § 200.80e by:

■ a. Adding introductory text; and

■ b. Revising the paragraph that begins, ''Search and review services:''.

The addition and revision read as follows:

§ 200.80e Appendix E—Schedule of fees for records services.

The requester will be charged search, review, and duplication fees according to his or her fee category. In addition, the SEC will charge the requester for any special handling or services performed in processing the request and/or appeal. Duplication fees also are applicable to records provided in response to requests made under the Privacy Act. Fees will not be charged under either the FOIA or the Privacy Act where the costs of collecting and processing the fee are likely to equal or exceed the amount of the fee or where the requester has met the requirements for a statutory fee waiver. Fees will be determined as follows:

Search and review services (review applies to commercial-use requesters only): (1) The Commission will establish and charge average rates for the groups of grades typically involved in search and review. Those groups will consist of employees at:

(i) Grades SK–8 or below;

(ii) Grades SK–9 to SK–13; and

(iii) Grades SK–14 or above.

(2) The average rates will be based on the hourly salary (*i.e.,* basic salary plus locality payment), plus 16 percent for benefits, of employees who routinely perform those services. Fees will be charged in quarter-hour increments. The average hourly rates are listed on the Commission's Web site at *http://www.sec.gov/foia/feesche.htm* and will be updated as salaries change.

* * * * *

By the Commission.

[17] 5 U.S.C. 605(b).

[18] 44 U.S.C. 3501–3520.

Dated: July 8, 2015.

Brent J. Fields,

Secretary.

[FR Doc. 2015–17179 Filed 7–14–15; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 161

[Docket No. FDA–2015–N–0011]

Canned Pacific Salmon; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA or we) is amending a regulation pertaining to canned Pacific salmon. The amendment removes a paragraph that contains an obsolete cross-reference.

DATES: This rule is effective July 15, 2015.

FOR FURTHER INFORMATION CONTACT: Loretta Carey, Center for Food Safety and Applied Nutrition (HFS–820), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 240–402–2371.

SUPPLEMENTARY INFORMATION: Our regulations at 21 CFR part 161 (''Fish and Shellfish'') establish requirements for specific standardized fish and shellfish. One provision, at § 161.170, pertains to canned Pacific salmon, and § 161.170(a)(5)(ii)(*b*) states that when the form of the pack and the words describing the pack are declared on the label, the label must ''bear the statements required by § 105.69 of this chapter.'' (The regulation, at § 161.170(a)(3), describes various ''forms of pack;'' one form of pack, for example, is named ''regular'' and is described as where the sections or steaks are cut transversely from the fish and filled vertically into the can.)

Section 105.69 was entitled ''Foods used to regulate sodium intake.'' In the **Federal Register** of June 3, 1996 (61 FR 27771), we revoked § 105.69 as part of a ''Reinventing Government'' initiative, and the revocation became effective on July 3, 1996 (see 61 FR 43963; August 27, 1996) (confirming the effective date for the revocation of various food regulations)). However, the revocation inadvertently omitted a corresponding change to § 161.170(a)(5)(ii)(*b*).

Consequently, through this document, we are amending § 161.170 by removing paragraph (a)(5)(ii)(*b*) entirely and redesignating paragraph (a)(5)(ii)(*a*) as paragraph (a)(5)(ii).

Publication of this document constitutes final action of these changes under the Administrative Procedure Act (5 U.S.C. 553). These amendments eliminate an obsolete reference to a rule that we revoked in 1996. FDA, therefore, for good cause, finds under 5 U.S.C. 553(b)(3)(B) and (d)(3) that notice and public comment are unnecessary.

FDA has determined, under 21 CFR 25.30(i), that this final rule is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

In addition, FDA has determined that this final rule contains no new collections of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

List of Subjects in 21 CFR Part 161

Food grades and standards, Frozen foods, Seafood.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 161 is amended as follows:

PART 161—FISH AND SHELLFISH

■ 1. The authority citation for 21 CFR part 161 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 343, 348, 371, 379e.

§ 161.170 [Amended]

■ 2. Amend § 161.170 by removing paragraph (a)(5)(ii)(*b*) and redesignating paragraph (a)(5)(ii)(*a*) as paragraph (a)(5)(ii).

Dated: July 9, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–17249 Filed 7–14–15; 8:45 am]

BILLING CODE 4164–01–P

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Part 4022

Benefits Payable in Terminated Single-Employer Plans; Interest Assumptions for Paying Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This final rule amends the Pension Benefit Guaranty Corporation's regulation on Benefits Payable in Terminated Single-Employer Plans to prescribe interest assumptions under the regulation for valuation dates in August 2015. The interest assumptions are used for paying benefits under terminating single-employer plans covered by the pension insurance system administered by PBGC.

DATES: Effective August 1, 2015.

FOR FURTHER INFORMATION CONTACT: Catherine B. Klion (*Klion.Catherine@pbgc.gov*), Assistant General Counsel for Regulatory Affairs, Pension Benefit Guaranty Corporation, 1200 K Street NW., Washington, DC 20005, 202–326–4024. (TTY/TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4024.)

SUPPLEMENTARY INFORMATION: PBGC's regulation on Benefits Payable in Terminated Single-Employer Plans (29 CFR part 4022) prescribes actuarial assumptions—including interest assumptions—for paying plan benefits under terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974. The interest assumptions in the regulation are also published on PBGC's Web site (*http://www.pbgc.gov*).

PBGC uses the interest assumptions in Appendix B to Part 4022 to determine whether a benefit is payable as a lump sum and to determine the amount to pay. Appendix C to Part 4022 contains interest assumptions for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using PBGC's historical methodology. Currently, the rates in Appendices B and C of the benefit payment regulation are the same.

The interest assumptions are intended to reflect current conditions in the financial and annuity markets. Assumptions under the benefit payments regulation are updated monthly. This final rule updates the benefit payments interest assumptions for August 2015.[1]

The August 2015 interest assumptions under the benefit payments regulation will be 1.50 percent for the period during which a benefit is in pay status and 4.00 percent during any years preceding the benefit's placement in pay

[1] Appendix B to PBGC's regulation on Allocation of Assets in Single-Employer Plans (29 CFR part 4044) prescribes interest assumptions for valuing benefits under terminating covered single-employer plans for purposes of allocation of assets under ERISA section 4044. Those assumptions are updated quarterly.

status. In comparison with the interest assumptions in effect for July 2015, these interest assumptions represent an increase of 0.25 percent in the immediate annuity rate and are otherwise unchanged.

PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public interest. This finding is based on the need to determine and issue new interest assumptions promptly so that the assumptions can reflect current market conditions as accurately as possible.

Because of the need to provide immediate guidance for the payment of benefits under plans with valuation dates during August 2015, PBGC finds that good cause exists for making the assumptions set forth in this amendment effective less than 30 days after publication.

PBGC has determined that this action is not a ''significant regulatory action'' under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

List of Subjects in 29 CFR Part 4022

Employee benefit plans, Pension insurance, Pensions, Reporting and recordkeeping requirements.

In consideration of the foregoing, 29 CFR part 4022 is amended as follows:

PART 4022—BENEFITS PAYABLE IN TERMINATED SINGLE-EMPLOYER PLANS

■ 1. The authority citation for part 4022 continues to read as follows:

Authority: 29 U.S.C. 1302, 1322, 1322b, 1341(c)(3)(D), and 1344.

■ 2. In appendix B to part 4022, Rate Set 262, as set forth below, is added to the table.

Appendix B to Part 4022—Lump Sum Interest Rates for PBGC Payments

* * * * *

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		i_1	i_2	i_3	n_1	n_2
*	*		*	*	*	*	*	*
262	8–1–15	9–1–15	1.50	4.00	4.00	4.00	7	8

■ 3. In appendix C to part 4022, Rate Set 262, as set forth below, is added to the table.

Appendix C to Part 4022—Lump Sum Interest Rates for Private-Sector Payments

* * * * *

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		i_1	i_2	i_3	n_1	n_2
*	*		*	*	*	*	*	*
262	8–1–15	9–1–15	1.50	4.00	4.00	4.00	7	8

Issued in Washington, DC, on this 7th day of July 2015.

Judith Starr,

General Counsel, Pension Benefit Guaranty Corporation.

[FR Doc. 2015–17376 Filed 7–14–15; 8:45 am]

BILLING CODE 7709–02–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

49 CFR Part 1002

[Docket No. EP 542 (Sub-No. 23)]

Regulations Governing Fees for Services Performed in Connection With Licensing and Related Services—2015 Update

AGENCY: Surface Transportation Board.

ACTION: Final rules.

SUMMARY: The Board updates for 2015 the fees that the public must pay to file certain cases and pleadings with the Board. The update will increase 11 fees by $50 or less, increase 34 fees by $100, increase 22 fees by more than $100, and keep the remaining 58 fees at their existing level.

DATES: These rules are effective August 14, 2015.

FOR FURTHER INFORMATION CONTACT: David T. Groves, (202) 245–0327, or Andrea Pope-Matheson (202) 245–0363. [TDD for the hearing impaired: 1–800–877–8339.]

SUPPLEMENTARY INFORMATION: The Board's regulations at 49 CFR 1002.3 provide for an annual update of the Board's entire user-fee schedule. Fees are generally revised based on the cost study formula set forth at 49 CFR 1002.3(d). As compared with the 2014 fee update, the 2015 fee changes adopted here reflect a combination of a 1% across-the-board increase to salary costs; no change in publication cost levels; increases to two of the three Board Overhead cost factors; and a modest decrease to the third Board Overhead cost factor from its comparable 2014 level, resulting from the mechanical application of the update formula in 49 CFR 1002.3(d). Results from the formula application indicate that justified fee amounts in this 2015 update decision either remain unchanged (58 fee items), increase $50 or less (11 fee items), increase by $100 (34 fee items) or increase over $100 (22 fee items) from their respective 2014 update levels. No *new* fee items are proposed in this proceeding. Therefore, the Board finds that notice and comment are unnecessary for this proceeding. *See Regulations Governing Fees for Servs.—1990 Update,* 7 I.C.C.2d 3 (1990); *Regulations Governing Fees for Servs.—1991 Update,* 8 I.C.C.2d 13 (1991); *Regulations Governing Fees for*

Servs.—1993 Update, 9 I.C.C.2d 855 (1993).

Additional information is contained in the Board's decision. To obtain a free copy of the full decision, visit the Board's Web site at *http://www.stb.dot.gov* or call (202) 245–0245. [Assistance for the hearing impaired is available through Federal Information Relay Services (FIRS): (800) 877–8339.]

List of Subjects in 49 CFR Part 1002

Administrative practice and procedure, Common carriers, and Freedom of information.

Decided: July 9, 2015.

By the Board, Chairman Elliott, Vice Chairman Begeman, and Commissioner Miller.

Kenyatta Clay,

Clearance Clerk.

For the reasons set forth in the preamble, title 49, chapter X, part 1002, of the Code of Federal Regulations is amended as follows:

PART 1002—FEES

■ 1. The authority citation for part 1002 continues to read as follows:

Authority: 5 U.S.C. 552(a)(4)(A) and 553; 31 U.S.C. 9701 and 49 U.S.C. 721(a). Section 1002.1(g)(11) is also issued under 5 U.S.C. 5514 and 31 U.S.C. 3717.

■ 2. Section 1002.1 is amended by revising paragraphs (a) through (c), (f)(1) and (g)(6) to read as follows:

§ 1002.1 Fees for records search, review, copying, certification, and related services.

* * * * *

(a) Certificate of the Records Officer, $18.00.

(b) Service involved in examination of tariffs or schedules for preparation of certified copies of tariffs or schedules or extracts therefrom at the rate of $42.00 per hour.

(c) Service involved in checking records to be certified to determine authenticity, including clerical work, etc. identical thereto, at the rate of $29.00 per hour.

* * * * *

(f) * * *

(1) A fee of $73.00 per hour for professional staff time will be charged when it is required to fulfill a request for ADP data.

* * * * *

(g) * * *

(6) The search and review hourly fees will be based upon employee grade levels in order to recoup the full, allowable direct costs attributable to their performance of these functions. They are as follows:

Grade	Rate
GS–1	$12.25
GS–2	13.33
GS–3	15.03
GS–4	16.87
GS–5	18.88
GS–6	21.04
GS–7	23.38
GS–8	25.90
GS–9	28.60
GS–10	31.50
GS–11	34.60
GS–12	41.48
GS–13	49.32
GS–14	58.28
GS–15 and over	68.56

* * * * *

■ 3. In 1002.2, paragraph (f) is revised to read as follows:

§ 1002.2 Filing fees.

* * * * *

(f) *Schedule of filing fees.*

Type of proceeding	Fee
PART I: Non-Rail Applications or Proceedings to Enter Into a Particular Financial Transaction or Joint Arrangement:	
(1) An application for the pooling or division of traffic	$4,700.
(2)(i) An application involving the purchase, lease, consolidation, merger, or acquisition of control of a motor carrier of passengers under 49 U.S.C. 14303.	$2,100.
(ii) A petition for exemption under 49 U.S.C. 13541 (other than a rulemaking) filed by a non-rail carrier not otherwise covered.	$3,400.
(iii) A petition to revoke an exemption filed under 49 U.S.C. 13541(d)	$2,800.
(3) An application for approval of a non-rail rate association agreement. 49 U.S.C. 13703	$29,500.
(4) An application for approval of an amendment to a non-rail rate association agreement:	
(i) Significant amendment	$4,900.
(ii) Minor amendment	$100.
(5) An application for temporary authority to operate a motor carrier of passengers. 49 U.S.C. 14303(i)	$500.
(6) A notice of exemption for transaction within a motor passenger corporate family that does not result in adverse changes in service levels, significant operational changes, or a change in the competitive balance with motor passenger carriers outside the corporate family.	$1,800.
(7)–(10) [Reserved]	
PART II: Rail Licensing Proceedings other than Abandonment or Discontinuance Proceedings:	
(11) (i) An application for a certificate authorizing the extension, acquisition, or operation of lines of railroad. 49 U.S.C. 10901.	$7,700.
(ii) Notice of exemption under 49 CFR 1150.31–1150.35	$1,900.
(iii) Petition for exemption under 49 U.S.C. 10502	$13,400.
(12) (i) An application involving the construction of a rail line	$79,700.
(ii) A notice of exemption involving construction of a rail line under 49 CFR 1150.36	$1,900.
(iii) A petition for exemption under 49 U.S.C. 10502 involving construction of a rail line	$79,700.
(iv) A request for determination of a dispute involving a rail construction that crosses the line of another carrier under 49 U.S.C. 10902(d).	$300.
(13) A Feeder Line Development Program application filed under 49 U.S.C. 10907(b)(1)(A)(i) or 10907(b)(1)(A)(ii)	$2,600.
(14)(i) An application of a class II or class III carrier to acquire an extended or additional rail line under 49 U.S.C. 10902.	$6,600.
(ii) Notice of exemption under 49 CFR 1150.41–1150.45	$1,900.
(iii) Petition for exemption under 49 U.S.C. 10502 relating to an exemption from the provisions of 49 U.S.C. 10902	$7,000.
(15) A notice of a modified certificate of public convenience and necessity under 49 CFR 1150.21–1150.24	$1,800.
(16) An application for a land-use-exemption permit for a facility existing as of October 16, 2008 under 49 U.S.C. 10909	$6,400.
(17) An application for a land-use-exemption permit for a facility not existing as of October 16, 2008 under 49 U.S.C. 10909.	$22,600.
(18)–(20) [Reserved]	

Type of proceeding	Fee
PART III: Rail Abandonment or Discontinuance of Transportation Services Proceedings:	
(21) (i) An application for authority to abandon all or a portion of a line of railroad or discontinue operation thereof filed by a railroad (except applications filed by Consolidated Rail Corporation pursuant to the Northeast Rail Service Act [Subtitle E of Title XI of Pub. L. 97–35], bankrupt railroads, or exempt abandonments).	$23,700.
(ii) Notice of an exempt abandonment or discontinuance under 49 CFR 1152.50	$3,900.
(iii) A petition for exemption under 49 U.S.C. 10502	$6,700.
(22) An application for authority to abandon all or a portion of a line of a railroad or operation thereof filed by Consolidated Rail Corporation pursuant to Northeast Rail Service Act..	$500.
(23) Abandonments filed by bankrupt railroads	$2,000.
(24) A request for waiver of filing requirements for abandonment application proceedings	$1,900.
(25) An offer of financial assistance under 49 U.S.C. 10904 relating to the purchase of or subsidy for a rail line proposed for abandonment.	$1,600.
(26) A request to set terms and conditions for the sale of or subsidy for a rail line proposed to be abandoned	$24,200.
(27) (i) A request for a trail use condition in an abandonment proceeding under 16 U.S.C.1247(d)	$300.
(ii) A request to extend the period to negotiate a trail use agreement	$450.
(28)–(35) [Reserved]	
PART IV: Rail Applications to Enter Into a Particular Financial Transaction or Joint Arrangement:	
(36) An application for use of terminal facilities or other applications under 49 U.S.C. 11102	$20,200.
(37) An application for the pooling or division of traffic. 49 U.S.C. 11322	$10,900.
(38) An application for two or more carriers to consolidate or merge their properties or franchises (or a part thereof) into one corporation for ownership, management, and operation of the properties previously in separate ownership. 49 U.S.C. 11324:.	
(i) Major transaction	$1,593,600.
(ii) Significant transaction	$318,700.
(iii) Minor transaction	$7,900.
(iv) Notice of an exempt transaction under 49 CFR 1180.2(d)	$1,800.
(v) Responsive application	$7,900.
(vi) Petition for exemption under 49 U.S.C. 10502	$10,000.
(vii) A request for waiver or clarification of regulations filed in a major financial proceeding as defined at 49 CFR 1180.2(a).	$5,900.
(39) An application of a non-carrier to acquire control of two or more carriers through ownership of stock or otherwise. 49 U.S.C. 11324:.	
(i) Major transaction	$1,593,600.
(ii) Significant transaction	$318,700.
(iii) Minor transaction	$7,900.
(iv) A notice of an exempt transaction under 49 CFR 1180.2(d)	$1,400.
(v) Responsive application	$7,900.
(vi) Petition for exemption under 49 U.S.C. 10502	$10,000.
(vii) A request for waiver or clarification of regulations filed in a major financial proceeding as defined at 49 CFR 1180.2(a).	$5,900.
(40) An application to acquire trackage rights over, joint ownership in, or joint use of any railroad lines owned and operated by any other carrier and terminals incidental thereto. 49 U.S.C. 11324:.	
(i) Major transaction	$1,593,600.
(ii) Significant transaction	$318,700.
(iii) Minor transaction	$7,900.
(iv) Notice of an exempt transaction under 49 CFR 1180.2(d)	$1,200.
(v) Responsive application	$7,900.
(vi) Petition for exemption under 49 U.S.C. 10502	$10,000.
(vii) A request for waiver or clarification of regulations filed in a major financial proceeding as defined at 49 CFR 1180.2(a).	$5,900.
(41) An application of a carrier or carriers to purchase, lease, or contract to operate the properties of another, or to acquire control of another by purchase of stock or otherwise. 49 U.S.C. 11324:.	
(i) Major transaction	$1,593,600.
(ii) Significant transaction	$318,700.
(iii) Minor transaction	$7,900.
(iv) Notice of an exempt transaction under 49 CFR 1180.2(d)	$1,400.
(v) Responsive application	$7,900.
(vi) Petition for exemption under 49 U.S.C. 10502	$7,000.
(vii) A request for waiver or clarification of regulations filed in a major financial proceeding as defined at 49 CFR 1180.2(a).	$5,900.
(42) Notice of a joint project involving relocation of a rail line under 49 CFR 1180.2(d)(5)	$2,500.
(43) An application for approval of a rail rate association agreement. 49 U.S.C. 10706	$74,600.
(44) An application for approval of an amendment to a rail rate association agreement. 49 U.S.C. 10706:	
(i) Significant amendment	$13,800.
(ii) Minor amendment	$100.
(45) An application for authority to hold a position as officer or director under 49 U.S.C. 11328	$800.
(46) A petition for exemption under 49 U.S.C. 10502 (other than a rulemaking) filed by rail carrier not otherwise covered	$8,500.
(47) National Railroad Passenger Corporation (Amtrak) conveyance proceeding under 45 U.S.C. 562	$300.
(48) National Railroad Passenger Corporation (Amtrak) compensation proceeding under Section 402(a) of the Rail Passenger Service Act.	$300.

Type of proceeding	Fee
(49)–(55) [Reserved]	
PART V: Formal Proceedings:	
(56) A formal complaint alleging unlawful rates or practices of carriers:.	
(i) A formal complaint filed under the coal rate guidelines (Stand-Alone Cost Methodology) alleging unlawful rates and/or practices of rail carriers under 49 U.S.C. 10704(c)(1).	$350.
(ii) A formal complaint involving rail maximum rates filed under the Simplified-SAC methodology	$350.
(iii) A formal complaint involving rail maximum rates filed under the Three Benchmark methodology	$150.
(iv) All other formal complaints (except competitive access complaints)	$350.
(v) Competitive access complaints	$150.
(vi) A request for an order compelling a rail carrier to establish a common carrier rate	$300.
(57) A complaint seeking or a petition requesting institution of an investigation seeking the prescription or division of joint rates or charges. 49 U.S.C. 10705.	$9,400.
(58) A petition for declaratory order:	
(i) A petition for declaratory order involving a dispute over an existing rate or practice which is comparable to a complaint proceeding.	$1,000.
(ii) All other petitions for declaratory order	$1,400.
(59) An application for shipper antitrust immunity. 49 U.S.C. 10706(a)(5)(A)	$7,500.
(60) Labor arbitration proceedings	$300.
(61) (i) An appeal of a Surface Transportation Board decision on the merits or petition to revoke an exemption pursuant to 49 U.S.C. 10502(d).	$300.
(ii) An appeal of a Surface Transportation Board decision on procedural matters except discovery rulings	$400.
(62) Motor carrier undercharge proceedings	$300.
(63) (i) Expedited relief for service inadequacies: A request for expedited relief under 49 U.S.C. 11123 and 49 CFR part 1146 for service emergency.	$300.
(ii) Expedited relief for service inadequacies: A request for temporary relief under 49 U.S.C. 10705 and 11102, and 49 CFR part 1147 for service inadequacy.	$300.
(64) A request for waiver or clarification of regulations except one filed in an abandonment or discontinuance proceeding, or in a major financial proceeding as defined at 49 CFR 1180.2(a).	$600.
(65)–(75) [Reserved]	
PART VI: Informal Proceedings:	
(76) An application for authority to establish released value rates or ratings for motor carriers and freight forwarders of household goods under 49 U.S.C. 14706.	$1,300.
(77) An application for special permission for short notice or the waiver of other tariff publishing requirements	$100.
(78) The filing of tariffs, including supplements, or contract summaries	$1 per page ($26 min. charge.)
(79) Special docket applications from rail and water carriers:	
(i) Applications involving $25,000 or less	$75.
(ii) Applications involving over $25,000	$150.
(80) Informal complaint about rail rate applications	$650.
(81) Tariff reconciliation petitions from motor common carriers:	
(i) Petitions involving $25,000 or less	$75.
(ii) Petitions involving over $25,000	$150.
(82) Request for a determination of the applicability or reasonableness of motor carrier rates under 49 U.S.C. 13710(a)(2) and (3).	$250.
(83) Filing of documents for recordation. 49 U.S.C. 11301 and 49 CFR 1177.3(c).	$43 per document.
(84) Informal opinions about rate applications (all modes)	$250.
(85) A railroad accounting interpretation	$1,200.
(86) (i) A request for an informal opinion not otherwise covered	$1,500.
(ii) A proposal to use on a voting trust agreement pursuant to 49 CFR 1013 and 49 CFR 1180.4(b)(4)(iv) in connection with a major control proceeding as defined at 49 CFR 1180.2(a).	$5,400.
(iii) A request for an informal opinion on a voting trust agreement pursuant to 49 CFR 1013.3(a) not otherwise covered.	$550.
(87) Arbitration of Certain Disputes Subject to the Statutory Jurisdiction of the Surface Transportation Board under 49 CFR 1108:	
(i) Complaint	$75.
(ii) Answer (per defendant), Unless Declining to Submit to Any Arbitration	$75.
(iii) Third Party Complaint	$75.
(iv) Third Party Answer (per defendant), Unless Declining to Submit to Any Arbitration	$75.
(v) Appeals of Arbitration Decisions or Petitions to Modify or Vacate an Arbitration Award	$150.
(88) Basic fee for STB adjudicatory services not otherwise covered	$300.
(89)–(95) [Reserved]	
PART VII: Services:	
(96) Messenger delivery of decision to a railroad carrier's Washington, DC, agent	$34 per delivery.
(97) Request for service or pleading list for proceedings	$26 per list.
(98) Processing the paperwork related to a request for the Carload Waybill Sample to be used in a Surface Transportation Board or State proceeding that:.	
(i) Does not require a **Federal Register** notice:	
(a) Set cost portion	$150.

Type of proceeding	Fee
(b) Sliding cost portion	$50 per party.
(ii) Does require a **Federal Register** notice:	
(a) Set cost portion	$400.
(b) Sliding cost portion	$50 per party.
(99) (i) Application fee for the Surface Transportation Board's Practitioners' Exam	$200.
(ii) Practitioners' Exam Information Package	$25.
(100) Carload Waybill Sample data:.	
(i) Requests for Public Use File for all years prior to the most current year Carload Waybill Sample data available, provided on CD–R.	$250 per year.
(ii) Specialized programming for Waybill requests to the Board	$114 per hour.

* * * * *

[FR Doc. 2015–17315 Filed 7–14–15; 8:45 am]

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Proposed Rules

Federal Register
Vol. 80, No. 135
Wednesday, July 15, 2015

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 AGRICULTURE

Food and Nutrition Service

7 CFR Parts 271, 274 and 278

RIN 0584–AE40

Supplemental Nutrition Assistance Program: Implementation of the Agricultural Act of 2014 Purchasing and Delivery Services for the Elderly and Disabled

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Proposed rule.

SUMMARY: This rule proposes to revise program regulations to implement changes made by the Agricultural Act of 2014 (the ''2014 Farm Bill''), which amends the definition of ''retail food store'' in the Food and Nutrition Act of 2008 (the FNA) to include governmental or private nonprofit food purchasing and delivery services (P&D Services) that purchase and deliver food to households in which the head of household is an individual who is unable to shop for food, and who is 60 years of age or older, or physically or mentally handicapped or otherwise disabled. Expansion of the definition of ''retail food store'' to allow P&D Services to become authorized Supplemental Nutrition Assistance Program (SNAP) retailers is expected to increase accessibility to the program for homebound elderly and disabled persons.

DATES: Written comments must be received on or before September 14, 2015 to be assured of consideration.

ADDRESSES: FNS invites interested persons to submit written comments on this proposed rule. Comments may be submitted in writing by one of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail:* Send comments to Vicky T. Robinson, Branch Chief, Retailer Management and Issuance Branch, Retailer Policy and Management Division, Rm. 418, 3101 Park Center Drive, Alexandria, Virginia 22302.
- All written comments submitted in response to this proposed rule will be included in the record and will be made available to the public. Please be advised that the substance of the comments and the identity of the individuals or entities submitting the comments will be subject to public disclosure. FNS will make the written comments publicly available on the Internet via *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Vicky T. Robinson, Branch Chief, Retailer Management and Issuance Branch, Retailer Policy and Management Division, Rm. 418, 3101 Park Center Drive, Alexandria, Virginia 22302, 703–305–2476.

SUPPLEMENTARY INFORMATION:

I. Background

This rule proposes to implement a provision of the Agricultural Act of 2014 (Pub. L. 113–79; the ''2014 Farm Bill''), which amends the definition of ''retail food store'' in Section 3(o) of the Food and Nutrition Act of 2008 (7 U.S.C. 2011 note; the ''FNA'') to include P&D Services that purchase and deliver food to households in which the head of household is an individual who is unable to shop for food, and who is 60 years of age or older, or physically or mentally handicapped, or otherwise disabled. Today, retail food stores are authorized to accept SNAP benefits in exchange for eligible foods, as defined in program regulations at 7 CFR part 271, at § 271.2. As a result of the 2014 Farm Bill, approved P&D Services will also be permitted to accept SNAP benefits for the SNAP eligible foods that they purchase and deliver to qualifying households.

Currently, a number of different types of firms may be authorized to accept SNAP benefits as retail food stores, including, but not limited to, public or private communal dining facilities, meal delivery services, private nonprofit cooperative food purchasing ventures and farmers' markets. All firms apply for authorization through FNS which may, or may not, authorize the firm as a SNAP retailer based upon the information provided in the application and a determination of whether the firm meets Program requirements and whether the firm's participation will further the purposes of the program. Accordingly, this rule proposes to amend and revise 7 CFR part 278 to include P&D Services as another type of firm which may be eligible for authorization as a retail food store, and to clarify and incorporate criteria for participation of P&D Services as SNAP retailers.

Although FNS is proposing this rule to amend and revise regulations in accordance with the 2014 Farm Bill, the Farm Bill also permits the Secretary to authorize up to 20 P&D Services as retail food stores prior to issuance of rules. FNS plans to authorize these stores in the upcoming year for a one year trial period and will incorporate any lessons learned into additional guidance for P&D Services' participation. Proposed amendments and revisions to program regulations are discussed more fully in the next section of the preamble.

II. Discussion of the Rule's Provisions

7 CFR Part 271

FNS is proposing three minor amendments or revisions to 7 CFR part 271 to clarify the definition of ''retail food store'' and to distinguish and define P&D Services as retail food stores. All three changes are proposed for the definitions section located at § 271.2.

First, FNS proposes to add to § 271.2 a definition for ''food purchasing and delivery services'' which says that the term means governmental or private nonprofit food purchasing and delivery services that purchase eligible foods for, and delivers these foods to, households in which the head of household is an elderly or disabled member who is unable to shop for food. Second, FNS proposes to revise the definition of ''house-to-house trade route'' to clarify that it includes any retail food business operated by selling eligible foods in inventory from a truck bus, pushcart or other mobile vehicle. FNS proposes to add ''by selling eligible foods in inventory'' to this definition to distinguish P&D Services, which may also operate from a mobile vehicle, but which will not maintain an inventory of foods. Rather, P&D Services typically purchase eligible foods from another retailer and deliver these foods to SNAP households. Finally, FNS proposes to amend the definition of ''retail food store'' by adding paragraph (6) under

the term, to incorporate P&D services as part of the definition of ''retail food store.''

7 CFR Part 274

FNS proposes a few amendments to § 274.7, to clarify which households may use SNAP benefits to purchase eligible foods through P&D Services and to clarify transaction limits for P&D services. Specifically, FNS proposes to amend paragraph (c) of this section regarding transaction limits. Currently, program regulations provide that no minimum dollar amount per transaction may be established. However, given that P&D services are providing a delivery service, it may not be economical or efficient for such services to make deliveries of small dollar values of eligible foods. Therefore, FNS proposes to amend this paragraph by allowing P&D Services to establish a minimum dollar amount per transaction. In proposed § 278.2(m)(4), FNS specifies that P&D Services may require an order minimum of not more than $50.

In § 274.7, FNS inserts a new paragraph (i), which proposes to allow households in which the head of household is an elderly or disabled member who is unable to shop for food to use SNAP benefits to purchase eligible foods through a food purchasing and delivery service authorized in accordance with § 278.1(j). FNS then moves current paragraph (i) to paragraph (j) and amends it. Currently, this paragraph says that State agencies must implement a method to ensure that access to prepared meals and hunting and fishing equipment is limited to eligible households. FNS proposes to amend this paragraph by adding the same implementation requirement of State agencies for households eligible for P&D Services.

7 CFR Part 278

In this rule, FNS proposes to revise and amend 7 CFR part 278 to incorporate criteria for the authorization and participation of P&D Services throughout. Following is a discussion of the major changes to this part proposed in this rule. Additional minor conforming changes are also being made to § 278.6, imposing the same penalty requirements of P&D Services as are required of other firms.

As for major changes, FNS proposes to amend § 278.1, which provides the process and criteria for authorization of various firms as retail food stores, by inserting paragraph (j), which adds P&D Services as a type of firm that may be authorized as a retail food store. FNS also proposes the requirements that P&D Services must meet in order to be authorized in this paragraph and clarifies that P&D Services may purchase and deliver to households foods or non-food items not eligible for purchase with SNAP benefits, as long as these purchases are not paid for using SNAP benefits.

FNS then proposes to amend paragraph (k) of § 278.1, as redesignated, which provides 5 years as the period of authorization for retail food stores. Because P&D Services do not maintain an inventory of eligible foods and must have third party sources of eligible foods, and because they work with particularly vulnerable SNAP households in their own homes, FNS finds it is prudent to require a shorter authorization period of 2 years. The shorter authorization period would allow FNS to have greater oversight of P&D Services, thereby ensuring stronger program integrity.

FNS also proposes to amend § 278.2(b) regarding equal treatment for SNAP customers. Specifically, one provision of this paragraph provides that FNS is not authorized to specify prices at which retail food stores may sell food. While this remains true, the 2014 Farm Bill specifies that food purchasing and delivery services must provide eligible foods to the participating household at the price paid by the service for the food, without any cost markup, as a condition of being authorized. Accordingly, FNS proposes to include this language in this paragraph (b). To note, this paragraph also prohibits retail food stores from charging tax on eligible foods. Likewise, P&D Services authorized as retail food stores would not be permitted to charge households tax on eligible foods.

Finally, FNS proposes to add a new paragraph (m) to § 278.2, which details the requirements of participation for retail food stores, by adding paragraphs (m)(1) through (7) which contain requirements specific to P&D Services. Paragraphs (m)(1) through (3) contain proposed requirements specifically articulated in the 2014 Farm Bill, while paragraphs (4) through (7) contain proposed requirements either necessary to ensure the legitimate use of SNAP benefits or to help ensure that the participation of P&D Services will further the purposes of the program.

In paragraph (m)(1), FNS proposes to require that P&D Services notify the participating household, at the time the household places a food order, of any delivery fee that will be charged for the purchase and delivery of foods. FNS also proposes that, at the same time, P&D Services notify the household that a delivery fee cannot be paid with SNAP benefits. This ensures that the household can consider the cost of the delivery fee when making decisions regarding the use of the service and the purchase of foods, and that the household is aware that it must use another form of payment besides SNAP benefits for delivery fees. A clear understanding of the delivery fee and its payment method is important for both the household and the P&D Service to have a successful transaction.

In paragraph (m)(2), FNS would require P&D Services to provide its food purchasing and delivery services at low or no cost, as required by the 2014 Farm Bill. Although the Farm Bill does not specify any limit on the amount of the delivery fee, FNS believes that, given the vulnerable population being served, it is important to propose a required limitation on the amount of the delivery fee to ensure that the cost of the delivery service is not excessive. Accordingly, FNS proposes that the delivery fee charged cannot exceed 25 percent of the order total, up to a maximum of $20 per delivery for all items purchased for delivery, including items not eligible for payment with SNAP benefits and which are paid for using another form of payment. However, FNS would encourage P&D Services to base any delivery fee, within these parameters, on a sliding scale taking into account factors such as the household's income.

In paragraph (m)(3), FNS proposes to require P&D Services to sell eligible foods purchased for the household at the price paid by the service for the food without any additional cost markup. Again, this requirement is specified in the 2014 Farm Bill. P&D Services should also be aware that 278.2(b) prohibits retail food stores from charging tax on eligible foods purchased with SNAP benefits. Therefore, P&D Services would not be permitted to charge any tax paid for these foods to the households they serve.

In paragraph (m)(4), FNS proposes to allow P&D Services, at their option, to impose a total order minimum of up to $50 per delivery for all items purchased for delivery, including items not eligible for payment with SNAP benefits and which are paid for using another form of payment. This provision recognizes that it may be difficult for P&D Services to provide their services for very small order amounts. However, a larger limit may make the service inaccessible to many eligible SNAP participants. The Agency would be very interested in receiving comments on this proposed provision.

In paragraph (m)(5), FNS proposes to require P&D Services to be able to accept orders for eligible foods, and deliver these foods, at least monthly.

This allows the homebound elderly and disabled persons served by P&D Services to have access to eligible foods with some regularity, and it allows them the opportunity to plan their collective food purchases during any given month.

In paragraph (m)(6), FNS proposes to require P&D Services to obtain the agreement of the household, at the time of the food order, of the date and timeframe of delivery. This proposed requirement, that both the P&D Service and the household agree to a specific date and timeframe of delivery, is intended to benefit both the service and the household. It is important that the household provides input and agreement as to the time that the delivery will take place. At the same time, it helps to ensure for the P&D Service that someone will be available to accept the delivery. While the proposed rule would not dictate the maximum window of delivery allowed, it is recommended that any delivery timeframe does not exceed two hours.

In paragraph (m)(7), FNS proposes that P&D Services may not impose any conditions on the use of the food purchase and delivery service which place a hardship on the SNAP household, or which are unrelated to the purchase and delivery of foods. Such additional conditions would include a requirement to tip the delivery driver or to participate in religious or affiliate activities. The eligible SNAP participants served by P&D Services are particularly vulnerable and will be accepting deliveries in their own homes. Conditions placed on delivery of eligible foods to these households may be perceived as being coercive, even if not intended as such. Therefore, FNS believes it is important that any conditions imposed on food purchase and delivery services be limited to those strictly necessary, and related to the purchase and delivery of foods.

Although FNS is proposing specific criteria related to the authorization and participation of P&D Services in SNAP, these retailers will be expected to meet all other existing program requirements for retailers, as appropriate. For example, in accordance with current 278.2(e), P&D Services may not redeem SNAP benefits before delivery of foods.

III. Procedural Matters

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. FNS considers that the benefits of this regulation justify its costs. Although governmental or private nonprofit food purchasing and delivery services may incur additional operational costs should the proposals in this rule become final, most SNAP retailers also incur such costs. These costs are outweighed by the benefit of the greater program flexibility of allowing food purchasing and delivery services to serve the homebound elderly and disabled.

This proposed rule has been determined to be not significant and was not reviewed by the Office of Management and Budget (OMB) in conformance with Executive Order 12866.

Regulatory Impact Analysis

This proposed rule has been designated as not significant by OMB. Therefore, no Regulatory Impact Analysis is required.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601–612) requires agencies to analyze the impact of rulemaking on small entities and consider alternatives that would minimize any significant impacts on a substantial number of small entities. Pursuant to that review, it has been certified that this proposed rule would not have a significant impact on a substantial number of small entities. Although the rulemaking proposes to allow additional small not-for-profit organizations to accept SNAP benefits, it is not anticipated that a substantial number of small entities will begin accepting SNAP benefits as a result of the rulemaking, nor will the impact on these small entities be significant given that some of these entities already use another process to accept SNAP benefits and because SNAP benefits are just one of the forms of payment accepted by these entities.

Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Public Law 104–4, establishes requirements for Federal agencies to assess the effects of their regulatory actions on State, local and tribal governments and the private sector. Under section 202 of the UMRA, the Department generally must prepare a written statement, including a cost-benefit analysis, for proposed and final rules with ''Federal mandates'' that may result in expenditures by State, local or Tribal governments, in the aggregate, or the private sector, of $100 million or more in any one year. When such a statement is needed for a rule, section 205 of the UMRA generally requires the Department to identify and consider a reasonable number of regulatory alternatives and adopt the most cost effective or least burdensome alternative that achieves the objectives of the rule.

This proposed rule contains no Federal mandates (under the regulatory provisions of Title II of the UMRA) for State, local and Tribal governments or the private sector of $100 million or more in any one year. Thus, the rule is not subject to the requirements of sections 202 and 205 of the UMRA.

Executive Order 12372

SNAP is listed in the Catalog of Federal Domestic Assistance Programs under 10.551. For the reasons set forth in the final rule in 7 CFR part 3015, subpart V, and related notice (48 FR 29115, June 24, 1983), this program is included in the scope of Executive Order 12372, which requires intergovernmental consultation with State and local officials.

Federalism Summary Impact Statement

Executive Order 13132 requires Federal agencies to consider the impact of their regulatory actions on State and local governments. Where such actions have federalism implications, agencies are directed to provide a statement for inclusion in the preamble to the regulations describing the agency's considerations in terms of the three categories called for under section (6)(b)(2)(B) of Executive Order 13121.

The Department has considered the impact of this proposed rule on State and local governments and has determined that this rule does not have federalism implications. Therefore, under section 6(b) of the Executive Order, a federalism summary is not required.

Executive Order 12988, Civil Justice Reform

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. This proposed rule is intended to have preemptive effect with respect to any State or local laws, regulations or policies which conflict with its provisions or which would otherwise impede its full and timely implementation. This proposed rule is not intended to have retroactive effect unless so specified in the Effective Dates section of the final rule. Prior to any judicial challenge to the provisions of

the final rule, all applicable administrative procedures must be exhausted.

Civil Rights Impact Analysis

FNS has reviewed this proposed rule in accordance with USDA Regulation 4300–4, ''Civil Rights Impact Analysis,'' to identify any major civil rights impacts the rule might have on program participants on the basis of religion, age, race, color, national origin, sex, political beliefs or disability. After a careful review of the rule's intent and provisions, FNS has determined that this proposed rule is not expected to negatively affect the participation of protected individuals in the Supplemental Nutrition Assistance Program.

Executive Order 13175

Executive Order 13175 requires Federal agencies to consult and coordinate with Tribes on a government-to-government basis on policies that have Tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have substantial direct effects 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. On February 18, 2015, as part of its regular quarterly Tribal consultation schedule, USDA engaged in a consultative session to obtain input by Tribal officials, or their designees, and Tribal members concerning the effect of this and other rules on the Tribes or Indian Tribal governments. No concerns regarding the provisions of this proposed rule were expressed.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. chap. 35; 5 CFR part 1320) requires the Office of Management and Budget (OMB) approve all collections of information by a Federal agency before they can be implemented. Respondents are not required to respond to any collection of information unless it displays a current valid OMB control number. This rule does not contain information collection requirements subject to approval by the Office of Management and Budget under the Paperwork Reduction Act of 1994.

E-Government Act Compliance

The Department is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

List of Subjects

7 CFR Part 271

Food stamps, Grant programs-social programs, Reporting and recordkeeping requirements.

7 CFR Part 274

Food stamps, Grant programs-social programs, Reporting and recordkeeping requirements.

7 CFR Part 278

Banks, banking, Food stamps, Grant programs-social programs, Penalties, Reporting and recordkeeping requirements.

For the reasons stated in the preamble, 7 CFR parts 271, 274, and 278 are proposed to be amended as follows:

PART 271—GENERAL INFORMATION AND DEFINITIONS

■ 1. The authority citation for part 271 continues to read as follows:

Authority: 7 U.S.C. 2011–2036.

■ 2. Amend § 271.2 as follows:

■ a. Add the definition, in alphabetical order, for ''Food purchasing and delivery services''; and

■ b. Revise the definitions of ''House-to-house trade route'' and ''Retail food store.''

The addition and revisions read as follows:

§ 271.2 Definitions.

* * * * *

Food purchasing and delivery services means governmental or private nonprofit food purchasing and delivery services that purchase eligible foods for, and delivers these foods to, households in which the head of household is an elderly or disabled member who is unable to shop for food.

* * * * *

House-to-house trade route means any retail food business operated by selling eligible foods in inventory from a truck, a bus, a pushcart, or other mobile vehicle.

* * * * *

Retail food store means:

(1) An establishment or house-to-house trade route that sells food for home preparation and consumption normally displayed in a public area, and either offers for sale, on a continuous basis, a variety of foods in sufficient quantities in each of the four categories of staple foods including perishable foods in at least two such categories (Criterion A) as set forth in § 278.1(b)(1) of this chapter, or has more than 50 percent of its total gross retail sales in staple foods (Criterion B) as set forth in § 278.1(b)(1) of this chapter as determined by visual inspection, marketing structure, business licenses, accessibility of food items offered for sale, purchase and sales records, counting of stockkeeping units, or other inventory or accounting recordkeeping methods that are customary or reasonable in the retail food industry as set forth in § 278.1(b)(1) of this chapter. Entities that have more than 50 percent of their total gross retail sales in hot and/or cold prepared, ready-to-eat foods that are intended for immediate consumption either for carry-out or on-premises consumption, and require no additional preparation, are not eligible for SNAP participation as retail food stores under § 278.1(b)(1) of this chapter.

(2) Public or private communal dining facilities and meal delivery services; private nonprofit drug addict or alcoholic treatment and rehabilitation programs; publicly operated community mental health centers which conduct residential programs for drug addicts and/or alcoholics; public or private nonprofit group living arrangements; public or private nonprofit shelters for battered women and children; public or private nonprofit establishments, approved by an appropriate State or local agency, that feed homeless persons; or a restaurant that contracts with an appropriate State agency to provide meals at concessional (low or reduced) prices to homeless SNAP households;

(3) Any stores selling equipment for procuring food by hunting and fishing to eligible households in Alaska, as specified in the definition of eligible foods;

(4) Any private nonprofit cooperative food purchasing venture, including those whose members pay for food prior to receipt of the food;

(5) A farmers' market; and

(6) A governmental or private nonprofit food purchasing and delivery service that purchases eligible foods for, and delivers these foods to, households in which the head of household is an elderly or disabled member who is unable to shop for food.

* * * * *

PART 274—ISSUANCE AND USE OF PROGRAM BENEFITS

■ 3. The authority citation for part 274 continues to read as follows:

Authority: 7 U.S.C. 2011–2036.

■ 4. In § 274.7:

■ a. Revise paragraph (c); and

■ b. Redesignate paragraph (i) as paragraph (j) and revise it, and add a new paragraph (i).

The revisions and addition read as follows:

§ 274.7 Benefit redemption by eligible households.

* * * * *

(c) *Transaction limits.* No minimum dollar amount per transaction or maximum limit on the number of transactions shall be established, except that food purchasing and delivery services authorized under § 278.1(j) may establish a minimum dollar amount per transaction in accordance with § 278.2(m)(4). In addition, no transaction fees shall be imposed on SNAP households utilizing the EBT system to access their benefits.

* * * * *

(i) Eligible households in which the head of household is an elderly or disabled member who is unable to shop for food may use Program benefits to purchase eligible foods through a food purchasing and delivery service authorized in accordance with § 278.1.(j) of this chapter.

(j) State agencies shall implement a method to ensure that access to prepared meals, hunting and fishing equipment, or delivered foods is limited to eligible households as described in paragraphs (g) through (i) of this section.

PART 278—PARTICIPATION OF RETAIL FOOD STORES, WHOLESALE FOOD CONCERNS AND INSURED FINANCIAL INSTITUTIONS

■ 5. The authority citation for part 278 continues to read as follows:

Authority: 7 U.S.C. 2011–2036.

■ 6. In § 278.1:

■ a. Redesignate paragraphs (j) through (t) as paragraphs (k) through (u), respectively, and add new paragraph (j);

■ b. Revise newly redesignated paragraph (k);

■ c. Amend newly redesignated paragraph (l)(1) by removing the words, ''or (i)'' and adding in their place the words, '',(i) or (j)'';

■ d. Amend newly redesignated paragraph (m)(1)(ii) by removing the words, ''or (i)'' and adding in their place the words, ''(i) or (j)'';

■ e. Amend newly redesignated paragraph (m)(1)(iii) by removing the words, ''paragraph (k)(2)'' and adding in their place the words, ''paragraph (l)(2)'';

■ f. Amend newly redesignated paragraph (m)(1)(iv) by removing the words, ''paragraph (k)(3)'' and adding in their place the words, ''paragraph (l)(3)'';

■ g. Amend newly redesignated paragraph (p) by removing the words, ''paragraph (k)'' and adding in their place the words, ''paragraph (l)'';

■ h. Amend newly redesignated paragraph (r) by removing the words, ''paragraph (q)(2)'' and ''paragraph (q)(3)'' and adding in their places the words, ''paragraph (r)(2)'' and ''paragraph (r)(3)'', respectively;

■ i. Amend newly redesignated paragraph (r)(1)(i) by removing the words, ''paragraph (q)(1)(ii)'' and adding in their place the words, ''paragraph (r)(1)(ii)'';

■ j. Amend newly redesignated paragraph (r)(1)(ii) by removing the words, ''paragraph (q)(1)(i)'' and adding in their place the words, ''paragraph (r)(1)(i)'';

■ k. Amend newly redesignated paragraph (r)(1)(v) by removing the words, ''paragraph (q)(1)(iv)'' and adding in their place the words, ''paragraph (r)(1)(iv)'';

■ l. Amend newly redesignated paragraph (r)(2)(iv) by removing the words, ''paragraph (q)(2)(ii)'' and adding in their place the words, ''paragraph (r)(2)(ii)'', and by removing the words, ''paragraph (q)(2)(iv) and adding in their place the words, ''paragraph (r)(2)(iv)''; and

■ m. Remove the Effective Date Note.

The revisions and additions read as follows:

§ 278.1 Approval of retail food stores and wholesale food concerns.

* * * * *

(j) *Food purchasing and delivery services for households with an elderly or disabled member.* FNS shall authorize as retail food stores governmental or private nonprofit food purchasing and delivery services that purchase eligible food for, and deliver the food to, households in which the head of household, as defined in § 273.1(d) of this chapter, is an elderly or disabled member, as defined in § 271.2 of this chapter, who is unable to shop for food. Such services must meet the requirements of paragraphs (a) and (b) of this section. Purchasing and delivery services may purchase and deliver foods or non-food items not eligible for purchase with SNAP benefits, as long as these items are not paid for with SNAP benefits. Private nonprofit food purchasing and delivery services eligible for authorization include only those which meet the requirements of paragraph (d)(1) of this section.

(k) *Authorization.* Upon approval, FNS shall issue a nontransferable authorization card to the firm. The authorization card shall be valid only for the time period for which the firm is authorized to accept and redeem SNAP benefits. The authorization card shall be retained by the firm until such time as the authorization period has ended, authorization in the program is superseded, or the card is surrendered or revoked as provided in this part. All firms, except those authorized under paragraph (j) of this section, will be authorized in the program for a period of 5 years. Firms authorized under paragraph (j) of this section will be authorized for a maximum period of 2 years. The specification of an authorization period in no way precludes FNS from periodically requesting information from a firm for purposes of reauthorization in the program or from withdrawing or terminating the authorization of a firm in accordance with this part.

* * * * *

■ 7. In § 278.2 revise the second and third sentences of paragraph (b) and add paragraph (m) to read as follows:

§ 278.2 Participation of retail food stores.

* * * * *

(b) * * * Although nothing in this part may be construed as authorizing FNS to specify the prices at which retail food stores may sell food, food purchasing and delivery services must provide eligible foods to the participating household at the price paid by the service for the food, without any cost markup. Further, public or private nonprofit homeless meal providers may only request *voluntary* use of SNAP benefits from homeless SNAP recipients and may not request such households using SNAP benefits to pay more than the average cost of the food *purchased* by the public or private nonprofit homeless meal provider contained in a meal served to the patrons of the meal service. * * *

* * * * *

(m) Food purchasing and delivery services authorized under § 278.1(j) must:

(1) Notify the participating household, at the time the household places a food order, the amount of any delivery fee that will be charged for the purchase and delivery of foods, and that the delivery fee cannot be paid for with SNAP benefits;

(2) Ensure that the food purchasing and delivery service is provided at low or no cost, and that any delivery fee charged will not exceed 25 percent of the order total, up to a maximum of $20 per delivery for all items purchased, including eligible foods purchased with SNAP benefits and items purchased with other tender, combined;

(3) Sell eligible foods purchased for the household at the price paid by the service for the food without any additional cost markup;

(4) Not impose a total order minimum of more than $50 per delivery for all items purchased, including eligible foods purchased with SNAP benefits and items purchased with other tender, combined;

(5) Offer to accept orders and be able to deliver foods at least monthly;

(6) Obtain the agreement of the participant, at the time of the food order, of the date and timeframe of delivery; and

(7) Not impose any conditions on the use of the food purchase and delivery service which place a hardship on the SNAP household or which are unrelated to the purchase and delivery of foods, such as tipping of the delivery driver or participation in religious or other affiliate activities.

§ 278.6 [Amended]

■ 8. In § 278.6:

■ a. Amend paragraph (e)(1)(iii)(A) by removing the words, ''and (h)'' and adding in their place the words, '',(h) and (i)''.

■ b. Amend paragraph (l) by removing the references, ''§ 278.1(k)'' and ''§ 278.1(j)'' and adding in their place the references, ''§ 278.1(l)'' and ''§ 278.1(k)'', wherever they occur, respectively.

■ c. Amend paragraph (m) by removing the references, ''§ 278.1(k)'' and ''§ 278.1(j)'' and adding in their place the references, ''§ 278.1(l)'' and ''§ 278.1(k)'', respectively.

Dated: June 21, 2015.

Jeffrey J. Tribiano,

Acting Administrator, Food and Nutrition Service.

[FR Doc. 2015–17354 Filed 7–14–15; 8:45 am]

BILLING CODE 3410–30–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Chapter I

[Docket No. FAA–2015–2022]

Petition of the Aircraft Owner and Pilots Association (AOPA) To Amend FAA Policy Concerning Flying Club Operations at Federally-Obligated Airports.

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petition; request for comments.

SUMMARY: This notice requests comments on a petition by the Aircraft Owner and Pilots Association (AOPA) to revise certain policies concerning flying clubs in the Federal Aviation Administration (FAA) Order 5190.6B, *FAA Airport Compliance Manual.* As part of its effort to promote flying clubs, AOPA has requested certain revisions to FAA guidance intended to lower barriers for new flying clubs. These revisions allow flight instructors and mechanics who are club members to receive monetary compensation for services provided to club members.

On April 3, 2015, the AOPA Senior Vice President for Government Affairs & Advocacy, James W. Coon, wrote to Mr. Randall Fiertz, FAA's Director of the Office of Airport Compliance and Management Analysis proposing revision to FAA guidance regarding compensation for flight instructors and persons maintaining aircraft within the context of flying club operations. AOPA seeks ''to help current flying clubs and airport sponsors comply with the FAA guidance outlined in 5190.6B, and to provide future flying clubs the opportunity to strengthen and unify general aviation pilots.'' AOPA states that its goal is ''to provide guidance that is attainable and ensures educated compliance from all airport users,'' and thus asks for ''updated guidance regarding compensation for flight instructors and maintainers'' because ''flight instructors and aviation mechanics are valuable assets to the aviation industry, and should be granted the privilege of fair compensation for their efforts on a local level.''

DATES: Send your comments on or before August 14, 2015. The FAA will consider comments on the petition. Any revisions resulting from the original petition or comments received will be adopted as of the date of a subsequent publication in the **Federal Register**.

ADDRESSES: You may send comments [identified by Docket Number FAA–2015–2022] using any of the following methods:

- *Government-wide rulemaking Web site:* Go to *http://www.regulations.gov* and follow the instructions for sending your comments electronically.
- *Mail:* Docket Operations, U.S. Department of Transportation, West Building, Ground Floor, Room W12–140, Routing Symbol M–30, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Fax:* 1–202–493–2251.
- *Hand Delivery:* To Docket Operations, Room W12–140 on the ground floor of the West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For more information on the notice and comment process, see the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: To read background documents or comments received, go to *http://www.regulations.gov* at any time or to Room W12–140 on the ground floor of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy: We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. Using the search function of our docket Web site, anyone can find and read the comments received into any of our dockets, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477–78).

Availability of Documents: You can get an electronic copy of this Policy and all other documents in this docket using the Internet by:

(1) Searching the Federal eRulemaking portal (*http://www.faa.gov/regulations/search*);

(2) Visiting FAA's Regulations and Policies Web page at (*http://www.faa.gov/regulations_policies;* or

(3) Accessing the Government Printing Office's Web page at (*http://www.gpoaccess.gov/index.html.*

You can also get a copy by sending a request to the Federal Aviation Administration, Office of Airport Compliance and Management Analysis, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 267–3085. Make sure to identify the docket number, notice number, or amendment number of this proceeding.

FOR FURTHER INFORMATION CONTACT: Miguel Vasconcelos, Airport Compliance Division, ACO–100, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591, telephone (202) 267–3085; facsimile: (202) 267–4620.

SUPPLEMENTARY INFORMATION: FAA Order 5190.6B, *FAA Airport Compliance Manual* (Order), published on September 30, 2009 defines flying clubs as: ''a nonprofit or not-for-profit entity (*e.g.,* corporation, association, or partnership) organized for the express purpose of providing its members with aircraft for their personal use and

enjoyment only.'' The Order states that ''the ownership of the club aircraft must be vested in the name of the flying club or owned by all its members. The property rights of the members of the club shall be equal; no part of the net earnings of the club will benefit any one individual in any form, including salaries, bonuses, etc. The flying club may not derive greater revenue from the use of its aircraft than the amount needed for the operation, maintenance and replacement of its aircraft.'' The Order also notes that ''flying clubs may not offer or conduct . . . aircraft rental operations. They may conduct aircraft flight instruction for regular members only, and only members of the flying club may operate the aircraft.'' While members may not be monetarily compensated, existing policy allows flying clubs to allow compensation only in the form of credit against payment of dues or flight time.

In addition, the Order states that ''no flying club shall permit its aircraft to be used for flight instruction for any person, including members of the club owning the aircraft, when such person pays or becomes obligated to pay for such instruction. An exception applies when the instruction is given by a lessee based on the airport who provides flight training and the person receiving the training is a member of the flying club. Flight instructors who are also club members may not receive payment for instruction except that they may be compensated by credit against payment of dues or flight time'' and that ''any qualified mechanic who is a registered member and part owner of the aircraft owned and operated by a flying club may perform maintenance work on aircraft owned by the club. The flying club may not become obligated to pay for such maintenance work except that such mechanics may be compensated by credit against payment of dues or flight time.'' [See FAA Order 5190.6B, paragraphs 10.6(a), (b), and (c).] Flying clubs are defined in such a way as to differentiate from for-profit aeronautical businesses offering aeronautical services to general public, *e.g.,* FBOs, flight schools and aircraft rental providers.

The owner of any airport (airport sponsor) developed with Federal grant assistance is required to operate the airport for the use and benefit of the public and to make it available to all types, kinds, and classes of aeronautical activity on fair and reasonable terms, and without unjust discrimination. This includes flying clubs. Assurance 22, *Economic Nondiscrimination,* of the prescribed sponsor assurances implements the provisions of 49 U.S.C. 47107(a)(l) through (6), and requires, in pertinent part, that the sponsor of a federally obligated airport

''. . . will make its airport available as an airport for public use on reasonable terms, and without unjust discrimination, to all types, kinds, and classes of aeronautical activities, including commercial aeronautical activities offering services to the public at the airport.'' Assurance 22(a)

''. . . may establish such fair, equal, and not unjustly discriminatory conditions to be met by all users of the airport as may be necessary for the safe and efficient operation of the airport.'' Assurance 22(h)

At issue is the fact that some entities operating at federally-obligated airports identify themselves as ''flying clubs,'' while not meeting the definition of a ''flying club.'' Rather, they are engaged in providing commercial services at the airport. In some instances, these ''flying clubs'' present themselves to the public as alternatives to traditional flight schools and aircraft rental providers. Some publish flight training rates, including instruction fees and rental rates, and only charge nominal annual ''club fees.'' FAA policy reflects the concern that some entities claiming to be flying clubs are actually commercial service providers. These commercial service providers use the term ''flying club'' to avoid compliance with airport minimum standards for commercials service providers. This can result in unjust discrimination because legitimate service providers at the airport would be at an economic disadvantage in competition with the flying club, contrary to the federal grant assurances, specifically Grant Assurance 22, *Economic Nondiscrimination* Therefore, if proposed changes to the definition of a flying club and the related activities must be consistent with Grant Assurance 22.

As part of its effort to promote flying clubs, AOPA has recommended revisions to FAA guidance. These recommendations, designed to promote flying clubs, include allowing flight instructors and mechanics who are club members to receive monetary compensation for services conducted for other club members or club aircraft. Specifically, AOPA proposes the following language for consideration in FAA flying club policies:

AOPA Policy Proposal Item 1:

''No flying club shall permit its aircraft to be used for flight instruction for any person, including members of the club owning the aircraft, when such person pays or becomes obligated to pay for such instruction except in the following circumstances; (a) The flight instruction is provided to a club member by a commercial operator authorized by the airport sponsor to provide flight instruction on field. (b) The flight instruction is provided to a club member by a flight instructor who is also a club member that is in good standing according to the club bylaws. In either case, the flight instructor may receive monetary compensation; however the flying club is prohibited from holding itself out to the public as a fixed based operator, a specialized aviation service operation, or a flight school. In the case of (b) above, the Airport Sponsor has the right to limit flight instruction for monetary compensation but must permit the club to compensate club instructors with credit against payment of dues or flight time.''

AOPA Policy Proposal Item 2:

''Any qualified mechanic who is a member of the flying club may perform maintenance work on aircraft owned or exclusively used by the flying club. The flying club may not become obligated to pay for such maintenance work except that such mechanics may be compensated not to exceed a reasonable rate for the work performed at the discretion of club members. The club however may not hold out to the public as operating as a fixed base operator, a specialized aviation service operation, or maintenance facility. The Airport Sponsor has the right to limit maintenance work for monetary compensation but must permit the club to compensate club mechanics with credit against payment of dues or flight time.''

In brief, AOPA requests that flight instructors and mechanics who are club members be permitted to receive monetary compensation for services conducted within the club. AOPA's request also emphasizes that airport sponsors *must* [emphasis added] permit the club to compensate club instructors and mechanics with credit against payment of dues or flight time.

AOPA-recommended revisions are available for review on the FAA Airports Web site, as well as in the docket locations described under *Availability of documents* in this notice.

Request for Comments: The FAA requests comments on whether AOPA's recommendations can be considered consistent with the FAA's general policies regarding commercial aeronautical services and flying clubs on an airport, and if so, whether the stated agency policy on flying clubs should be revised to amend its definition of flying clubs. In particular, the FAA seeks comments from commercial service providers that engage in flight training and aircraft rental, from associations representing such service providers, and other interested parties.

Issued in Washington, DC, on July 9, 2015.

Randall S. Fiertz,

Director, Office of Airport Compliance and Management Analysis.

[FR Doc. 2015–17324 Filed 7–14–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 35

[Docket No. RM15–21–000]

Generator Interconnection Rules and Procedures

AGENCY: Federal Energy Regulatory Commission, DOE.

ACTION: Opportunity to comment on petition for rulemaking.

SUMMARY: Take notice that on June 19, 2015, the American Wind Energy Association filed a petition requesting that the Commission initiate a rulemaking to revise provisions of the *pro forma* Large Generator Interconnection Procedures and *pro forma* Large Generator Interconnection Agreement.

DATES: Comments are due August 6, 2015.

FOR FURTHER INFORMATION CONTACT:
Tony Dobbins (General Information), Federal Energy Regulatory Commission, Office of Energy Policy and Innovation, 888 First Street NE., Washington, DC 20426, (202) 502–6630
Adam Pan (Legal Information), Federal Energy Regulatory Commission, Office of the General Counsel, 888 First Street NE., Washington, DC 20426, (202) 502–6023

SUPPLEMENTARY INFORMATION:

Opportunity To Comment on Petition for Rulemaking

Take notice that on June 19, 2015, the American Wind Energy Association, pursuant to sections 205 and 206 of the Federal Power Act, 16 U.S.C. 824d and 824e (2012), and Rule 207(a)(4) of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.207(a)(4) (2014), filed a petition requesting that the Commission initiate a rulemaking to revise provisions of the *pro forma* Large Generator Interconnection Procedures and *pro forma* Large Generator Interconnection Agreement.

Any person that wishes to comment in this proceeding must file comments in accordance with Rule 211 of the Commission's Rules of Practice and Procedure, 18 CFR 385.211 (2014). Comments will be considered by the Commission in determining the appropriate action to be taken. Comments must be filed on or before the comment date.

The Commission encourages electronic submission of comments in lieu of paper using the ''eFiling'' link at *http://www.ferc.gov.* Persons unable to file electronically should submit an original and 5 copies of the comments to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible on-line at *http://www.ferc.gov,* using the ''eLibrary'' link and is available for review in the Commission's Public Reference Room in Washington, DC. There is an ''eSubscription'' link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov,* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Comment Date: 5:00 p.m. Eastern Time on August 6, 2015.

Dated: July 7, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–17306 Filed 7–14–15; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2013–0816; FRL–9930–29–Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Delaware; Nonattainment New Source Review; Emission Offset Provisions; Reopening of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule; reopening of comment period.

SUMMARY: Environmental Protection Agency (EPA) is reopening the comment period for a notice of proposed rulemaking (NPR) published on May 26, 2015. In the NPR, EPA proposed disapproval of a revision to the Delaware State Implementation Plan (SIP) related to nonattainment New Source Review (NSR) preconstruction permit program requirements for emission offsets. A commenter requested additional time to review the proposal and prepare comments. In response to this request, EPA is reopening the comment period for this proposal through August 14, 2015. All comments received on or before August 14, 2015 will be entered into the public record and considered by EPA before taking final action on the proposed rule. Comments submitted between the close of the original comment period and the reopening of this comment period will be accepted and considered.

DATES: The comment period for the notice of proposed rulemaking (NPR) published on May 26, 2015 (80 FR 30015), is reopened. Comments must be received on or before August 14, 2015.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA–R03–OAR–2013–0816 by one of the following methods:

A. *www.regulations.gov.* Follow the on-line instructions for submitting comments.

B. *Email: campbell.dave@epa.gov.*

C. *Mail:* EPA–R03–OAR–2013–0816, Mr. David Campbell, Associate Director, Office of Permits and Air Toxics, Mailcode 3AP10, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. 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–R03–OAR–2013–0816. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *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 *www.regulations.gov* or email. The *www.regulations.gov* Web site 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 *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 electronic docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *i.e.,* CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the State submittal are available at the Delaware Department of Natural Resources and Environmental Control, 89 Kings Highway, P.O. Box 1401, Dover, Delaware 19903.

FOR FURTHER INFORMATION CONTACT: Mrs. Amy Johansen, (215) 814–2156, or by email at *johansen.amy@epa.gov.*

SUPPLEMENTARY INFORMATION: On May 26, 2015, EPA published a notice of proposed rulemaking (80 FR 30015). In the NPR, EPA proposed disapproval of a revision to the Delaware SIP related to nonattainment NSR preconstruction permit program requirements for emission offsets. In that action, EPA proposed disapproval, because the submittal did not satisfy the requirements of Clean Air Act (CAA) or the Federal implementing regulations, which establish the criteria under which the owner or operator of a new or modified major stationary source must obtain the required emission offsets ''from the same source or other sources in the same nonattainment area'' with limited exceptions, for Delaware's nonattainment NSR preconstruction permitting program. In addition, EPA proposed disapproval of the SIP revision because Delaware exercises authorities that are reserved for EPA under section 107 of the CAA.

Dated: June 25, 2015.

Shawn M. Garvin,

Regional Administrator, Region III.

[FR Doc. 2015–16919 Filed 7–14–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R08–OAR–2012–0974, FRL–9930–42–Region–8]

Promulgation of State Implementation Plan Revisions; Infrastructure Requirements for the 2008 Lead, 2008 Ozone, and 2010 NO_2 National Ambient Air Quality Standards; North Dakota

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve elements of State Implementation Plan (SIP) revisions from the State of North Dakota to demonstrate the State meets infrastructure requirements of the Clean Air Act (Act or CAA) for the National Ambient Air Quality Standards (NAAQS) promulgated for ozone on March 12, 2008, lead (Pb) on October 15, 2008 and nitrogen dioxide (NO_2) on January 22, 2010. EPA is also proposing to approve element 4 of CAA section 110(a)(2)(D)(i)(II) for the 2006 fine particulate matter ($PM_{2.5}$) NAAQS. Section 110(a) of the CAA requires that each state submit a SIP for the implementation, maintenance, and enforcement of each NAAQS promulgated by EPA.

DATES: Written comments must be received on or before August 14, 2015.

ADDRESSES: The EPA has established a docket for this action under Docket Identification Number EPA–R08–OAR–2012–0974. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the index, some information may not be publicly available, *i.e.,* Confidential Business Information or other information the disclosure of which is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in the hard copy form. Publicly available docket materials are available either electronically through *http://www.regulations.gov* or in hard copy at EPA Region 8, Office of Partnership and Regulatory Assistance, Air Program, 1595 Wynkoop Street, Denver, Colorado 80202–1129. The EPA requests that you contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section to view the hard copy of the docket. The Regional Office's official hours of business are Monday through Friday, 8:00 a.m.–4:00 p.m., excluding federal holidays. An electronic copy of the State's SIP compilation is also available at *http://www.epa.gov/region8/air/sip.html.*

FOR FURTHER INFORMATION CONTACT: Abby Fulton, Air Program, U.S. Environmental Protection Agency (EPA), Region 8, Mail Code 8P–AR, 1595 Wynkoop Street, Denver, Colorado 80202–1129. 303–312–6563, *fulton.abby@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

What should I consider as I prepare my comments for EPA?

1. *Submitting Confidential Business Information (CBI).* Do not submit CBI to EPA through *http://www.regulations.gov* or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information on a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- Identify the rulemaking by docket number and other identifying information (subject heading, **Federal Register** volume, date, and page number);
- Follow directions and organize your comments;
- Explain why you agree or disagree;
- Suggest alternatives and substitute language for your requested changes;
- Describe any assumptions and provide any technical information and/or data that you used;
- If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced;
- Provide specific examples to illustrate your concerns, and suggest alternatives;
- Explain your views as clearly as possible, avoiding the use of profanity or personal threats; and,
- Make sure to submit your comments by the comment period deadline identified.

II. Background

On March 12, 2008, EPA promulgated a new NAAQS for ozone, revising the levels of the primary and secondary 8-

hour ozone standards from 0.08 parts per million (ppm) to 0.075 ppm (73 FR 16436). Subsequently, on October 15, 2008, EPA revised the level of the primary and secondary Pb NAAQS from 1.5 micrograms per cubic meter (μg/m^3) to 0.15 μg/m^3 (73 FR 66964). On January 22, 2010, EPA promulgated a new 1-hour primary NAAQS for NO_2 at a level of 100 parts per billion (ppb) while retaining the annual standard of 53 ppb. The 2010 NO_2 NAAQS is expressed as the three year average of the 98th percentile of the annual distribution of daily maximum 1-hour average concentrations. The secondary NO_2 NAAQS remains unchanged at 53 ppb (75 FR 6474, Feb. 9, 2010).

EPA promulgated a revised NAAQS for $PM_{2.5}$ on October 17, 2006, tightening the level of the 24-hour standard to 35 μg/m^3 and retaining the level of the annual $PM_{2.5}$ standard at 15 μg/m^3. EPA approved element 110(a)(2)(D)(i)(I) (discussed below) of North Dakota's infrastructure SIP for this NAAQS on July 29, 2013 (78 FR 45457). EPA approved all other infrastructure elements (aside from element 110(a)(2)(D)(i)(II) regarding visibility) of North Dakota's 2006 $PM_{2.5}$ infrastructure SIP on July 30, 2013 (78 FR 45866). We are acting on the visibility element in this action.

Under sections 110(a)(1) and (2) of the CAA, states are required to submit infrastructure SIPs to ensure their SIPs provide for implementation, maintenance, and enforcement of the NAAQS. These submissions must contain any revisions needed for meeting the applicable SIP requirements of section 110(a)(2), or certifications that their existing SIPs for ozone, Pb, and NO_2 already meet those requirements. EPA highlighted this statutory requirement in an October 2, 2007, guidance document entitled ''Guidance on SIP Elements Required Under Sections 110(a)(1) and (2) for the 1997 8-hour Ozone and $PM_{2.5}$ National Ambient Air Quality Standards'' (2007 Memo). On September 25, 2009, EPA issued an additional guidance document pertaining to the 2006 $PM_{2.5}$ NAAQS entitled ''Guidance on SIP Elements Required Under Sections 110(a)(1) and (2) for the 2006 24-Hour Fine Particle ($PM_{2.5}$) National Ambient Air Quality Standards (NAAQS)'' (2009 Memo), followed by the October 14, 2011, ''Guidance on Infrastructure SIP Elements Required Under Sections 110(a)(1) and (2) for the 2008 Lead (Pb) National Ambient Air Quality Standards (NAAQS)'' (2011 Memo). Most recently, EPA issued ''Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act Sections 110(a)(1) and (2)'' on September 13, 2013 (2013 Memo).

III. What is the scope of this rulemaking?

EPA is acting upon the SIP submissions from North Dakota that address the infrastructure requirements of CAA sections 110(a)(1) and 110(a)(2) for the 2008 ozone, 2008 Pb, and 2010 NO_2 NAAQS. The requirement for states to make a SIP submission of this type arises out of CAA section 110(a)(1). Pursuant to section 110(a)(1), states must make SIP submissions ''within 3 years (or such shorter period as the Administrator may prescribe) after the promulgation of a national primary ambient air quality standard (or any revision thereof),'' and these SIP submissions are to provide for the ''implementation, maintenance, and enforcement'' of such NAAQS. The statute directly imposes on states the duty to make these SIP submissions, and the requirement to make the submissions is not conditioned upon EPA taking any action other than promulgating a new or revised NAAQS. Section 110(a)(2) includes a list of specific elements that ''[e]ach such plan'' submission must address.

EPA has historically referred to these SIP submissions made for the purpose of satisfying the requirements of CAA sections 110(a)(1) and 110(a)(2) as ''infrastructure SIP'' submissions. Although the term ''infrastructure SIP'' does not appear in the CAA, EPA uses the term to distinguish this particular type of SIP submission from submissions that are intended to satisfy other SIP requirements under the CAA, such as ''nonattainment SIP'' or ''attainment plan SIP'' submissions to address the nonattainment planning requirements of part D of title I of the CAA; ''regional haze SIP'' submissions required by EPA rule to address the visibility protection requirements of CAA section 169A; and nonattainment new source review (NSR) permit program submissions to address the permit requirements of CAA, title I, part D.

Section 110(a)(1) addresses the timing and general requirements for infrastructure SIP submissions, and section 110(a)(2) provides more details concerning the required contents of these submissions. The list of required elements provided in section 110(a)(2) contains a wide variety of disparate provisions, some of which pertain to required legal authority, some of which pertain to required substantive program provisions, and some of which pertain to requirements for both authority and substantive program provisions.[1] EPA therefore believes that while the timing requirement in section 110(a)(1) is unambiguous, some of the other statutory provisions are ambiguous. In particular, EPA believes that the list of required elements for infrastructure SIP submissions provided in section 110(a)(2) contains ambiguities concerning what is required for inclusion in an infrastructure SIP submission.

Examples of some of these ambiguities and the context in which EPA interprets the ambiguous portions of section 110(a)(1) and 110(a)(2) are discussed at length in our notice of proposed rulemaking: Promulgation of State Implementation Plan Revisions; Infrastructure Requirements for the 1997 and 2006 $PM_{2.5}$, 2008 Lead, 2008 Ozone, and 2010 NO2 National Ambient Air Quality Standards; South Dakota (79 FR 71040 Dec. 1, 2014) under ''III. What is the Scope of this Rulemaking?''

With respect to certain other issues, EPA does not believe that an action on a state's infrastructure SIP submission is necessarily the appropriate type of action in which to address possible deficiencies in a state's existing SIP. These issues include: (i) Existing provisions related to excess emissions from sources during periods of startup, shutdown, or malfunction (SSM) that may be contrary to the CAA and EPA's policies addressing such excess emissions; (ii) existing provisions related to ''director's variance'' or ''director's discretion'' that may be contrary to the CAA because they purport to allow revisions to SIP-approved emissions limits while limiting public process or not requiring further approval by EPA; and (iii) existing provisions for Prevention of Significant Deterioration (PSD) programs that may be inconsistent with current requirements of EPA's ''Final NSR Improvement Rule,'' 67 FR 80186, Dec. 31, 2002, as amended by 72 FR 32526, June 13, 2007. (''NSR Reform'').

IV. What infrastructure elements are required under sections 110(a)(1) and (2)?

CAA section 110(a)(1) provides the procedural and timing requirements for SIP submissions after a new or revised NAAQS is promulgated. Section

[1] For example: Section 110(a)(2)(E)(i) provides that states must provide assurances that they have adequate legal authority under state and local law to carry out the SIP; section 110(a)(2)(C) provides that states must have a SIP-approved program to address certain sources as required by part C of title I of the CAA; and section 110(a)(2)(G) provides that states must have legal authority to address emergencies as well as contingency plans that are triggered in the event of such emergencies.

110(a)(2) lists specific elements the SIP must contain or satisfy. These infrastructure elements include requirements such as modeling, monitoring, and emissions inventories, which are designed to assure attainment and maintenance of the NAAQS. The elements that are the subject of this action are listed below.

- 110(a)(2)(A): Emission limits and other control measures.
- 110(a)(2)(B): Ambient air quality monitoring/data system.
- 110(a)(2)(C): Program for enforcement of control measures.
- 110(a)(2)(D): Interstate transport.
- 110(a)(2)(E): Adequate resources and authority, conflict of interest, and oversight of local governments and regional agencies.
- 110(a)(2)(F): Stationary source monitoring and reporting.
- 110(a)(2)(G): Emergency powers.
- 110(a)(2)(H): Future SIP revisions.
- 110(a)(2)(J): Consultation with government officials; public notification; and PSD and visibility protection.
- 110(a)(2)(K): Air quality modeling/data.
- 110(a)(2)(L): Permitting fees.
- 110(a)(2)(M): Consultation/participation by affected local entities.

A detailed discussion of each of these elements is contained in the next section.

Two elements identified in section 110(a)(2) are not governed by the three year submission deadline of section 110(a)(1) and are therefore not addressed in this action. These elements relate to part D of Title I of the CAA, and submissions to satisfy them are not due within three years after promulgation of a new or revised NAAQS, but rather are due at the same time nonattainment area plan requirements are due under section 172. The two elements are: (1) Section 110(a)(2)(C) to the extent it refers to permit programs (known as ''nonattainment NSR'') required under part D, and (2) section 110(a)(2)(I), pertaining to the nonattainment planning requirements of part D. As a result, this action does not address infrastructure elements related to the nonattainment NSR portion of section 110(a)(2)(C) or related to 110(a)(2)(I). Furthermore, EPA interprets the CAA section 110(a)(2)(J) provision on visibility as not being triggered by a new NAAQS because the visibility requirements in part C, title 1 of the CAA are not changed by a new NAAQS.

V. How did North Dakota address the infrastructure elements of sections 110(a)(1) and (2)?

The North Dakota Department of Health (Department or NDDH) submitted certification of North Dakota's infrastructure SIP for the 2008 Pb NAAQS on May 25, 2012, and joint certifications for the 2008 ozone and the 2010 NO_2 NAAQS on March 7, 2013. North Dakota's infrastructure certifications demonstrate how the State, where applicable, has plans in place that meet the requirements of section 110 for the 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS. These plans reference the current North Dakota Air Pollution Control Rules (NDAC) and North Dakota Century Code (NDCC). These submittals are available within the electronic docket for today's proposed action at *www.regulations.gov*. The NDAC and NDCC referenced in the submittals are publicly available at *https://www.ndhealth.gov/aq/AirRules.htm* and *http://www.legis.nd.gov/general-information/north-dakota-century-code*. North Dakota's SIP, air pollution control regulations, and statutes that have been previously approved by EPA and incorporated into the North Dakota SIP can be found at 40 CFR 52.1820.

VI. Analysis of the State Submittals

1. *Emission limits and other control measures:* Section 110(a)(2)(A) requires SIPs to include enforceable emission limitations and other control measures, means, or techniques (including economic incentives such as fees, marketable permits, and auctions of emissions rights), as well as schedules and timetables for compliance as may be necessary or appropriate to meet the applicable requirements of this Act.

Multiple SIP-approved State air quality regulations within the NDAC and cited in North Dakota's certifications provide enforceable emission limitations and other control measures, means of techniques, schedules for compliance, and other related matters necessary to meet the requirements of the CAA section 110(a)(2)(A) for the 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS, subject to the following clarifications.

First, this infrastructure element does not require the submittal of regulations or emission limitations developed specifically for attaining the 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS. Furthermore, North Dakota has no areas designated as nonattainment for the 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS. North Dakota's certifications (contained within this docket) generally listed provisions within its SIP which regulate pollutants through various programs, including major and minor source permit programs. This suffices, in the case of North Dakota, to meet the requirements of section 110(a)(2)(A) for the 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS.

Second, as previously discussed, EPA is not proposing to approve or disapprove any existing state rules with regard to director's discretion or variance provisions. A number of states, including North Dakota, have such provisions which are contrary to the CAA and existing EPA guidance (52 FR 45109, Nov. 24, 1987), and the agency plans to take action in the future to address such state regulations. In the meantime, EPA encourages any state having a director's discretion or variance provision which is contrary to the CAA and EPA guidance to take steps to correct the deficiency as soon as possible.

Finally, in this action, EPA is also not proposing to approve or disapprove any existing state provision with regard to excess emissions during SSM of operations at a facility. A number of states, including North Dakota, have SSM provisions which are contrary to the CAA and existing EPA guidance [2] and the agency is addressing such state regulations separately (80 FR 33840, June 12, 2015).

Therefore, EPA is proposing to approve North Dakota's infrastructure SIP for the 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS with respect to the general requirement in section 110(a)(2)(A) to include enforceable emission limitations and other control measures, means, or techniques to meet the applicable requirements of this element.

2. *Ambient air quality monitoring/data system:* Section 110(a)(2)(B) requires SIPs to provide for establishment and operation of appropriate devices, methods, systems, and procedures necessary to ''(i) monitor, compile, and analyze data on ambient air quality, and (ii) upon request, make such data available to the Administrator.''

Ambient monitoring is covered in Chapter 6 of the North Dakota SIP. It provides for the design and operation of a monitoring network, reporting of data obtained from the monitors, and annual network review including notification to

[2] Steven Herman, Assistant Administrator for Enforcement and Compliance Assurance, and Robert Perciasepe, Assistant Administrator for Air and Radiation, Memorandum to EPA Air Division Directors, ''State Implementation Plans (SIPs): Policy Regarding Emissions During Malfunctions, Startup, and Shutdown.'' (September 20, 1999).

EPA of any changes, and public notification of exceedances of NAAQS. EPA approved North Dakota's Division of Air Quality's (DAQ) 2013 Ambient Air Monitoring Network Plan for the 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS on April 2, 2015. North Dakota's air monitoring programs and data systems meet the requirements of CAA section 110(a)(2)(B) for the 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS.

3. *Program for enforcement of control measures:* Section 110(a)(2)(C) requires SIPs to include a program to provide for the enforcement of the measures described in subparagraph (A), and regulation of the modification and construction of any stationary source within the areas covered by the plan as necessary to assure NAAQS are achieved, including a permit program as required in parts C and D.

To generally meet the requirements of section 110(a)(2)(C), the State is required to have SIP-approved PSD, nonattainment NSR, and minor NSR permitting programs adequate to implement 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS. As explained elsewhere in this action, EPA is not evaluating nonattainment related provisions, such as the nonattainment NSR program required by part D of the Act. EPA is evaluating the State's PSD program as required by part C of the Act, and the State's minor NSR program as required by 110(a)(2)(C).

PSD Requirements

With respect to elements (C) and (J), EPA interprets the CAA to require each state to make an infrastructure SIP submission for a new or revised NAAQS that demonstrates that the air agency has a complete PSD permitting program meeting the current requirements for all regulated NSR pollutants. The requirements of element (D)(i)(II) may also be satisfied by demonstrating the air agency has a complete PSD permitting program correctly addressing all regulated NSR pollutants. North Dakota has shown that it currently has a PSD program in place that covers all regulated NSR pollutants, including greenhouse gases (GHGs).

North Dakota implements the PSD program by, for the most part, incorporating by reference the federal PSD program as it existed on a specific date. The State periodically updates the PSD program by revising the date of incorporation by reference and submitting the change as a SIP revision. As a result, the SIP revisions generally reflect changes to PSD requirements that EPA has promulgated prior to the revised date of incorporation by reference.

On June 3, 2010 (75 FR 31291), we approved a North Dakota SIP revision that revised the date of incorporation by reference of the federal PSD program to August 1, 2007. That revision addressed the PSD requirements of the Phase 2 Ozone Implementation Rule promulgated in 2005 (70 FR 71612). As a result, the approved North Dakota PSD program meets current requirements for ozone.

Similarly, on October 23, 2012 (77 FR 64736), we approved a North Dakota SIP revision that revised the date of incorporation by reference of the federal PSD program to July 2, 2010. As explained in the notice for that action, that revision addressed the PSD requirements related to GHGs provided in EPA's June 3, 2010 ''Prevention of Significant Deterioration and Title V Greenhouse Gas Tailoring Rule'' (75 FR 31514). The approved North Dakota PSD program thus also meets current requirements for GHGs.

On June 23, 2014, the United States Supreme Court issued a decision addressing the application of PSD permitting requirements to GHG emissions, *Utility Air Regulatory Group* v. *Environmental Protection Agency,* 134 S.Ct. 2427. The Supreme Court said that EPA may not treat GHGs as an air pollutant for purposes of determining whether a source is a major source required to obtain a PSD permit. The Supreme Court also said that EPA could continue to require that PSD permits, otherwise required based on emissions of pollutants other than GHGs, contain limitations on GHG emissions based on the application of Best Available Control Technology (BACT). In order to act consistently with its understanding of the Court's decision pending further judicial action to effectuate the decision, EPA is not continuing to apply EPA regulations that would require that SIPs include permitting requirements that the Supreme Court found impermissible. Specifically, EPA is not applying the requirement that a state's SIP-approved PSD program require that sources obtain PSD permits when GHGs are the only pollutant (i) that the source emits or has the potential to emit above the major source thresholds, or (ii) for which there is a significant emissions increase and a significant net emissions increase from a modification (*e.g.,* 40 CFR 51.166(b)(48)(v)). EPA anticipates a need to revise federal PSD rules in light of the Supreme Court opinion. In addition, EPA anticipates that many states will revise their existing SIP-approved PSD programs in light of the Supreme Court's decision. The timing and content of subsequent EPA actions with respect to EPA regulations and state PSD program approvals are expected to be informed by additional legal process before the United States Court of Appeals for the District of Columbia Circuit. At this juncture, EPA is not expecting states to have revised their PSD programs for purposes of infrastructure SIP submissions and is only evaluating such submissions to assure that the state's program correctly addresses GHGs consistent with the Supreme Court's decision.

At present, EPA has determined that North Dakota's SIP is sufficient to satisfy elements (C), (D)(i)(II), and (J) with respect to GHGs because the PSD permitting program previously approved by EPA into the SIP continues to require that PSD permits (otherwise required based on emissions of pollutants other than GHGs) contain limitations on GHG emissions based on the application of BACT. Although the approved North Dakota PSD permitting program may currently contain provisions that are no longer necessary in light of the Supreme Court decision, this does not render the infrastructure SIP submission inadequate to satisfy elements (C), (D)(i)(II), and (J). The SIP contains the necessary PSD requirements at this time, and the application of those requirements is not impeded by the presence of other previously-approved provisions regarding the permitting of sources of GHGs that EPA does not consider necessary at this time in light of the Supreme Court decision. Accordingly, the Supreme Court decision does not affect EPA's proposed approval of North Dakota's infrastructure SIP as to the requirements of elements (C), (D)(i)(II), and (J).

Finally, we evaluate the PSD program with respect to current requirements for $PM_{2.5}$. In particular, on May 16, 2008, EPA promulgated the rule, ''Implementation of the New Source Review Program for Particulate Matter Less Than 2.5 Micrometers ($PM_{2.5}$)'' (73 FR 28321) and on October 20, 2010 EPA promulgated the rule, ''Prevention of Significant Deterioration (PSD) for Particulate Matter Less Than 2.5 Micrometers ($PM_{2.5}$)—Increments, Significant Impact Levels (SILs) and Significant Monitoring Concentration (SMC)'' (75 FR 64864). EPA regards adoption of these $PM_{2.5}$ rules as a necessary requirement when assessing a PSD program for the purposes of element (C).

On January 4, 2013, the U.S. Court of Appeals, in *Natural Resources Defense Council* v. *EPA,* 706 F.3d 428 (D.C. Cir.), issued a judgment that remanded EPA's 2007 and 2008 rules implementing the 1997 $PM_{2.5}$ NAAQS. The court ordered

EPA to ''repromulgate these rules pursuant to Subpart 4 consistent with this opinion.'' *Id.* at 437. Subpart 4 of part D, Title 1 of the CAA establishes additional provisions for particulate matter nonattainment areas.

The 2008 implementation rule addressed by the court decision, ''Implementation of New Source Review (NSR) Program for Particulate Matter Less Than 2.5 Micrometers ($PM_{2.5}$),'' (73 FR 28321, May 16, 2008), promulgated NSR requirements for implementation of $PM_{2.5}$ in nonattainment areas (nonattainment NSR) and attainment/unclassifiable areas (PSD). As the requirements of Subpart 4 only pertain to nonattainment areas, EPA does not consider the portions of the 2008 Implementation rule that address requirements for $PM_{2.5}$ attainment and unclassifiable areas to be affected by the court's opinion. Moreover, EPA does not anticipate the need to revise any PSD requirements promulgated in the 2008 Implementation rule in order to comply with the court's decision. Accordingly, EPA's proposed approval of North Dakota's infrastructure SIP as to elements C or J with respect to the PSD requirements promulgated by the 2008 Implementation rule does not conflict with the court's opinion.

The court's decision with respect to the nonattainment NSR requirements promulgated by the 2008 Implementation rule also does not affect EPA's action on the present infrastructure action. EPA interprets the Act to exclude nonattainment area requirements, including requirements associated with a nonattainment NSR program, from infrastructure SIP submissions due three years after adoption or revision of a NAAQS. Instead, these elements are typically referred to as nonattainment SIP or attainment plan elements, which would be due by the dates statutorily prescribed under subpart 2 through 5 under part D, extending as far as 10 years following designations for some elements.

The second PSD requirement for $PM_{2.5}$ is contained in EPA's October 20, 2010 rule, ''Prevention of Significant Deterioration (PSD) for Particulate Matter Less Than 2.5 Micrometers ($PM_{2.5}$)—Increments, Significant Impact Levels (SILs) and Significant Monitoring Concentration (SMC)'' (75 FR 64864). EPA regards adoption of the $PM_{2.5}$ increments as a necessary requirement when assessing a PSD program for the purposes of element (C).

As mentioned above, EPA previously approved a North Dakota SIP revision that revised the date of incorporation by reference of the federal PSD program to July 2, 2010 (77 FR 64736, Oct. 23, 2012). This SIP revision also addressed the requirements of the 2008 $PM_{2.5}$ NSR Implementation Rule. On January 1, 2012, the State submitted revisions to chapter 33–15–15–01.2, Scope, of the NDAC that adopted all elements of the 2010 $PM_{2.5}$ Increment Rule by incorporating by reference the federal PSD program at 40 CFR part 52, section 21, as it existed on January 1, 2012. The submitted revisions make North Dakota's PSD program up to date with respect to current requirements for $PM_{2.5}$. EPA approved the necessary portions of North Dakota's January 24, 2013 submission which incorporate the requirements of the 2010 $PM_{2.5}$ Increment Rule on July 30, 2013 (78 FR 45866). North Dakota's SIP-approved PSD program meets current requirements for $PM_{2.5}$. EPA therefore is proposing to approve North Dakota's SIP for the 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS with respect to the requirement in section 110(a)(2)(C) to include a PSD permit program in the SIP as required by part C of the Act.

Minor NSR

The State has a SIP-approved minor NSR program, adopted under section 110(a)(2)(C) of the Act. The minor NSR program was originally approved by EPA on August 21, 1995 (60 FR 43401). Since approval of the minor NSR program, the State and EPA have relied on the program to assure that new and modified sources not captured by the major NSR permitting programs do not interfere with attainment and maintenance of the NAAQS.

EPA is proposing to approve North Dakota's infrastructure SIP for the 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS with respect to the general requirement in section 110(a)(2)(C) to include a program in the SIP that regulates the enforcement, modification and construction of any stationary source as necessary to assure that the NAAQS are achieved.

4. *Interstate Transport:* The interstate transport provisions in CAA section 110(a)(2)(D)(i) (also called ''good neighbor'' provisions) require each state to submit a SIP that prohibits emissions that will have certain adverse air quality effects in other states. CAA section 110(a)(2)(D)(i) identifies four distinct elements related to the impacts of air pollutants transported across state lines. The two elements under 110(a)(2)(D)(i)(I) require SIPs to contain adequate provisions to prohibit any source or other type of emissions activity within the state from emitting air pollutants that will (element 1) contribute significantly to nonattainment in any other state with respect to any such national primary or secondary NAAQS, and (element 2) interfere with maintenance by any other state with respect to the same NAAQS. The two elements under 110(a)(2)(D)(i)(II) require SIPs to contain adequate provisions to prohibit emissions that will interfere with measures required to be included in the applicable implementation plan for any other state under part C (element 3) to prevent significant deterioration of air quality or (element 4) to protect visibility. In this action, EPA is addressing all four elements of CAA section 110(a)(2)(D)(i).

EPA is addressing the 2008 Pb and 2010 NO_2 NAAQS with regard to elements 1 (significant contribution) and 2 (interference with maintenance). EPA is addressing elements 3 (interference with PSD) and 4 (interference with visibility protection) of 110(a)(2)(D)(i) with regard to the 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS, and element 4 of 110(a)(2)(D)(i) with regard to the 2006 $PM_{2.5}$ NAAQS. We are not addressing elements 1 and 2 for the 2008 ozone NAAQS in this action. These elements will be addressed in a later rulemaking.

A. Evaluation of Significant Contribution to Nonattainment and Interference With Maintenance

2008 Pb NAAQS

North Dakota's analysis of potential interstate transport for the 2008 Pb NAAQS includes considerations of Pb emissions at sources near the State's borders and the distance of Pb sources in North Dakota to the nearest nonattainment area. The State's analysis is available in the docket for this action.

As noted in our 2011 Memo, there is a sharp decrease in Pb concentrations, at least in the coarse fraction, as the distance from a Pb source increases. For this reason, EPA found that the ''requirements of subsection (2)(D)(i)(I) (prongs 1 and 2) could be satisfied through a state's assessment as to whether or not emissions from Pb sources located in close proximity to their state borders have emissions that impact the neighboring state such that they contribute significantly to nonattainment or interfere with maintenance in that state.'' [3] In that guidance document, EPA further specified that any source appeared unlikely to contribute significantly to nonattainment unless it was located less than 2 miles from a state border and emitted at least 0.5 tons per year of Pb.

[3] 2011 Memo, at pg 8.

North Dakota's 110(a)(2)(D)(i)(I) analysis specifically noted that there are no sources in the State that meet both of these criteria. EPA concurs with the State's analysis and conclusion that no North Dakota sources have the combination of Pb emission levels and proximity to nearby nonattainment or maintenance areas to contribute significantly to nonattainment in or interfere with maintenance by other states for this NAAQS. North Dakota's SIP is therefore adequate to ensure that such impacts do not occur. We are proposing to approve North Dakota's submission in that its SIP meets the requirements of section 110(a)(2)(D)(i) for the 2008 Pb NAAQS.

2010 NO_2 NAAQS

North Dakota's 2010 NO_2 transport analysis for element 1 of 110(a)(2)(D)(i) notes that there are no designated nonattainment areas for the 2010 NO_2 NAAQS. The State asserts that, because there are no nonattainment areas for this NAAQS, North Dakota does not significantly contribute to nonattainment.

North Dakota's analysis for element 2 of 110(a)(2)(D)(i) considered the distance to the South Coast Air Basin in California, the only NO_2 maintenance area in the U.S., as well as the low monitored NO_2 values in North Dakota and the historically decreasing NO_2 emission levels in the State. North Dakota also noted that it anticipated further decreases in NO_X emissions going forward, specifically noting the decreases resulting from the State's regional haze SIP. The State's analysis is available in the docket for this action. EPA concurs with the technical components of North Dakota's 2010 NO_2 transport analyses for both elements 1 and 2, but clarifies that element 1 is not specific to designated nonattainment areas. In addition to the factors considered in the State's analysis, EPA also notes that the highest monitored NO_2 design values in each state bordering or near North Dakota are significantly below the NAAQS (see Table 2, below). This fact further supports the State's contention that significant contribution to nonattainment or interference with maintenance of the NO_2 NAAQS from North Dakota is very unlikely based on the lack of relatively nearby areas with high NO_2. This is especially relevant for element 2 (interference with maintenance), because in addition to the lack of nonattainment areas, there are also no areas near the State approaching violation of the 2010 NO_2 NAAQS which might therefore have difficulty with maintenance of the standard.

TABLE 2—HIGHEST MONITORED 2010 NO_2 NAAQS DESIGN VALUES

State	2011–2013 design value	% of NAAQS (100 ppb)
Minnesota	46 ppb	46
Montana	46 ppb [4]	46
South Dakota	37 ppb	37
Wyoming	35 ppb	35

* Source: *http://www.epa.gov/airtrends/values.html.*

In addition to the monitored levels of NO_2 in states near North Dakota being well below the NAAQS, North Dakota's highest design value from 2011–2013 was also significantly below this NAAQS (37 ppb).[5]

Based on all of these factors, EPA concurs with the State's conclusion that North Dakota does not contribute significantly to nonattainment or interfere with maintenance of the 2010 NO_2 NAAQS in other states. EPA is therefore proposing to determine that North Dakota's SIP includes adequate provisions to prohibit sources or other emission activities within the State from emitting NO_2 in amounts that will contribute significantly to nonattainment in or interfere with maintenance by any other state with respect specifically to the NO_2 NAAQS.

B. Evaluation of Interference With Measures To Prevent Significant Deterioration (PSD)

With regard to the PSD portion of section 110(a)(2)(D)(i)(II), this requirement may be met by a state's confirmation in an infrastructure SIP submission that new major sources and major modifications in the state are subject to a comprehensive EPA-approved PSD permitting program in the SIP that applies to all regulated NSR pollutants and that satisfies the requirements of EPA's PSD implementation rule(s).[6] As discussed in section VI.3 of this proposed action, North Dakota has such a PSD-permitting program.

As stated in the 2013 Memo, in-state sources not subject to PSD for any one or more of the pollutants subject to regulation under the CAA because they are in a nonattainment area for a NAAQS related to those particular pollutants may also have the potential to interfere with PSD in an attainment or unclassifiable area of another state. North Dakota does not contain any nonattainment areas. The consideration of nonattainment NSR for element 3 is therefore not relevant as all major sources locating in the State are subject to PSD. As North Dakota's SIP meets structural PSD requirements for all regulated NSR pollutants, and does not have any nonattainment areas, EPA is proposing to approve the infrastructure SIP submission as meeting the applicable requirements of element 3 of section 110(a)(2)(D)(i) for the 2008 Ozone, 2008 Pb and 2010 NO_2 NAAQS.

C. Evaluation of Interference With Measures To Protect Visibility

The determination of whether the CAA section 110(a)(2)(D)(i)(II) requirement for visibility is satisfied is closely connected to EPA's Regional Haze (RH) program. Under the RH program, each state with a Class I area is required to submit a SIP with reasonable progress goals for each such area that provides for an improvement in visibility for the most impaired days and ensures no degradation of the best days. CAA § 169A.

Because of the often significant impacts on visibility from the interstate transport of pollutants, we interpret the provisions of CAA section 110(a)(2)(D)(i)(II) described above as requiring states to include in their SIPs measures to prohibit emissions that would interfere with the reasonable progress goals set to protect Class I areas in other states. This is consistent with the requirements in the RH program which explicitly require each state to address its share of the emission reductions needed to meet the reasonable progress goals for

[4] Montana's maximum design value was calculated using EPA's AirData Web site, at *http://www.epa.gov/airquality/airdata/ad_rep_mon.html.*

[5] *http://www.epa.gov/airtrends/values.html.*

[6] See 2013 Memo.

surrounding Class I areas. 64 FR 35714, 35735 (July 1, 1999). States working together through a regional planning process are required to address an agreed upon share of their contribution to visibility impairment in the Class I areas of their neighbors. Given these requirements in the RH program we have concluded that a fully approved RH SIP satisfies the requirements of section 110(a)(2)(D)(i)(II) with respect to visibility.

In the absence of a fully approved RH SIP, a state can still make a demonstration that its SIP satisfies the visibility requirements of section 110(a)(2)(D)(i)(II).[7] States worked through regional planning organizations (RPOs), such as the Western Regional Air Partnership (WRAP) in the case of North Dakota, to develop strategies to address RH. To help states in establishing reasonable progress goals, the RPOs modeled future visibility conditions. The modeling assumed emissions reductions from each state, based on extensive consultation among the states as to appropriate strategies for addressing haze. In setting reasonable progress goals, states generally relied on this modeling. As a result, we generally consider a SIP that ensures emission reductions commensurate with the assumptions underlying the reasonable progress goals to meet the visibility requirement of CAA section 110(a)(2)(D)(i)(II).

In its 2006 $PM_{2.5}$, 2008 ozone, 2008 Pb and 2010 NO_2 infrastructure certifications, North Dakota points to existing portions in the North Dakota SIP, specifically referencing the North Dakota RH SIP, to certify that the State meets the visibility requirements of section 110(a)(2)(D)(i). For the 2006 $PM_{2.5}$, 2008 ozone, 2008 Pb and 2010 NO_2 NAAQS, the State also references the PSD (NDAC 33–15–15) and Visibility Protection (NDAC 33–15–19) portions of its SIP, as well as EPA's RH federal implementation plan (FIP).[8] While Pb emissions have less impact on visibility, North Dakota addressed Pb no differently than other NAAQS in its 2008 Pb certification. Regardless, EPA noted in the 2013 Memo that ''Pb-related visibility impacts were found to be insignificant,'' and that ''significant impacts from Pb emissions from stationary sources are expected to be limited to short distances from the source.''[9] As stated earlier in this section, North Dakota does not have any Pb sources near bordering states.

In this action, we are proposing to find that the emissions reductions approved into North Dakota's RH SIP are sufficient to ensure that emissions from sources within the State do not interfere with the reasonable progress goals of nearby states. North Dakota participated in a regional planning process with the WRAP. In the regional planning process, North Dakota accepted and incorporated the WRAP-developed visibility modeling into its RH SIP, and the SIP included the controls assumed in the modeling.

EPA did not fully approve the North Dakota RH SIP, as we partially disapproved, among other elements, the State's selection of NO_X Best Available Retrofit Technology (BART) controls for Great River Energy's Coal Creek Station. 77 FR 20894 (April 6, 2012). As a result of our partial disapproval, North Dakota's SIP does not ensure NO_X emission reductions from Coal Creek Station, emission reductions which were assumed in the WRAP's visibility modeling that was relied on in setting reasonable progress goals in nearby states.[10] We note, however, that the North Dakota RH SIP also adopted NO_X controls that were not included in the WRAP's modeling for Otter Tail Power Company's Coyote Station. EPA approved these controls into the North Dakota RH SIP as part of our April 6, 2012 final action. The SIP provision will reduce NO_X emissions at Coyote Station by approximately 4,213 tons per year, a larger decrease in emissions than the assumed NO_X BART reductions for Coal Creek Station of approximately 3,200 tons per year. As Coal Creek and Coyote Stations are roughly 32 miles apart, a relatively short distance, the visibility impacts from NO_X emission reductions at either source on out-of-state Class I areas would be similar.

Because the reductions in North Dakota's approved RH SIP are greater than those assumed by the WRAP modeling, EPA is proposing to find that North Dakota's SIP includes controls sufficient to address the relevant requirements related to impacts on Class I areas in other states.

5. *Interstate and International transport provisions:* CAA section 110(a)(2)(D)(ii) requires SIPs to include provisions ensuring compliance with the applicable requirements of CAA sections 126 and 115 (relating to interstate and international pollution abatement). Specifically, CAA section 126(a) requires new or modified major sources to notify neighboring states of potential impacts from the source.

Section 126(a) of the CAA requires notification to affected, nearby states of major proposed new (or modified) sources. Sections 126(b) and (c) pertain to petitions by affected states to the Administrator of the EPA (Administrator) regarding sources violating the ''interstate transport'' provisions of section 110(a)(2)(D)(i). Section 115 of the CAA similarly pertains to international transport of air pollution.

With regard to section 126(a), North Dakota's SIP-approved PSD program requires notice of proposed new sources or modifications to states whose lands may be significantly affected by emissions from the source or modification (see NDAC 33–15–15–01.2(q)(2)(d)). This provision satisfies the notice requirement of section 126(a).

North Dakota has no pending obligations under sections 126(c) or 115(b); therefore, its SIP currently meets the requirements of those sections. In summary, the SIP meets the requirements of CAA section 110(a)(2)(D)(ii) for the 2008 ozone, 2008 Pb and 2010 NO_2 NAAQS.

6. *Adequate resources:* Section 110(a)(2)(E)(i) requires states to provide necessary assurances that the State will have adequate personnel, funding, and authority under state law to carry out the SIP (and is not prohibited by any provision of federal or state law from carrying out the SIP or portion thereof). Section 110(a)(2)(E)(ii) also requires each state to comply with the requirements respecting state boards under CAA section 128. Section 110(a)(2)(E)(iii) requires states to ''provide necessary assurances that, where the State has relied on a local or regional government, agency, or instrumentality for the implementation of any [SIP] provision, the State has responsibility for ensuring adequate implementation of such [SIP] provision.''

a. *Sub-elements (i) and (iii): Adequate personnel, funding, and legal authority under state law to carry out its SIP, and related issues.*

NDCC 23–25–03 provides adequate authority for the State of North Dakota and the Department to carry out its SIP obligations with respect to the 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS. The State receives section 103 and 105 grant funds through its Performance Partnership Grant from EPA along with

[7] See 2013 Memo at 34. See also 76 FR 22036 (April 20, 2011) (EPA's approval of the visibility requirement of 110(a)(2)(D)(i)(II) based on a demonstration by Colorado that did not rely on the Colorado Regional Haze SIP).

[8] EPA's final action including a partial approval, partial disapproval and FIP of the North Dakota RH SIP was published in the **Federal Register** April 6, 2012 (77 FR 20894).

[9] See 2013 Memo at 33–34.

[10] EPA notes that we also disapproved and promulgated a FIP for the State's reasonable progress determination for Basin Electric's Antelope Valley Station.

required state matching funds to provide funding necessary to carry out North Dakota's SIP requirements. North Dakota's resources meet the requirements of CAA section 110(a)(2)(E).

With respect to section 110(a)(2)(E)(iii), the regulations cited by North Dakota in their certifications and verified through additional communication [11] (NDCC 23–25–02(01), 33–15–04–02, 23–01–05(02), 23–25–03(5), and 23–25–10) and contained within this docket also provide the necessary assurances that the State has responsibility for adequate implementation of SIP provisions by local governments. Therefore, we propose to approve North Dakota's SIP as meeting the requirements of section 110(a)(2)(E)(i) and (E)(iii) for the 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS.

b. *Sub-element (ii): State boards.*

Section 110(a)(2)(E)(ii) requires each state's SIP to contain provisions that comply with the requirements of section 128 of the CAA. That provision contains two explicit requirements: (i) That any board or body which approves permits or enforcement orders under the CAA shall have at least a majority of members who represent the public interest and do not derive a significant portion of their income from persons subject to such permits and enforcement orders; and (ii) that any potential conflicts of interest by members of such board or body or the head of an executive agency with similar powers be adequately disclosed.

On July 30, 2013 (78 FR 45866) EPA approved revised language in North Dakota's SIP, chapter 2, section 15, Respecting Boards to include provisions for addressing conflict of interest requirements. Details on how this portion of chapter 2, section 15 rules meet the requirements of section 128 are provided in our May 13, 2013 proposal notice (78 FR 27898). North Dakota's SIP continues to meet the requirements of section 110(a)(2)(E)(ii), and we propose to approve the infrastructure SIP for the 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS for this element.

7. *Stationary source monitoring system:* Section 110(a)(2)(F) requires: (i) The installation, maintenance, and replacement of equipment, and the implementation of other necessary steps, by owners or operators of stationary sources to monitor emissions from such sources; (ii) Periodic reports on the nature and amounts of emissions and emissions-related data from such sources; and (iii) Correlation of such reports by the state agency with any emission limitations or standards established pursuant to the Act, which reports shall be available at reasonable times for public inspection.

The North Dakota statutory provisions listed in the State's certifications (NDCC 23–25–03) and contained within this docket provide authority to establish a program for measurement and testing of sources, including requirements for sampling and testing. North Dakota's SIP-approved minor source and PSD programs provide for monitoring, recordkeeping, and reporting requirements for sources subject to minor and major source permitting. The State cites several regulations (NDAC 33–15–14–02.9, 33–15–14–03.6, 33–15–14–06.5 and contained within this docket) requiring monitoring of emissions from stationary sources, recordkeeping and reporting of emissions, and monitoring date. Source surveillance is also addressed in Chapter 8 of the SIP. This chapter provides for the permitting of sources, inspection of the sources, recordkeeping and reporting by sources, and compliance determinations. Section 8.2 of the SIP commits the Department to the correlation of data with the applicable requirements. All reports are available for public inspection in accordance with NDAC 33–15–01–16.1.

Additionally, North Dakota is required to submit emissions data to the EPA for purposes of the National Emissions Inventory (NEI). The NEI is the EPA's central repository for air emissions data. The EPA published the Air Emissions Reporting Rule (AERR) on December 5, 2008, which modified the requirements for collecting and reporting air emissions data (73 FR 76539). The AERR shortened the time states had to report emissions data from 17 to 12 months, giving states one calendar year to submit emissions data. All states are required to submit a comprehensive emissions inventory every three years and report emissions for certain larger sources annually through the EPA's online Emissions Inventory System. States report emissions data for the six criteria pollutants and their associated precursors—nitrogen oxides, sulfur dioxide, ammonia, lead, carbon monoxide, particulate matter, and volatile organic compounds. Many states also voluntarily report emissions of hazardous air pollutants. North Dakota made its latest update to the NEI on October 23, 2014. EPA compiles the emissions data, supplementing it where necessary, and releases it to the general public through the Web site *http://www.epa.gov/ttn/chief/eiinformation.html*.

Based on the analysis above, we propose to approve the North Dakota SIP as meeting the requirements of CAA section 110(a)(2)(F) for the 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS.

8. *Emergency powers:* Section 110(a)(2)(G) of the CAA requires infrastructure SIPs to ''provide for authority comparable to that in [CAA section 303] and adequate contingency plans to implement such authority.''

Under CAA section 303, the EPA Administrator has authority to bring suit to immediately restrain an air pollution source that presents an imminent and substantial endangerment to public health or welfare, or the environment.[12] If such action may not practicably assure prompt protection, then the Administrator has authority to issue temporary administrative orders to protect the public health or welfare, or the environment, and such orders can be extended if EPA subsequently files a civil suit.

Chapter 23–25 of the NDCC provides relevant language and authority for ''Air Pollution Control.'' The purpose of this chapter is ''to achieve and maintain the best air quality possible'' and to ''protect human health, welfare and property, [and] prevent injury to plant and animal life'' (NDCC 23–25–01(2)). NDCC 23–25–01 defines ''air pollution'' as ''the presence in the outdoor atmosphere of one or more air contaminants in such quantities and duration as is or may be injurious to human health, welfare, or property, animal or plant life, or which unreasonably interferes with the enjoyment of life or property.'' As such, the chapter aims to protect all three areas required by section 303; human health, welfare, and environment. The ''Air Pollution Control'' chapter provides general grants of authority to maintain actions in certain situations. We find these grants provide comparable authority to that provided in Section 303. Furthermore, the NDAC 33–15–01–15(1) makes it unlawful to ''permit or cause air pollution'' as defined in NDCC 23–25–01. A person causing or contributing to emissions that endanger public health, welfare, or the environment, would be causing ''air pollution'' within the meaning of North Dakota law, and would therefore be in

[11] *See* Email from Tom Bachman ''Request for Clarificaitons_ND iSIP 2008 ozone, 2008 Pb, and 2010 NO2 NAAAQS'' April 13, 2015, available within docket.

[12] A discussion of the requirements for meeting CAA section 303 is provided in our notice of proposed rulemaking: Promulgation of State Implementation Plan Revisions; Infrastructure Requirements for the 1997 and 2006 p.m.2.5, 2008 Lead, 2008 Ozone, and 2010 NO2 National Ambient Air Quality Standards; South Dakota (79 FR 71040, Dec. 1, 2014) under ''VI. Analysis of State Submittals, 8. Emergency powers.''

violation of NDAC 33–15–01–15(1). This could occur in either an emergency or non-emergency situation.[13]

NDCC 23–25–10(5) provides that ''the department has the authority to maintain an action in the name of the state against any person to enjoin any threatened or continuing violation of any provision of this chapter or any permit condition, rule, order, limitation, or other applicable requirement implementing this chapter.'' Under NDCC 23–25–10(5), the Department has the authority to bring an action to enjoin a violation of NDCC 23–25 or its rules. The Department may seek a court order to restrain a source from causing or contributing to emissions that endanger public health, welfare, or the environment. In an emergency, this may take the form of an injunction or temporary restraining order (*see* NDCC 32–06–02).[14] Therefore, the NDDH has the authority to seek judicial actions during emergency situations.

North Dakota's statutes also provide the NDDH with the authority to issue administrative orders and emergency rules to protect the public health, welfare, and the environment under certain circumstances. NDCC 23–25–08, as cited in North Dakota's SIP submittals, authorizes that in the event of ''an emergency requiring immediate action to protect the public health and safety,'' the NDDH has the authority to ''issue an order reciting the existence of such emergency and requiring that such action be taken as is necessary'' to meet the emergency. The emergency order is effective immediately. Any person who violates the order is subject to enforcement, penalties, and injunctions under NDCC 23–25–10.

Furthermore, as cited in North Dakota's SIP submittals, the NDDH has the authority to ''use an emergency adjudicative proceeding, in its discretion, in an emergency situation involving imminent peril to the public health, safety, or welfare'' (NDCC 28–32–32). Accordingly, ''in an emergency, the administrative agency may take action pursuant to a specific statute as is necessary to prevent or avoid imminent peril to the public health, safety, or welfare'' (NDCC–28–32–32.1). In the absence of a specific statute requiring other administrative action, ''the administrative agency shall issue an order'' (NDCC 28–32–32(4)).

Further supplemental authority is found in a broad provision, cited by the State in their SIP submittals, granting additional authority to the NDDH. The NDDH has the authority to ''[i]ssue such orders as may be necessary to effectuate the purposes'' of the ''Air Pollution Control'' chapter NDCC 23–25–03.5. These orders can be enforced ''by all appropriate administrative and judicial procedures'' (NDCC 23–25–03.5). Thus, this broad grant of authority includes the authority to issue administrative orders during air pollution emergencies which would disrupt protection of human health, welfare, and animal and plant life.

The combination of NDCC and NDAC provisions discussed above provide for authority comparable to section 303 to immediately bring suit to restrain, issue emergency orders against, and use special rule adoption procedures for applicable emergencies to take prompt administrative action against, any person causing or contributing to air pollution that presents an imminent and substantial endangerment to public health or welfare, or the environment. We propose that they are sufficient to meet the authority requirement of CAA section 110(a)(2)(G).

States must also have adequate contingency plans adopted into their SIP to implement the air agency's emergency episode authority (as discussed above). This can be done by submitting a plan that meets the applicable requirements of 40 CFR part 51, subpart H for the relevant NAAQS if the NAAQS is covered by those regulations.

Subpart H of 40 CFR part 51 requires states to classify regions and to develop contingency plans (also known as emergency episode plans) after ambient concentrations of certain criteria pollutants in an area have exceeded specified levels. For example, if ambient concentrations of nitrogen dioxide in an area have exceeded 0.06 ppm (annual arithmetic mean), then the area is classified as a Priority I region, and the state must develop a contingency plan that meets the requirements of sections 51.151 and 51.152. North Dakota has not monitored any values above the priority cut point for ozone or NO_2.

Prevention of air pollution emergency episodes is addressed in Section 5 of North Dakota's SIP and was approved on May 31, 1972 (37 FR 10842). We find that North Dakota's air pollution emergency provisions establish stages of episode criteria (Section 5.2), provide for public announcement whenever any episode stage has been determined to exist (Section 5.3), and specify emission control actions to be taken at each episode stage (Section 5.5) consistent with the EPA emergency episode SIP requirements set forth at 40 CFR part 51, subpart H (prevention of air pollution emergency episode) for ozone and NO_2.

As noted in the October 14, 2011 guidance,[15] based on EPA's experience to date with the Pb NAAQS and designating Pb nonattainment areas, EPA expects that an emergency episode associated with Pb emissions would be unlikely and, if it were to occur, would be the result of a malfunction or other emergency situation at a relatively large source of Pb. Accordingly, EPA believes the central components of a contingency plan would be to reduce emissions from the source at issue and communicate with the public as needed. We note that 40 CFR part 51, subpart H (51.150–51.152) and 40 CFR part 51, Appendix L do not apply to Pb.

Based on the above analysis, we propose approval of North Dakota's SIP as meeting the requirements of CAA section 110(a)(2)(G) for the 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS.

9. *Future SIP revisions:* Section 110(a)(2)(H) requires that SIPs provide for revision of such plan: (i) From time to time as may be necessary to take account of revisions of such national primary or secondary ambient air quality standard or the availability of improved or more expeditious methods of attaining such standard; and (ii), except as provided in paragraph (3)(C), whenever the Administrator finds on the basis of information available to the Administrator that the SIP is substantially inadequate to attain the NAAQS which it implements or to otherwise comply with any additional requirements under this [Act].

EPA approved relevant sections of the North Dakota SIP on September 17, 2012 (77 FR 57029). North Dakota's statutory provision at NDCC 23–25–03 provides adequate authority for the Department to carry out such revisions. Therefore, we propose to approve North Dakota's SIP as meeting the requirements of CAA section 110(a)(2)(H).

10. *Consultation with government officials, public notification, PSD and visibility protection:* Section 110(a)(2)(J) requires that each SIP ''meet the applicable requirements of section 121 of this title (relating to consultation), section 127 of this title (relating to public notification), and part C of this

[13] *See* Email from Tom Bachman ''Request for Clarifications_ND iSIP 2008 ozone, 2008 Pb, and 2010 NO2 NAAAQS'' April 13, 2015, available within docket.

[14] *See* Email from Tom Bachman ''Request for Clarifications_ND iSIP 2008 ozone, 2008 Pb, and 2010 NO_2 NAAAQS'' April 13, 2015, available within docket.

[15] ''Guidance on Infrastructure State Implementation Plan (SIP) Elements Required Under Sections 110(a)(1) and 110(a)(2) for the 2008 Lead (Pb) National Ambient Air Quality Standards (NAAQS).'' Steve Page, OAQPS Director, October 14, 2011, at p. 13.

subchapter (relating to PSD of air quality and visibility protection).''

The State has demonstrated it has the authority and rules in place through its certifications (contained within this docket) to provide a process of consultation with general purpose local governments, designated organizations of elected officials of local governments and any Federal Land Manager having authority over federal land to which the SIP applies, consistent with the requirements of CAA section 121. Furthermore, EPA previously addressed the requirements of CAA section 127 for the North Dakota SIP and determined public notification requirements are appropriate (45 FR 53475, Aug. 12, 1980).

As discussed above, the State has a SIP-approved PSD program that incorporates by reference the federal program at 40 CFR 52.21. EPA has further evaluated North Dakota's SIP approved PSD program in this proposed action under element (C) and determined the State has satisfied the requirements of element 110(a)(2)(C), as noted above. Therefore, the State has also satisfied the requirements of element 110(a)(2)(J).

Finally, with regard to the applicable requirements for visibility protection, EPA recognizes states are subject to visibility and regional haze program requirements under part C of the Act. In the event of the establishment of a new NAAQS, however, the visibility and regional haze program requirements under part C do not change. Thus, we find that there are no applicable visibility requirements under section 110(a)(2)(J) when a new NAAQS becomes effective.

Based on the above analysis, we propose to approve the North Dakota SIP as meeting the requirements of CAA section 110(a)(2)(J) for the 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS.

11. *Air quality and modeling/data:* Section 110(a)(2)(K) requires each SIP provide for: (i) The performance of such air quality modeling as the Administrator may prescribe for the purpose of predicting the effect on ambient air quality of any emissions of any air pollutant for which the Administrator has established a NAAQS; and (ii) the submission, upon request, of data related to such air quality modeling to the Administrator.

North Dakota's PSD program requires estimates of ambient air concentrations be based on applicable air quality models specified in Appendix W of 40 CFR part 51, and incorporates by reference the provisions at 40 CFR 52.21(I)(2) requiring that modification or substitution of a model specified in Appendix W must be approved by the Administrator. Section 7.7, Air Quality Modeling, of North Dakota's SIP commits the Department to performing air quality modeling to predict the impact of a source on air quality, and providing data to EPA upon request. As a result, the SIP provides for such air quality modeling as the Administrator has prescribed. Therefore, we propose to approve the North Dakota SIP as meeting the CAA section 110(a)(2)(K) for the 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS.

12. *Permitting fees:* Section 110(a)(2)(L) requires the owner or operator of each major stationary source to pay to the permitting authority, as a condition of any permit required under this act, a fee sufficient to cover: (i) The reasonable costs of reviewing and acting upon any application for such a permit; and (ii) if the owner or operator receives a permit for such source, the reasonable costs of implementing and enforcing the terms and conditions of any such permit (not including any court costs or other costs associated with any enforcement action), until such fee requirement is superseded with respect to such sources by the Administrator's approval of a fee program under title V.

The State cites the SIP approved fee provisions for construction permits (NDAC 33–15–23–02 approved at 62 FR 19224, April 21, 1997), which include costs of processing not covered by the application fee. We also note that all the State SIPs we are proposing to approve in this action cite the regulation that provides for collection of permitting fees under North Dakota's approved title V permit program (64 FR 32433, June 17, 1999). As discussed in that approval, the State demonstrated that the fees collected were sufficient to administer the program.

Therefore, based on the State's experience in relying on the funds collected through application and processing fees at NDAC 33–15–23, and the use of title V fees to implement and enforce PSD permits once they are incorporated into title V permits, we propose to approve the submissions as supplemented by the State for the 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS.

13. *Consultation/participation by affected local entities:* Section 110(a)(2)(M) requires states to provide for consultation and participation in SIP development by local political subdivisions affected by the SIP.

The statutory provisions cited in North Dakota's SIP submittals (NDCC 23–25–03 and 23–25–02, contained within this docket) meet the requirements of CAA section 110(a)(2)(M), so we propose to approve North Dakota's SIP as meeting these requirements for the 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS.

VII. What action is EPA taking?

In this action, EPA is proposing to approve the following infrastructure elements for the 2008 Pb, 2008 ozone, and 2010 NO_2 NAAQS: (A), (B), (C) with respect to minor NSR and PSD requirements, (D)(i)(II) elements 3 and 4, (D)(ii), (E), (F), (G), (H), (J), (K), (L), and (M). EPA proposes to approve element 4 of 110(a)(2)(D)(i)(II) for the 2006 $PM_{2.5}$ NAAQS. Finally, EPA proposes approval of D(i)(I) elements 1 and 2 for the 2008 Pb, and 2010 NO_2 NAAQS. EPA will act separately on infrastructure element (D)(i)(I), interstate transport, for the 2008 ozone NAAQS.

VIII. Statutory and Executive Orders Review

Under the CAA, 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, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this proposed action merely approves some state law as meeting federal requirements and disapproves other state law because it does not meet federal requirements; this proposed action does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, Oct. 4, 1993);
- 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, Aug. 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

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

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

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

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

List of Subjects in 40 CFR Part 52

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

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

Dated: June 25, 2015.

Debra H. Thomas,

Acting Regional Administrator, Region 8.

[FR Doc. 2015–17380 Filed 7–14–15; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

49 CFR Part 192

[Docket No. PHMSA–2011–0009]

RIN 2137–AE71

Pipeline Safety: Expanding the Use of Excess Flow Valves in Gas Distribution Systems to Applications Other Than Single-Family Residences

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: Excess Flow Valves (EFVs), which are safety devices installed on natural gas pipelines to reduce the risk of accidents, are currently required for new or replaced gas service lines servicing single-family residences (SFR). PHMSA is proposing to make changes to part 192 to expand this requirement to include new or replaced branched service lines servicing SFRs, multi-family residences, and small commercial entities consuming gas volumes not exceeding 1,000 Standard Cubic Feet per Hour (SCFH). PHMSA is also proposing to require the use of manual service line shut-off valve (*e.g.,* curb valves) for new or replaced service lines with meter capacities exceeding 1,000 SCFH. Finally, PHMSA is proposing that operators notify customers of their right to request installation of an EFV on service lines that are not being newly installed or replaced. PHMSA is proposing to delegate the question of who bears the cost of installing EFVs to service lines that are not being newly installed or replaced to the operator, customer, and the appropriate State regulatory agency.

DATES: Persons interested in submitting written comments on this Notice of Proposed Rulemaking (NPRM) must do so by September 14, 2015. PHMSA will consider late-filed comments so far as practicable.

ADDRESSES: You may submit comments identified by the docket number PHMSA–2011–0009 by any of the following methods:

Comments should reference Docket No. PHMSA–2011–0009 and may be submitted in the following ways:

• *Web site: http://www.regulations.gov*. This site allows the public to enter comments on any **Federal Register** notice issued by any agency. Follow the online instructions for submitting comments.

• *Fax:* 1–202–493–2251.

• *Mail:* U.S. Department of Transportation (DOT) Docket Operations Facility (M–30), West Building, 1200 New Jersey Avenue SE., Washington, DC 20590.

• *Hand Delivery:* DOT Docket Operations Facility, West Building, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC, 20590 between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays.

Instructions: Identify the docket number, PHMSA–2011–0009, at the beginning of your comments. If you mail your comments, submit two copies. In order to confirm receipt of your comments, include a self-addressed, stamped postcard.

Note: All comments are posted electronically in their original form, without changes or edits, including any personal information.

Privacy Act Statement

Anyone can search the electronic comments associated with any docket by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). DOT's complete Privacy Act Statement was published in the **Federal Register** on April 11, 2000, (65 FR 19477).

FOR FURTHER INFORMATION CONTACT: Mike Israni, by telephone at 202–366–4571, by fax at 202–366–4566, or by mail at DOT, PHMSA, 1200 New Jersey Avenue SE., PHP–1, Washington, DC 20590–0001.

SUPPLEMENTARY INFORMATION:

I. Background

An EFV is a mechanical safety device installed inside the natural gas service line between the street and residential meter. The EFV will ''trip or close'' if there is sufficient damage to the line to minimize the flow of gas through the line and thus, the amount of gas that escapes into the atmosphere. During normal use, the valve is kept pushed open against oncoming gas flow by a spring. EFVs are designed so that general usage, such as turning on appliances, will not shut the valve. However, during a significant increase in the flow of gas (*e.g.,* due to a damaged line), the spring cannot overcome the force of gas, and the valve will close and stay closed until the correct pressure is restored. When the correct pressure is restored, the EFV automatically resets itself.

On July 7, 1998, in South Riding, Virginia, a residential gas explosion resulted in one death and three injuries. It is not known if the explosion occurred on a branched or non-branched service line servicing an SFR; however, PHMSA believes that this proposed rule or its previous rule requiring EFVs on single lines serving SFRs would have mitigated the consequences of the explosion. An investigation by the National Transportation Safety Board (NTSB) found the explosion likely would not have occurred if an EFV had been installed for this single-family home. Similarly, PHMSA strongly believes this incident would have likely been would have been mitigated at a minimum. As a result, on June 22, 2001, the NTSB issued Safety Recommendation P–01–2, recommending that PHMSA require excess flow valves in all new and renewed gas service lines, regardless of a customer's classification, when the

operating conditions are compatible with readily available valves.

In December of 2005, the ''Integrity Management for Gas Distribution: Report of Phase I Investigations,'' [1] developed by a multi-stakeholder group, was published. In the report, the stakeholder group recommended that ''[A]s part of its distribution integrity management plan, an operator should consider the mitigative value of excess flow valves (EFVs). EFVs meeting performance criteria in § 192.381 and installed in accordance with § 192.383 may reduce the need for other mitigation options.''

In an effort to study the possible benefits of expanding EFVs beyond SFR applications, PHMSA began development of the Interim Evaluation in early 2009. In June and August of 2009, PHMSA held public meetings on NTSB Recommendation P–01–2.

The meeting participants included the National Association of Regulatory Utility Commissioners, the National Association of Pipeline Safety Representatives, the International Association of Fire Chiefs, the National Association of State Fire Marshals, natural gas distribution operators, trade associations, manufacturers, and the Pipeline Safety Trust. As a result of these meetings, PHMSA issued a report titled: ''Interim Evaluation: NTSB Recommendation P–01–2 Excess Flow Valves in Applications Other Than Service Lines Serving One SFR'').[2]

On December 4, 2009, PHMSA amended the pipeline safety regulations to require the use of EFVs for new or replaced gas lines servicing SFRs.[3] While this requirement met the mandate of the Pipeline Inspection, Protection, Enforcement and Safety Act (PIPES Act) enacted in 2006, distribution lines, including those that serve branched SFRs, apartment buildings, other multi-residential dwellings, commercial properties, and industrial service lines, are still not required to use EFVs. These structures are susceptible to the same risks as SFR service lines. PHMSA, already aware of this risk, was awaiting completion of the Interim Evaluation, which studied the possible expansion of EFVs beyond SFRs and the challenges of application. The Interim Evaluation also addressed other practical alternatives such as the use of manual isolation devices, such as curb valves. The evaluation identified challenges related to the feasibility and practicality of the proposed solutions, as well as significant cost factors and benefit factors. The evaluation found that there are no other devices or viable options to shut off gas supply quickly when gas services line ruptures.

On November 25, 2011, PHMSA published an Advance Notice of Proposed Rulemaking (ANPRM) (76 FR 72666) asking the public to comment on the findings of the Interim Evaluation and issues relating to the expanded use of EFVs in gas distribution systems. PHMSA also sought comments from gas distribution operators on their experiences using EFVs, including:

- Technical challenges of installing EFVs on services other than SFRs;
- Categories of service to be considered for expanded EFV use;
- Cost factors;
- Data analysis in the Interim Evaluation;
- Technical standards for EFV devices; and
- Potential safety and societal benefits, small business and environmental impacts, and costs of modifying the existing regulatory requirements.

The ANPRM comments received by PHMSA will assist in the finalization of the Interim Evaluation and in determining what regulatory changes may be necessary to fulfill this mandate.

In 2012, the President signed the Pipeline Safety, Regulatory Certainty, and Job Creation Act of 2011, which requires PHMSA to study the possibility of expanding the use of EFVs beyond SFRs and issue a final report on the evaluation of the NTSB's recommendation on excess flow valves within 2 years after enactment of the Act. PHMSA is also mandated to, if appropriate, issue regulations requiring the use of EFVs or equivalent technology, where ''economically, technically and operationally feasible'', for new or entirely replaced distribution branch services, multi-family lines, and small commercial service lines. PHMSA has determined for the purpose of this proposed rule, based on the study, that the safety benefits of expanding EFVs justify the cost and is appropriate. The only proposed exceptions are for large apartment buildings, industrial or commercial users for whom EFVs may not be practical due to inherent design complexity, continuous supply demands and/or contamination issues. Additionally, PHMSA is proposing that services exceeding 1,000 SFCH install curb valves on new or replaced gas service lines.

The proposed required use of curb valves for large commercial (greater than 1,000 SFCH) goes beyond the Section 22 language of the Pipeline Safety, Job Creation, and Regulatory Certainty Act of 2011, however it is based on ANPRM comments received from industry, trade associations and other stakeholders. PHMSA and industry in general believe that EFVs are not suitable larger commercial facilities over 1,000 SFCH. Curb valves are the best alternative to an EFV and provide an effective added level of safety for these facilities. These valves also are a feasible alternative based on the cost/benefit analyses.

PHMSA's authority for regulating natural gas pipelines was first established by the Natural Gas Pipeline Safety Act of 1968, Public Law 90–481, and has since been enlarged by additional legislation. The Pipeline Safety Laws specifically delegate authority to DOT to develop, prescribe, and enforce minimum Federal safety standards for the transportation of natural gas. PHMSA has used this statutory authority to promulgate comprehensive minimum safety standards. While the 2011 Act specifically directed PHMSA to require the installation of EFVs on new and replaced branched lines serving SFRs, multi-family and small commercial facilities, DOT's underlying prior statutory authority under 49 U.S.C. 60104 provides PHMSA with the authority to require the installation of curb valves for large commercial facilities.

In the time since the 1998 incident in South Riding, Virginia, the NTSB has investigated an additional 8 incidents, which resulted in 10 fatalities that could have possibly been averted if an EFV had been in place. The most recent incident occurred on November 23, 2012, when a gas pipeline exploded in Springfield, Massachusetts. The Springfield explosion injured 21 people and damaged more than 40 buildings. It is important also to note that this incident occurred on the day after Thanksgiving and the daycare adjacent to the explosion was closed. If the daycare would have been open, it is highly likely this incident would have resulted in even more losses. This incident is currently under investigation

[1] *http://www.regulations.gov/#!documentDetail;D=PHMSA-RSPA-2004-19854-0070.*

[2] The Interim Evaluation Report was issued in 2010 by PHMSA. The purpose of the interim report was to respond to the NTSB safety recommendation P–01–02 and evaluate the possibility of expansion of EFVs to applications other than service lines serving one single family residence (above 10 psig). The interim report also built a foundation for an economic analysis, considered the need for enhanced technical standards or guidelines, and suggested that any new technical standards include criteria for pressure drops across the EFV. The interim report can be found at: *http://www.regulations.gov/#!documentDetail;D=PHMSA-2011-0009-0002.*

[3] ''Pipeline Safety: Integrity Management Programs for Gas Distribution Pipelines,'' 74 FR 63906 (December 4, 2009) RIN 2137–AE15.

by the NTSB. All eight of these incidents occurred on lines that would be affected by this rulemaking.

II. Analysis of ANPRM

Nineteen organizations and individuals submitted comments in response to the ANPRM. The individual docket item numbers are listed for each comment.

Trade Associations

- Northeast Gas Association (NGA) (PHMSA–2011–0009–0012).
- Texas Pipeline Association (TPA) (PHMSA–2011–0009–0016).
- American Gas Association (AGA) (PHMSA–2011–0009–0023).
- American Public Gas Association (APGA) (PHMSA–2011–0009–0024).

Gas Transmission and Distribution Pipeline Companies

- MidAmerican Energy Company (MAE) (PHMSA–2011–0009–0011).
- Avista Utilities (AU) (PHMSA–2011–0009–0013).
- Southwest Gas Corporation (SWC) (PHMSA–2011–0009–0015).
- National Grid (NG) (PHMSA–2011–0009–0022) (Supported AGA comments).
- Laclede Gas (LG) (PHMSA–2011–0009–0018) (Supported AGA comments).
- Kansas Gas Service (KGS) (PHMSA–2011–0009–0017).
- Nicor Gas (PHMSA–2011–0009–0014).

Government/Municipalities

- City of Ellensburg, Washington (PHMSA–2011–0009–0004).
- NTSB (PHMSA–2011–0009–0009).
- Iowa Utilities Board (IUB) (PHMSA–2011–0009–0020).

Pipeline Industry Suppliers

- R.W. Lyall (PHMSA–2011–0009–0021).
- Gas Breaker, Inc. (GBI) (PHMSA–2011–0009–0019).

Citizens

- Rebecca Lee Roter (PHMSA–2011–0009–0006).
- Courtney D. Brown (PHMSA–2011–0009–0010).
- Anonymous (PHMSA–2011–0009–0008) (The anonymous commenter expressed concerns regarding pipeline safety versus job creation, corruption, and politics. These topics are beyond the scope of this NPRM and are not discussed further.)

PHMSA reviewed all of the comments received in response to the ANPRM. The comments received from the trade associations largely supported expanded EFV use with certain limitations. The operators that responded with comments raised some concerns with expanded EFV use generally related to logistics and implementation. Municipality comments reflected a concern that State laws already in place could conflict with any new Federal requirements. The NTSB expressed strong approval of the expanded EFV use. The comments submitted are discussed below in the same order as presented in the questions from the ANPRM.

A. Technical Challenges of Installing EFVs on Services Other Than SFRs

A.1. Does the Interim Evaluation address all challenges associated with expanded EFV use (changing gas usage patterns, snap loads, business-critical gas supply applications, system configuration, pressure ratings, and size of commercially available EFVs)?

The ANPRM solicited feedback and comments regarding whether the Interim Evaluation fairly and accurately explained the challenges of expanded EFV use. These challenges, identified in the Interim Evaluation from a variety of stakeholders, may limit or exclude future EFV expansion beyond SFR applications due to safety reasons. The challenges included changing gas-usage patterns, snap loads (*i.e.* loads that lead to false closures), business-critical gas supply applications, system configurations, pressure ratings, and the sizes of commercially available EFVs. Among the challenges discussed by the commenters, snap loads (loads that lead to false closures), load variation, and proper EFV sizing seemed to be of the greatest concern.

Overall, industry, trade association, government, and municipality commenters agreed that the Interim Evaluation failed to accurately and fully portray a variety of the technical and operational challenges and costs and benefits associated with expanded EFV requirements. These commenters either stated the report was lacking in certain areas or did not comment. In general, commenters, including AGA and APGA, strongly cautioned against the broad expansion of EFV requirements beyond those for SFRs, citing operators' lack of experience and design complexities. Specifically, APGA, SWC, AGA, LG, NG, AU, TPA, IUB, NGA, and MAE all found the Interim Evaluation's discussion of the challenges of proper EFV sizing protocols, system configuration, and changes in gas-usage patterns to be inadequate and to contain false assumptions. Due to these concerns, MAE suggested that any EFV requirements should only affect new installations. Likewise, AGA supported the installation of EFVs on new and entirely replaced service lines in the following applications only:

- Service lines to SFRs;
- SFR service lines and branched SFR service lines installed at the same time;
- A branched SFR service line branching off an existing SFR service line that does not contain an EFV provided there is sufficient line capacity;
- A branched SFR service line branching off an existing SFR service line that contains an EFV sized appropriately for both customers provided there is sufficient line capacity;
- Multi-family installations, including duplexes, triplexes, and fourplexes, with individual meter sets, a known customer load (based on meter capacity) not exceeding 1,000 standard cubic feet per hour (SCFH), and a load that is not expected to increase over time; and
- Small commercial customers with a known customer load (based on meter capacity) not exceeding 1,000 SCFH through a single service line and where the load is not expected to increase over time.

AU, KGS, APGA, SWC, GBI, AGA, and the City of Ellensburg, WA, were concerned with the challenges of snap loads and the loss of continuous supply. Snap loads may occur when the amount of natural gas required to meet demand suddenly increases, which is generally due to many appliances being turned on at one time. GBI, AU, and AGA suggested that requiring EFVs for lines not exceeding 1,000 SCFH based on meter size is reasonable, but the false closure and load variation challenges make using EFVs for applications that exceed 1,000 SCFH difficult. AU specifically stated that the failure (false closure or malfunction) of EFVs at high loads during winter frost is difficult to mitigate and is an inconvenience to customers who lose service. AU stated that winter frost makes pipeline excavation to repair lines difficult due to frozen soil. SWC commented that business disruptions and loss of service in vital areas such as high-occupancy dwellings created a safety hazard. KGS recommended that service lines serving multiple customers should not use a single EFV due to the increased degree of variation in the gas flow rates.

PHMSA received different approaches from commenters regarding the proper selection of an EFV for a pipeline, or what is referred to in the Interim Evaluation as ''EFV sizing''. The trip point is the specific point in which the

EFV ''trips'', or closes, the valve due to gas pressure differential and is essentially the factor that guides the size selection of an EFV. In the Interim Evaluation, PHMSA suggested an EFV's trip point should be less than, but close to, the flow rate of a complete line rupture.

Commenters indicated that PHMSA's approach for trip point selection either led to tripping too easily or not at all. R.W. Lyall, an EFV manufacturer, further submitted that EFVs should be sized so that the EFV trip point, at the minimum system pressure, is above the maximum anticipated load and is above meter capacity. GBI suggested an EFV should be selected that operates at least 1.5 times the meter rating at the minimum design inlet pressure. Finally, SWC and NGA specifically commented that, due to the complexity of design found in multi-family industrial and commercial service lines, a common approach for sizing is not possible. With regard to the challenges of commercially available EFVs, PHMSA received two comments. GBI, an EFV manufacturer, commented that the commercial availability for most applications, even those considered large, is not a problem. In contrast, MAE stated that the commercial availability of EFVs for non-residential load profiles is an assumption made on the part of PHMSA that may be inaccurate.

PHMSA Response

A number of the comments PHMSA received focused on a concern that EFVs could trip inadvertently and may cause unnecessary service disruptions. PHMSA agrees that variations in the configuration of service lines make it difficult to impose specific sizing requirements for various types of service lines and customers. However, if an operator installs an EFV and operates it in accordance with a manufacturer's specifications, the EFV should operate safely without the need for a prescriptive sizing requirement even when customer gas usage changes, unless the change were so large as to require a new service line.

Overall, PHMSA disagrees with the comments that EFVs are prone to failure and inadvertent tripping due to variations in gas flow, location, etc. Research and available data has shown very few failures with EFVs in actual usage. Operators in the United States have gained considerable experience with EFVs since 1999 mainly with SFRs. The NRRI conducted a survey on EFV installation and operators' experiences with EFVs installed on single family residential service lines found of 2.5 million EFVs installed on SFRs only 223 failed.[4] In Europe, BEGAS, the government owned gas company in Eastern Austria, reported that EFVs have been installed since 1993 on service lines to hospitals, large facilities, production plants, etc. Out of 26,000 BEGAS installations there have been no spurious failures.[5] PHMSA maintains proper operator installation using manufacture direction and maintenance of EFVs is paramount to their success. Therefore, PHMSA is not proposing a protocol for EFV installation. PHMSA is only advising operators to install EFVs as the manufacturer directs and the service safely requires.

Operators and manufacturers that PHMSA contacted stated they typically size an EFV in such a way that it trips at 20% to 30% above the maximum service load it will encounter. It is possible that this trip point could be too high for small leaks, however, EFVs are intended to react to ruptures, not small holes.

Likewise, one commenter mentioned winter time excavation of lines to repair them due to EFV failure was a concern. PHMSA suggests that digging in frozen ground in winter is not any more difficult than digging concrete or curbside if valve is located underneath. Again, PHMSA believes, proper sizing of an EFV is the key to avoiding all these issues. PHMSA has surveyed twice in the past, and there were only one or two instances of EFV failure in greater than a million services over many years. All major EFV manufacturers PHMSA contacted indicated that they are available to help operators to properly size their valves.

PHMSA received no information to indicate that pressure ratings and/or the size of commercially available EFVs are a problem for the expansion of EFVs to certain other types of service. Currently, the normal minimum pressure design (the minimum anticipated design pressure) is 10 psig. The maximum pressure of composite materials (250 psig), plastic (125 psig), and steel (1,000 psig and up), does not pose a problem. There is no pressure limit on an EFV's performance except that, when activated, the EFV seat must be able to withstand the pressure. The pressure limit is normally constrained by the design of the carrier pipe. EFVs covered by ASTM F2138 must have a maximum inlet pressure of at least 125 psig, while ASTM F1802 applies to EFVs with a pressure rating of up to 125 psig. However, for very high-volume EFV applications, such as those for industrial customers, technical standards may need to address operating design pressures that exceed 125 psig.

Therefore, PHMSA proposes to expand EFV applications to new or replaced service lines for SFRs with branched lines; multi-family installations, including duplexes, triplexes, and fourplexes with individual meter sets and known customer loads not exceeding 1,000 SCFH; and small commercial customers with known loads not exceeding 1,000 SCFH. EFVs will not be required in the above-mentioned applications if one of the existing § 192.383 exceptions is present.

While the proposed expansion of EFVs would have costs, PHMSA believes the costs are justified by the added protection for gas customers, as the only proposed exceptions are for large apartment buildings, industrial or commercial users for whom EFVs may not be practical due to inherent design complexity and continuous supply demands. In those situations (loads exceeding 1,000 SFCH), PHMSA believes curb valves will provide the best possible option for improved safety at this time. PHMSA does not have definitive data, but some commenters stated that 2% to 5% of customers would fall into one of the exceptions for EFVs, which would include many of those facilities over with loads exceeding 1,000 SFCH.

A.2. Additional Challenges Not Addressed by the Interim Evaluation

The ANPRM also solicited comments on whether additional challenges existed beyond those discussed in the Interim Evaluation. MAE commented that the addition of more EFVs in natural gas systems could create an increase in safety hazards resulting from the maintenance of failed EFVs and EFVs that fail to trip on small leaks (*i.e.,* pinhole corrosion). These safety hazards would be due to increased excavation activities, which place more workers in high-traffic and congested areas. MAE also mentioned that excavation contractors may be less cautious around service lines if they believe they will not leak because of an installed EFV. TPA stated that the mandated use of EFVs for new or replaced transmission or gathering lines should not be pursued until further study is completed.

[4] ''Survey on Excess Flow Valves: Installations, Cost, Operating Performance and Gas Operator Policy'', Ken Costello, The National Regulatory Research Institute, March 2007.

[5] ''Operational Experiences with Excess Flow Valves for Service Lines and Main Lines in Network Operation'', Peter Masloff, Technology Department Director, BEGAS—Burgenlandische Erdgasversorgungs AG. *http://pipelife-gasstop.com/media/gasstop/pdf_englisch/GWF_7_2003_Excess-Flow-Valves_Experience-report.pdf.*

PHMSA Response

MAE's comment regarding excavation damage prevention can be addressed with proper EFV installation techniques and the normal course of training for pipeline operator personnel, including training on excavation damage prevention. Excavation contractors hired by operators go thru same damage prevention training as operators regarding safe digging practices and are aware of the dangers of gas leaks and explosions. In regard to TPA's comment, PHMSA agrees at this time and is proposing to expand EFV use only to distribution lines, not gathering or transmission lines. PHMSA has found that there is a lack of experience with EFVs on gathering and transmission lines in addition to problems with contaminants and other factors.

A.3. Use of Curb Valves (Manual Shut-Off Valve) as an Alternative to EFVs

The ANPRM sought comments on the use of curb valves as an alternative to EFVs. Most commenters agreed that use of a curb valve is a viable alternative to EFV use in some cases. In fact, the City of Ellensburg, Washington, stated the installation of a curb valve should be considered by PHMSA to be equivalent to the installation of an EFV. The City of Ellensburg mentioned that current Washington State regulations require the use of a curb valve if an EFV is not installed.

MAE, APGA, and APA commented that operators have experience with curb valves, but their use presents certain challenges. The technical challenges expressed by commenters with regard to curb valve use include: Maintenance of the valve; location of the valve for accessibility; third-party damage to the valve; recordkeeping as to the location of the valve; ensuring the box does not place stress on the pipe; and the delayed shut-off response inherent in curb valve design during emergency situations. APGA commented that curb valves require trained personnel to manually close the valve with a special key. APGA further stated that ''squeezing'' off the gas in the line is sometimes quicker than using a curb valve for stopping the flow of gas.

PHMSA Response

Historically, curb valves have proven to be a very effective mechanism for interrupting the flow of gas in both routine maintenance situations and in emergencies. Other than a curb valves, distribution operators have tools (large pliers) to squeeze pipe to shut off gas supply. Curb valves require that a person make a conscious decision to physically close the valve itself, thereby avoiding inadvertent closures. Curb valves are slightly more expensive than EFVs and require some maintenance and need to be located in an accessible site. The primary disadvantage curb valves have is the time it can take to mobilize to the valve site and close the valve.

It is not technically feasible to expand EFV use to service lines operating at loads exceeding 1,000 SCFH. This is largely due to issues with reliable service, load fluctuation, the lack of experience with EFV usage in larger applications, and the complexity of design issues. Therefore, in the case of service lines operating at more than 1,000 SCFH, PHMSA proposes to require curb valves be installed and maintained in such a manner that emergency personnel can access them. Although it does not come at a prohibitive cost, the installation of curb valves is slightly more expensive than the installation of EFVs.

A.4. Additional Situations Where the Installation of EFVs May Not Be Feasible

The ANPRM solicited comments concerning additional situations not found in the Interim Evaluation where the installation of an EFV may not be feasible or practical. AGA and SWC commented that they agreed with the examples cited in section 10.3.1 of the Interim Evaluation. MAE commented that lines containing contaminants, and distribution systems with a history of transporting liquids, may create situations where EFVs are impracticable.

PHMSA Response

Section 192.383 currently includes exceptions for EFV installations with regard to SFRs. With respect to MAE's concern regarding lines containing contaminants and distribution systems with a history of transporting liquids, the proposed exceptions would waive the EFV requirement for those systems for which installing EFVs would be impracticable. This proposed rule incorporates the existing § 192.383 exceptions in place and would extend them to the additional service line applications covered in this NPRM.

B. Economic Analysis Considerations

PHMSA requested comments on the potential costs of modifying the existing regulatory requirements. PHMSA requested that commenters provide information and supporting data on the potential quantifiable safety and societal benefits, the potential impacts on small businesses, and the potential environmental impacts of modifying the existing regulatory requirements. The economic analysis for the installation of EFVs on services other than SFRs involves challenges including the quantification and monetization of costs and benefits.

B.1. Categories of Service for Expanded Use of EFVs

The ANPRM requested comments on section 10.3.2. of the Interim Evaluation. This section describes the ''Categories of Services'' in which PHMSA could expand EFV requirements. PHMSA sought input as to whether the categories accurately represented current ''real world'' applications and which categories are most likely to benefit from EFV expansion.[6]

AGA largely agreed with the categories of service presented in the Interim Evaluation, while MAE commented that the categories are sufficient for economic analysis only. MAE further states that if the rule in its final form creates different requirements among these five categories, the rule may prove difficult to implement because an operator may not be clear which category a service may fall into.

AGA, APGA, AU, Nicor, and SWC advised PHMSA not to apply the EFV requirements to all five categories named in the Interim Evaluation. Specifically, the commenters supported all categories of service with the exception of those with services requiring greater than 1,000 SCFH. Those services with 1,000 SCFH requirements or higher are generally sensitive to loss of supply and may have complex configurations not conducive to EFVs. Nicor, APGA, and AGA commented that service lines serving one multi-family building with one meter should be limited to duplexes, triplexes, and fourplexes with known loads not exceeding 1,000 SCFH, and that non-residential services to space and water heater customers should be limited to 1,000 SCFH due to possible snap loads. Additionally, AGA stated that there are factors to consider for applying EFVs to non-residential service lines such as commercial food sales, food service, and health care, and that these applications would require unique analysis. These service applications are susceptible to loss of service issues and

[6] The categories of service from the Interim Evaluation are: Branched service line serving single-family residence; Service line serving one (or two adjoining) multi-family residential building(s) with one meter or one meter header or manifold; Non-residential services to space and water heat customers; Other applications where the service line configuration or EFV specification is more complex; and Industrial customers.

frequently have complex designs. SWC likewise stated that EFVs work in applications not exceeding 1,000 SCFH. The industrial customer's category was mentioned by all those commenting on this question as a category not suitable for mandated EFV use due to unpredictable load changes over the life of the service and inherent design complexities.

PHMSA Response

PHMSA has reviewed the comments on the possible expansion of categories of gas services requiring EFVs. PHMSA proposes expansion of EFV use for only certain categories of service presented in the Interim Evaluation. Specifically, PHMSA proposes to expand EFV requirements to include:

- Branched SFR service lines off of existing SFR service lines that do not contain an EFV and have a known load not exceeding 1,000 SFCH based on meter capacity;
- SFR service lines and branched SFR service lines installed at the same time with a known load not exceeding 1,000 SFCH based on meter capacity;
- Branched SFR service lines off of existing SFR service lines with a known load not exceeding 1,000 SFCH based on meter capacity;
- Multi-family residences with individual meter sets and a known customer load not exceeding 1,000 standard cubic feet per hour (SCFH) based on meter capacity; and
- Small commercial customers with a known customer load (based on meter capacity) not exceeding 1,000 SCFH through a single service line.

Operators with services lines with loads exceeding 1,000 SCFH will be required to utilize curb valves. Since PHMSA has found commercial and industrial service lines often have complex designs and/or require constant reliable service requirements, PHMSA has decided that these categories of service are not good candidates for requiring EFV use. Often these services meet or exceed a demand for 1,000 SCFH. PHMSA therefore proposes the 1,000 SCFH threshold based on comments and PHMSA experience however we invite comment.

B.2. Cost Factors Associated With Mandatory EFV or Curb Valve Installation

The ANPRM sought comments as to whether there are any other issues related to the costs associated with mandatory EFV or curb valve installation that should be considered aside from those mentioned in the Interim Evaluation. Both AGA and SWC noted that cleaning labor for EFVs on larger service lines, inadvertent trips and the subsequent loss of business for commercial customers and accidental environmental discharges are additional costs to the operator that PHSMA should consider. APGA commented that EFV installation costs for large-volume EFVs may be higher due to the fact there is less demand for them, and PHMSA should not assume the same unit price as a SFR EFV. Both NGA and Nicor mentioned that installation of EFVs may conflict with restrictions placed by local jurisdictions on excavating paved roads to access existing or install new EFVs.

PHMSA Response

PHMSA has determined that installing EFVs by using manufacturer guidelines should eliminate most EFV tripping errors. EFVs are commercially available in a wide variety of pipe sizes. Some manufacturers report that they make EFVs for larger than 2-inch IPS (Iron Pipe Size) diameters (typical SFR size), and at least one manufacturer is developing a 10,000 SCFH EFV. The principles of operation remain the same as valve size and trip point increase, making EFVs for larger loads and pipe sizes technically feasible. PHMSA also noted that SFR installation of EFVs, which began in 2010, depended on manufacturer guidelines for installation. No PHMSA guidance was issued. Since 2010 the SFR EFVs required to be installed have resulted in no false trips or failures if installed as manufacturer directed. PHMSA has found manufacture guidelines to be well within the safety margin and they know their product better than PHMSA in most instances.

Additional costs for purging lines are minimal as documented by AGA estimates. AGA states many operators either have already installed EFVs on some services beyond SFRs or are planning to start. The price per unit has decreased in recent years given the development, improved availability, and quality of EFVs. Higher installation costs for high volume EFVs have been taken into account in the cost/benefit analysis through the averaged cost. Similarly, installation costs for curb valves are more expensive than smaller volume EFVs and the cost/benefit analysis considered that aspect.

B.3. Who should pay for the installation and maintenance of EFVs or other alternatives and why?

PHMSA sought comments as to who should pay for the costs of installation and maintenance of EFVs. Comments were received from AGA, SWC, and MAE concerning who should be expected to pay for the installation and maintenance of EFVs or other alternatives if applicable regulatory requirements were implemented. MAE stated that operators should pay for the initial installation of valves, but any changes to customer loads requiring EFV installation should be at the customer's expense.

PHMSA Response

Because operators would already be newly installing or replacing pipelines, *i.e.* they would already have a trench open and be in place to work at the site, the addition of an EFV adds only minor costs (PHMSA estimates the cost of an EFV including installation is $30). This is supported by the AGA response to the excess flow valve census (Docket PHMSA–2012–0086, page 2), in which AGA indicated ''the incremental cost per installation of EFVs is relatively minimal.'' AGA further committed to expand the installation of EFVs beyond SFR services by June 2013. This also supports the notion that cost is not a major factor for the expansion of EFV use on new and fully replaced service lines beyond SFRs as proposed by this NPRM. PHMSA additionally utilized ANPRM comments which included numerical data on the costs for EFVs provided by operators as well as PHMSA Technical Advisory Committee [7] input for this proposed rulemaking.

B.4. Are there any opportunity costs associated with the installation of EFVs? A particular time of day that is optimal for installation? How long does installation take?

The ANPRM sought comment as to any opportunity costs and installation timelines that EFVs or alternatives may require. AGA, APGA, SWC, MAE, and Nicor commented on this question. These commenters all mentioned the loss of gas supply as a potential opportunity loss for customers due to the longer period of time needed to install an EFV on larger service lines. Additionally, the operators would spend more time and resources installing EFVs or alternatives versus maintenance, construction, operation, and inspection activities. APGA responded that EFVs do not need to be installed at any particular time of day, with most installations occurring during normal business hours.

PHMSA Response

Given industry's commitment to support EFV installation on new and

[7] Joint Meeting of the PHMSA Technical Advisory Committees held Dec. 11–13, 2012, Alexandria, Virginia. Transcripts available at Regulations.gov., docket PHMSA–2009–0203.

fully replaced service lines where practically and technically feasible, PHMSA believes that the cost of installation of EFVs, as proposed by the regulation, are sufficiently low that they will not interfere with other operator expenditures. PHMSA agrees with industry that the incremental cost per installation is minimal and would be utilized during the new construction or the replacement of service lines when industry resources (labor) are already at the installation sites.

B.5. Are there any other issues related to benefits associated with the mandatory EFV or curb valve installation that should be considered when performing the benefit/cost analysis, other than those listed in section 10.5 ''Defining Benefit Factors'' of the Interim Evaluation? Does the methodology utilized in the Interim Evaluation appropriately quantify the expected number of incidents or consequences averted? Can a conclusion be satisfactorily made concerning the cost and benefits of EFV or curb valve installation as presented in the Interim Evaluation?

PHMSA asked for comments concerning any other issues that had not yet been considered regarding benefits associated with mandatory EFV or curb valve installation. IUB, NGA, MAE, and AGA commented on additional cost/benefit factors that had not yet been considered. NGA stated that upgrading existing EFVs to meet the increased demand loads will add significant costs to customers and will conflict with restrictions placed by local jurisdictions on excavating paved roads to access existing or install new EFVs. Similarly, MAE stated that load changes due to changes in ownership may cause extra expenses from service modifications and industrial process equipment damage. AGA and SWC were unaware of any additional cost/benefit factors other than those in the Interim Evaluation.

In terms of the methods PHMSA used in the Interim Evaluation to study EFV expansion, the comments were generally supportive. MAE, SWC, APGA, and AGA commented that they typically agreed with the methodology used by PHMSA. However, some trade association comments also indicated there was some concern about the assumptions PHMSA made with its methodology. In particular, there were concerns with the ''incidents averted calculation,'' including the associated root cause analyses and assumed continued operations of all lines over 10 psi. AGA further commented that the analysis could not draw reliable conclusions. IUB suggested PHMSA should develop a separate analysis for each of the classes of service.

PHMSA Response

PHMSA's analysis was based on incident-specific data, which were obtained from the incident reports submitted by operators. PHMSA explained how it used the data, including the assumptions it made in applying the operational and other data obtained from incident reports, to filter past incidents that would likely not have been averted or mitigated had an EFV been installed. The remaining candidate incidents might have been averted or mitigated had an EFV been installed, but PHMSA did not conclusively assert that all of those candidate incidents definitively would have been averted or mitigated. However, based on the analysis of the best available data, PHMSA is convinced that the installation of EFVs on additional service lines could help avert or mitigate future incidents. The candidate incidents, incidents that PHMSA can classify as preventable by EFV installation, represent the scope of incidents that might have benefited from an EFV during the time period studied. PHMSA requests comments on whether the incidents that PHMSA has identified are likely to have been averted or mitigated if an EFV or manual service line shut-off valve had been in place. In addition, PHMSA does not have an EFV sizing protocol, nor was one proposed in the Interim Evaluation. The methodology for sizing EFVs was one of the challenges described in section 9.1 of the Interim Evaluation.

C. Technical Standards and Guidance for EFVs

The OMB circular A–119, ''Federal Participation in the Development and Use of Voluntary Consensus Standards in Conformity Assessment Activities,'' directs Federal agencies to utilize voluntary standards, both domestic and international, whenever feasible and consistent with law and regulation. The current regulation at 49 CFR 192.381 only requires EFVs to be manufactured and tested by the manufacturer according to an industry specification or the manufacturer's written specification. The regulation does not prescribe a precise specification. PHMSA solicited comments as to the need for the adoption of consensus standards for EFV specification.

C.1. Should PHMSA incorporate by reference the following standards? Manufacturers Standardization Society (MSS) SP–115–2006 Design, Performance & Test, ASTM International (ASTM) F1802–04—Standard Specification for Excess Flow Valves for Natural Gas Service, and ASTM International (ASTM) F2138–01—Standard Specification for Excess Flow Valves for Natural Gas Service?

The comments received by PHMSA largely indicated that the incorporation by reference of any standards for EFVs is not necessary. AGA, supported by MAE, stated in their comments that manufacturers already construct and test EFVs according to industry consensus standards MSS SP–115–2006, ASTM F–1802, and ASTM F–2138. Operators have been successfully installing EFVs using manufacturer guidance with no known safety issues arising. Similarly, AGA and SWC expressed concern regarding the incorporation by reference of any industry standards due to the delay in updating the pipeline safety statutes, which in turn would prevent the timely installation of the newest and best EFVs on the market. As an alternative to PHMSA incorporating standards, commenters suggested that PHMSA continue to allow operators to utilize manufacturer installation guidance already available.

PHMSA Response

PHMSA will not be incorporating any new standards by reference for EFVs into the pipeline statutes at this time but may do so in the future. All EFVs currently available have been manufactured and tested to current consensus standards. Additionally, PHMSA has not incorporated any standards for EFVs into the pipeline safety regulations for SFRs and has not found any issues with that approach. If the need for incorporation by reference does become necessary, PHMSA will review the issue.

C.2. Are there alternatives to the standards referenced in C.1.?

PHMSA also asked for comments on three current consensus standards and if there are alternatives to them. APGA and APA stated they were unaware of additional standards beyond those listed in the Interim Evaluation, with the exception of ''*MSS SP–142–2012 Excess Flow Valve for fuel gas service, NPS 1 1/2 through 12*'' for larger sized EFVs. Similarly, MAE, deferring to AGA comments, stated it was aware of no other standards except for the Gas

Piping Technology Committee (GPTC) Appendix G192–8 in the Z380 Guide.

PHMSA Response

PHMSA is also unaware of any alternatives to the three standards listed in the Interim Evaluation for EFVs for natural gas service. As for selection and sizing guidelines, PHMSA will request GPTC to develop comprehensive standards for selection, installation, and performance testing of EFVs for a variety of design considerations and service line configurations and operating conditions. This guidance will be in addition to guidance provided by manufacturers and will act as a supplement to address various situations which may not be elaborated on in manufacturer guidance. PHMSA will also issue advisory bulletins if we become aware of new conditions of concern for EFV installation.

C.3. Are guidelines or technical standards needed for developing and if so, why?

PHMSA asked for comments as to whether EFV guidelines or technical standards are in need of development, and if so, why. Both MAE and SWC commented that a standard approach or some sort of guidance for sizing EFVs, and criteria for identifying adverse conditions, may be needed. SWC agreed and stated that additional guidance, not necessarily standards, need to be developed. SWC additionally asked PHMSA to issue advisory bulletins if PHMSA finds additional conditions in which an EFV installation is advisable. Likewise, AGA stated that the current industry standards used in manufacturing are satisfactory, and EFV performance testing using industry standards cannot be accomplished in an economically, technically, and operationally feasible manner on installed service lines.

PHMSA Response

PHMSA finds that additional technical standards development for EFVs at this time is not necessary. However, PHMSA is considering requesting a new or existing industry committee to develop guidelines for a standard approach to the sizing and installation of EFVs. Industry guidelines have already been developed for the implementation of (Distribution Integrity Management Program) DIMP by the GPTC and industry gas associations. PHMSA believes these guidelines should be developed in a more comprehensive manner to include the selection, installation, and performance testing of EFVs for a variety of design considerations and service line configurations. The identification of operating conditions and system configurations that are incompatible with EFVs could also be included in the guidelines.

D. Additional Comments

Only one commenter, MAE, provided additional information and supporting data with regard to additional potential costs and impacts of expanding EFV use. Specifically, MAE stated that it had installed 5,102 EFVs on SFRs in 2010. If applications beyond SFRs were required for service lines, MAE would have installed an additional 1,123 EFVs in 2010. MAE stated the estimated average cost for an EFV is $50.00 and that there would be no anticipated significant impact on the environment.

Several comments from members of the public were received in response to the ANPRM. One commenter, Courtney D. Brown, supported the expanded use of EFVs to protect people in the vicinity of large businesses and/or entertainment venues. Brown commented that the cost of installing EFVs does not outweigh the loss of lives, homes, or businesses when an incident occurs. Commenter Rebecca Lee Roter expressed concern with the lack of regulatory requirements in place for natural gas and transmission lines in Class 1 areas. Roter indicated that these areas required little routine inspection and no emergency plans.

PHMSA Response

PHMSA received several additional comments on the topic of the expanded use of EFVs. The information from MAE was helpful for PHMSA to get a better understanding of the costs and impacts of expanding EFV use. PHMSA has estimated an average cost of $30 per valve—see the initial RIA for further discussion. Additionally, PHMSA is aware of the concern for public safety expressed by Brown and Roter.

III. Section by Section Analysis

Section 192.381 Service Lines: Excess Flow Valve Performance Standards

PHMSA is proposing to revise the language used in § 192.381(a) to remove the words ''single residence''. This change reflects the proposed expansion of EFVs to applications beyond SFRs.

Section 192.383 Excess Flow Valve Installation

PHMSA is proposing to revise § 192.383(b) to include the proposed new categories of service on which EFVs would be installed. The existing category of service (new or replaced service line serving a SFR) would remain. The new categories of service would include branched service lines to a SFR installed concurrently with the primary SFR service line; branched service lines to a SFR installed off a previously installed SFR service line that does not contain an EFV; and small commercial customers and multi-family installations. The existing exceptions for EFV installation found in § 192.383(b)(1) through (4) would remain but would be moved to § 192.383(c)(1) through (4).

PHMSA is proposing the addition of § 192.383(d) to allow existing service line customers the option of requesting an EFV installation on their service line if one or more of the exceptions listed in § 192.383(c)(1) through (4) are not met. Operators would install an EFV at the request of customer on a mutually agreeable date and time. This option would be available to service line customers on existing service lines when the customer applies for service and for a period of 90 days after service has started. Operators will rely upon the appropriate State regulatory agencies to determine who would bear the costs of installation for customer requested EFVs.

With regard to the issue of installation costs of a customer requested EFV, PHMSA has no jurisdiction concerning natural gas rates or any costs incurred due to installation of an optional EFV at a consumer's request. Rather, the appropriate State regulatory agency will determine all issues related to the costs of installation.

PHMSA proposes to add paragraphs (e)(1) through (2) which would require that operators notify existing service line customers of their right to request an EFV in writing. Master meter operators may continuously post a general notification in a prominent location frequented by customers. Operators must also have evidence of customer notification. Operator evidence of notification could include such items as a statement printed on customer bills or mailings. Small Master meters would be ask to prove that they posted a notice at some common location. Each operator must maintain a copy of the customer EFV notice for three years. This notice must be available for inspection by the Administrator or a State agency participating under 49 U.S.C. 60105 or 60106.

Section 192.385 Manual Service Line Shut-Off Valve Installation

PHMSA is proposing the addition of § 192.385 to require the installation of a manual service line shut-off valve, such as a curb valve, when an EFV is not installed in accordance with § 192.383. This proposed section also includes a

definition for ''Manual service line shut-off valve'' to further clarify the applicability of this provision.

V. Regulatory Notices

A. Statutory/Legal Authority for This Rulemaking

This Notice of Proposed Rulemaking is published under the authority of the Federal pipeline safety law (49 U.S.C. 60101 *et seq.*). Section 60102 authorizes the Secretary of Transportation to issue regulations governing design, installation, inspection, emergency plans and procedures, testing, construction, extension, operation, replacement, and maintenance of pipeline service lines. Further, section 60109(e)(3)(B) states that ''the Secretary, if appropriate, shall by regulation require the use of excess flow valves, or equivalent technology, where economically, technically, and operationally feasible on new or entirely replaced distribution branch services, multifamily facilities, and small commercial service facilities.''

B. Executive Order 12866, Executive Order 13563, and DOT Regulatory Policies and Procedures

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review) require agencies to regulate in the ''most cost-effective manner,'' to make a ''reasoned determination that the benefits of the intended regulation justify its costs,'' and to develop regulations that ''impose the least burden on society.'' Expansion of the use of EFVs and curb valves is a non-significant regulatory action under Executive Order 12866 and the Department of Transportation's (DOT's) Regulatory Policies and Procedures. This proposed requirement has been reviewed by the Office of Management and Budget in accordance with Executive Order 13563 and Executive Order 12866 and is consistent with the requirements in both Orders.

During the initial stages of the development of the regulatory evaluation, PHMSA developed the survey recommended by the Interim Evaluation, which was aimed at gathering data on EFV and curb valve costs and benefits. PHMSA intended to send the survey to all operators in order to ensure that any proposed changes were based upon comprehensive and useful data. The goal was to have a better understanding of the costs of EFVs on installations beyond SFRs from those who have deployed them already, and on the costs and effectiveness of curb valves. Nine companies were asked to pilot the census, and a copy was published in the **Federal Register.**

Both the census pilot and the comments to the proposed census published in the **Federal Register** quickly revealed that company databases are not currently set up to provide the necessary data. Load and customer type data are stored separately from data on EFVs and from data on incidents, and grouping customers into the census categories would, in some cases, cost more in labor for the database work and analysis than it would cost to implement this proposed rule itself. As a result of discussions with industry representatives and the NTSB, PHMSA chose to propose a rule similar to the framework included in Section 22 of the Pipeline Safety, Regulatory Certainty, and Job Creation Act of 2011.

The initial Regulatory Impact Analysis (RIA), which is included in the docket for this rulemaking, does not address the benefits and costs of the proposal to require operators to install EFVs on branched service lines servicing SFRs because the benefits and costs of this proposal were addressed in the regulatory impact analysis for a previous rulemaking [8]. The initial RIA found that the estimated monetized benefits do not exceed the monetized costs in all cases. For the proposal to require EFVs on new or replaced service lines servicing MFRs, the monetized costs exceed monetized benefits even when using lower bound cost estimates. PHMSA believes that the proposals are nevertheless justified by the significant unquantifiable benefits, such as avoided evacuations and environmental damage from EFV-preventable incidents, including incidents that could not be included in the analysis because they do not meet PHMSA reporting criteria. EFVs also provide protection against a low-probability but high-consequence incident that could inflict mass casualties.

The proposed rule is assumed to affect approximately 1,289 natural gas distribution operators and 222,114 service lines per year on average. The RIA assumed valves do not have network effects, in other words, each EFV operates independently and the costs and benefits of EFV installation simply scale linearly. The total annual benefits of the rule are $7,735,725 when discounted at 7 percent, while the costs range from $4,381,734 to $17,848,499 depending on the costs of the valve. At the 3% discount rate the total benefits of the rule are $2,748,456, while the costs range from $4,967,145 to $20,311,030. PHMSA requests public comments on its monetized estimates of the proposed rule's benefits and costs.

The following tables summarize the quantified benefits and costs of this proposed rule at the 3 and 7% discount rates:

[8] ''Pipeline Safety: Integrity Management Programs for Gas Distribution Pipelines.'' 74 FR 63906 (December 4, 2009) RIN 2137–AE15.

ESTIMATED BENEFITS AND COSTS: LOW AND HIGH SCENARIOS, 7% DISCOUNT RATE

Category	Number of valves installed, year 1	Annualized benefit	Annualized cost, low scenario ($15 EFV, $10 curb valve)	Annualized cost, from DIMP Analysis ($20–$30 per EFV)	Annualized cost, high scenario ($50 EFV, $100 curb valve)
SFR (as upper bound estimate for Branched SFR)[9].		*$11–27 million*		*$8 million*	
Multi-Family EFV	153,985	$1,144,372	$3,102,295		$10,340,985
Commercial EFV	27,174	$1,434,683	547,467		1,824,890
Industrial/Large Other Curb Valve[10].	40,955	$5,156,671	550,073		5,500,726
Notification and Recordkeeping.			181,899		181,899
Total	222,114	$7,735,725	4,381,734		17,848,499

ESTIMATED BENEFITS AND COSTS: LOW AND HIGH SCENARIOS, 3% DISCOUNT RATE

Category	Number of valves installed, year 1	Annualized benefit	Annualized cost, low scenario ($15 EFV, $10 curb valve)	Annualized cost, high scenario ($50 EFV, $100 curb valve)
Multi-Family EFV	153,985	$1,958,991	$3,534,722	$11,782,405
Commercial EFV	27,174	2,748,456	623,778	2,079,259
Industrial/Large Other Curb Valve	40,955	10,240,363	626,747	6,267,467
Notification and Recordkeeping			181,899	181,899
Total	222,114	14,947,810	4,967,145	20,311,030

Additional unquantified benefit areas include:

- Equity: Provides a fair and equal level of safety to members of society who do not live in single-family residences.
- Additional incident costs avoided for which no PHMSA incident data are available: Mitigates the consequences (death, injury, property damage) of incidents when customer piping or equipment is involved and thus the incident would not be reflected in PHMSA records.
- Additional incident costs which are not recorded in incident reports, including costs of evacuations, emergency response costs, and business downtime.
- Environmental externalities associated with methane release (discussed in Appendix).
- Peace of mind for operators and customers.
- Protection against seismic events and intentional tampering.

PHMSA requests public comments on methods and information sources that could be used to quantify and monetize these unquantified benefits.

C. Executive Order 13132: Federalism

This NPRM has been analyzed in accordance with the principles and criteria contained in Executive Order 13132 (''Federalism''). PHMSA issues pipeline safety regulations applicable to interstate and intrastate pipelines. The requirements in this proposed rule apply to operators of distribution pipeline systems, primarily intrastate pipeline systems. Under 49 U.S.C. 60105, a state may regulate intrastate pipeline facility or intrastate pipeline transportation, after submitting a certification to PHMSA. Thus, state pipeline safety regulatory agencies with a valid certification on file with PHMSA will be the primary enforcer of the safety requirements proposed in this NPRM. Under 49 U.S.C. 60107, PHMSA provides grant money to participating states to carry out their pipeline safety enforcement programs. Although a few states choose not to participate in the natural gas pipeline safety grant program, every state has the option to participate. This grant money is used to defray additional costs incurred by enforcing the pipeline safety regulations.

PHMSA has concluded this proposed rule does not include any regulation that: (1) Has substantial direct effects on states, relationships between the national government and the states, or distribution of power and responsibilities among various levels of government; (2) imposes substantial direct compliance costs on states and local governments; or (3) preempts state law. Therefore, the consultation and funding requirements of Executive Order 13132 (64 FR 43255; August 10, 1999) do not apply.

D. Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires an agency to review regulations to assess their impact on small entities, unless the agency determines that a rule is not expected to have a significant impact on a substantial number of small entities. This NPRM has been developed in accordance with Executive Order 13272 (''Proper Consideration of Small Entities in Agency Rulemaking'') and DOT's procedures and policies to promote

[9] Benefit and cost information is taken from the DIMP rulemaking analysis. No information is available to estimate the proportion of SFR service lines that are branched; PHMSA believes it to be very roughly in the range of 10%. The DIMP analysis used different estimates for the cost of an EFV and used the then-prevailing USDOT values for injury prevention. Although DIMP did not cover branched SFR, benefits and costs were calculated as if they were, because there were no data available to create a more precise estimate.

[10] This category is defined by service characteristics (size, flow) for which a curb valve is more appropriate than an EFV. No data are available on customer classification within the category, though it likely includes larger MFR, commercial and industrial facilities, and other similar customers.

compliance with the Regulatory Flexibility Act to ensure that potential impacts of rules on small entities are properly considered.

This NPRM proposes to require small and large gas pipeline operators to comply with the new EFV installation requirements. The Small Business Administration (SBA) criteria for defining a small entity in the natural gas pipeline distribution industry is one that employs less than 500 employees as specified in the North American Industry Classification System (NAICS) codes.

PHMSA calculated the number of small businesses affected by reviewing annual reports submitted by gas pipeline operators and data provided by Dunn and Bradstreet. PHMSA estimated that of the 1,289 operators who submitted an annual report to PHMSA on their gas distribution activities, 1,221, or 95 percent, of these natural gas operators are classified as being ''small business.'' The natural gas distribution industry does have a substantial number of small entities as defined by the SBA. However, we believe that this rule would not have a significant impact on small entities because the additional costs are minimal: approximately $30 per EFV installed and $55 per curb valve installed. Industry comments have described these additional costs as ''relatively minimal'' [11] and the one-time cost is largely offset by incident cost avoidance over the 50-year lifetime of the valves. The notification and recordkeeping costs associated with the new notification requirement for optional EFV installation are estimated at $42 per firm annually, which is a minimal cost even for the smallest operators.

Accordingly, the head of the agency certifies under Section 605(b) of the RFA that the proposed rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. PHMSA seeks comment on the Initial Regulatory Flexibility Analysis. A copy of the Initial Regulatory Flexibility Analysis has been placed in the docket.

E. Unfunded Mandates Reform Act of 1995

This proposed rule does not impose unfunded mandates under the Unfunded Mandates Reform Act of 1995. It would not result in costs of $147.6 million, adjusted for inflation, or more in any one year to State, local, or tribal governments, in the aggregate, or to the private sector, and is the least burdensome alternative that achieves the objective of the proposed rule. Installation of EFVs and curb valves significantly protects the safety of the public and is technically and economically feasible.

F. National Environmental Policy Act

PHMSA analyzed this NPRM in accordance with section 102(2)(c) of the National Environmental Policy Act (42 U.S.C. 4332), the Council on Environmental Quality regulations (40 CFR parts 1500 through 1508), and DOT Order 5610.1C, and has preliminarily determined that this action will not significantly affect the quality of the human environment. A preliminary environmental assessment of this NPRM is available in the docket, and PHMSA invites comment on the environmental impacts of this proposed rule.

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

This NPRM has been analyzed in accordance with the principles and criteria contained in Executive Order 13175 (''Consultation and Coordination with Indian Tribal Governments''). Because this NPRM does not have tribal implications and does not impose substantial direct compliance costs on Indian tribal governments, the funding and consultation requirements of Executive Order 13175 do not apply.

H. Executive Order 13211: Energy Supply, Distribution, or Use

This proposed rule is not a ''significant energy action'' under Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use). It is not likely to have a significant adverse effect on supply, distribution, or energy use. The Office of Information and Regulatory Affairs has not designated this proposed rule as a significant energy action.

I. Paperwork Reduction Act

Pursuant to 5 CFR 1320.8(d), PHMSA is required to provide interested members of the public and affected agencies with an opportunity to comment on information collection and recordkeeping requests. As a result of the requirements proposed in this notice of proposed rulemaking, the following information collection impacts are expected:

Gas Distribution Annual Report Revision

PHMSA is proposing to revise § 192.383, to require the installation of EFVs beyond single family residences as currently required. Further, PHMSA is proposing to add § 192.385 which would require the installation of manual service line shut-off valves. As a result, PHMSA wants to track the number of new installations related to these provisions on an annual basis. This will lead to changes to the Gas Distribution Annual Report which is contained in the currently approved information collection titled ''Annual Report for Gas Distribution Operators'' identified under OMB Control Number 2137–0629. PHMSA proposes to revise the Gas Distribution Annual report to collect the number of EFVs installed on multi-family dwellings and small commercial businesses and the number of manual service line shut-off valves installed. Currently, operators are required to submit the total number of excess flow valves installed on single-family residences and the total number of EFVs within their system. Therefore, PHMSA does not expect operators to experience an increase in burden beyond the burden currently estimated for the Gas Distribution Annual Report.

Customer Notification

PHMSA proposes to revise § 192.383 to require operators to notify customers of their right to request the installation of EFVs. PHMSA estimates that approximately half of the 6,184 operators categorized as either master meter operators or small LPG systems will be impacted, resulting in 3,092 operators. This estimate is based on the premise that only half of these operators have systems that can accommodate an EFV. PHMSA also estimates that 1,289 gas distribution operators will be impacted. Therefore PHMSA estimates a total impacted community of 4,381 (3,092 master meter/small LPG operators and 1,289 gas distribution operators). PHMSA estimates that each impacted operator will take approximately 30 minutes per year to complete this notification and an additional 30 minutes per year to maintain the associated records. Therefore, PHMSA will request a new information collection to address these reporting and recordkeeping requirements.

As a result of the changes listed above, PHMSA proposes to submit an information collection revision request as well as a new information collection request to OMB for approval based on the requirements in this proposed rule. These information collections are contained in the pipeline safety regulations, 49 CFR parts 190 through 199. The following information is provided for these information

[11] PHMSA–2012–0086–0003, Comment by the American Gas Association, submitted July 17, 2012, pg. 2.

collections: (1) Title of the information collection; (2) OMB control number; (3) Current expiration date; (4) Type of request; (5) Abstract of the information collection activity including a description of the changes applicable to the rulemaking action; (6) Description of affected public; (7) Estimate of total annual reporting and recordkeeping burden; and (8) Frequency of collection. The information collection burden for the following information collection will be requested as follows:

1. Title: Annual Report for Gas Distribution Operators.

OMB Control Number: 2137–0629.

Current Expiration Date: May 31, 2018.

Type of Request: Revision.

Abstract: This information collection covers the collection of annual report data for information from Gas distribution pipeline operators for Incidents and Annual reports. This information collection will only be revised to reflect the amendment to the Gas Distribution Annual Report which will not result in a burden hour increase.

Affected Public: Gas Distribution Pipeline Operators.

Annual Reporting and Recordkeeping Burden:

Total Annual Responses: 1,440. (no change).

Total Annual Burden Hours: 2,300. (no change).

Frequency of Collection: Annual.

2. Title: Customer Notifications for Installation of Excess Flow Valves.

OMB Control Number: TBD.

Current Expiration Date: Not Applicable.

Type of Request: New Information Collection.

Abstract: This new information collection will cover the reporting and recordkeeping requirements for gas pipeline operators associated with customer notifications pertaining to the installation of excess flow valves.

Affected Public: Gas Pipeline Operators.

Annual Reporting and Recordkeeping Burden:

Total Annual Responses: 4,381 responses.

Total Annual Burden Hours: 4,381 hours.

Frequency of Collection: On occasion.

Requests for a copy of this information collection should be directed to Cameron Satterthwaite, Office of Pipeline Safety (PHP–30), Pipeline and Hazardous Materials Safety Administration (PHMSA), 2nd Floor, 1200 New Jersey Avenue SE, Washington, DC 20590–0001, Telephone 202–366–4595.

J. Privacy Act Statement

Anyone is able to search the electronic form of all comments received for any dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (65 FR 19477), or at *http://www.regulations.gov.*

K. Regulation Identifier Number

A regulation identifier number (RIN) is assigned to each regulatory action listed in the Unified Agenda of Federal Regulations. The Regulatory Information Service Center publishes the Unified Agenda in April and October of each year. The RIN contained in the heading of this document may be used to cross-reference this action with the Unified Agenda.

List of Subjects in 49 CFR Part 192

Excess flow valve installation, Excess flow valve performance standards, Pipeline safety, Service lines.

In consideration of the foregoing, PHMSA proposes to amend 49 CFR part 192 as follows:

PART 192—TRANSPORTATION OF NATURAL AND OTHER GAS BY PIPELINE: MINIMUM FEDERAL SAFETY STANDARDS

■ 1. The authority citation for part 192, as revised at 80 FR 12762 (March 11, 2015), effective October 1, 2015, continues to read as follows:

Authority: 49 U.S.C. 5103, 60102, 60104, 60108, 60109, 60110, 60113, 60116, 60118, and 60137, and 49 CFR 1.97.

■ 2. In § 192.381, the introductory text of paragraph (a) is revised to read as follows:

§ 192.381 Service lines: Excess flow valve performance standards.

(a) Excess flow valves to be used on service lines that operate continuously throughout the year at a pressure not less than 10 p.s.i. (69 kPa) gage must be manufactured and tested by the manufacturer according to an industry specification, or the manufacturer's written specification, to ensure that each valve will:

* * * * *

■ 3. Section 192.383 is revised to read as follows:

§ 192.383 Excess flow valve installation.

(a) *Definitions.* As used in this section:

Replaced service line means a gas service line where the fitting that connects the service line to the main is replaced or the piping connected to this fitting is replaced.

Service line serving single-family residence (SFR) means a gas service line that begins at the fitting that connects the service line to the main and serves only one SFR.

(b) *Installation required.* An excess flow valve (EFV) installation must comply with the performance standards in § 192.381. After January 3, 2014, each operator must install an EFV on any new or replaced services line serving the following types of services before the line is activated:

(1) A single service line to one SFR;

(2) A branched service line to a SFR installed concurrently with the primary SFR service line (*i.e.,* a single EFV may be installed to protect both service lines);

(3) A branched service line to a SFR installed off a previously installed SFR service line that does not contain an EFV;

(4) Multi-family residences with known customer loads not exceeding 1,000 SCFH per service, at time of service installation based on installed meter capacity, and

(5) A single, small commercial customer served by a single service line with a known customer load not exceeding 1,000 SCFH, at the time of meter installation, based on installed meter capacity.

(c) *Exceptions to excess flow valve installation requirement.* An operator need not install an excess flow valve if one or more of the following conditions are present:

(1) The service line does not operate at a pressure of 10 psig or greater throughout the year;

(2) The operator has prior experience with contaminants in the gas stream that could interfere with the EFV's operation or cause loss of service to a customer;

(3) An EFV could interfere with necessary operation or maintenance activities, such as blowing liquids from the line; or

(4) An EFV meeting performance standards in § 192.381 is not commercially available to the operator.

(d) *Customer's right to request an EFV.* Existing service line customers, who desire an EFV on service lines not exceeding 1,000 SFCH and not meeting the conditions in paragraph (b) of this section, may request an EFV be installed on their service line. If a service line customer requests EFV installation, an operator must install the EFV at a mutually agreeable date. The appropriate State regulatory agency

determines whom and/or how the costs of the requested EFVs are distributed.

(e) *Operator notification of customers concerning EFV installation.* Operators must notify customers of their right to request an EFV in the following manner:

(1) Except as specified in paragraph (e)(2) of this section, each operator must provide written notification to the customer of their right to request the installation of an EFV within 90 days of the customer first receiving gas at a particular location.

(2) Operators of master meter systems may continuously post a general notification in a prominent location frequented by customers.

(f) *Operator evidence of customer notification.* Each operator must maintain a copy of the customer EFV notice for three years. This notice must be available for inspection by the Administrator or a State agency participating under 49 U.S.C. 60105 or 60106.

(g) *Reporting.* Each operator must report the EFV measures detailed in the annual report required by § 191.11 of this chapter.

■ 4. Section 192.385 is added to subpart H to read as follows:

§ 192.385 Manual service line shut-off valve installation.

(a) *Definitions.* As used in this section:

Manual service line shut-off valve means a curb valve or other manually operated valve located near the service main or a common source of supply that is accessible to first responders and operator personnel to manually shut off gas flow to the service line in the event of an emergency.

(b) The operator must install a manual service line shut-off valve for any new or replaced service line, with installed meter capacity exceeding 1,000 SCFH.

(c) Manual service line shut-off valves for any new or replaced service line must be installed in such a way to allow accessibility during emergencies.

Issued in Washington, DC, on July 7, 2015, under authority delegated in 49 CFR 1.97.

Jeffrey D. Wiese,

Associate Administrator for Pipeline Safety.

[FR Doc. 2015–17195 Filed 7–14–15; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

RIN 0648–BE38

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Snapper-Grouper Fishery and Golden Crab Fishery of the South Atlantic, and Dolphin and Wahoo Fishery of the Atlantic

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

ACTION: Notice of availability; request for comments.

SUMMARY: The South Atlantic Fishery Management Council (Council) has submitted Amendment 34 to the Fishery Management Plan (FMP) for the Snapper-Grouper Fishery of the South Atlantic Region, Amendment 9 to the FMP for the Golden Crab Fishery of the South Atlantic Region, and Amendment 8 to the FMP for the Dolphin and Wahoo Fishery of the Atlantic; collectively referred to as the Generic Accountability Measures (AMs) and Dolphin Allocation Amendment (Generic AM Amendment) for review, approval, and implementation by NMFS. If approved by the Secretary of Commerce, the Generic AM Amendment would revise the commercial and recreational AMs for numerous snapper-grouper species and golden crab. This amendment would also revise commercial and recreational sector allocations for dolphin in the Atlantic. The proposed actions are intended to make the AMs consistent for the snapper-grouper species addressed in this amendment and for golden crab, and revise the allocations between the commercial and recreational sectors for dolphin.

DATES: Written comments on the Generic AM Amendment must be received on or before September 14, 2015.

ADDRESSES: You may submit comments on the proposed amendment and environmental assessment identified by ''NOAA–NMFS–2013–0181'' by either of the following methods:

• *Electronic Submission:* Submit all electronic comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2013-0181,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.

• *Mail:* Submit all written comments to Mary Janine Vara, NMFS Southeast Regional Office (SERO), 263 13th Avenue South, St. Petersburg, FL 33701.

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, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Electronic copies of the Generic AM Amendment may be obtained from *www.regulations.gov* or the Southeast Regional Office Web site at *http://sero.nmfs.noaa.gov.* The Generic AM Amendment includes an environmental assessment, initial regulatory flexibility analysis (IRFA), regulatory impact review, and fishery impact statement.

FOR FURTHER INFORMATION CONTACT: Mary Janine Vara, NMFS SERO, telephone: 727–824–5305, or email: *mary.vara@noaa.gov.*

SUPPLEMENTARY INFORMATION: The Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) requires each regional fishery management council to submit any fishery management plan or amendment to NMFS for review and approval, partial approval, or disapproval. The Magnuson-Stevens Act also requires that NMFS, upon receiving a plan or amendment, publish an announcement in the **Federal Register** notifying the public that the plan or amendment is available for review and comment.

Actions Contained in the Generic AM Amendment

Modifications to AMs for Snapper-Grouper Species and Golden Crab

This amendment would revise the AMs for golden tilefish, snowy grouper, gag, red grouper, black grouper, scamp, the shallow-water grouper complex, greater amberjack, the other jacks complex, bar jack, yellowtail snapper, mutton snapper, the other snappers complex, gray triggerfish, wreckfish (recreational sector), Atlantic spadefish, hogfish, red porgy, the other porgies complex, and golden crab (commercial sector).

Currently, the snapper-grouper species and golden crab addressed in

this amendment have slightly different AMs in place compared to other snapper-grouper species. The Generic AM Amendment intends to modify the AMs for these species and species complexes to make them consistent with the majority of AMs already in place for other snapper-grouper species. Specifically, the recreational AMs would be updated to allow NMFS to close the recreational sectors in-season when the recreational ACLs are met or projected to be met. The proposed action would also modify the AMs to trigger post-season reductions in the following year's catch limit in the commercial and recreational sectors if the species, or one or more species in a species complex, is overfished and the total (commercial and recreational combined) ACL has been exceeded. Additionally, for the recreational sector, the fishing season may also be shortened to compensate for a total ACL overage in the previous year if the species or one or more species in a species complex is overfished. Modifying the AMs in this manner would create regulatory consistency among most federally managed species in the South Atlantic region.

Modifications to Commercial and Recreational Sector Allocations for Dolphin

The Generic AM Amendment revises the sector allocations for dolphin. The current sector allocations for dolphin are 92.46 percent for the recreational sector and 7.54 percent for the commercial sector. The Council chose these allocations using a sector allocation formula where 50 percent of the sector allocations are based on landings from a longer time series (1999–2008) and 50 percent of the sector allocations are based on landings from a shorter time series (2006–2008). This results in the current annual catch limits (ACL) of 1,157,001 lb (524,807 kg), round weight, for the commercial sector and 14,187,845 lb (6,435,498 kg), round weight, for the recreational sector. The Generic AM Amendment would revise the sector allocation formula for dolphin to be based on the average of the percentages of the total catch for 2008–2012. The recreational sector allocation for dolphin would be 90 percent with an ACL of 13,810,361 lb (6,264,274 kg), round weight, and the commercial sector allocation would be 10 percent with an ACL of 1,534,485 lb (696,031 kg), round weight.

The Council has submitted the Generic AM Amendment for Secretarial review, approval, and implementation. The decision to approve, partially approve, or disapprove the Generic AM Amendment will be based, in part, on consideration of comments, recommendations, and information received during the comment period on this notice of availability.

Proposed Rule for the Generic AM Amendment

A proposed rule that would implement the Generic AM Amendment has been drafted. In accordance with the Magnuson-Stevens Act, NMFS is evaluating the proposed rule to determine whether it is consistent with the FMP, the Magnuson-Stevens Act, and other applicable laws. If that determination is affirmative, NMFS will publish the proposed rule in the **Federal Register** for public review and comment.

Consideration of Public Comments

Comments received by September 14, 2015 will be considered by NMFS in the decision to approve, disapprove, or partially approve the amendment. Comments received after that date will not be considered by NMFS in this decision. All comments received by NMFS on the amendment or the proposed rule during their respective comment periods will be addressed in the final rule.

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

Dated: July 10, 2015.

Emily H. Menashes,

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

[FR Doc. 2015–17334 Filed 7–14–15; 8:45 am]

BILLING CODE 3510–22–P

Notices

Federal Register

Vol. 80, No. 135

Wednesday, July 15, 2015

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

Beginning Farmers and Ranchers Advisory Committee

AGENCY: Office of Advocacy and Outreach, USDA.

ACTION: Notice of public meeting.

SUMMARY: Pursuant to the Federal Advisory Committee Act (FACA), the Office of Advocacy and Outreach (OAO) is announcing a meeting of the Beginning Farmers and Ranchers Advisory Committee's (BFRAC). The committee is being convened to consider issues involving access to land, farm business transition, and land tenure. The members will deliberate on recommendations to be prepared for USDA Secretarial consideration.

DATES: The committee meeting is scheduled for Monday and Tuesday, August 3 and 4, 2015, from 8:00 a.m.–4:30 p.m. CST. The meeting will be open to the public. All persons wishing to make comments during this meeting must check in between 8:00 a.m. and 9:00 a.m. and 2:00 p.m. and 3:00 p.m. CST, on both days, at the registration table. All public commenters will be allowed a maximum of three minutes. If the number of registrants requesting to speak is greater than what can be reasonably accommodated during the scheduled open public meeting timeframe, speakers will be scheduled on a first-come basis. Public written comments for the committee's consideration may be submitted by close of business on July 31, 2015, to Mrs. Kenya Nicholas, Designated Federal Official, USDA OAO, 1400 Independence Avenue SW., Room 520–A, Washington, DC 20250–0170, Phone (202) 720–6350, Fax (202) 720–7704, *Email: acbfr@osec.usda.gov.* Written submissions are encouraged to either be less than one page in length, or be accompanied by an executive summary and a summary of policy initiatives. A listen-only line will be available during the entire meeting for all who wish to listen in on the meeting or make public comments through the following telephone number: (800) 369–1878 and enter passcode 2814434. Members of the public may also submit written comments for consideration to the committee.

ADDRESSES: This public advisory committee meeting will be held at the Kansas City Airport Marriott, 775 Brasilia Avenue, Kansas City, MO 64153. The meeting will be in conference rooms Salon A and Salon B. There will also be signs directing attendees to the meeting rooms.

FOR FURTHER INFORMATION CONTACT: Questions should be directed to Phyllis Morgan, Executive Assistant, OAO, 1400 Independence Ave. SW., Whitten Bldg., 520–A, Washington, DC 20250, Phone: (202) 720–6350, Fax: (202) 720–7136, email: *Phyllis.Morgan@osec.usda.gov.*

SUPPLEMENTARY INFORMATION: The BFRAC Subcommittee on Land Tenure met in Des Moines, Iowa, on June 22 and 23, 2015. The Secretary tasked the BFRAC with providing recommendations on access to land, farm business transition, and land tenure. Prior to that meeting, the BFRAC met in Austin, TX on September 23–24, 2015, to deliberate upon the final set of recommendations for the Secretary on issues involving communications, service, and advocacy in identifying barriers for beginning farmers and ranchers. They also considered issues around lending and credit in parsing statistics generated by USDA. Please visit our Web site at: *http://www.outreach.usda.gov/smallbeginning/index.htm* for additional information on the BFRAC.

The public is asked to pre-register for the meeting by July 31, 2015. You may pre-register for the public meeting by submitting an email to *acbfr@osec.usda.gov* with your name, organization or affiliation, or any comments for the committee's consideration. You may also fax this information to (202) 720–7704. Members of the public who wish to make comments during the committee meeting must register at the check-in table.

The agenda is as follows: Day 1: Committee discussions and public comments; Day 2: Committee discussions, public comments, and committee deliberations. Please visit the Beginning Farmers and Ranchers Advisory Committee Web site for the full agenda. All agenda topics and documents will be made available to the public at: *http://www.outreach.usda.gov/smallbeginning/index.htm.* Copies of the agenda will also be distributed at the meeting.

Meeting Accommodations: USDA is committed to ensuring that everyone is accommodated in our work environment, programs, and events. If you are a person with a disability and request reasonable accommodations to participate in this meeting, please note the request in your registration and you may contact Mrs. Kenya Nicholas in advance of the meeting by or before close of business on July 31, 2015, by phone at (202) 720–6350, fax (202) 720–7704, or email: *kenya.nicholas@osec.usda.gov.*

Christian Obineme,

Associate Director, Office of Advocacy and Outreach.

[FR Doc. 2015–17389 Filed 7–14–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS–2015–0030]

Notice of Request To Renew an Approved Information Collection (Petitions for Rulemaking)

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 and Office of Management and Budget (OMB) regulations, the Food Safety and Inspection Service (FSIS) is announcing its intention to renew the approved information collection regarding petitions for rulemaking. FSIS is making no changes to the approved collection. The approval for this information collection will expire on October 31, 2015.

DATES: Submit comments on or before September 14, 2015.

ADDRESSES: FSIS invites interested persons to submit comments on this information collection. Comments may

be submitted by one of the following methods:

• *Federal eRulemaking Portal:* This Web site provides the ability to type short comments directly into the comment field on this Web page or attach a file for lengthier comments. Go to *http://www.regulations.gov.* Follow the on-line instructions at that site for submitting comments.

• *Mail, including CD–ROMs, etc.:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Docket Clerk, Patriots Plaza 3, 1400 Independence Avenue SW., Mailstop 3782, Room 8–163A, Washington, DC 20250–3700.

• *Hand- or courier-delivered submittals:* Deliver to Patriots Plaza 3, 355 E Street SW., Room 8–163A, Washington, DC 20250–3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2015–0022. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to *http://www.regulations.gov.*

Docket: For access to background documents or comments received, go to the FSIS Docket Room at Patriots Plaza 3, 355 E Street SW., Room 8–164, Washington, DC 20250–3700 between 8:00 a.m. and 4:30 p.m., Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Gina Kouba, Paperwork Reduction Act Coordinator, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW., Room 6067, South Building, Washington, DC 20250; (202) 690–6510.

SUPPLEMENTARY INFORMATION:

Title: Petitions for Rulemaking.

OMB Control Number: 0583–0136.

Type of Request: Renewal of an approved information collection.

Abstract: FSIS has been delegated the authority to exercise the functions of the Secretary (7 CFR 2.18, 2.53) as specified in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601, *et seq.*), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, *et seq.*), and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031, *et seq.*). FSIS protects the public by verifying that meat, poultry, and egg products are safe, wholesome, not adulterated, and correctly labeled.

The Administrative Procedure Act requires that Federal agencies give interested persons the right to petition for issuance, amendment, or repeal of a rule (5 U.S.C. 553(e)).

FSIS has regulations to govern the submission to the Agency of petitions for rulemaking (9 CFR part 392). These regulations are designed to encourage the filing of well-supported petitions that contain information that the Agency needs to evaluate a requested rulemaking in a timely manner. FSIS uses the information associated with a petition to assess the merits of the requested action and to determine whether to issue, amend, or repeal regulations in response to the petition.

FSIS is requesting a renewal of the approved information collection addressing paperwork requirements regarding petitions submitted to the Agency. FSIS is making no changes to the approved collection.

FSIS has made the following estimates based upon an information collection assessment.

Estimate of Burden: FSIS estimates that it takes respondents an average of 40 hours per year to complete and submit a petition.

Respondents: Official establishments, official plants, firms, trade associations, and public interest groups.

Estimated Number of Respondents: 10.

Estimated Number of Responses per Respondent: 1.

Estimated Total Annual Burden on Respondents: 400 hours. Copies of this information collection assessment can be obtained from Gina Kouba, Paperwork Reduction Act Coordinator, Food Safety and Inspection Service, USDA, 1400 Independence, SW., Room 6077, South Building, Washington, DC 20250, (202) 690–6510.

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of FSIS's functions, including whether the information will have practical utility; (b) the accuracy of FSIS's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology. Comments may be sent to both FSIS, at the addresses provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20253.

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.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS Web page located at: *http://www.fsis.usda.gov/federal-register.*

FSIS also will make copies of this publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: *http://www.fsis.usda.gov/subscribe.* Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

USDA Non-Discrimination Statement

No agency, officer, or employee of the USDA shall, on the grounds of race, color, national origin, religion, sex, gender identity, sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, or political beliefs, exclude from participation in, deny the benefits of, or subject to discrimination any person in the United States under any program or activity conducted by the USDA.

How To File a Complaint of Discrimination

To file a complaint of discrimination, complete the USDA Program Discrimination Complaint Form, which may be accessed online at *http://www.ocio.usda.gov/sites/default/files/docs/2012/Complain_combined_6_8_12.pdf,* or write a letter signed by you or your authorized representative.

Send your completed complaint form or letter to USDA by mail, fax, or email:

Mail

U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW., Washington, DC 20250–9410, Fax: (202) 690–7442, Email: *program.intake@usda.gov.*

Persons with disabilities who require alternative means for communication (Braille, large print, audiotape, etc.), should contact USDA's TARGET Center at (202) 720–2600 (voice and TDD).

Done at Washington, DC, on July 10, 2015.

Alfred V. Almanza,

Acting Administrator.

[FR Doc. 2015–17338 Filed 7–14–15; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–970]

Multilayered Wood Flooring From the People's Republic of China: Final Results of Antidumping Duty Administrative Review and Final Results of New Shipper Review; 2012–2013

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

SUMMARY: On January 9, 2015, the Department of Commerce (''the Department'') published the preliminary results of a new shipper review (''NSR'') and the second administrative review (''AR'') of the antidumping duty (''AD'') order on multilayered wood flooring (''MLWF'') from the People's Republic of China (''the PRC''), in accordance with sections 751(a)(1)(B) and 751(a)(2)(B) of the Tariff Act of 1930, as amended (''the Act'').[1] The period of review (''POR'') for the AR and NSR is December 1, 2012, through November 30, 2013. The NSR covers one producer/exporter of subject merchandise: Linyi Anying Wood Co., Ltd., (''Anying'').[2] The AR covers 69 companies. The mandatory respondents in this review are: (1) Dalian Dajen Wood Co., Ltd. (''Dajen'') and (2) Jiangsu Senmao Bamboo and Wood Products Co., Ltd. (''Senmao''). We invited interested parties to comment on our *NSR Preliminary Results* and *Preliminary Results.* No parties commented on the *NSR Preliminary Results.* Accordingly, we continue to find that Anying has not made sales of subject merchandise at less than normal value. For the AR, we received comments from interested parties. Based on our analysis of the comments received, we made changes to the margin calculations for the final results of the AD AR. The final dumping margins are listed below in the ''Final Results'' section of this notice.

DATES: *Effective date:* July 15, 2015.

FOR FURTHER INFORMATION CONTACT: Lilit Astvatsatrian, Maisha Cryor, or William Horn, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–6412, (202) 482–5831, or (202) 482–2615, respectively.

Background

As noted above, on January 9, 2015, the Department published its *NSR Preliminary Results* and *Preliminary Results.* The Department invited parties to submit case briefs and hearing requests related to the *NSR Preliminary Results* and *Preliminary Results.* No briefs or hearing requests were received regarding the *NSR Preliminary Results.* On February 9, 2015, regarding the *Preliminary Results,* the Department received case briefs from Old Master Products Inc. (''Old Master''); Lumber Liquidators Services, LLC (''Lumber Liquidators''); Linyi Bonn Flooring Manufacturing Co., Ltd. (''Linyi Bonn''); Baishan Huafeng Wood Product Co. Ltd.,. (collectively, ''Baishan'');[3] Fine Furniture (Shanghai) Limited (''Fine Furniture''); Dajen, Senmao, and various separate rate applicants (collectively, ''Dajen/Senmao''); Armstrong Wood Products (Kunshan) Co. Ltd. and Armstrong World Industries (collectively, ''Armstrong''); the Alliance for Free Choice and Jobs in Flooring;[4] and the Coalition for American Hardwood Parity (''CAHP'').[5] On February 18, 2015, the Department received rebuttal briefs from Fine Furniture, Dajen/Senmao, and CAHP. On February 25, 2015 the Department received the resubmission of its February 18 rebuttal brief from Lumber Liquidators. On February 9, 2015 the Department received requests for a hearing from Fine Furniture, CAHP, Old Master, and Dajen/Senmao regarding the second administrative review. Various interested parties participated in a public hearing on April 1, 2015. On April 22, 2015, we extended the time period for issuing the final results of the AR and NSR by 60 days, until July 8, 2015.

Scope of the Order

The merchandise covered by the order includes MLWF, subject to certain exceptions.[6] Imports of the subject merchandise are provided for under the following subheadings of the HTSUS: 4412.31.0520; 4412.31.0540; 4412.31.0560; 4412.31.2510; 4412.31.2520; 4412.31.4040; 4412.31.4050; 4412.31.4060; 4412.31.4070; 4412.31.5125; 4412.31.5135; 4412.31.5155; 4412.31.5165; 4412.31.6000; 4412.31.9100; 4412.32.0520; 4412.32.0540; 4412.32.0560; 4412.32.2510; 4412.32.2520; 4412.32.3125; 4412.32.3135; 4412.32.3155; 4412.32.3165; 4412.32.3175; 4412.32.3185; 4412.32.5600; 4412.39.1000; 4412.39.3000; 4412.39.4011; 4412.39.4012; 4412.39.4019; 4412.39.4031; 4412.39.4032; 4412.39.4039; 4412.39.4051; 4412.39.4052; 4412.39.4059; 4412.39.4061; 4412.39.4062; 4412.39.4069; 4412.39.5010; 4412.39.5030; 4412.39.5050; 4412.94.1030; 4412.94.1050; 4412.94.3105; 4412.94.3111; 4412.94.3121; 4412.94.3131; 4412.94.3141; 4412.94.3160; 4412.94.3171; 4412.94.4100; 4412.94.5100; 4412.94.6000; 4412.94.7000; 4412.94.8000; 4412.94.9000; 4412.94.9500; 4412.99.0600; 4412.99.1020; 4412.99.1030; 4412.99.1040; 4412.99.3110; 4412.99.3120; 4412.99.3130; 4412.99.3140; 4412.99.3150; 4412.99.3160; 4412.99.3170; 4412.99.4100; 4412.99.5100; 4412.99.5710;

[1] *See Multilayered Wood Flooring from the People's Republic of China; Preliminary Results of Antidumping Duty New Shipper Review; 2012–2013,* 80 FR 1391 (January 9, 2015) (''*NSR Preliminary Results*''), and accompanying Preliminary Decision Memorandum; *Multilayered Wood Flooring from the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review; 2012–2013,* 80 FR 1388 (January 9, 2015) (''*Preliminary Results*'') and accompanying Preliminary Decision Memorandum.

[2] *See NSR Preliminary Results.*

[3] *see* Memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Lynn M. Fischer Fox Deputy Assistant Secretary for Policy & Negotiation, dated and issued concurrently with this notice, regarding ''Issues and Decision Memorandum for Final Results of 2012–2013 Antidumping Duty Administrative Review of Multilayered Wood Flooring from the People's Republic of China'' (''Issues and Decision Memorandum'') at 1 for a full list.

[4] The Alliance for Free Choice and Jobs in Flooring consists of the following domestic producers of the like product: Swiff Train Co.; Metropolitan Hardwood Floors, Inc.; Real Wood Floors, LLC.; Galleher Corp; Crescent Hardwood Supply; Custom Wholesale Floors, Inc.; Urban Global LLC; Pinnacle Interior Elements, Ltd.; Timeless Design Import LCC; CDC Distributors, Inc.; CLBY Inc. (dba D&M Flooring); Johnson's Premium Hardwood Flooring, Inc.; The Master's Craft Corp.; BR Custom Surface; Doma Source LLC; Wego Chemical & Chemical & Mineral Corp. and V.A.L. Floors, Inc.

[5] The member-companies of the CAHP are as follows: Anderson Hardwood Floors, LLC; From the Forest; Howell Hardwood Flooring; Mannington Mills, Inc.; Nydree Flooring; and Shaw Industries Group, Inc.

[6] For a complete description of the scope of the order, *see Issues and Decision Memorandum.*

4412.99.6000; 4412.99.7000; 4412.99.8000; 4412.99.9000; 4412.99.9500; 4418.71.2000; 4418.71.9000; 4418.72.2000; 4418.72.9500; and 9801.00.2500.[7] While HTSUS subheadings are provided for convenience and customs purposes, the written description of the subject merchandise is dispositive.

Final Determination of No Shipments

In the *Preliminary Results,* we found that Anhui Longhua Bamboo Product Co., Ltd., Benxi Wood Company, Guangzhou Homebon Timber Manufacturing Co., Ltd., Jiaxing Brilliant Import & Export Co. Ltd., Pinge Timber Manufacturing (Zhejiang) Co., Ltd., Power Dekor Group Co., Ltd., and Shenyang Senwang Wooden Industry Co., Ltd. had no shipments during the POR.[8] Additionally, we found that Dalian Huade Wood Product Co., Ltd. and Zhejiang Fuerjia Wooden Co., Ltd. did not have any qualifying shipments for the Department to review, due to their certification that their only POR shipments underwent review during their respective NSRs. We did not receive comments with respect to any of these companies. Thus, for these final results of review, we continue to find that those companies had no shipments during the POR. Consistent with our ''automatic assessment'' clarification, we will issue appropriate instructions with respect to these companies to U.S. Customs and Border Protection (''CBP'') based on our final results.[9]

Analysis of Comments Received

All issues raised in the case and rebuttal briefs filed by parties in the AR are addressed in the Issues and Decision Memorandum, which is hereby adopted by this notice. A list of the issues that parties raised and to which we responded in the Issues and Decision Memorandum follows as an appendix to this notice. The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (''ACCESS''). ACCESS is available to registered users at *http://access.trade.gov* and in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at *http://enforcement.trade.gov/frn/.* The paper copy and electronic version 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 regarding our *Preliminary Results,* we made revisions to the margin calculations for Dajen and Senmao.[10] These changes are discussed in the relevant sections of the Issues and Decision Memorandum and company-specific analysis memoranda, as appropriate.

Separate Rates and Partial Rescission

In our *Preliminary Results,* we determined that eight separate rate applicant companies and 60 separate rate certifier companies demonstrated their eligibility for separate rate status.[11] Subsequent to the publication of the *Preliminary Results,* we received comments from Baroque Timber Industries (Zhongshan) Co., Ltd., Riverside Plywood Corporation, Samling Elegant Living Trading (Labuan) Limited, and Samling Riverside Co. Limited (collectively, the ''Samling Group'') noting that the Samling Group was recognized in the final results of the first administrative review to be excluded from the AD order on MLWF pursuant to court order.[12] Samling Group further requested rescission of its administrative review for the second review period as its entries are not subject to the AD order.

The Department agrees that Samling Group and another company subject to this review, Zhejiang Layo Wood Industry Co., Ltd. (''Layo Wood''), have been excluded from the AD order on MLWF as a result of litigation.[13] Further, both Samling Group and Layo Wood certified for this review that they did not export subject merchandise to the United States other than from the manufacturer/exporter combination specifically excluded from the order following the investigation, and the shipment data that we examined did not show U.S. entries of subject merchandise during the POR from other producer/exporter combinations.[14] Therefore, we are rescinding the review with respect to the Samling Group and Layo Wood. No other changes have been made for the separate rate companies listed in the *Preliminary Results.*

Final Results of the New Shipper Review and AR

Regarding the *NSR Preliminary Results,* no interested parties filed case briefs in response to the Department's invitation to comment on the *NSR Preliminary Results.* Therefore, because the record contains no other information or evidence that calls into question our *NSR Preliminary Results,* for these final results, the Department has made no changes to its calculations announced in the *NSR Preliminary Results.* Therefore, for the final results of the NSR, the Department continues to determine that the following weighted-average dumping margin exists for the POR from December 1, 2012, through November 30, 2013:

Exporter	Producer	Weighted-average dumping margin percent)
Linyi Anying Wood Co., Ltd.	Linyi Anying Wood Co., Ltd.	0.00

Regarding the AR, we determine that the following weighted-average dumping margins exist for the POR from December 1, 2012, through November 30, 2013:

[7] On August 28, 2013, in consultation with CBP, the Department added the following HTSUS classification to the AD/CVD module for wood flooring: 9801.00.2500. *See* Letter to the File from Lilit Astvatsatrian, Case Analyst, Enforcement and Compliance, Office IV, regarding ''Multilayered Wood Flooring from the PRC, Modification of the Case Reference File in ACE,'' (November 18, 2013).

[8] *See Preliminary Results,* 80 FR at 1389 n. 4.

[9] *See Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 4, 2011); *see also* the ''Assessment'' section of this notice, below.

[10] *See* Issues and Decision Memorandum.

[11] *See* Preliminary Decision Memorandum.

[12] *See* Letter from Samling Group re: Samling Group Request for Correction of Preliminary Results (January 8, 2015).

[13] *See Multilayered Wood Flooring from the People's Republic of China: Notice of Court Decision Not in Harmony With the Final Determination and Amended Final Determination of the Antidumping Duty Investigation,* 79 FR 25109 (May 2, 2014).

[14] See Liquidation Instructions for MLWF from the PRC, produced and exported by the Samling Group, CBP Message No. 4143304 (May, 23, 2014).

[15] The *Initiation Notice* (*Initiation of Antidumping and Countervailing Duty Administrative Reviews and Request for Revocation in Part,* 79 FR 6147 (February 3, 2014)) included Hangzhou Dazhuang Floor Co. (dba Dasso Industrial Group Co., Ltd.); however, Dasso Industrial Group Co., Ltd. (''Dasso'') certified in its March 21, 2014 separate-rate certification that it no longer uses the name Hangzhou Dazhuang Floor Co., Ltd., and did not use that name during the POR. Therefore, the separate-rate status applies only to Dasso.

[16] The following companies are collectively known as The Fusong Jinlong Group (''Fusong Jinlong Group''): Dalian Qianqiu Wooden Product Co., Ltd.; Fusong Jinlong Wooden Group Co., Ltd.; Fusong Jinqiu Wooden Product Co., Ltd.; and Fusong Qianqiu Wooden Product Co., Ltd.

[17] The Department determined that Linyi Youyou Wood Co., Ltd. is the successor-in-interest to Shanghai Lizhong Wood Products Co., Ltd./The Lizhong Industry Limited Company of Shanghai. *See Multilayered Wood Flooring From the People's Republic of China: Final Results of Changed Circumstances Review,* 79 FR 58740 (September 30, 2014).

Continued

Exporter	Weighted-average dumping margin (percent)
Dalian Dajen Wood Co., Ltd	0.00
Jiangsu Senmao Bamboo and Wood Industry Co., Ltd	13.74
A&W (Shanghai) Woods Co., Ltd	13.74
Armstrong Wood Products (Kunshan) Ltd	13.74
Baishan Huafeng Wood Product Co., Ltd	13.74
Changbai Mountain Development and Protection Zone Hongtu Wood Industrial Co., Ltd	13.74
Changzhou Hawd Flooring Co., Ltd	13.74
Chinafloors Timber (China) Co., Ltd	13.74
Dalian Huilong Wooden Products Co., Ltd	13.74
Dalian Jiuyuan Wood Industry Co., Ltd	13.74
Dalian Kemian Wood Industry Co., Ltd	13.74
Dalian Penghong Floor Products Co., Ltd	13.74
Dalian T-Boom Wood Products Co., Ltd	13.74
Dasso Industrial Group Co., Ltd [15]	13.74
Dongtai Fuan Universal Dynamics, LLC	13.74
Dunhua City Dexin Wood Industry Co., Ltd	13.74
Dunhua City Hongyuan Wood Industry Co., Ltd	13.74
Dun Hua City Jisen Wood Industry Co., Ltd	13.74
Dunhua City Wanrong Wood Industry Co., Ltd	13.74
Dun Hua Sen Tai Wood Co., Ltd	13.74
Fine Furniture (Shanghai) Limited or Double F Limited	13.74
Fusong Jinlong Wooden Group [16]	13.74
GTP International Ltd	13.74
Guangdong Yihua Timber Industry Co., Ltd	13.74
Guangzhou Panyu Kangda Board Co., Ltd	13.74
Guangzhou Panyu Southern Star Co., Ltd	13.74
HaiLin LinJing Wooden Products, Ltd	13.74
Hangzhou Hanje Tec Co., Ltd	13.74
Hangzhou Zhengtian Industrial Co., Ltd	13.74
Hunchun Forest Wolf Wooden Industry Co., Ltd	13.74
Huzhou Chenghang Wood Co., Ltd	13.74
Huzhou Fulinmen Imp. & Exp. Co., Ltd	13.74
Huzhou Jesonwood Co., Ltd	13.74
Huzhou Sunergy World Trade Co., Ltd	13.74
Jianfeng Wood (Suzhou) Co., Ltd	13.74
Jiangsu Guyu International Trading Co., Ltd	13.74
Jiangsu Kentier Wood Co., Ltd	13.74
Jiangsu Mingle Flooring Co., Ltd	13.74
Jiangsu Simba Flooring Co., Ltd	13.74
Jiashan HuiJiaLe Decoration Material Co., Ltd	13.74
Jilin Forest Industry Jinqiao Flooring Group Co., Ltd	13.74
Jilin Xinyuan Wooden Industry Co., Ltd	13.74
Karly Wood Product Limited	13.74
Kemian Wood Industry (Kunshan) Co., Ltd	13.74
Shanghai Lizhong Wood Products Co., Ltd./The Lizhong Wood Industry Limited Company of Shanghai/Linyi Youyou Wood Co., Ltd [17]	13.74
Metropolitan Hardwood Floors, Inc	13.74
Mudanjiang Bosen Wood Industry Co., Ltd	13.74
Nakahiro Jyou Sei Furniture (Dalian) Co., Ltd	13.74
Nanjing Minglin Wooden Industry Co., Ltd	13.74
Puli Trading Limited	13.74
Shanghai Eswell Timber Co., Ltd	13.74
Shanghai Lairunde Wood Co., Ltd	13.74
Shanghai New Sihe Wood Co., Ltd	13.74
Shanghai Shenlin Corp	13.74
Shenyang Haobainian Wooden Co., Ltd	13.74
Shenzhenshi Huanwei Woods Co., Ltd	13.74
Suzhou Dongda Wood Co., Ltd	13.74
Tongxiang Jisheng Import and Export Co., Ltd	13.74
Xiamen Yung De Ornament Co., Ltd	13.74
Xuzhou Shenghe Wood Co., Ltd	13.74
Yingyi-Nature (Kunshan) Wood Industry Co., Ltd	13.74
Yixing Lion-King Timber Industry Co., Ltd	13.74
Zhejiang Biyork Wood Co., Ltd	13.74
Zhejiang Dadongwu Greenhome Wood Co., Ltd	13.74
Zhejiang Fudeli Timber Industry Co., Ltd	13.74
Zhejiang Fuma Warm Technology Co., Ltd	13.74
Zhejiang Longsen Lumbering Co., Ltd	13.74
Zhejiang Shiyou Timber Co., Ltd	13.74
Zhejiang Tianzhen Bamboo & Wood Development Co., Ltd	13.74
PRC-Wide Entity [18]	58.84

[18] The following companies were named in the *Initiation Notice* but did not submit a certification of no shipment, separate rate application or separate rate certification; therefore they are part of the PRC-wide entity: Baiying Furniture Manufacturer Co., Ltd.; Dunhua Jisheng Wood Industry Co., Ltd.; Dunhua Shengda Wood Industry Co., Ltd.; Fu Lik Timber (HK) Co., Ltd.; Guangdong Fu Lin Timber Technology Limited, Guanghzhou Panyu Shatou Trading Co., Ltd.; Hunchun Xingjia Wooden Flooring Inc.; Huzhou Fuma Wood Bus. Co., Ltd.; Huzhou Ruifeng Imp. & Exp. Co., Ltd.; Jiazing Brilliant Import & Export Co., Ltd. Linyi Bonn; Sennorwell International Group (Hong Kong) Limited; Shenyang Sende Wood Co., Ltd.; Suzhou Anxin Weiguang Timber Co., Ltd.; Vicwood Industry (Suzhou) Co., Ltd.; Yekalon Industry, Inc.; Zhejiang AnJi XinFeng Bamboo & Wood Co., Ltd.; Zhejiang Desheng Wood Industry Co., Ltd.; Zhejiang Haoyun Wood Co., Ltd.; and Zhejiang Jeson Wood Co., Ltd.

Assessment Rates

The Department will determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review. The Department intends to issue assessment instructions to CBP 15 days after the publication date of these final results of this review. In accordance with 19 CFR 351.212(b)(1), we are calculating importer- (or customer-) specific assessment rates for the merchandise subject to this review. For any individually examined respondent whose weighted-average dumping margin is above *de minimis* (*i.e.,* 0.50 percent), the Department will calculate importer- (or customer)-specific assessment rates for merchandise subject to this review. Where appropriate, we calculated an *ad valorem* rate for each importer (or customer) by dividing the total dumping margins for reviewed sales to that party by the total entered values associated with those transactions. For duty-assessment rates calculated on this basis, we will direct CBP to assess the resulting *ad valorem* rate against the entered customs values for the subject merchandise. Where appropriate, we calculated a per-unit rate for each importer (or customer) by dividing the total dumping margins for reviewed sales to that party by the total sales quantity associated with those transactions. For duty-assessment rates calculated on this basis, we will direct CBP to assess the resulting per-unit rate against the entered quantity of the subject merchandise.[19] We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review when the importer-specific assessment rate is above *de minimis.* Where either the respondent's weighted-average dumping margin is zero or *de minimis,* or an importer-specific assessment rate is zero or *de minimis,* we will instruct CBP to liquidate the

[19] *See Antidumping Proceedings: Calculation of the Weighted-Average Dumpin7g Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification,* 77 FR 8101, 8103 (February 14, 2012).

appropriate entries without regard to antidumping duties. For Anying, whose weighted average dumping margin is zero, the Department will instruct CBP to liquidate appropriate entries without regard to antidumping duties.[20] We intend to instruct CBP to liquidate entries of subject merchandise exported by the PRC-wide entity at the PRC-wide rate.

If the Department determines that an exporter under review had no shipments of subject merchandise, any suspended entries that entered under that exporter's case number will be liquidated at the PRC-wide rate.[21]

For the companies not selected for individual examination, we will instruct CBP to apply the rate listed above to the entries of subject merchandise exported by such companies and entered during the period from December 1, 2012 through November 30, 2013. This rate is the same as the rate for the one mandatory respondent with a weighted-average dumping margin that is above *de minimis*.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of these reviews for shipments of the subject merchandise from the PRC entered, or withdrawn from warehouse, for consumption on or after the publication date in the **Federal Register** of the final results of review, as provided by section 751(a)(2)(C) of the Act. First, with respect to Anying, the new shipper respondent, the Department established a combination cash deposit rate for this company, consistent with its practice, as follows: (1) For subject merchandise produced and exported by Anying, a zero cash deposit will be required; (2) for subject merchandise exported by Anying, but not produced by Anying, the cash deposit rate will be the rate for the PRC-wide entity; (3) for subject merchandise produced by Anying, but not exported by Anying, the cash deposit rate will be the rate applicable to the exporter. For Dajen, Senmao, and the non-examined, separate rate respondents, the cash deposit rate will be equal to their weighted-average dumping margins established in the final results of this review, except if the rate is zero or *de minimis,* then no cash deposit will be required. For Anhui Longhua Bamboo Product Co., Ltd., Benxi Wood Company, Guangzhou Homebon Timber Manufacturing Co., Ltd., Jiaxing Brilliant Import & Export Co. Ltd., Pinge Timber Manufacturing (Zhejiang) Co., Ltd., Power Dekor Group Co., Ltd., and Shenyang Senwang Wooden Industry Co., Ltd., which claimed no shipments, the cash deposit rate will remain unchanged from their rate assigned in the most recently completed review of the company. Likewise, for Dalian Huade Wood Product Co., Ltd. and Zhejiang Fuerjia Wooden Co., Ltd., the cash deposit rate will remain unchanged from the rate assigned in the recently completed new shipper reviews of these companies. For previously investigated or reviewed PRC and non-PRC exporters not listed above that received a separate rate in a prior segment of this proceeding, the cash deposit rate will continue to be the most-recently established exporter-specific rate. For all PRC exporters of subject merchandise that have not been found to be entitled a separate rate, the cash deposit rate will be that for the PRC-wide entity established in the final determination of the less than fair value investigation (*i.e.,* 58.84 percent). For all non-PRC exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporter that supplied that non-PRC exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Disclosure

We intend to disclose the calculations performed regarding these AR final results within five days of the date of publication of this notice in this proceeding in accordance with 19 CFR 351.224(b).[22]

Notification to Importers Regarding the Reimbursement of Duties

This notice also serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in the Department's presumption that reimbursement of antidumping duties has occurred and the subsequent assessment of doubled antidumping duties.

Administrative Protective Order ("APO")

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

We are issuing and publishing this AR, NSR, and notice in accordance with sections 751(a)(1), 751(a)(2)(B), and 777(i) of the Act.

Dated: July 8, 2015.

Lynn M. Fischer Fox,

Deputy Assistant Secretary for Policy & Negotiation.

Appendix—Issues and Decision Memorandum

Summary
Background
Scope of the Order
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Discussion of the Issues
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Comment 2: Whether the VAT Adjustment is Correctly Applied
Comment 3: Fine Furniture's Status as a Voluntary Respondent
Comment 4: Whether Fine Furniture's Liquidation Instructions Should Include the Name of Its Affiliate Listed on the Import Documentation Submitted to U.S. CBP
Comment 5: Whether the Department Correctly Applied the PRC-Wide Rate to Linyi Bonn
Comment 6: Paint and Pigments
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[20] *See* 19 CFR 351.212(b)(1).

[21] For a full discussion of this practice, *see Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties,* 76 FR 65694 (October 24, 2011).

[22] Regarding the NSR, there are no calculations to disclose for these final results, as no changes have been made to our analysis subsequent to our *NSR Preliminary Results.*

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–918]

Steel Wire Garment Hangers From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review; 2013–2014

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

SUMMARY: The Department of Commerce (the ''Department'') is conducting the sixth administrative review of the antidumping duty order on steel wire garment hangers from the People's Republic of China (''PRC'').[1] The Department individually reviewed two respondents, Shanghai Wells,[2] and Ningbo Dasheng Hanger Ind. Co., Ltd., (''Ningbo Dasheng''). The Department preliminarily determines that Shanghai Wells sold subject merchandise in the United States at prices below normal value during the period of review (''POR''), October 1, 2013, through September 30, 2014, and that Ningbo Dasheng is not eligible for a separate and, therefore, is considered part of the PRC-wide entity.[3] If these preliminary results are adopted in our final results of review, we will instruct U.S. Customs and Border Protection (''CBP'') to assess antidumping duties on all appropriate entries of subject merchandise during the POR. We invite interested parties to comment on these preliminary results.

DATES: *Effective Date:* July 15, 2015.

FOR FURTHER INFORMATION CONTACT: Alexis Polovina or Katie Marksberry, AD/CVD Operations, Office V, Enforcement and Compliance, International Trade Administration, Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–3927 or (202) 482–7906, respectively.

SUPPLEMENTARY INFORMATION:

Scope of the Order

The product covered by the order is steel wire garment hangers. This product is classified under the Harmonized Tariff Schedule of the United States (''HTSUS'') subheadings: 7326.20.0020, 7323.99.9060, and 7323.99.9080. Although the HTSUS subheadings are provided for convenience and customs purposes, the written product description remains dispositive.[4]

PRC-Wide Entity

Two Non-Responsive Mandatories failed to respond to the Department's requests for information.[5] These companies, therefore, are not eligible for separate rate status.[6] Additionally, Ningbo Dasheng failed to adequately respond to all parts of the questionnaire, and therefore, is also not eligible for a separate rate. Accordingly, the Department preliminarily finds that the PRC-wide entity includes these companies.[7]

The Department's change in policy regarding conditional review of the PRC-wide entity applies to this administrative review.[8] Under this policy, the PRC-wide entity will not be under review unless a party specifically requests, or the Department self-initiates, a review of the entity. Because no party requested a review of the PRC-wide entity in this review, the entity is not under review and the entity's rate is not subject to change, (*i.e.,* 187.25 percent).[9]

Methodology

The Department conducted this review in accordance with section 751(a)(1)(B) of the Act. We calculated constructed export prices and export prices in accordance with section 772 of the Act. Because the PRC is a nonmarket economy within the meaning of section 771(18) of the Act, we calculated normal value in accordance with section 773(c) of the Act.

For a full description of the methodology underlying our conclusions, *see* the Preliminary Decision Memorandum, dated concurrently with these results and hereby adopted by this notice.[10] 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/login.aspx* and to all parties in the Central Records Unit (''CRU''), room 7046 of the main Department of Commerce building. In addition, parties can obtain a complete version of the Preliminary Decision Memorandum on the Internet at *http://trade.gov/enforcement/frn/index.html.* The signed Preliminary Decision Memorandum and the electronic versions of the Preliminary Decision Memorandum are identical in content.

Preliminary Results of Review

Regarding the administrative review, the Department preliminarily determines that the following weighted-average dumping margins exist for the period October 1, 2013, through September 30, 2014:

Exporter	Weighted-average dumping margin (%)
Shanghai Wells Hanger Co., Ltd.[11]	33.24

Disclosure, Public Comment & Opportunity To Request a Hearing

The Department will disclose the calculations used in its analysis to parties in this review within five days of the date of publication of this notice.[12]

Interested parties may submit case briefs within 30 days after the date of publication of these preliminary results

[1] *See Notice of Antidumping Duty Order: Steel Wire Garment Hangers from the People's Republic of China,* 73 FR 58111 (October 6, 2008) (''*Order*'').

[2] The Department previously found that Shanghai Wells Hanger Co., Ltd., Hong Kong Wells Ltd. (''HK Wells'') and Hong Kong Wells Ltd. (USA) (''Wells USA'') are affiliated and that Shanghai Wells Hanger Co., Ltd. and HK Wells comprise a single entity (collectively, ''Shanghai Wells''). Because there were no changes in this review to the facts that supported that decision, we continue to find Shanghai Wells Hanger Co., Ltd., HK Wells, and USA Wells are affiliated and that Shanghai Wells Hanger Co., Ltd. and HK Wells comprise a single entity. *See Steel Wire Garment Hangers From the People's Republic of China: Preliminary Results and Preliminary Rescission, in Part, of the First Antidumping Duty Administrative Review,* 75 FR 68758, 68761 (November 9, 2010), unchanged in *First Administrative Review of Steel Wire Garment Hangers From the People's Republic of China: Final Results and Final Partial Rescission of Antidumping Duty Administrative Review,* 76 FR 27994, 27996 (May 13, 2011).

[3] *See* Steel Wire Garment Hangers from the People's Republic of China: Decision Memorandum for the Preliminary Results of the 2013–2014 Antidumping Duty Administrative Review, dated concurrently with this notice (Preliminary Decision Memorandum) at ''Respondent Selection'' and ''Companies Not Eligible for a Separate Rate'' sections.

[4] *See* the Preliminary Decision Memorandum for a complete description of the scope of the *Order.*

[5] *Id.,* at ''Respondent Selection'' section.

[6] *See Initiation of Antidumping and Countervailing Duty Administrative Reviews,* 79 FR 70850, 70851 (November 28, 2014).

[7] *See* Preliminary Decision Memorandum.

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

[9] *See Steel Wire Garment Hangers From the People's Republic of China: Final Results of Antidumping Duty Administrative Review, 2012–2013,* 80 FR 13332, and accompanying Issues and Decision Memorandum (''*5th AR Hangers Final Results*'').

[10] *See* Preliminary Decision Memorandum.

[11] Shanghai Wells consists of Shanghai Wells Hanger Co., Ltd., and Hong Kong Wells Ltd.

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

of review in the **Federal Register**.[13] Rebuttals to case briefs, which must be limited to issues raised in the case briefs, must be filed within five days after the time limit for filing case briefs.[14] Parties who submit arguments are requested to submit with the argument: (1) A statement of the issue, (2) a brief summary of the argument, not to exceed five pages, and (3) a table of authorities.[15]

Any interested party may request a hearing within 30 days of publication of this notice.[16] Hearing requests should contain the following information: (1) The party's name, address, and telephone number; (2) the number of participants; and (3) a list of the issues to be discussed. Oral presentations will be limited to issues raised in the case and rebuttal briefs.[17] If a party requests a hearing, the Department will inform parties of the scheduled date for the hearing which will be held at the U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, at a time and location to be determined. Parties should confirm by telephone the date, time, and location of the hearing.

The Department intends to issue the final results of this review, including the results of its analysis of the issues raised in any written briefs, not later than 120 days after the date of publication of this notice, pursuant to section 751(a)(3)(A) of the Act.

Assessment Rates

Upon issuance of the final results, the Department will determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review.[18] The Department intends to issue assessment instructions to CBP 15 days after the publication date of the final results of review.

In these preliminary results, the Department applied the assessment rate calculation method adopted in *Final Modification for Reviews, i.e.,* on the basis of monthly average-to-average comparisons using only the transactions associated with that importer with offsets being provided for non-dumped comparisons.[19]

Where the respondent reported reliable entered values, we calculated importer- (or customer) specific *ad valorem* rates by aggregating the dumping margins calculated for all U.S. sales to each importer (or customer) and dividing this amount by the total entered value of the sales to each importer (or customer).[20] Where the Department calculated a weighted-average dumping margin by dividing the total amount of dumping for reviewed sales to that party by the total sales quantity associated with those transactions, the Department will direct CBP to assess importer-specific assessment rates based on the resulting per-unit rates.[21] Where an importer- (or customer-) specific *ad valorem* or per-unit rate is greater than *de minimis,* the Department will instruct CBP to collect the appropriate duties at the time of liquidation.[22] Where an importer- (or customer-) specific *ad valorem* or per-unit rate is zero or *de minimis,* the Department will instruct CBP to liquidate appropriate entries without regard to antidumping duties.[23]

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of these reviews for shipments of the subject merchandise from the PRC entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(2)(C) of the Act: (1) For the companies listed above, the cash deposit rate will be established in the final results of these reviews (except, if the rate is zero or *de minimis,* then zero cash deposit will be required); (2) for previously investigated or reviewed PRC and non-PRC exporters not listed above that received a separate rate in a prior segment of this proceeding, the cash deposit rate will continue to be the exporter-specific rate published for the most recent period; (3) for all PRC exporters of subject merchandise that have not been found to be entitled to a separate rate, the cash deposit rate will be the PRC-wide rate of 187.25 percent; and (4) for all non-PRC exporters of subject merchandise which have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporter that supplied that non-PRC exporter.

These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Department's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

This determination is issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: July 6, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

Attachment

List of Topics Discussed in the Preliminary Decision Memorandum

1. Background
2. Respondent Selection
3. Scope of the Order
4. Affiliations
5. NME Country Status
6. Separate Rates
7. Separate Rates Recipients
8. PRC-Wide Entity
9. Surrogate Country and Surrogate Value Data
10. Surrogate Country
11. Date of Sale
12. Determination of Comparison Method
13. Results of Differential Pricing Analysis
14. U.S. Price
15. Value-Added Tax
16. Normal Value
17. Factor Valuations
18. Currency Conversion
19. Conclusion

[FR Doc. 2015–17367 Filed 7–14–15; 8:45 am]

BILLING CODE 3510–DS–P

[13] *See* 19 CFR 351.309(c)(1)(ii).

[14] *See* 19 CFR 351.309(d)(1) and (2).

[15] *See* 19 CFR 351.309(c) and (d).

[16] *See* 19 CFR 351.310(c).

[17] *Id.*

[18] *See* 19 CFR 351.212(b).

[19] *See Antidumping Proceeding: Calculation of the Weighted-Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings; Final Modification,* 77 FR 8101, 8103 (February 14, 2012) (''*Final Modification for Reviews*'').

[20] *See* 19 CFR 351.212(b)(1).

[21] *Id.*

[22] *Id.*

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

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Submission for OMB Review; Comment Request

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

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Aleutian Islands Pollock Fishery.

OMB Control Number: 0648–0513.

Form Number(s): None.

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

Number of Respondents: 1.

Average Hours per Response: 1.

Burden Hours: 1.

Needs and Uses: This request is for revision and extension of a currently approved information collection.

Amendment 82 to the Fishery Management Plan for the Groundfish Fishery of the Bering Sea and Aleutian Islands Management Area (FMP) established a framework for the management of the Aleutian Islands subarea (AI) directed pollock fishery. The Aleutian Islands pollock fishery was allocated to the Aleut Corporation, Adak, Alaska, for the purpose of economic development in Adak, Alaska. The Aleut Corporation is identified in Public Law 108–199 as a business incorporated pursuant to the Alaska Native Claims Settlement Act (43 U.S.C. 1601 *et seq.*). Regulations implementing the FMP appear at 50 CFR part 679.

Participants are identified and approved through a letter from the Aleut Corporation which is approved by National Marine Fisheries Service (NMFS). This letter includes a list of approved participants. A copy of the letter must be on each participating vessel.

Appeals are no longer included in this information collection. There have not been any appeals submitted since the inception of the program.

Affected Public: Business or other for-profit organizations; individuals or households.

Frequency: Annually.

Respondent's Obligation: Mandatory.

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

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

Dated: July 9, 2015.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2015–17325 Filed 7–14–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XZ29

Notice of Rescission of NOAA Policy on Prohibited and Approved Uses of the Asset Forfeiture Fund

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

ACTION: Notice.

SUMMARY: The National Oceanic and Atmospheric Administration (NOAA) announces the rescission of its previously published NOAA Policy on Prohibited and Approved Uses of the Asset Forfeiture Fund.

FOR FURTHER INFORMATION CONTACT: Brian T. Pawlak, 301–427–8720.

SUPPLEMENTARY INFORMATION: On March 23, 2011 (76 FR 16386), NOAA published in the **Federal Register** its Policy on Prohibited and Approved Uses of the Asset Forfeiture Fund. That Policy articulated the prohibited and approved uses of asset forfeiture funds to ensure that no conflict of interest—either real or perceived—could be associated with its use while continuing to promote a sound enforcement program dedicated to conserving and protecting our nation's marine resources. NOAA has recently revised its Policy on Prohibited and Approved Uses of the Asset Forfeiture Fund; therefore, this serves as Notice of the rescission of the NOAA Policy published on March

23, 2011. A copy of NOAA's revised Policy on Prohibited and Approved Uses of the Asset Forfeiture Fund can be found at: *http://www.nmfs.noaa.gov/ole/index.html.*

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

Dated: July 10, 2015.

Paul N. Doremus,

Deputy Assistant Administrator for Operations, National Marine Fisheries Service.

[FR Doc. 2015–17356 Filed 7–14–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Coastal and Estuarine Land Conservation Planning, Protection or Restoration

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before September 14, 2015.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *JJessup@doc.gov).*

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Patmarie Nedelka, (301) 713–3155 ext. 127 or *Patmarie.Nedelka@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for extension of a currently approved information collection.

The FY 2002 Commerce, Justice, State Appropriations Act directed the Secretary of Commerce to establish a Coastal and Estuarine Land Conservation Program (CELCP) to protect important coastal and estuarine areas that have significant conservation, recreation, ecological, historical, or aesthetic values, or that are threatened by conversion, and to issue guidelines for this program delineating the criteria for grant awards. The guidelines establish procedures for eligible applicants who choose to participate in the program to use when developing state conservation plans, proposing or soliciting projects under this program, applying for funds, and carrying out projects under this program in a manner that is consistent with the purposes of the program. Guidelines for the CELCP can be found on NOAA's Web site at: *http://www.coast.noaa.gov/czm/landconservation/*or may be obtained upon

request via the contact information listed above. The CELCP was reauthorized in under Public Law 111–111, the Omnibus Public Lands Management Act, as a component of the Coastal Zone Management Act. NOAA also has, or is given, additional authority under the Coastal Zone Management Act, annual appropriations or other authorities, to issue funds to coastal states, localities or other recipients for planning, conservation, acquisition, protection, restoration, or construction projects. The required information enables NOAA to implement the CELCP, under its current or future authorization, and facilitate the review of similar projects under different, but related, authorities.

II. Method of Collection

Electronic formats are the preferred method for submitting CELCP plans, project applications, performance reports and other required materials. However, respondents may submit materials in electronic or paper formats. Project applications are normally submitted electronically via Grants.gov, but may be submitted by mail in paper form if electronic submittal is not a viable option. Methods of submittal for plans, performance reports or other required materials may include electronic submittal via email or NOAA Grants Online, mail and facsimile transmission of paper forms, or submittal of electronic files on compact disc.

III. Data

OMB Control Number: 0648–0459.

Form Number: None.

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

Affected Public: State, Local, or Tribal Government; not-for-profit institutions.

Estimated Number of Respondents: 50.

Estimated Time per Response: CELCP Plans, 120 hours to develop, 35 hours to revise or update; project application and checklist, 20 hours; semi-annual and annual reporting, 5 hours each.

Estimated Total Annual Burden Hours: 1,410.

Estimated Total Annual Cost to Public: $205 in recordkeeping/reporting costs.

IV. Request for Comments

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, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: July 10, 2015.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2015–17361 Filed 7–14–15; 8:45 am]

BILLING CODE 3510–08–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE047

Mid-Atlantic Fishery Management Council; Public Meeting

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

ACTION: Notice of public meeting.

SUMMARY: The Mid-Atlantic Fishery Management Council's (MAFMC) Summer Flounder, Scup, and Black Sea Bass Advisory Panel will hold a public meeting.

DATES: The meeting will be held on Wednesday, July 29, 2015, from 9 a.m. until noon.

ADDRESSES: The meeting will be held via webinar with a telephone-only connection option. Details on webinar registration and telephone-only connection details are available at: *http://www.mafmc.org.*

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

FOR FURTHER INFORMATION CONTACT: Christopher M. Moore Ph.D., Executive Director, Mid-Atlantic Fishery Management Council, 800 N. State Street, Suite 201, Dover, DE 19901; telephone: (302) 526–5255.

SUPPLEMENTARY INFORMATION: The Mid-Atlantic Fisheries Management Council's (MAFMC) Summer Flounder, Scup, and Black Sea Bass Advisory Panel (AP) will meet jointly with the Atlantic States Marine Fisheries Commission's (ASMFC) Summer Flounder, Scup, and Black Sea Bass AP. The purpose of this meeting is for the advisors to review and comment on recent stock assessment information as well as the reports of the MAFMC's Scientific and Statistical Committee (SSC) and the Summer Flounder, Scup, and Black Sea Bass Monitoring Committee meetings held in July 2015. The MAFMC and the ASMFC will consider the input from the AP in August when setting fishery specifications (*i.e.* catch and landings limits and management measures) for 2016–18.

Special Accommodations

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

Dated: July 10, 2015.

Tracey L. Thompson,

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

[FR Doc. 2015–17343 Filed 7–14–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Solicitation of Nominations for the National Sea Grant Advisory Board

AGENCY: National Oceanic and Atmospheric Administration, Commerce.

ACTION: Notice.

SUMMARY: This notice responds to Section 209 of the Sea Grant Program Improvement Act of 1976 (Pub. L. 94–461, 33 U.S.C. 1128), which requires the Secretary of Commerce (Secretary) to solicit nominations at least once a year for membership on the National Sea Grant Advisory Board (Board), a Federal Advisory Committee that provides advice on the implementation of the National Sea Grant College Program. To apply for membership to the Board, applicants should submit a current resume as indicated in the **ADDRESSES** section. A cover letter highlighting specific areas of expertise relevant to the purpose of the Board is helpful, but not required. NOAA is an equal opportunity employer.

DATES: Solicitation of nominations is open ended. Resumes may be sent to the address specified at any time.

ADDRESSES: Nominations will be accepted by email or mail. They should

be sent to the attention of Mrs. Jennifer Hinden, National Sea Grant College Program, National Oceanic and Atmospheric Administration, 1315 East-West Highway, SSMC 3, Room 11717, Silver Spring, Maryland 20910, or *Jennifer.Hinden@noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Mrs. Jennifer Hinden, National Sea Grant College Program or *Jennifer.Hinden@noaa.gov.* If you need additional assistance, call 301–734–1088.

SUPPLEMENTARY INFORMATION: Established by Section 209 of the Act and as amended the National Sea Grant College Program Amendments Act of 2008 (Pub. L. 110–394), the duties of the Board are as follows:

(1) In general. The Board shall advise the Secretary and the National Sea Grant College Program Director (Director) concerning:

(A) Strategies for utilizing the Sea Grant College Program to address the Nation's highest priorities regarding the understanding, assessment, development, management, utilization, and conservation of ocean, coastal, and Great Lakes resources;

(B) The designation of Sea Grant Colleges and Sea Grant Institutes; and

(C) Such other matters as the Secretary refers to the Board for review and advice.

(2) Biennial Report. The Board shall report to the Congress every two years on the state of the National Sea Grant College Program. The Board shall indicate in each such report the progress made toward meeting the priorities identified in the strategic plan in effect under section 204(c). The Secretary shall make available to the Board such information, personnel, and administrative services and assistance as it may reasonably require to carry out its duties under this title.

The Board shall consist of 15 voting members who will be appointed by the Secretary for a 4-year term. The Director and a director of a Sea Grant program who is elected by the various directors of Sea Grant programs shall serve as nonvoting members of the Board. Not less than 8 of the voting members of the Board shall be individuals who, by reason of knowledge, experience, or training, are especially qualified in one or more of the disciplines and fields included in marine science. The other voting members shall be individuals who, by reason of knowledge, experience, or training, are especially qualified in, or representative of, education, marine affairs and resource management, coastal management, extension services, State government, industry, economics, planning, or any other activity which is appropriate to, and important for, any effort to enhance the understanding, assessment, development, management, utilization, or conservation of ocean, coastal, and Great Lakes resources. No individual is eligible to be a voting member of the Board if the individual is (A) the director of a Sea Grant College or Sea Grant Institute; (B) an applicant for, or beneficiary (as determined by the Secretary) of, any grant or contract under section 205 [33 USCS § 1124]; or (C) a full-time officer or employee of the United States.

Individuals Selected for Federal Advisory Committee Membership: Upon selection and agreement to serve on the National Sea Grant Advisory Board, you become a Special Government Employee (SGE) of the United States Government. According to 18 U.S.C. 202(a), an SGE is an officer or employee of an agency who is retained, designated, appointed, or employed to perform temporary duties, with or without compensation, not to exceed 130 days during any period of 365 consecutive days, either on a fulltime or intermittent basis. Please be aware that after the selection process is complete, applicants selected to serve on the Board must complete the following actions before they can be appointed as a Board member:

(a) Security clearance (on-line background security check process and fingerprinting), and other applicable forms, both conducted through NOAA Workforce Management; and (b) Confidential Financial Disclosure Report—As an SGE, you are required to file a Confidential Financial Disclosure Report annually to avoid involvement in a real or apparent conflict of interest. You may find the Confidential Financial Disclosure Report at the following Web site. *http://www.oge.gov/Forms-Library/OGE-Form-450-Confidential-Financial-Disclosure-Report/.*

Dated: July 9, 2015.

Jason Donaldson,

Chief Financial Officer, Office of Oceanic and Atmospheric Research, National Oceanic and Atmospheric Administration.

[FR Doc. 2015–17357 Filed 7–14–15; 8:45 am]

BILLING CODE 3510–KA–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Submission for OMB Review; Comment Request

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

Agency: National Oceanic and Atmospheric Administration (NOAA).

Title: Southeast Region Permit Family of Forms.

OMB Control Number: 0648–0205.

Form Number(s): None.

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

Number of Respondents: 13,409.

Average Hours per Response: 30 minutes.

Burden Hours: 5,836.

Needs and Uses: The collection consists of vessel and dealer permits that are part of the National Marine Fisheries Service (NMFS) program to manage fisheries in the Southeast Region. The fisheries in the Southeast Region are managed under the Magnuson-Stevens Fishery Conservation and Management Act (MSA) (16 U.S.C. 1801) and regulations at 50 CFR part 622, 50 CFR part 635 and 50 CFR prt 300. NMFS issues permits to fishing vessels and dealers in order to collect information necessary to comply with domestic and international fisheries obligations, secure compliance with regulations, and disseminate necessary information.

This revision would amend the ''Federal Permit Application for Vessels Fishing in the Exclusive Economic Zone (EEZ)'' to add the collection of an International Maritime Organization/Lloyd's Registry (IMO/LR) number to the permit application for commercial HMS vessels ≥20 meters (65′7″) in length that are obtaining or renewing a HMS limited access permit, including the Atlantic tuna longline, shark incidental, shark directed, swordfish incidental, swordfish directed, and swordfish handgear permits. The International Commission for the Conservation of Atlantic Tunas (ICCAT) approved a recommendation (13–13) for Contracting Parties to require commercial vessels ≥20 meters (65′7″) in length to obtain an IMO/LR number from IHS/Fairplay by no later than January 1, 2016. Permit applications that do not contain the required supporting documents will be considered incomplete.

This revision would also change the Report for the Deposit or Harvest of Aquacultured Live Rock by adding language to the instructions, specifically, ''If not originally approved, then provide a new sample of rock,'' adding the USCG documentation number or state registration number for

the primary vessel the permit is used on, changing the wording in the instructions for the box describing the deposited material to include the ''type and specific geographic origin'' of the material, and adding a yes/no check box for whether a sample of the deposit material has been provided to NMFS.

Also, this revision removes the responses, time and cost burden associated with the South Atlantic rock shrimp VMS requirement and transfers those responses, time and cost burden to the OMB Control No. 0648–0544 information collection.

Affected Public: Business or other for-profit organizations.

Frequency: Annually and on occasion.

Respondent's Obligation: Mandatory.

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

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

Dated: July 9, 2015.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2015–17326 Filed 7–14–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE048

North Pacific Fishery Management Council; Public Meetings

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

ACTION: Notice of public meetings.

SUMMARY: The North Pacific Fishery Management Council (Council) Electronic Monitoring Workgroup (EMWG) will meet in Anchorage, AK.

DATES: The meetings will be held July 30–31st, 2015, from 8 a.m. to 5 p.m.

ADDRESSES: The meetings will be held at the Coast International Inn, 3450 Aviation Avenue, Anchorage, AK.

Council address: North Pacific Fishery Management Council, 605 W. 4th Ave., Suite 306, Anchorage, AK 99501–2252.

FOR FURTHER INFORMATION CONTACT: Diana Evans, Council staff; phone: (907) 271–2809.

SUPPLEMENTARY INFORMATION: The agenda will include: (a) Discussion of 2015 research results; (b) discussion of the draft 2016 EM pre-implementation proposal; (c) update on budget; (d) discussion of EM research on pot cod vessels; (e) any other business. The Agenda is subject to change, and the latest version will be posted at *http://www.npfmc.org/.*

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Shannon Gleason at (907) 271–2809 at least 7 working days prior to the meeting date.

Dated: July 10, 2015.

Tracey L. Thompson,

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

[FR Doc. 2015–17344 Filed 7–14–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XR52

Marine Mammals; File No. 14534

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

ACTION: Notice; issuance of permit amendment.

SUMMARY: Notice is hereby given that NOAA's Office of Science and Technology, Silver Spring, MD, (Brandon Southall, Ph.D.—Principal Investigator) has been issued a minor amendment to Scientific Research Permit No. 14534–02.

ADDRESSES: The amendment and related documents are available for review upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376.

FOR FURTHER INFORMATION CONTACT: Courtney Smith or Howard Goldstein, (301) 427–8401.

SUPPLEMENTARY INFORMATION: The requested amendment has been granted under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*) and the regulations governing the taking and importing of marine mammals (50 CFR part 216), the Endangered Species Act of 1973, as amended (ESA; 16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222 through 226).

The original permit (No. 14534), issued on July 2, 2010 (75 FR 39665) through June 30, 2015 authorized research on a variety of marine mammals, and involves temporarily attaching individual recording tags to measure vocalization, diving and other behaviors, and physiological parameters before, during, and after carefully controlled exposures of sound in conventional playback experiments. The research is focused in the waters within the U.S. Navy's Southern California Range Complex, and primarily near the vicinity of San Clemente Island. A minor amendment to the permit (No. 14534–01) was issued on August 30, 2010 to combine long-beaked common dolphins and short-beaked common dolphins into a single ''unidentified common dolphin'' category for takes by harassment incidental to the playbacks.

A second, major amendment (No. 14534–02) was issued on May 14, 2012 (77 FR 33199) that added endangered humpback whales (*Megaptera novaengliae*) as an additional focal species for tagging and intentional exposure to sound playbacks with associated behavioral observations. The amendment also increased the number of non-ESA listed minke whales (*Balaenoptera acutorostrata*) and killer whales (*Orcinus orca*) that may be harassed annually.

The current minor amendment (No. 14534–03) extends the duration of the permit through June 30, 2016, but does not change any other terms or conditions of the permit.

Dated: July 9, 2015.

Julia Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2015–17349 Filed 7–14–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Designation of Fishery Management Council Members and Application for Reinstatement of State Authority

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before September 14, 2015.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at *JJessup@doc.gov*).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Tracey Thompson, (301) 427–8505 or *Tracey.Thompson@noaa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for an extension of a currently approved information collection.

The Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), as amended in 1996, provides for the nomination for members of Fishery Management Councils by state governors and Indian treaty tribes, for the designation of a principal state fishery official who will perform duties under the Magnuson-Stevens Act, and for a request by a state for reinstatement of state authority over a managed fishery. Nominees for council membership must provide the governor or tribe with background documentation, which is then submitted to NOAA with the nomination. The information submitted with these actions will be used to ensure that the requirements of the Magnuson-Stevens Act are being met.

II. Method of Collection

State governors and Indian treaty tribes submit written nominations to the Secretary of Commerce, together with recommendations and statements of candidates' qualifications. Designations of state officials and requests for reinstatement of state authority are also made in writing in response to regulations. No forms are used.

III. Data

OMB Control Number: 0648–0314.

Form Number(s): None.

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

Affected Public: State, Local or Tribal government.

Estimated Number of Respondents: 275.

Estimated Time per Response: 1 hour to designate a principal state fishery official(s) or for a request to reinstate authority; 80 hours for a nomination for a Council appointment; 16 hours for background documentation for nominees.

Estimated Total Annual Burden Hours: 4,607.

Estimated Total Annual Cost to Public: $795 in recordkeeping/reporting costs.

IV. Request for Comments

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, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: July 9, 2015.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2015–17327 Filed 7–14–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

Multistakeholder Process To Develop Consumer Data Privacy Code of Conduct Concerning Facial Recognition Technology

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 meeting of a privacy multistakeholder process concerning the commercial use of facial recognition technology on July 28, 2015.

DATES: The meeting will be held on July 28, 2015 from 1:00 p.m. to 5:00 p.m., Eastern Time. See Supplementary Information for details.

ADDRESSES: The meeting will be held in the Boardroom at the American Institute of Architects, 1735 New York Avenue NW., Washington, DC 20006.

FOR FURTHER INFORMATION CONTACT: John Verdi, National Telecommunications and Information Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Room 4725, Washington, DC 20230; telephone (202) 482–8238; email *jverdi@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: On February 23, 2012, the White House released *Consumer Data Privacy in a Networked World: A Framework for Protecting Privacy and Promoting Innovation in the Global Digital Economy* (the ''Privacy Blueprint'').[1] The Privacy Blueprint directs NTIA to convene multistakeholder processes to develop legally enforceable codes of conduct that specify how the Consumer Privacy Bill of Rights applies in specific business contexts.[2] On December 3, 2013, NTIA announced that it would convene a multistakeholder process with the goal of developing a code of conduct to protect consumers' privacy and promote trust regarding facial recognition technology in the commercial context.[3] On February 6, 2014, NTIA convened the first meeting of the multistakeholder process, followed by additional meetings through June 2015.

Matters to Be Considered: The July 28, 2015 meeting is a continuation of a series of NTIA-convened multistakeholder discussions concerning facial recognition technology. Stakeholders will engage in an open, transparent, consensus-driven process to develop a code of conduct regarding facial recognition technology. The July 28, 2015 meeting will build on stakeholders' previous work. More information about stakeholders' work is available at: *http://www.ntia.doc.gov/*

[1] The Privacy Blueprint is available at *http://www.whitehouse.gov/sites/default/files/privacy-final.pdf.*

[2] *Id.*

[3] NTIA, *Facial Recognition Technology, http://www.ntia.doc.gov/other-publication/2013/privacy-multistakeholder-process-facial-recognition-technology.*

other-publication/2014/privacy-multistakeholder-process-facial-recognition-technology.

Time and Date: NTIA will convene a meeting of the privacy multistakeholder process regarding facial recognition technology on July 28, 2015, from 1:00 p.m. to 5:00 p.m., Eastern Time. The meeting date and time are subject to change. The meeting is subject to cancelation if stakeholders complete their work developing a code of conduct. Please refer to NTIA's Web site, *http://www.ntia.doc.gov/other-publication/2014/privacy-multistakeholder-process-facial-recognition-technology,* for the most current information.

Place: The meeting will be held in the Boardroom at the American Institute of Architects, 1735 New York Avenue NW., Washington, DC 20006. The location of the meeting is subject to change. Please refer to NTIA's Web site, *http://www.ntia.doc.gov/other-publication/2014/privacy-multistakeholder-process-facial-recognition-technology,* for the most current information.

Other Information: The meeting is open to the public and the press. The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to John Verdi at (202) 482–8238 or *jverdi@ntia.doc.gov* at least seven (7) business days prior to the meeting. The meeting will also be webcast. Requests for real-time captioning of the webcast or other auxiliary aids should be directed to John Verdi at (202) 482–8238 or *jverdi@ntia.doc.gov* at least seven (7) business days prior to the meeting. 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. Please refer to NTIA's Web site, *http://www.ntia.doc.gov/other-publication/2013/privacy-multistakeholder-process-facial-recognition-technology,* for the most current information.

Dated: July 10, 2015.

Milton Brown,

Acting Chief Counsel, National Telecommunications and Information Administration.

[FR Doc. 2015–17335 Filed 7–14–15; 8:45 am]

BILLING CODE 3510–60–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Science Board; Notice of Advisory Committee Meetings

AGENCY: Department of Defense.

ACTION: Notice of Advisory Committee Meetings.

SUMMARY: The Defense Science Board 2015 Summer Study on Autonomy will meet in closed session on August 17–28, 2015, from 8 a.m. to 5 p.m. at the Arnold and Mabel Beckman Center, 100 Academy Drive, Irvine, CA 92617.

DATES: August 17–28, 2015, from 8 a.m. to 5 p.m.

ADDRESSES: Arnold and Mabel Beckman Center, 100 Academy Drive, Irvine, CA 92617.

FOR FURTHER INFORMATION CONTACT: Ms. Debra Rose, Executive Officer, Defense Science Board, 3140 Defense Pentagon, Room 3B888A, Washington, DC 20301–3140, via email at *debra.a.rose20.civ@mail.mil,* or via phone at (703) 571–0084.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150.

The mission of the Defense Science Board is to advise the Secretary of Defense and the Under Secretary of Defense for Acquisition, Technology & Logistics on scientific and technical matters as they affect the perceived needs of the Department of Defense. At this meeting, the Board will discuss interim finding and recommendations resulting from ongoing Task Force activities. The Board will also discuss plans for future consideration of scientific and technical aspects of specific strategies, tactics, and policies as they may affect the U.S. national defense posture and homeland security.

In accordance with section 10(d) of the Federal Advisory Committee Act, Public Law 92–463, as amended (5 U.S.C. App. 2) and 41 CFR 102–3.155, the Department of Defense has determined that the Defense Science Board meeting for August 17–28, 2015, 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 all sessions of meeting for August 17–28, 2015, will be closed to the public because it will consider matters covered by 5 U.S.C. 552b(c)(1) and (4).

In accordance with 41 CFR 102–3.140 and section 10(a)(3) of the Federal Advisory Committee Act, interested persons may submit a written statement for consideration by the Defense Science Board. Individuals submitting a written statement must submit their statement to the Designated Federal Official at the address detailed in **FOR FURTHER INFORMATION CONTACT**; at any point, however, if a written statement is not received at least 10 calendar days prior to the meeting, which is the subject of this notice, then it may not be provided to or considered by the Defense Science Board. The Designated Federal Official will review all timely submissions with the Defense Science Board Chairperson, and ensure they are provided to members of the Defense Science Board before the meeting that is the subject of this notice.

Dated: July 10, 2015.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2015–17322 Filed 7–14–15; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal No. 15–29]

36(b)(1) Arms Sales Notification

AGENCY: Department of Defense, Defense Security Cooperation Agency.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104–164 dated July 21, 1996.

FOR FURTHER INFORMATION CONTACT: Ms. Sarah A. Ragan or Ms. Heather N. Harwell, DSCA/LMO, (703) 604–1546 or (703) 607–5339.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittal 15–29 with attached Policy Justification and Sensitivity of Technology.

Dated: July 10, 2015.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

The Honorable John A. Boehner
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

JUN 04 2015

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 15-29, concerning the Department of the Army's proposed Letter(s) of Offer and Acceptance to Lebanon for defense articles and services estimated to cost $146 million. After this letter is delivered to your office, we plan to issue a press statement to notify the public of this proposed sale.

Sincerely,

J. W. Rixey
Vice Admiral, USN
Director

Enclosures:
1. Transmittal
2. Policy Justification
3. Sensitivity of Technology
4. Regional Balance (Classified Document Provided Under Separate Cover)

Transmittal No. 15–29

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Lebanon

(ii) *Total Estimated Value:*

Major Defense Equipment* ..	$140 million
Other	$ 6 million
TOTAL	$146 million

(iii) *Description and Quantity or Quantities of Articles or Services under Consideration for Purchase:* 1,000 AGM–114 Hellfire II missiles, containers, repair and return, spare and repair parts, support equipment, publications and technical documentation, personnel training and training equipment, U.S. Government and contractor logistics and technical support services, and other related elements of logistics and program support.

(iv) *Military Department:* Army (WFB Amendment #1)

(v) *Prior Related Cases, if any:* FMS Case WFB–$19M–12Nov14

(vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed To Be Paid:* None

(vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed To Be Sold:* See Attached Annex

(viii) *Date Report Delivered to Congress:* 04 JUNE 2015

* As defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Lebanon—AGM–114 Hellfire II missiles

The Government of Lebanon has requested possible sale of 1,000 AGM–114 Hellfire II missiles, containers, repair and return, spare and repair parts,

support equipment, publications and technical documentation, personnel training and training equipment, U.S. Government and contractor logistics and technical support services, and other related elements of logistics and program support. The estimated cost is $146 million.

This proposed sale will enhance the foreign policy and national security of the United States by helping to improve the security of a strategic partner. This proposed sale directly supports the Government of Lebanon and serves the interests of the people of Lebanon and the United States.

The proposed sale will improve Lebanon's capability to meet current and future threats. Lebanon will use the enhanced capability to strengthen its homeland defense and to replenish existing stock levels. Lebanon will have no difficulty absorbing these Hellfire missiles into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The prime contractor will be Lockheed Martin Missile and Fire Control in Dallas, Texas. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale will not require any additional U.S. Government or contractor representatives to Lebanon.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 15–29

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The AGM–114 Hellfire II missile is an air-to-ground missile used against light armored targets, thin-skinned vehicles, urban structures, bunkers, caves and personnel. The highest level of release for the Hellfire missile is Secret, based upon the software. The highest level of classified information that could be disclosed by a proposed sale or by testing of the end item is Secret; the highest level that must be disclosed for production, maintenance, or training is Confidential. Reverse engineering could reveal confidential information. Vulnerability data, countermeasures, vulnerability/susceptibility analyses, and threat definitions are classified Secret or Confidential.

2. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures which might reduce weapon system effectiveness or be used in the development of a system with similar or advanced capabilities.

3. A determination has been made that the Government of Lebanon can provide substantially the same degree of protection for the technology being released as the US Government. The sale is necessary in furtherance of the US foreign policy and notional security objectives as outlined in the policy justification of the notification.

4. All defense articles and services listed in this transmittal have been authorized for release and export to Lebanon.

[FR Doc. 2015–17369 Filed 7–14–15; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Department of the Army Corps of Engineers

Notice of Intent To Prepare an Environmental Impact Statement for Commercial Dredging of Construction Aggregate From the Kansas River in the State of Kansas

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

ACTION: Notice of intent.

SUMMARY: The U.S. Army Corps of Engineers (COE) is preparing an Environmental Impact Statement (EIS) to analyze the direct, indirect, and cumulative effects of commercial dredging of sand and gravel from the Kansas River in the State of Kansas. The proposed dredging will occur within portions of the river between the mouth of the Kansas River and river mile 170 at the confluence of the Kansas, Republican and Smokey Hill Rivers. Department of the Army (DA) authorization under Section 10 of the River and Harbors Act is required for the work to obtain sand and gravel materials from the Kansas River by hydraulic suction dredging operations. Commercial dredging in the Kansas River has occurred for more than 100 years but the quantity of sand and gravel materials annually withdrawn from the river has increased over time. The existing permits for dredging, last issued in 2007, allowed for a potential annual total of 3,150,000 tons of materials to be extracted from the Kansas River. The current DA permits originally scheduled to expire on December 31, 2012 were indefinitely extended until after completion of an EIS. Five applicants are currently requesting to extract 1,900,000 tons of material per year from the river at eight locations.

DATES: A scoping meeting will be held: August 4, 2015, 4:00 to 7:00 p.m. in Lawrence, Kansas.

ADDRESSES: The scoping meeting location is: Lawrence Public Library Auditorium, 707 Vermont Street, Lawrence, Kansas.

FOR FURTHER INFORMATION CONTACT: Questions and comments regarding the proposed action and EIS should be addressed to Mr. Brian Donahue, Regulatory Project Manager, U.S. Army Corps of Engineers, 601 East 12th Street, Room 402, Kansas City, MO 64106; (816) 389–3703; *brian.t.donahue@usace.army.mil.* For special needs (visual or hearing impaired, Spanish translation, etc.) requests during the scoping meetings, please call Brian Donahue by July 20, 2015.

SUPPLEMENTARY INFORMATION: The COE will be conducting a public scoping meeting at the location above to describe the proposed activity, preliminary alternatives, the National Environmental Policy Act process and to solicit input on the issues and alternatives to be evaluated and other related matters. Written comments for scoping will be accepted until September 15, 2015. The COE has prepared a scoping announcement to familiarize agencies, the public and interested organizations with the proposed Project and potential environmental issues that may be involved. The scoping announcement includes a list of the dredgers' requested annual extraction tonnage and the requested dredging reaches. Copies of the scoping announcement will be available at the public scoping meetings or can be requested by mail.

The permit applicants include the four following currently authorized dredgers: Holliday Sand and Gravel Company, LLC, (Lenexa, Kansas); Masters Dredging, (Lawrence, Kansas); Kaw Valley Companies, Inc. (Kansas City, Kansas); and Builders Choice Aggregates, (Topeka, Kansas). One permit applicant not currently authorized to dredge but seeking a permit is LBB, LLC (Topeka, Kansas). The final EIS would also apply to future applications for similar dredging operations on the Kansas River.

The COE has documented degradation or down-cutting of the river bed in some areas where dredging activity has been concentrated. Bed degradation may affect water intake structures, initiate tributary head cuts, promote bank erosion or levee instability, undermine

pipelines and bridge piers, increase encroachment of the high bank, affect aquatic habitat and create navigation hazards.

The EIS will be prepared according to the COE's procedures for implementing the National Environmental Policy Act of 1969, as amended, 42 U.S.C. 4332(2)(c), and consistent with the COE's policy to facilitate public understanding and review of agency proposals. As part of the EIS process, a full range of reasonable alternatives including the proposed dredging and no dredging will be evaluated.

The COE will invite the U.S. Environmental Protection Agency, the U.S. Fish and Wildlife Service, the U.S. Geologic Survey, the Kansas Department of Health and Environment, the Kansas State Historical Society, the Kansas Department of Wildlife, Parks and Tourism and the Kansas Geologic Survey to be contributing agencies in the formulation of the EIS.

Brian Donahue,

Regulatory Project Manager, Regulatory Branch.

[FR Doc. 2015–17355 Filed 7–14–15; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Intent To Grant Exclusive Patent License; GoXtudio, LLC

AGENCY: DoD Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: The invention listed below is assigned to the United States Government as represented by the Secretary of the Navy. The Department of the Navy hereby gives notice of its intent to grant to GoXtudio, LLC, a revocable, nonassignable, exclusive license to practice in the United States, the Government-owned invention described below: U.S. Patent 8,744,783 (Navy Case 99838): Issued June 3, 2014, entitled ''SYSTEM AND METHOD FOR MEASURING POWER GENERATED DURING LEGGED LOCOMOTION.''

DATES: Anyone wishing to object to the grant of this license has fifteen (15) days from the date of this notice to file written objections along with supporting evidence, if any.

ADDRESSES: Written objections are to be filed with Naval Surface Warfare Center, Crane Div, Code OOL, Bldg. 2, 300 Highway 361, Crane, IN 47522–5001.

FOR FURTHER INFORMATION CONTACT: Mr. Christopher Monsey, Naval Surface Warfare Center, Crane Div, Code OOL, Bldg. 2, 300 Highway 361, Crane, IN 47522–5001, telephone 812–854–4100.

Authority: 35 U.S.C. 207, 37 CFR part 404.

Dated: July 8, 2015.

N.A. Hagerty-Ford,

Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2015–17333 Filed 7–14–15; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Intent To Grant Exclusive Patent License; WarpSpec, Inc.

AGENCY: DoD Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: The invention listed below is assigned to the United States Government as represented by the Secretary of the Navy. The Department of the Navy hereby gives notice of its intent to grant to WarpSpec, Inc., a revocable, nonassignable, exclusive license to practice in the United States, the Government-owned inventions described below:

U.S. Patent 7,999,230 (Navy Case 99997): issued August 16, 2011, entitled ''TUNABLE DETECTION SYSTEM AND METHOD OF USE''//U.S. Patent 8,368,996 (Navy Case 99577): Issued February 5, 2013, entitled ''TUNABLE DETECTION SYSTEM''//and U.S. Patent 8,526,097 (Navy Case 102056): issued September 3, 2013, entitled ''TUNABLE DETECTION SYSTEM.''

DATES: Anyone wishing to object to the grant of this license has fifteen (15) days from the date of this notice to file written objections along with supporting evidence, if any.

ADDRESSES: Written objections are to be filed with Naval Surface Warfare Center, Crane Div, Code OOL, Bldg. 2, 300 Highway 361, Crane, IN 47522–5001.

FOR FURTHER INFORMATION CONTACT: Mr. Christopher Monsey, Naval Surface Warfare Center, Crane Div, Code OOL, Bldg 2, 300 Highway 361, Crane, IN 47522–5001, telephone 812–854–4100.

Authority: 35 U.S.C. 207, 37 CFR part 404.

Dated: July 8, 2015.

N.A. Hagerty-Ford,

Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2015–17332 Filed 7–14–15; 8:45 am]

BILLING CODE 3810–FF–P

DEFENSE NUCLEAR FACILITIES SAFETY BOARD

Sunshine Act Notice

AGENCY: Defense Nuclear Facilities Safety Board.

ACTION: Notice of closed meeting.

SUMMARY: Pursuant to the provisions of the Government in the Sunshine Act 5 U.S.C. 552b, and the Defense Nuclear Facilities Safety Board's (Board) regulations implementing the Government in the Sunshine Act, notice is hereby given of the Board's closed meeting described below.

DATES: 1:00 p.m.–2:00 p.m., July 29, 2015.

ADDRESSES: Defense Nuclear Facilities Safety Board, 625 Indiana Avenue NW., Room 425, Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: Mark Welch, General Manager, Defense Nuclear Facilities Safety Board, 625 Indiana Avenue NW., Suite 700, Washington, DC 20004–2901, (800) 788–4016. This is a toll-free number.

SUPPLEMENTARY INFORMATION: The meeting will be closed to the public. No participation from the public will be considered during the meeting.

Status

Closed. During the closed meeting, the Board Members will discuss issues dealing with potential Recommendations to the Secretary of Energy. The Board is invoking the exemption to close a meeting described in 5 U.S.C. 552b(c)(3) and 10 CFR 1704.4(c). The Board has determined that it is necessary to close the meeting since conducting an open meeting is likely to disclose matters that are specifically exempted from disclosure by statute. In this case, the deliberations will pertain to potential Board Recommendations which, under 42 U.S.C. 2286d(b) and (h)(3), may not be made publicly available until after they have been received by the Secretary of Energy or the President, respectively.

Matters To Be Considered

The meeting will proceed in accordance with the closed meeting agenda which is posted on the Board's public Web site at *www.dnfsb.gov*. Technical staff may present information to the Board. The Board Members are expected to conduct deliberations regarding potential Recommendations to the Secretary of Energy.

Dated: July 8, 2015.

Jessie H. Roberson,

Vice Chairman.

[FR Doc. 2015–17401 Filed 7–13–15; 11:15 am]

BILLING CODE 3670–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2015–ICCD–0059]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Migrant Student Information Exchange (MSIX)

AGENCY: Office of Elementary and Secondary Education (OESE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a reinstatement of a previously approved information collection.

DATES: Interested persons are invited to submit comments on or before August 14, 2015.

ADDRESSES: Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting Docket ID number ED–2015–ICCD–0059 or via postal mail, commercial delivery, or hand delivery. If the regulations.gov site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov. Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted; ED will ONLY accept comments during the comment period in this mailbox when the regulations.gov site is not available.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Mailstop L–OM–2–2E319, Room 2E115, Washington, DC 20202.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Patricia Meyertholen, 202–260–1394.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Migrant Student Information Exchange (MSIX).

OMB Control Number: 1810–0683.

Type of Review: A reinstatement of a previously approved information collection.

Respondents/Affected Public: State, Local and Tribal Governments.

Total Estimated Number of Annual Responses: 17, 520.

Total Estimated Number of Annual Burden Hours: 360, 491.

Abstract: The U.S. Department of Education (ED) is proposing new regulations to implement the Migrant Student Information Exchange (MSIX), a nationwide, electronic records exchange mechanism mandated under Title I, Part C of the Elementary and Secondary Education Act (ESEA), as amended by the No Child left Behind Act. As a condition of receiving a grant of funds under the Migrant Education Program (MEP), each State educational agency (SEA) would be required to collect, maintain, and submit minimum health and education-related data to MSIX within established timeframes. The proposed regulations would facilitate timely school enrollment, placement, and accrual of secondary course credits for migratory children and help us determine accurate migratory child counts and meet other MEP reporting requirements. The MEP is authorized under sections 1301–1309 in Title I, Part C of the ESEA. MSIX and the minimum data elements (MDEs) are authorized specifically under section 1308(b) of the ESEA.

This collection replaces the current collection for the MSIX MDEs under OMB No. 1810–0683. The burden hours and costs associated with this data collection are required to ensure that States implement and utilize MSIX for interstate migrant student records exchange, which will then enable the Department to meet the statutory mandate in section 1308(b) of the ESEA to facilitate the electronic exchange of MDEs by SEAs to address the educational and related needs of migratory children. The information collection addresses the following statutory requirements in the ESEA: Section 1304(b)(3), which requires SEAs to promote interstate and intrastate coordination of services for migratory children, including providing educational continuity through the timely transfer of pertinent school records (including health information) when children move from one school to another, whether or not the move occurs during the regular school year. Section 1308(b)(1), which requires ED to assist SEAs in providing for the electronic transfer of migrant student records. Section 1308(b)(2), which requires ED, in consultation with SEAs, to ensure the linkage of migrant student record systems for the purpose of electronically exchanging health and educational information regarding migrant children among States and determine the MDEs that each SEA shall collect and maintain for electronic exchange. Section 1309(2), which provides the statutory definition of a migratory child.

Dated: July 9, 2015.

Tomakie Washington,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2015–17284 Filed 7–14–15; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF EDUCATION

[Docket No.: ED–2015–ICCD–0058]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Application for the Rural Education Achievement Program (REAP)

AGENCY: Office of Elementary and Secondary Education (OESE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44

U.S.C. chapter 3501 *et seq.*), ED is proposing a reinstatement of a previously approved information collection.

DATES: Interested persons are invited to submit comments on or before August 14, 2015.

ADDRESSES: Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting Docket ID number ED–2015–ICCD–0058 or via postal mail, commercial delivery, or hand delivery. If the regulations.gov site is not available to the public for any reason, ED will temporarily accept comments at *ICDocketMgr@ed.gov. Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted; ED will ONLY accept comments during the comment period in this mailbox when the regulations.gov site is not available.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Mailstop L–OM–2–2E319, Room 2E115, Washington, DC 20202.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Jean Marchowsky, 202–205–2161.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Application for the Rural Education Achievement Program (REAP).

OMB Control Number: 1810–0646.

Type of Review: A reinstatement of a previously approved information collection.

Respondents/Affected Public: State, Local and Tribal Governments.

Total Estimated Number of Annual Responses: 549.

Total Estimated Number of Annual Burden Hours: 3,377.

Abstract: This data collection is pursuant to the Secretary's authority under Part B of Title VI of the Elementary and Secondary Education Act (ESEA), to award funds under two grant programs designed to address the unique needs of rural school districts—the Small, Rural School Achievement (SRSA) program (ESEA Section 6212) and the Rural and Low-Income School (RLIS) program (ESEA Section 6221). Under the SRSA program, the Secretary awards grants directly to eligible local educational agencies (LEAs) on a formula basis. Under the RLIS program, eligible school districts are sub-recipients of funds the Department awards to State educational agencies (SEAs) on a formula basis. For both grant programs, the Department awards funds based on a determination of the eligibility of individual school districts and the calculation of the allocation each eligible district should receive according to formula prescribed in the statute. This data collection package consists of two forms and related documents that are used to accomplish the grant award process each year: (1) A spreadsheet used by SEAs to submit information to identify RLIS and SRSA-eligible LEAs and to allocate funds based on the appropriate formula, and (2) an application form for SRSA-eligible LEAs to apply for funding. This submission requests a three-year extension of the current approved collection package (OMB #1810–0646). The REAP eligibility spreadsheet (Form 1) has no substantive changes or revisions from the previously-approved collection under OMB#1810–0646. Similarly, the SRSA Application (Form 2) is essentially unchanged from the previous collection. The instructions accompanying both Form 1 and Form 2 remain unchanged from the previously-approved collection, except for minor changes to update dates and contact information. None of these changes require SEAs to submit additional data.

Dated: July 9, 2015.

Tomakie Washington,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2015–17283 Filed 7–14–15; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Biological and Environmental Research Advisory Committee Meeting; Cancellation

AGENCY: Department of Energy.

ACTION: Notice of cancellation.

SUMMARY: On June 17, 2015, in 80 FR 34627, the Department of Energy (DOE) published a notice of open teleconference announcing a meeting on July 17, 2015 of the Biological and Environmental Research Advisory Committee. Due to the uncompleted report to be discussed during the meeting, this notice announces the postponement of this meeting until further notice.

FOR FURTHER INFORMATION CONTACT: Dr. Sharlene Weatherwax, Designated Federal Officer, BERAC, U.S. Department of Energy, Office of Science, Office of Biological and Environmental Research, SC–23/Germantown Building, 1000 Independence Avenue SW., Washington, DC 20585–1290. Telephone (301) 903–3251; fax (301) 903–5051 or email: *sharlene.weatherwax@science.doe.gov.*

Issued in Washington, DC, on July 9, 2015.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2015–17346 Filed 7–14–15; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Energy Efficiency and Renewable Energy

Biomass Research and Development Technical Advisory Committee

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

ACTION: Notice for solicitation of members.

SUMMARY: In accordance with the Federal Advisory Committee Act, 5 U.S.C. App. 2, the U.S. Department of Energy is soliciting nomination for candidates to fill vacancies on the Biomass Research and Development Technical Advisory Committee (Committee).

DATES: Deadline for Technical Advisory Committee member nominations is August 14, 2015.

ADDRESSES: The nominee's name, resume, biography, and any letters of support must be submitted via one of the following methods:

(1) Email to *elliott.levine@ee.doe.gov.*

(2) Overnight delivery service to Elliott Levine, Designated Federal Officer, Office of Energy Efficiency and Renewable Energy, U.S. Department of Energy, Mail Stop EE–3B, 1000 Independence Avenue SW., Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT: Elliott Levine, Designated Federal Officer for the Committee, Office of Energy Efficiency and Renewable Energy, U.S. Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585; (202) 586–1476; Email: *elliott.levine@ee.doe.gov.*

Committee Web site: http://biomassboard.gov/committee/committee.html.

SUPPLEMENTARY INFORMATION: The Biomass Research and Development Act of 2000 (Biomass Act) [Pub. L. 106–224] requires cooperation and coordination in biomass research and development (R&D) between the U.S. Department of Agriculture (USDA) and U.S. Department of Energy (DOE). The Biomass Act was repealed in June 2008 by section 9008 of the Food, Conservation and Energy Act of 2008 (FCEA) [Pub. L. 110–246, 122 Stat. 1651, enacted June 18, 2008, H.R. 6124]. The Biomass Act was re-authorized in the Agricultural Act of 2014.

FCEA section 9008(d) established the Biomass Research and Development Technical Advisory Committee and lays forth its meetings, coordination, duties, terms, and membership types. Committee members are paid travel and per diem for each meeting. The Committee must meet quarterly and should not duplicate the efforts of other Federal advisory committees. Meetings are typically two days in duration. Three meetings are held in the Washington, DC area and the fourth is held at a site to be determined each year. The Committee advises DOE and USDA points of contact with respect to the Biomass R&D Initiative (Initiative) and priority technical biomass R&D needs and makes written recommendations to the Biomass R&D Board (Board). Those recommendations regard whether: (A) Initiative funds are distributed and used consistent with Initiative objectives; (B) solicitations are open and competitive with awards made annually; (C) objectives and evaluation criteria of the solicitations are clear; and (D) the points of contact are funding proposals selected on the basis of merit, and determined by an independent panel of qualified peers.

The committee members may serve two, three-year terms and committee membership must include: (A) An individual affiliated with the biofuels industry; (B) an individual affiliated with the biobased industrial and commercial products industry; (C) an individual affiliated with an institution of higher education that has expertise in biofuels and biobased products; (D) 2 prominent engineers or scientists from government (non-federal) or academia that have expertise in biofuels and biobased products; (E) an individual affiliated with a commodity trade association; (F) 2 individuals affiliated with environmental or conservation organizations; (G) an individual associated with state government who has expertise in biofuels and biobased products; (H) an individual with expertise in energy and environmental analysis; (I) an individual with expertise in the economics of biofuels and biobased products; (J) an individual with expertise in agricultural economics; (K) an individual with expertise in plant biology and biomass feedstock development; (L) an individual with expertise in agronomy, crop science, or soil science; and (M) at the option of the points of contact, other members (REF: FCEA 2008 section 9008(d)(2)(A)). All nominees will be carefully reviewed for their expertise, leadership, and relevance to an expertise. Appointments will be made for three-year terms as dictated by the legislation.

Nominations this year are needed for the following categories in order to address the Committee's needs: (B) An individual affiliated with the biobased industrial and commercial products industry; (D) prominent engineers or scientists from government (non-federal) or academia that have expertise in biofuels and biobased products; and (L) an individual with expertise in agronomy, crop science, or soil science. Nominations for other categories will also be accepted. Nomination categories C, D, H, I, J, K, L, and M are considered Special Government Employees and require submittal of an annual financial disclosure form. In addition to the required categories, other areas of expertise of interest to the Committee are individuals with expertise in process engineering related to biorefineries, or biobased coproducts that enable fuel production.

Nominations are solicited from organizations, associations, societies, councils, federations, groups, universities, and companies that represent a wide variety of biomass research and development interests throughout the country. Nominations for one individual that fits several of the categories listed above *or* for more than one person that fits one category will be accepted. In your nomination letter, please indicate the specific membership category of interest. Each nominee must submit their resume and biography along with any letters of support by the deadline above. If you were nominated in previous years but were not appointed to the committee and would still like to be considered, please submit your nomination package again in response to this notice with all required materials. All nominees will be vetted before selection.

Nominations are open to all individuals without regard to race, color, religion, sex, national origin, age, mental or physical handicap, marital status, or sexual orientation. To ensure that recommendations of the Technical Advisory Committee take into account the needs of the diverse groups served by DOE, membership shall include, to the extent practicable, individuals with demonstrated ability to represent the needs of women and men of all racial and ethnic groups and persons with disabilities. Please note that registered lobbyists, individuals already serving another Federal Advisory Committee, and federal employees are ineligible for nomination.

Appointments to the Biomass Research and Development Technical Advisory Committee will be made by the Secretary of Energy and the Secretary of Agriculture.

Issued in Washington, DC, on July 9, 2015.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2015–17347 Filed 7–14–15; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER15–623–004.

Applicants: PJM Interconnection, L.L.C.

Description: Compliance filing: Compliance Filing pursuant to the June 9, 2015 Order on Proposed Tariff Rev to be effective 4/1/2015.

Filed Date: 7/9/15.

Accession Number: 20150709–5186.

Comments Due: 5 p.m. ET 7/30/15.

Docket Numbers: ER15–2144–000.

Applicants: Michigan Electric Transmission Company, LLC

Description: § 205(d) Rate Filing: Filing of Fiber License Agreement to be effective 9/8/2015.

Filed Date: 7/9/15.

Accession Number: 20150709–5156.

Comments Due: 5 p.m. ET 7/30/15.

Docket Numbers: ER15–2145–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2015–07–09_Schedule 43H Revision White Pine 1 SSR to be effective 4/16/2015.

Filed Date: 7/9/15.

Accession Number: 20150709–5189.

Comments Due: 5 p.m. ET 7/30/15.

Take notice that the Commission received the following public utility holding company filings:

Docket Numbers: PH15–16–000.

Applicants: Cross & Company, PLLC.

Description: Gas Natural, Inc. submits FERC 65–B Notification of Change in Exemption Notification.

Filed Date: 7/9/15.

Accession Number: 20150709–5197.

Comments Due: 5 p.m. ET 7/30/15.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 9, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–17352 Filed 7–14–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER11–4363–006.

Applicants: Osage Wind, LLC.

Description: Notice of Non-Material Change in Status of Osage Wind, LLC.

Filed Date: 7/8/15.

Accession Number: 20150708–5217.

Comments Due: 5 p.m. ET 7/29/15.

Docket Numbers: ER11–4498–009; ER11–4499–009; ER14–325–006; ER11–4500–009; ER11–4507–008; ER12–128–007; ER11–4501–010; ER12–979–009; ER12–2542–006; ER12–2448–009; ER13–2409–005; ER14–2858–004

Applicants: Smoky Hills Wind Farm, LLC, Smoky Hills Wind Project II, LLC, Enel Cove Fort, LLC, Enel Stillwater, LLC, Canastota Windpower, LLC, EGP Stillwater Solar, LLC, Caney River Wind Project, LLC, Rocky Ridge Wind Project, LLC, Prairie Rose Wind, LLC, Chisholm View Wind Project, LLC, Buffalo Dunes Wind Project, LLC, Origin Wind Energy, LLC

Description: Notice of Change in Status of Smoky Hills Wind Farm, LLC, *et al.*

Filed Date: 7/8/15.

Accession Number: 20150708–5213.

Comments Due: 5 p.m. ET 7/29/15.

Docket Numbers: ER15–1728–000.

Applicants: BIF II Safe Harbor Holdings, LLC.

Description: Supplement to May 15, 2015 BIF II Safe Harbor Holdings, LLC tariff filing.

Filed Date: 7/8/15.

Accession Number: 20150708–5015.

Comments Due: 5 p.m. ET 7/29/15.

Docket Numbers: ER15–2132–000.

Applicants: Wisconsin Electric Power Company.

Description: § 205(d) Rate Filing: Wisconsin Electric FERC Electric Tariff Volume 9—2015 to be effective 9/6/2015.

Filed Date: 7/8/15.

Accession Number: 20150708–5182.

Comments Due: 5 p.m. ET 7/29/15.

Docket Numbers: ER15–2133–000.

Applicants: Wisconsin Electric Power Company.

Description: § 205(d) Rate Filing: Wisconsin Electric and WPPI Rate Schedule FERC No. 90—2015 to be effective 9/6/2015.

Filed Date: 7/8/15.

Accession Number: 20150708–5183.

Comments Due: 5 p.m. ET 7/29/15.

Docket Numbers: ER15–2134–000.

Applicants: Sky River Asset Holdings, LLC.

Description: Baseline eTariff Filing: Sky River Asset Holdings, LLC Application for Market-Based Rates to be effective 9/7/2015.

Filed Date: 7/8/15.

Accession Number: 20150708–5184.

Comments Due: 5 p.m. ET 7/29/15.

Docket Numbers: ER15–2135–000.

Applicants: Alexander Wind Farm, LLC.

Description: Baseline eTariff Filing: Alexander Wind Farm Initial Baseline MBR Application Filing to be effective 9/8/2015.

Filed Date: 7/9/15.

Accession Number: 20150709–5088.

Comments Due: 5 p.m. ET 7/30/15.

Docket Numbers: ER15–2136–000.

Applicants: PJM Interconnection, L.L.C., PPL Electric Utilities Corporation.

Description: § 205(d) Rate Filing: PPL Electric submits Coordination Agreement No. 1016 with Borough of Duncannon to be effective 1/1/2014.

Filed Date: 7/9/15.

Accession Number: 20150709–5090.

Comments Due: 5 p.m. ET 7/30/15.

Docket Numbers: ER15–2137–000.

Applicants: PJM Interconnection, L.L.C., PPL Electric Utilities Corporation.

Description: § 205(d) Rate Filing: PPL Electric submits Coordination Agreement No. 1017 with Borough of Ephrata to be effective 1/1/2014.

Filed Date: 7/9/15.

Accession Number: 20150709–5091.

Comments Due: 5 p.m. ET 7/30/15.

Docket Numbers: ER15–2138–000.

Applicants: PJM Interconnection, L.L.C.,PPL Electric Utilities Corporation.

Description: § 205(d) Rate Filing: PPL submits Coordination Agreement No. 1020 with Borough of Leighton to be effective 1/1/2014.

Filed Date: 7/9/15.

Accession Number: 20150709–5092.

Comments Due: 5 p.m. ET 7/30/15.

Docket Numbers: ER15–2139–000.

Applicants: PJM Interconnection, L.L.C., PPL Electric Utilities Corporation.

Description: § 205(d) Rate Filing: PPL submits Coordination Agreement No. 1021 with Borough of Mifflinburg to be effective 1/1/2014.

Filed Date: 7/9/15.

Accession Number: 20150709–5097.

Comments Due: 5 p.m. ET 7/30/15.

Docket Numbers: ER15–2140–000.

Applicants: PJM Interconnection, L.L.C., PPL Electric Utilities Corporation.

Description: § 205(d) Rate Filing: PPL submits Coordination Agreement No. 1023 with Borough of Perkasie to be effective 1/1/2014.
Filed Date: 7/9/15.
Accession Number: 20150709–5099.
Comments Due: 5 p.m. ET 7/30/15.

Docket Numbers: ER15–2141–000.
Applicants: PJM Interconnection, L.L.C., PPL Electric Utilities Corporation.
Description: § 205(d) Rate Filing: PPL submits Coordination Agreement No. 1025 with Borough of Schuylkill Haven to be effective 1/1/2014.
Filed Date: 7/9/15.
Accession Number: 20150709–5101.
Comments Due: 5 p.m. ET 7/30/15.

Docket Numbers: ER15–2142–000.
Applicants: PJM Interconnection, L.L.C., PPL Electric Utilities Corporation.
Description: § 205(d) Rate Filing: PPL submits Coordination Agreement No. 1026 with Borough of St. Clair to be effective 1/1/2014.
Filed Date: 7/9/15.
Accession Number: 20150709–5104.
Comments Due: 5 p.m. ET 7/30/15.

Docket Numbers: ER15–2143–000.
Applicants: PJM Interconnection, L.L.C., PPL Electric Utilities Corporation.
Description: § 205(d) Rate Filing: PPL submits Coordination Agreement No. 1028 with Borough of Weatherly to be effective 1/1/2014.
Filed Date: 7/9/15.
Accession Number: 20150709–5111.
Comments Due: 5 p.m. ET 7/30/15.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 9, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–17351 Filed 7–14–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP15–1114–000.
Applicants: Enable Mississippi River Transmission, L.
Description: Section 4(d) Rate Filing: Negotiated Rate Filing to Amend LER 5680's Attachment A_7–6–15 to be effective 7/6/2015.
Filed Date: 7/6/15.
Accession Number: 20150706–5208.
Comments Due: 5 p.m. ET 7/20/15.

Docket Numbers: RP15–1115–000.
Applicants: Dogwood Energy LLC.
Description: Request for Waiver and Expedited Action of Dogwood Energy LLC, et al. under RP15–1115.
Filed Date: 7/6/15.
Accession Number: 20150706–5234.
Comments Due: 5 p.m. ET 7/15/15.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP15–101–003.
Applicants: Florida Gas Transmission Company, LLC.
Description: Compliance filing RP15–101 Compliance on Technical Issues to be effective 8/1/2015.
Filed Date: 7/7/15.
Accession Number: 20150707–5152.
Comments Due: 5 p.m. ET 7/20/15.

Docket Numbers: RP15–850–001.
Applicants: Natural Gas Pipeline Company of America.
Description: Compliance filing Second Revised Compliance Filing to be effective 5/1/2015.
Filed Date: 7/7/15.
Accession Number: 20150707–5153.
Comments Due: 5 p.m. ET 7/15/15.

Any person desiring to protest in any of the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 8, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–17261 Filed 7–14–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER15–2115–000.
Applicants: Southwest Power Pool, Inc.
Description: Section 205(d) Rate Filing: Northwest Iowa Power Cooperative Formula Rate to be effective 10/1/2015.
Filed Date: 7/7/15.
Accession Number: 20150707–5150.
Comments Due: 5 p.m. ET 7/28/15.

Docket Numbers: ER15–2116–000.
Applicants: NorthWestern Corporation.
Description: Section 205(d) Rate Filing: RS 271—REC Silicon O and M Agreement to be effective 7/9/2015.
Filed Date: 7/8/15.
Accession Number: 20150708–5045.
Comments Due: 5 p.m. ET 7/29/15.

Docket Numbers: ER15–2117–000.
Applicants: Midcontinent Independent System Operator, Inc.
Description: Tariff Cancellation: 2015–07–08_Cancellation of Index of Customers to be effective 9/6/2015.
Filed Date: 7/8/15.
Accession Number: 20150708–5047.
Comments Due: 5 p.m. ET 7/29/15.

Docket Numbers: ER15–2118–000.
Applicants: CalPeak Power—Border LLC.
Description: Section 205(d) Rate Filing: Notice re Cat 2 Seller in SW Region to be effective 7/9/2015.
Filed Date: 7/8/15.
Accession Number: 20150708–5049.
Comments Due: 5 p.m. ET 7/29/15.

Docket Numbers: ER15–2119–000.
Applicants: CalPeak Power—Enterprise LLC.
Description: Section 205(d) Rate Filing: Notice re Cat 2 Seller in SW Region to be effective 7/9/2015.

Filed Date: 7/8/15.
Accession Number: 20150708–5050.
Comments Due: 5 p.m. ET 7/29/15.

Docket Numbers: ER15–2120–000.
Applicants: CalPeak Power—Panoche LLC.
Description: Section 205(d) Rate Filing: Notice re Cat 2 Seller in SW Region to be effective 7/9/2015.
Filed Date: 7/8/15.
Accession Number: 20150708–5051.
Comments Due: 5 p.m. ET 7/29/15.

Docket Numbers: ER15–2121–000.
Applicants: CalPeak Power—Vaca Dixon LLC.
Description: Section 205(d) Rate Filing: Notice re Cat 2 Seller in SW Region to be effective 7/9/2015.
Filed Date: 7/8/15.
Accession Number: 20150708–5052.
Comments Due: 5 p.m. ET 7/29/15.

Docket Numbers: ER15–2122–000.
Applicants: CalPeak Power LLC.
Description: Section 205(d) Rate Filing: Notice re Cat 2 Seller in SW Region to be effective 7/9/2015.
Filed Date: 7/8/15.
Accession Number: 20150708–5053.
Comments Due: 5 p.m. ET 7/29/15.

Docket Numbers: ER15–2123–000.
Applicants: Midway Peaking, LLC.
Description: Section 205(d) Rate Filing: Notice re Category 2 Seller Status to be effective 7/9/2015.
Filed Date: 7/8/15.
Accession Number: 20150708–5055.
Comments Due: 5 p.m. ET 7/29/15.

Docket Numbers: ER15–2124–000.
Applicants: EDF Industrial Power Services (IL), LLC.
Description: Tariff Cancellation: Notice of cancellation to be effective 7/9/2015.
Filed Date: 7/8/15.
Accession Number: 20150708–5061.
Comments Due: 5 p.m. ET 7/29/15.

Docket Numbers: ER15–2125–000.
Applicants: EDF Industrial Power Services (NY), LLC.
Description: Tariff Cancellation: Notice of cancellation to be effective 7/9/2015.
Filed Date: 7/8/15.
Accession Number: 20150708–5064.
Comments Due: 5 p.m. ET 7/29/15.

Docket Numbers: ER15–2126–000.
Applicants: EDF Industrial Power Services (OH), LLC.
Description: Tariff Cancellation: Notice of cancellation to be effective 7/9/2015.
Filed Date: 7/8/15.
Accession Number: 20150708–5068.
Comments Due: 5 p.m. ET 7/29/15.

Docket Numbers: ER15–2127–000.
Applicants: Niagara Mohawk Power Corporation, New York Independent System Operator, Inc.
Description: Section 205(d) Rate Filing: NiMo filing of an amended and restate IA on behalf of NiMo and Sithe to be effective 6/30/2015.
Filed Date: 7/8/15.
Accession Number: 20150708–5079.
Comments Due: 5 p.m. ET 7/29/15.

Docket Numbers: ER15–2128–000.
Applicants: New York Independent System Operator, Inc., Niagara Mohawk Power Corporation.
Description: Section 205(d) Rate Filing: Cost Reimbursement Agreement (SA 2223) between Ntnl Grd and RG&E to be effective 3/5/2015.
Filed Date: 7/8/15.
Accession Number: 20150708–5088.
Comments Due: 5 p.m. ET 7/29/15.

Docket Numbers: ER15–2129–000.
Applicants: Slate Creek Wind Project, LLC.
Description: Baseline eTariff Filing: Slate Creek Wind Initial Baseline MBR Application Filing to be effective 9/7/2015.
Filed Date: 7/8/15.
Accession Number: 20150708–5130.
Comments Due: 5 p.m. ET 7/29/15.

Docket Numbers: ER15–2130–000.
Applicants: Roosevelt Wind Project, LLC.
Description: Baseline eTariff Filing: Roosevelt Wind Initial Baseline MBR Application Filing to be effective 9/7/2015.
Filed Date: 7/8/15.
Accession Number: 20150708–5142.
Comments Due: 5 p.m. ET 7/29/15.

Docket Numbers: ER15–2131–000.
Applicants: Milo Wind Project, LLC.
Description: Baseline eTariff Filing: Milo Wind Initial Baseline MBR Application Filing to be effective 9/7/2015.
Filed Date: 7/8/15.
Accession Number: 20150708–5155.
Comments Due: 5 p.m. ET 7/29/15.

Take notice that the Commission received the following electric reliability filings:

Docket Numbers: RD14–14–001; RD15–3–001; RD15–5–001.
Applicants: North American Electric Reliability Corporation.
Description: Revisions of the North American Electric Reliability Corporation to the Violation Risk Factors for Reliability Standards PRC–004–3, PRC–004–4 and PRC–004–5.
Filed Date: 7/7/15.
Accession Number: 20150707–5189.
Comments Due: 5 p.m. ET 8/7/15.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5:00 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: July 8, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–17260 Filed 7–14–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM98–1–000]

Records Governing Off-the-Record Communications; Public Notice

This constitutes notice, in accordance with 18 CFR 385.2201(b), of the receipt of prohibited and exempt off-the-record communications.

Order No. 607 (64 FR 51222, September 22, 1999) requires Commission decisional employees, who make or receive a prohibited or exempt off-the-record communication relevant to the merits of a contested proceeding, to deliver to the Secretary of the Commission, a copy of the communication, if written, or a summary of the substance of any oral communication.

Prohibited communications are included in a public, non-decisional file associated with, but not a part of, the decisional record of the proceeding. Unless the Commission determines that the prohibited communication and any responses thereto should become a part of the decisional record, the prohibited off-the-record communication will not be considered by the Commission in reaching its decision. Parties to a proceeding may seek the opportunity to respond to any facts or contentions made in a prohibited off-the-record communication, and may request that the Commission place the prohibited communication and responses thereto in the decisional record. The Commission will grant such a request only when it determines that fairness so requires. Any person identified below as

having made a prohibited off-the-record communication shall serve the document on all parties listed on the official service list for the applicable proceeding in accordance with Rule 2010, 18 CFR 385.2010.

Exempt off-the-record communications are included in the decisional record of the proceeding, unless the communication was with a cooperating agency as described by 40 CFR 1501.6, made under 18 CFR 385.2201(e)(1)(v).

The following is a list of off-the-record communications recently received by the Secretary of the Commission. The communications listed are grouped by docket numbers in ascending order. These filings are available for electronic review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site at *http://www.ferc.gov* using the eLibrary link. Enter the docket number, excluding the last three digits, in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or for TTY, contact (202) 502–8659.

Docket No.	File date	Presenter or requester
Prohibited:		
1. CP13–552–000; CP13–553–000	6–29–15	Cheniere Energy Inc.
2. CP14–554–000	6–29–15	Wil Byrd.
3. P–1494–000	6–30–15	Joe D. Harwood.
4. P–1494–000	6–30–15	Rusty Fleming.
5. P–1494–000	6–30–15	Joe D. Harwood.
Exempt:		
1. CP15–500–00	6–19–15	U.S. Representative Will Hurd.
2. CP13–483–000; CP13–492–000	6–29–15	FERC Staff.[1]
3. P–2210–000	6–30–15	U.S. Senator Mark R. Warner.
4. CP13–492–000	7–2–15	FERC Staff.[2]
5. CP09–6–001	7–8–15	FERC Staff.[3]

[1] Letter dated 4–8–15 from U.S. Department of Interior Bureau of Land Management regarding analysis of Blue Ridge Alternative.
[2] Letter dated 4–8–15from U.S. Department of Interior Bureau of Land Management, staff conveying 4 technical reports for Pacific Connector Pipeline Project.
[3] Record of 6–26–15 Oregon LNG conference call.

Dated: July 9, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–17353 Filed 7–14–15; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2011–0891; FRL–9930–58–OEI]

Information Collection Request Submitted to OMB for Review and Approval; Comment Request; Recordkeeping and Periodic Reporting of the Production, Import, Recycling, Destruction, Transhipment, and Feedstock Use of Ozone-Depleting Substances (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency has submitted an information collection request (ICR), ''Recordkeeping and Periodic Reporting of the Production, Import, Recycling, Destruction, Transhipment, and Feedstock Use of Ozone-Depleting Substances (Renewal)'' (EPA ICR No. 1432.31, OMB Control No. 2060–0170) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). Public comments were previously requested via the **Federal Register** (80 FR 24917) on May 1, 2015 during a 60-day comment period. This notice allows for an additional 30 days for public comments. A fuller description of the ICR is given below, including its estimated burden and cost to the public. 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.

DATES: Additional comments may be submitted on or before August 14, 2015.

ADDRESSES: Submit your comments, referencing Docket ID Number EPA–HQ–OAR–2011–0891, to (1) EPA online using *www.regulations.gov* (our preferred method) or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460, and (2) OMB via email to *oira_submission@omb.eop.gov.* Address comments to OMB Desk Officer for EPA.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Robert Burchard, Stratospheric Protection Division, Office of Atmospheric Programs (6205J), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 343–9126; email address: *Burchard.robert@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents, which explain in detail the information that the EPA will be collecting, are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Abstract: The Montreal Protocol on Substances that Deplete the Ozone Layer (Protocol) and Title VI of the Clean Air Act Amendments of 1990 (CAA) established limits on total U.S. production, import, and export of Class I and Class II controlled ozone depleting substances (ODSs). Under its Protocol commitments, the United States has been obligated to cease production and import of Class I controlled substances with exemptions for essential uses, critical uses, previously used material, and material that will be transformed, destroyed, or exported to developing countries. The Protocol also establishes limits and reduction schedules leading

to the eventual phaseout of Class II controlled substances with similar exemptions beyond the phaseout. Additionally, the CAA has its own limits on production and consumption of controlled substances that EPA must adhere to and enforce.

To ensure the United States' compliance with the limits and restrictions established by the Protocol and the CAA, the ODS phaseout regulations establish control measures for individual companies. EPA monitors compliance with the limits and restrictions for individual United States companies through the recordkeeping and reporting requirements established in the regulations at 40 CFR part 82, subpart A. To submit required information, regulated entities can download reporting forms, complete them, and then send them to EPA via mail, fax, or electronically. Upon receipt of the reports, EPA enters and stores the data in the ODS Tracking System. The Tracking System is a secure database that maintains all of the data that is submitted to EPA and allows the Agency to: (1) Track over total production and consumption of controlled substances to satisfy conditions of the CAA and fulfill the United States obligations under the Protocol; (2) monitor compliance with limits and restrictions on production, imports, exports, and specific exemptions to the phaseout for individual U.S. companies; and (3) enforce against illegal imports and violations related to the control of Class I and Class II substances. Additionally, reporting on the exemptions allows an entity to retain the benefit of being able to produce or import a controlled Class I ODS beyond the date of complete phaseout.

Pursuant to regulations 40 CFR part 2, subpart B, reporting businesses are entitled to assert a business confidentiality claim covering any part of the submitted business information as defined in 40 CFR part 2, subpart B.

Respondents/affected entities: Chemical Producers, Importers, and Exporters (CFCs); Research and Development (Laboratories); and MeBr Producers, Importers, Exporters, Distributors, and Applicators.

Estimated number of respondents: 1845 (total).

Frequency of response: quarterly, annually, occasionally.

Total estimated burden: 2583 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $280,055 (per year), includes $5,535 annualized capital or operation & maintenance costs.

Changes in the Estimates: There is no change in the total estimated respondent burden compared with the ICR currently approved by OMB.

Courtney Kerwin,

Acting Director, Collection Strategies Division.

[FR Doc. 2015–17316 Filed 7–14–15; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[3060–0986]

Information Collection Being Submitted for Review and Approval to the Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments should be submitted on or before August 14, 2015. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, OMB, via email *Nicholas_A._Fraser@omb.eop.gov;* and to Nicole Ongele, FCC, via email *PRA@fcc.gov* and to *Nicole.Ongele@fcc.gov.* Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** section below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Nicole Ongele at (202) 418–2991.

To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the Web page <*http://www.reginfo.gov/public/do/PRAMain*>, (2) look for the section of the Web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the OMB control number of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0986.

Title: Competitive Carrier Line Count Report and Self-Certification as a Rural Carrier.

Form Number: FCC Form 481, FCC Form 505, FCC Form 507, FCC Form 508, FCC Form 509, and FCC Form 525.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit, not-for-profit institutions and state, local or tribal government.

Number of Respondents: 1,957 respondents; 12,885 responses.

Estimated Time per Response: .5 hours to 100 hours.

Frequency of Response: On occasion, quarterly and annual reporting requirements, recordkeeping requirement and third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. 151–154, 155, 201–206, 214, 218–220, 251, 252, 254, 256, 303(r), 332, 403, 405, 410, and 1302.

Total Annual Burden: 266,868 hours.

Total Annual Cost: No cost.

Privacy Act Impact Assessment: This information collection does not affect individuals or households; thus, there are no impacts under the Privacy Act.

Nature and Extent of Confidentiality: We note that USAC must preserve the confidentiality of all data obtained from respondents; must not use the data except for purposes of administering the universal service programs; and must not disclose data in company-specific form unless directed to do so by the Commission.

Needs and Uses: On November 18, 2011, the Commission released an order reforming its high-cost universal service support mechanisms. Connect America Fund; A National Broadband Plan for Our Future; Establish Just and Reasonable Rates for Local Exchange Carriers; High-Cost Universal Service Support; Developing a Unified Intercarrier Compensation Regime; Federal-State Joint Board on Universal Service; Lifeline and Link-Up; Universal Service Reform—Mobility Fund, WC Docket Nos. 10–90, 07–135, 05–337, 03–109; GN Docket No. 09–51; CC Docket Nos. 01–92, 96–45; WT Docket No. 10–208, Order and Further Notice of Proposed Rulemaking, 26 FCC Rcd 17663 (2011) (*USF/ICC Transformation Order*); and the Commission and Wireline Competition Bureau have since adopted a number of orders that implement the *USF/ICC Transformation Order;* see also Connect America Fund et al., WC Docket No. 10–90 et al., Third Order on Reconsideration, 27 FCC Rcd 5622 (2012); Connect America Fund et al., WC Docket No. 10–90 et al., Order, 27 FCC Rcd 605 (Wireline Comp. Bur. 2012); Connect America Fund et al., WC Docket No. 10–90 et al., Fifth Order on Reconsideration, 27 FCC Rcd 14549 (2012); Connect America Fund et al., WC Docket No. 10–90 et al., Order, 28 FCC Rcd 2051 (Wireline Comp. Bur. 2013); Connect America Fund et al., WC Docket No. 10–90 et al., Order, 28 FCC Rcd 7227 (Wireline Comp. Bur. 2013). The Commission has received OMB approval for most of the information collections required by these orders. At a later date the Commission plans to submit additional revisions for OMB review to address other reforms adopted in the orders (*e.g.,* 47 CFR 54.313(a)(11)). The revision proposed here contains information collection requirements already reviewed and approved by OMB. Specifically, the Commission proposes to merge the existing universal service information collection requirements from OMB Control No. 3060–1188 into this control number. The Commission proposes to add FCC Form 505, currently approved under collection 3060–1188, to this information collection. There are no changes to the currently approved FCC Form 505. The Commission also proposes certain changes to FCC Form 481 and its instructions as a result of merging the information collection requirements contained in 3060–0986 and 3060–1188. These changes include revising FCC Form 481 and its instructions to incorporate the certifications and census block data collection requirements for certain recipients of Connect America Phase I incremental support that are currently approved under collection 3060–1188. The Commission also proposes to reduce the number of respondents for reporting and certification requirements related to Connect America Phase I incremental support to reflect the number of price cap carriers that actually accepted such support. Once the Commission receives OMB approval to merge the requirements contained in 3060–1188 under this control number, the Commission will discontinue 3060–1188.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2015–17267 Filed 7–14–15; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0031]

Information Collection Being Submitted for Review and Approval to the Office of Management and Budget

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid Office of Management and Budget (OMB) control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written comments should be submitted on or before August 14, 2015. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contacts below as soon as possible.

ADDRESSES: Direct all PRA comments to Nicholas A. Fraser, OMB, via email *Nicholas_A._Fraser@omb.eop.gov;* and to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.* Include in the comments the OMB control number as shown in the **SUPPLEMENTARY INFORMATION** section below.

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection, contact Cathy Williams at (202) 418–2918. To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the Web page <*http://www.reginfo.gov/public/do/PRAMain*>, (2) look for the section of the Web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the OMB control number of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

SUPPLEMENTARY INFORMATION:

Control Number: 3060–0031.

Title: Application for Consent to Assignment of Broadcast Station Construction Permit or License, FCC Form 314; Application for Consent to Transfer Control of Entity Holding Broadcast Station Construction Permit or License, FCC Form 315; Section 73.3580, Local Public Notice of Filing of Broadcast Applications.

Form Number: FCC Forms 314 and 315.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities; Not-for-profit institutions; State, local or Tribal government.

Number of Respondents and Responses: 4,840 respondents and 12,880 responses.

Estimated Time per Response: 0.084 to 6 hours.

Frequency of Response: On occasion reporting requirement; Third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this collection of information is contained in Sections 154(i), 303(b) and 308 of the Communications Act of 1934, as amended.

Total Annual Burden: 18,670 hours.

Total Annual Cost: $52,519,656.

Privacy Impact Assessment(s): No impacts.

Nature and Extent of Confidentiality: There is no need for confidentiality and respondents are not being asked to submit confidential information to the Commission.

Needs and Uses: FCC Form 314 and the applicable exhibits/explanations are required to be filed when applying for consent for assignment of an AM, FM, LPFM or TV broadcast station construction permit or license. In addition, the applicant must notify the Commission when an approved assignment of a broadcast station construction permit or license has been consummated.

FCC Form 315 and applicable exhibits/explanations are required to be filed when applying for transfer of control of an entity holding an AM, FM, LPFM or TV broadcast station construction permit or license. In addition, the applicant must notify the Commission when an approved transfer of control of a broadcast station construction permit or license has been consummated. Due to the similarities in the information collected by these two forms, OMB has assigned both forms OMB Control Number 3060–0031.

47 CFR 73.3580 requires local public notice in a newspaper of general circulation published in the community in which a station is located of the filing of all applications for transfer of control or assignment of the license/permit. This notice must be completed within 30 days of the tendering of the application. This notice must be published at least twice a week for two consecutive weeks in a three-week period. A copy of this notice and the application must be placed in the station's public inspection file along with the application, pursuant to Section 73.3527. Additionally, an applicant for transfer of control of a license must broadcast the same notice over the station at least once daily on four days in the second week immediately following the tendering for filing of the application.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2015–17268 Filed 7–14–15; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0999]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burden and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501–3520), the Federal Communications Commission invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s). Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information burden for small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid 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 (PRA) that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before September 14, 2015. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email *PRA@fcc.gov* and to *Cathy.Williams@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418–2918.

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060–0999.

Title: Hearing Aid Compatibility Status Report and Section 20.19, Hearing Aid-Compatible Mobile Handsets (Hearing Aid Compatibility Act).

Form Number: FCC Form 655.

Type of Review: Extension of a currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents: 925 respondents; 925 responses.

Estimated Time per Response: 13.041081 hours per response (average).

Frequency of Response: On occasion and annual reporting requirements and third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. Statutory authority for this information collection is contained in 47 U.S.C. Sections 151, 154(i), 157, 160, 201, 202, 208, 214, 301, 303, 308, 309(j), 310 and 610 of the Communications Act of 1934, as amended.

Total Annual Burden: 12,063 hours.

Total Annual Cost: No costs.

Privacy Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: Information requested in the reports may include confidential information. However, covered entities are allowed to request that such materials submitted to the Commission be withheld from public inspection.

Needs and Uses: The Commission will submit this information collection as an extension to the Office of Management and Budget (OMB) after this 60-day comment period to obtain the full three year clearance for the collection. There is no change in number of respondents/responses, total annual burden hours, or total annual cost from the previously approved estimates. As part of the extension request, the Commission will submit certain non-substantive changes for approval, as described below.

The collection is necessary to implement certain disclosure requirements that are part of the Commission's wireless hearing aid compatibility rule. In a Report and

Order in WT Docket No. 01–309, FCC 03–168, adopted and released in September 2003, implementing a mandate under the Hearing Aid Compatibility Act of 1988, the Commission required digital wireless phone manufacturers and service providers to make certain digital wireless phones capable of effective use with hearing aids, label certain phones they sold with information about their compatibility with hearing aids, and report to the Commission (at first every six months, then on an annual basis) on the numbers and types of hearing aid-compatible phones they were producing or offering to the public. These reporting requirements were subsequently amended on several occasions, and the existing, OMB-approved collection under this OMB control number includes these modifications.

As part of this extension request, the Commission is requesting approval of certain non-substantive changes to the form and instructions. Changes to the form include updating the edition form date for the electronic form to reflect the current date, and adding certain additional language drawn from the instructions to the question on device disclosures through Public Web sites. In the instructions, the Commission is updating the edition form date to reflect the current date, updating a Web site link that has become inactive, adding certain informational text to make the instructions easier to understand, and updating figures as necessary to reflect the non-substantive changes in the form.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary.

[FR Doc. 2015–17269 Filed 7–14–15; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments on the agreements to the Secretary, Federal Maritime Commission, Washington, DC 20573, within twelve days of the date this notice appears in the **Federal Register**. Copies of the agreements are available through the Commission's Web site (*www.fmc.gov*) or by contacting the Office of Agreements at (202) 523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 012350.

Title: Hoegh/Hyundai Glovis West Africa Space Charter Agreement.

Parties: Hoegh Autoliners AS and Hyundai Glovis Co. Ltd.

Filing Party: Wayne R. Rohde, Esq.; Cozen O'Connor; 1627 I Street NW., Suite 1100; Washington, DC 20036.

Synopsis: The agreement authorizes the parties to charter space to each other in the trade between the U.S. East and Gulf Coasts on the one hand, and Benin and Nigeria, on the other hand.

Agreement No.: 012351.

Title: Zim/NYK Equipment Repositioning Agreement.

Parties: ZIM American Integrated Shipping Service, Ltd. and Nippon Yusen Kaisha.

Filing Party: Mark E. Newcomb; ZIM American Integrated Shipping Services, Co., LLC; 5801 Lake Wright Dr.; Norfolk, VA 23508.

Synopsis: The agreement authorizes the parties to charter slots on each other's vessels for the carriage of empty containers.

By Order of the Federal Maritime Commission.

Dated: July 10, 2015.

Karen V. Gregory,

Secretary.

[FR Doc. 2015–17362 Filed 7–14–15; 8:45 am]

BILLING CODE 6731–AA–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0149; Docket 2015–0055; Sequence 21]

Federal Acquisition Regulation; Information Collection; Subcontract Consent

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for public comments regarding an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning subcontract consent.

DATES: Submit comments on or before September 14, 2015.

ADDRESSES: Submit comments identified by Information Collection 9000–0149, Subcontract Consent, by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link ''Submit a Comment'' that corresponds with ''Information Collection 9000–0149, Subcontract Consent''. Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''Information Collection 9000–0149, Subcontract Consent'' on your attached document.
- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405. ATTN: Ms. Flowers/IC 9000–0149, Subcontract Consent.

Instructions: Please submit comments only and cite Information Collection 9000–0149, Subcontract Consent, in all correspondence related to this collection. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided.

FOR FURTHER INFORMATION CONTACT: Ms. Mahruba Uddowla, Procurement Analyst, Office of Government-wide Policy, contact via telephone 703–605–2828 or email at *mahruba.uddowla@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

Federal Acquisition Regulation (FAR) clause 52.244–2, Subcontracts, requires prime contractors to provide contracting officers notification before the award of any cost-plus-fixed-fee subcontract, or certain fixed-price subcontracts. This requirement for advance notification is driven by statutory requirements in 10 U.S.C. 2306 and 41 U.S.C. 3905. FAR clause 52.244–2 also requires prime contractors to get consent to subcontract for cost-reimbursement, time-and-materials, labor-hour, or letter contracts, and also for unpriced actions under fixed-price contracts that exceed the simplified acquisition threshold.

The objective of requiring consent to subcontract, as discussed in FAR Part 44, is to evaluate the efficiency and effectiveness with which the contractor spends Government funds, and complies with Government policy when subcontracting. The Government requires a contractor to provide certain information (*e.g.,* subcontractor's name, type of subcontract, price, description of supply or services, etc.) reasonably in advance of placing a subcontract to

ensure that the proposed subcontract is appropriate for the risks involved and consistent with current policy and sound business judgment. The information provides the Government a basis for granting, or withholding consent to subcontract.

B. Annual Reporting Burden

Based on information from the Federal Procurement Data System (FPDS) regarding contracts that would be required to provide information pursuant to FAR clause 52.244–2, an upward adjustment is being made to the number of respondents. As a result, an upward adjustment is being made to the estimated annual reporting burden hours since the notice regarding the previous extension to this clearance was published in the **Federal Register** at 77 FR 56644, on September 13, 2012.

Number of Respondents: 6,601.

Responses per Respondent: 3.

Total Responses: 19,803.

Average Burden Hours per Response: 1.846.

Total Burden Hours: 36,557.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the Federal Acquisition Regulation (FAR), and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 9000–0149, Subcontract Consent, in all correspondence.

Dated: July 9, 2015.

Edward Loeb,

Acting Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2015–17373 Filed 7–14–15; 8:45 am]

BILLING CODE 6820–14–P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–0112; Docket 2015–0001; Sequence 9]

Submission for OMB Review; Federal Management Regulation; State Agency Monthly Donation Report of Surplus Property, GSA Form 3040

AGENCY: Federal Acquisition Service, General Services Administration (GSA).

ACTION: Notice of request for public comments regarding a renewal to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement regarding State Agency Monthly Donation Report of Surplus Property, GSA Form 3040. A notice was published in the **Federal Register** at 80 FR 18843, on April 8, 2015. No comments were received.

DATES: Submit comments on or before August 14, 2015.

ADDRESSES: Submit comments identified by Information Collection 3090–0112, State Agency Monthly Donation Report of Surplus Personal Property by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching for Information Collection 3090–0112. Select the link ''Comment Now'' that corresponds with ''Information Collection 3090–0112; State Agency Monthly Donation Report of Surplus Personal Property'' under the heading ''Enter Keyword or ID'' and select ''Search''. Select the link ''Submit a Comment'' that corresponds with ''Information Collection 3090–0112, State Agency Monthly Donation Report of Surplus Personal Property''. Follow the instructions provided on the screen. Please include your name, company name (if any), and ''Information Collection 3090–0112, State Agency Monthly Donation Report of Surplus Personal Property'' on your attached document.
- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405. ATTN: Ms. Flowers/IC 3090–0112, State Agency Monthly Donation Report of Surplus Personal Property.

Instructions: Please submit comments only and cite Information Collection 3090–0112, State Agency Monthly Donation Report of Surplus Personal Property, in all correspondence related to this collection. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided.

FOR FURTHER INFORMATION CONTACT: Joyce Spalding, Federal Acquisition Service, GSA at telephone 703–605–2888 or via email to *joyce.spalding@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

This report complies with Public Law 94–519, which requires annual reports of donations of personal property to public agencies for use in carrying out such purposes as conservation, economic development, education, parks and recreation, public health, and public safety.

B. Annual Reporting Burden

Respondents: 55.

Responses per Respondent: 4.

Total Responses: 220.

Hours per Response: 1.5.

Total Burden Hours: 330.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate and based on valid assumptions and methodology; and ways to enhance the quality, utility, and clarity of the information to be collected.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20006, telephone 202–501–4755. Please cite OMB Control No. 3090–0112, GSA Form 3040, State Agency Monthly Donation Report of Surplus Personal Property, in all correspondence.

Dated: July 6, 2015.

David Shive,

Acting Chief Information Officer.

[FR Doc. 2015–17374 Filed 7–14–15; 8:45 am]

BILLING CODE 6820–34–P

GENERAL SERVICES ADMINISTRATION

[OMB Control No. 3090–0014; Docket 2015–0001; Sequence 8]

Submission for OMB Review; Transfer Order—Surplus Personal Property and Continuation Sheet, Standard Form (SF) 123

AGENCY: Federal Acquisition Service, General Services Administration (GSA).

ACTION: Notice of request for an extension to an existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement regarding the Transfer Order—Surplus Personal Property and Continuation Sheet, Standard Form (SF) 123. A notice was published in the **Federal Register** at 80 FR 21719, on April 20, 2015. No comments were received.

DATES: Submit comments on or before: August 14, 2015.

ADDRESSES: Submit comments identified by Information Collection 3090–0014, Transfer Order—Surplus Personal Property and Continuation Sheet, Standard Form (SF) 123, by any of the following methods:

- *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link ''Comment Now'' that corresponds with ''Information Collection 3090–0014, Transfer Order—Surplus Personal Property and Continuation Sheet, Standard Form (SF) 123''. Follow the instructions provided on the screen. Please include your name, company name (if any), and ''Information Collection 3090–0014, Transfer Order—Surplus Personal Property and Continuation Sheet, Standard Form (SF) 123,'' on your attached document.
- *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405. ATTN: Ms. Flowers/IC 3090–0014.

Instructions: Please submit comments only and cite Information Collection 3090–0014, Transfer Order—Surplus Personal Property and Continuation Sheet, Standard Form (SF) 123, in all correspondence related to this collection. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided.

FOR FURTHER INFORMATION CONTACT: Joyce Spalding, Property Disposal Specialist, Federal Acquisition Service, at telephone 703–605–2888 or via email to *joyce.spalding@gsa.gov.*

SUPPLEMENTARY INFORMATION:

A. Purpose

The Transfer Order—Surplus Personal Property and Continuation Sheet, Standard form (SF) 123, is used by public agencies, nonprofit educational or public health activities, programs for the elderly, service educational activities, and public airports to apply for donation of Federal surplus personal property. The SF 123 serves as the transfer instrument and includes item descriptions, transportation instructions, nondiscrimination assurances, and approval signatures.

B. Annual Reporting Burden

Respondents: 20,110.

Responses per Respondent: 1.

Total Number of Respondents: 20,110.

Hours per Response: 0.019.

Total Burden Hours: 382.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20006, telephone 202–501–4755. Please cite OMB Control No. 3090–0014, Transfer Order—Surplus Personal Property and Continuation Sheet, Standard Form (SF) 123, in all correspondence.

Dated: July 6, 2015.

David A. Shive,

Acting Chief Information Officer.

[FR Doc. 2015–17375 Filed 7–14–15; 8:45 am]

BILLING CODE 6820–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–6057–N2]

Medicare Program; Extension of Medicare Prior Authorization for Power Mobility Devices (PMDs) Demonstration

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces an extension of the Medicare Prior Authorization for Power Mobility Devices (PMDs) demonstration.

DATES: This demonstration will now end on August 31, 2018.

FOR FURTHER INFORMATION CONTACT: Doris M. Jackson, (410) 786–4459.

Questions regarding the Medicare Prior Authorization for Power Mobility Device Demonstration should be sent to *pademo@cms.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 402(a)(1)(J) of the Social Security Amendments of 1967 (42 U.S.C. 1395b–1(a)(1)(J)), authorizes the Secretary to conduct demonstrations designed to develop or demonstrate improved methods for the investigation and prosecution of fraud in the provision of care or services provided under the Medicare program.

On September 1, 2012, we implemented the Medicare Prior Authorization for Power Mobility Devices (PMDs) Demonstration that would operate for a period of 3 years (September 1, 2012 through August 31, 2015). The demonstration was initially implemented in California, Florida, Illinois, Michigan, New York, North Carolina, and Texas. These states were selected for the demonstration based upon their history of having high levels of improper payments and incidents of fraud related to PMDs. On October 1, 2014, we expanded the demonstration to 12 additional states (Pennsylvania, Ohio, Louisiana, Missouri, Washington, New Jersey, Maryland, Indiana, Kentucky, Georgia, Tennessee, and Arizona) that have high expenditures and improper payments for PMDs based on 2012 billing data.

The objective of the demonstration is to develop improved methods for the investigation and prosecution of fraud in order to protect the Medicare Trust Funds from fraudulent actions and any resulting improper payments. The

demonstration's extension will continue to provide the agency with valuable data through which the agency, working with its partners, can develop new avenues for combating the submission of fraudulent claims to the Medicare program for PMDs and improving methods for the investigation and prosecution of PMD fraud. We will continue to share demonstration data within the agency, with our contractors, with state Medicaid agencies, and with law enforcement partners for further analysis and investigation. We believe that data evidencing changes in physician ordering and supplier billing practices that coincide with this demonstration could provide investigators and law enforcement with important information for determining how and where to focus their investigations concerning fraud in the provision of PMDs. For instance, results from this demonstration could potentially indicate collaboration between ordering physicians and suppliers in submitting fraudulent claims for PMDs. This data could assist investigators and law enforcement in targeting their investigations in this area. Additionally, changes in billing practices that result from this demonstration could provide specific leads for investigators and law enforcement personnel. For instance, where a supplier that frequently submitted claims prior to the demonstration stops submitting claims during the demonstration, law enforcement may determine it prudent to investigate that supplier. Our data analysis will include the following:

- Suppliers who no longer bill or have a significant decrease in billing during the demonstration.
- Physicians/treating practitioners with a high volume of submissions.
- Codes that show a dramatic increase in use.

Based on preliminary data collected, spending per month on PMDs in the seven original demonstration states decreased after September 2012, indicating that physicians ordering and supplier billing practices have changed as a result of the demonstration. In addition, based on the preliminary data, spending per month on PMDs decreased in the non-demonstration states. National suppliers have adjusted their billing practices nationwide and appear to have increased compliance with our policies in all locations, not just their offices in the demonstration states.

II. Provisions of the Notice

This notice announces the extension of the Medicare PMDs demonstration for an additional 3 years, until August 31, 2018. Extending the demonstration allows us to continue developing improved methods to investigate and prosecute fraud in order to protect the Medicare Trust Funds from fraudulent actions and any resulting improper payments. This continuation will provide the agency with additional information through which the agency can develop new avenues for combating the submission of fraudulent claims to the Medicare program for PMDs and improving methods for the investigation and prosecution of PMD fraud. We will continue to share demonstration data within the agency, with our contractors, with state Medicaid agencies, and with law enforcement partners for further analysis and investigation.

This notice will serve as notification of the extended demonstration. In addition, we will publicize the extended demonstration through postings to our Web site and tweets.

CMS or its agents will continue to conduct outreach and education including webinars, state meetings, and other educational sessions as appropriate. Updated information will be posted to the CMS Web site (*http://go.cms.gov/PADemo*). We will also continue to work to limit the impact on Medicare beneficiaries by educating the Medicare beneficiaries about their protections.

We will continue to follow the policies and procedures that are currently in place for the demonstration. In accordance with current demonstration policy, a request for prior authorization and all relevant documentation to support the medical necessity along with the written order for the covered item must be submitted when one of the following Healthcare Common Procedures Coding System (HCPCS) codes for a PMD is ordered:

- Group 1 Power Operated Vehicles (K0800 through K0802 and K0812).
- All standard power wheelchairs (K0813 through K0829).
- All Group 2 complex rehabilitative power wheelchairs (K0835 through K0843).
- All Group 3 complex rehabilitative power wheelchairs without power options (K0848 through K0855).
- Pediatric power wheelchairs (K0890 and K0891).
- Miscellaneous power wheelchairs (K0898).

Under this demonstration, a physician, treating practitioner, or supplier may submit the prior authorization request and all relevant documentation to support Medicare coverage of the PMD item along with the written order for the covered item to their Durable Medical Equipment (DME) Medicare Administrative Contractor (MAC). The physician, treating practitioner, or supplier who submits the request is referred to as the ''submitter.''

In order to be affirmed, the request for prior authorization must meet all applicable rules, policies, and National Coverage Determination (NCD)/Local Coverage Determination (LCD) requirements for PMD claims. The LCD documentation requirement mandates that the physician or treating practitioner shall complete the seven element order, face-to-face encounter, and any other clinical documentation that is necessary to determine medical necessity regardless of which entity is functioning as the submitter. The supplier must also complete the detailed product description (DPD) regardless of which entity is functioning as the submitter.

After receipt of all relevant documentation, CMS or its agents will make every effort to conduct a complex medical review and postmark the notification of their decision with the prior authorization number within 10 business days. Notification is provided to the physician/treating practitioner, supplier, and the Medicare beneficiary for the initial submission. If a subsequent prior authorization request is submitted after a non-affirmative decision on a prior authorization request, CMS or its agents will make every effort to conduct a review and postmark the notification of decision with the prior authorization number within 20 business days.

If the prior authorization request is not affirmed, and the claim is subsequently submitted by the supplier, the claim will be denied. Medicare beneficiaries may use existing appeal rights to contest claim denials. Suppliers must issue an Advance Beneficiary Notice of Noncoverage (ABN) to the beneficiary, per CMS policy, prior to delivery of the item for the beneficiary to be held financially liable when a Medicare payment denial is expected for a PMD.

Submitters may also request expedited reviews in emergency situations where a practitioner indicates clearly, with supporting rationale, that the standard (routine) timeframe for a prior authorization decision (10 days) could seriously jeopardize the beneficiary's life or health. The expedited request must be accompanied by the required supporting documentation for this request to be considered complete, thus commencing the 48-hour review. Inappropriate expedited requests may be downgraded to standard requests. After conducting

an expedited review, CMS or its agents will communicate a decision for the prior authorization request to the submitter within 48-hours of the complete submission.

The following explains the various prior authorization scenarios:

• *Scenario 1:* A submitter sends a prior authorization request to the DME MAC with appropriate documentation, and all relevant Medicare coverage and documentation requirements are met for the PMD. The DME MAC then sends an affirmative prior authorization decision to the physician or treating practitioner, supplier, and Medicare beneficiary. The supplier submits the claim to the DME MAC, and the claim is linked to the prior authorization via the claims processing system. Provided all requirements in the applicable NCD/LCD are met, the claim is paid.

• *Scenario 2:* A submitter sends a prior authorization request, but all relevant Medicare coverage and documentation requirements are not met for the PMD. The DME MAC sends a non-affirmative prior authorization decision to the physician or treating practitioner, supplier, and Medicare beneficiary advising them that Medicare will not pay for the item. If the supplier delivers the PMD and submits a claim with a non-affirmative prior authorization decision, the DME MAC would deny the claim. The supplier or the Medicare beneficiary would then have the Medicare denial for secondary insurance purposes and would have full appeal rights. Existing liability provisions with respect to delivery of a valid ABN apply.

• *Scenario 3:* A submitter sends a prior authorization request where documentation is incomplete. The DME MAC sends back the prior authorization request to the submitter with an explanation about what information is missing and notifies the physician or treating practitioner, supplier, and Medicare beneficiary. The submitter may resubmit the prior authorization request.

• *Scenario 4:* An applicable PMD claim is submitted without a prior authorization decision or the DME supplier fails to submit a prior authorization request, but nonetheless delivers the item to the Medicare beneficiary and submits the claim to the DME MAC for payment. The claim will be stopped and documentation will be requested to conduct medical review. The PMD claim is reviewed under normal medical review processing timeframes, and if approved, a 25-percent payment reduction would apply.

++ If the claim is determined to be not medically necessary, or insufficiently documented, the claim will be denied. The supplier or Medicare beneficiary can appeal the claim denial. If the claim, after review, is deemed not payable, then all current Medicare beneficiary/supplier liability policies and procedures and appeal rights remain in effect.

++ If the claim is determined to be payable, it will be paid. However, a 25-percent reduction in the Medicare payment will be applied for failure to receive a prior authorization decision before the submission of a claim. This payment reduction will not be applied to competitive bidding program contract suppliers submitting claims for Medicare beneficiaries who maintain a permanent residence in a competitive bidding area according to the Common Working File (CWF). These contract suppliers will continue to receive the applicable single payment amount as determined in their contract. The 25-percent payment reduction is non-transferrable to the Medicare beneficiary for claims that are deemed payable and is not subject to appeal. In the case of capped rental items, the payment reduction will be applied to all claims in the series. After a claim is submitted and processed, appeal rights are available if necessary.

If the prior authorization request is not affirmed, and the claim is submitted by the supplier, the claim will be denied. Medicare beneficiaries may use existing appeal rights to contest claim denials. Suppliers must issue an ABN to the beneficiary, per CMS policy, prior to delivery of the item in order for the beneficiary to be held financially liable when a Medicare payment denial is expected for a PMD.

Additional information is available on the CMS Web site (*http://go.cms.gov/PADemo*).

III. Collection of Information Requirements

This notice announces the extension of the Medicare PMDs Demonstration and does not impose any new information collection burden under the Paperwork Reduction Act of 1995. However, there is an information collection burden associated with the demonstration that is currently approved under OMB control number 0938–1169 which expires January 31, 2018.

IV. Regulatory Impact Statement

This document announces an extension of the Medicare PMDs Demonstration. Therefore, there are no regulatory impact implications associated with this notice.

Dated: July 1, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2015–17365 Filed 7–14–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Job Search Assistance (JSA) Strategies Evaluation.

OMB No.: 0970–0440.

Description: The Administration for Children and Families (ACF) is proposing a data collection activity as part of the Job Search Assistance (JSA) Strategies Evaluation. The JSA evaluation aims to determine which JSA strategies are most effective in moving TANF applicants and recipients into work. The impact study will randomly assign individuals to contrasting JSA approaches and then compare their employment and earnings to determine their relative effectiveness. The implementation study will describe services participants receive under each approach as well as provide operational lessons gathered directly from practitioners.

Data collection efforts previously approved for JSA, include: Data collection activities to document program implementation, a staff survey and a baseline information form for program participants. These collection activities will continue with this new request.

This **Federal Register** Notice provides the opportunity to comment on a proposed new information collection activity for JSA: A follow-up survey for JSA participants approximately 6 months after program enrollment. The purpose of the survey is to follow-up with study participants and document their job search assistance services and experiences including their receipt of job search assistance services, their knowledge and skills for conducting a job search, the nature of their job search process, including tools and services used to locate employment, and their search outputs and outcomes, such as the number of applications submitted, interviews attended, offers received and jobs obtained. In addition, the survey will provide an opportunity for

respondents to provide contact data for possible longer-term follow-up.

Respondents: JSA study participants and program staff.

Annual Burden Estimates

EXTENSION OF PREVIOUSLY APPROVED INFORMATION COLLECTIONS

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Baseline Information Form	6,400	3,200	1	.2	640
Implementation Study Site Visits	600	300	1	1	300
JSA Staff Survey	440	220	1	.33	73

PROPOSED NEW INFORMATION COLLECTIONS

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
6 Month Follow-Up Survey	6,400	3,200	1	.333	1,066
Contact Update Form	6,400	3,200	11	.033	1,162

Estimated Total Annual Burden Hours: 3,241.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, 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, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@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.

Karl Koerper,

Reports Clearance Officer.

[FR Doc. 2015–17264 Filed 7–14–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Preparation for International Cooperation on Cosmetics Regulation

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

The Food and Drug Administration (FDA or we) is announcing a public meeting entitled ''International Cooperation on Cosmetics Regulation (ICCR)—Preparation for ICCR–9 Meeting.'' The purpose of the meeting is to invite public input on various topics pertaining to the regulation of cosmetics. We may use this input to help us prepare for the ICCR–9 meeting that will be held November 4–6, 2015, in Brussels, Belgium.

Date and Time: The public meeting will be held on September 10, 2015, from 2 p.m. to 4 p.m.

Location: This meeting will be held at the Food and Drug Administration, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., Wiley Auditorium (first floor), College Park, MD 20740.

Contact Person: Maria Rossana (Rosemary) Cook, Office of Cosmetics and Colors, Food and Drug Administration, 4300 River Rd., College Park, MD 20740, email: *maria.cook@fda.hhs.gov,* or FAX: 301–436–2975.

Registration and Requests for Oral Presentations: Send registration information (including your name, title, firm name, address, telephone number, fax number, and email address), written material, and requests to make an oral presentation, to the contact person by August 27, 2015.

If you need special accommodations due to a disability, please contact Maria Rossana (Rosemary) Cook by September 3, 2015.

SUPPLEMENTARY INFORMATION: You may present proposals for future ICCR agenda items, data, information, or views, orally or in writing, on issues pending at the public meeting. Time allotted for oral presentations may be limited to 10 minutes or less for each presenter. If you wish to make an oral presentation, you should notify the contact person by August 27, 2015, and submit a brief statement of the general nature of the evidence or arguments that you wish to present, your name, address, telephone number, fax number, and email address, and indicate the approximate amount of time you need to make your presentation.

Transcripts: As soon as a transcript is available, it will be accessible at *http://www.regulations.gov.* It may also be viewed at the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20850. A transcript will also be available in either hardcopy or on CD–ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information, (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

The Purpose of the Multilateral Framework on the ICCR: The purpose of the multilateral framework on the ICCR is to pave the way for the removal of regulatory obstacles to international trade while maintaining global consumer protection.

ICCR is a voluntary international group of cosmetics regulatory authorities from the United States, Japan, the European Union, Canada, and Brazil. These regulatory authority members will enter into constructive dialogue with their relevant cosmetics industry trade associations and public advocacy groups. Currently, the ICCR members are: Health Canada; the European Commission Directorate-General for Internal Market, Industry, Entrepreneurship, and Subject Matter Experts; the Ministry of Health, Labor, and Welfare of Japan; the Brazilian Health Surveillance Agency; and FDA. All decisions made by consensus will be compatible with the laws, policies, rules, regulations, and directives of the respective administrations and governments. Members will implement and/or promote actions or documents within their own jurisdictions and seek convergence of regulatory policies and practices. Successful implementation will need input from stakeholders.

Agenda: We will make the agenda for the public meeting available on the Internet at *http://www.fda.gov/Cosmetics/InternationalActivities/ICCR/default.htm*. Depending on the number of requests for oral presentations, we intend to have an agenda available by September 3, 2015. We may use the information that you provide to us during the public meeting to help us prepare for the November 4–6, 2015, ICCR–9 meeting.

Dated: July 9, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–17248 Filed 7–14–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: HHS–0990–0279–60D]

Agency Information Collection Activities; Proposed Collection; Public Comment Request

AGENCY: Office of the Assistant Secretary for Health, HHS.

ACTION: Notice.

SUMMARY: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Office of the Secretary, Department of Health and Human Services (HHS), announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). The ICR is for extending the use of the approved information collection assigned OMB control number 0990–0279, which expires on August 31, 2015. Prior to submitting that ICR to OMB, OS seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on the ICR must be received on or before September 14, 2015.

ADDRESSES: Submit your comments to *Information.CollectionClearance@hhs.gov* or by calling (202) 690–6162.

FOR FURTHER INFORMATION CONTACT: Information Collection Clearance staff, *Information.CollectionClearance@hhs.gov* or (202) 690–6162.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the document identifier 0990–0279 for reference.

Information Collection Request Title: Institutional Review Board Form—OMB No. 0990–0279, Assistant Secretary for Health, Office for Human Research Protections.

Abstract: Section 491(a) of Public Law 99–158 states that the Secretary of HHS shall by regulation require that each entity applying for HHS support (*e.g.,* a grant, contract, or cooperative agreement) to conduct research involving human subjects submit to HHS assurances satisfactory to the Secretary that it has established an institutional review board (IRB) to review the research in order to ensure protection of the rights and welfare of the human research subjects. IRBs are boards, committees, or groups formally designated by an entity to review, approve, and have continuing oversight of research involving human subjects.

The Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) are requesting a three-year extension of the OMB No. 0990–0279, Institutional Review Board (IRB) Registration Form. This form was modified in 2009 to be consistent with IRB registration requirements, 45 CFR part 46, subpart E and 21 CFR 56.106 that were adopted in July 2009 OHRP and FDA, respectively.

Need and Proposed Use of the Information: The information collected through the Institutional Review Board registration collection requirements is the minimum necessary to satisfy the registration requirements of Section 491 (a) of the Public Health Service Act, 45 CFR part 46, subpart E and 21 CFR 56.106.

Likely Respondents: Institutions or organizations operating IRBs that review human subjects research conducted or supported by HHS, or, in the case of FDA's regulations, IRBs in the United States that review clinical investigations regulated by FDA under sections 505(i) or 520(g) of the Federal Food, Drug and Cosmetic Act; and, IRBs in the United States that review clinical investigations that are intended to support applications for research or marketing permits for FDA-regulated products.

Burden Statement: The burden estimates for the IRB registration form include those approved by OMB in March 2015 under Control Number 0990–0263, the Assurance Identification/IRB Certification/Declaration of Exemption form (former Optional Form 310). Those burden estimates are not included as part of the burden estimate presented below.

ESTIMATED ANNUALIZED BURDEN TABLE

Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
IRB Registration 0990–0279	5,900	2	1	11,800
	500	2	1	1,000
Total				12,800

OS specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Terry S. Clark,

Asst Information Collection Clearance Officer.

[FR Doc. 2015–17348 Filed 7–14–15; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (PLCO) (NCI)

SUMMARY: Under the provisions of Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the National Institutes of Health (NIH), has submitted to the Office of Management and Budget (OMB) a request for review and approval of the information collection listed below. This proposed information collection was previously published in the **Federal Register** on April 21, 2015 (80 FR 22211), and allowed 60-days for public comment. No public comments were received. The purpose of this notice is to allow an additional 30 days for public comment. The National Cancer Institute (NCI), National Institutes of Health, may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

Direct Comments to OMB: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, should be directed to the: Office of Management and Budget, Office of Regulatory Affairs, *OIRA_submission@omb.eop.gov* or by fax to 202–395–6974, Attention: NIH Desk Officer.

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30 days of the date of this publication.

FOR FURTHER INFORMATION CONTACT: To obtain a copy of the data collection plans and instruments or request more information on the proposed project contact: Kelly Yu, Ph.D., Division of Cancer Prevention, 9609 Medical Center Drive, Room 5E230, Rockville, MD 20850 call non-toll-free number 240–276–7041 or Email your request, including your address to: *yuke@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (PLCO) 0925–0407, Revision, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: This is a request for a revision of the Prostate, Lung, Colorectal and Ovarian Cancer Screening Trial (PLCO). This trial was designed to determine if cancer screening for prostate, lung, colorectal, and ovarian cancer can reduce mortality from these cancers which caused an estimated 253,320 deaths in the U.S in 2014. The design is a two-armed randomized trial of men and women aged 55 to 74 at entry. OMB first approved this study in 1993 and has approved it every 3 years since then. Recruitment was completed in 2001, baseline cancer screening was completed in 2006, and data collection continues on the current cohort of 77,281 participants who are actively being followed. The additional follow-up will provide data that will clarify further the long term effects of the screening on cancer incidence and mortality for the four targeted cancers. Further, demographic and risk factor information may be used to analyze the differential effectiveness of cancer screening in high versus low risk individuals.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 26,320.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Type of respondents	Number of respondents	Number of responses per respondent	Average time per response (minutes/hour)	Annual burden hours
Annual Study Update (ASU) Form	Participants who complete the ASU	77,281	1	5/60	6,440
ASU Telephone Script	Non Responders to the ASU	3,091	1	5/60	258
Authorization to Release Medical Records.	Participants who report new cancers	2,700	1	3/60	135
Health Status Questionnaire (Female) (HSQ).	Female participants who complete the HSQ.	960	1	5/60	80
Health Status Questionnaire (Male) (HSQ).	Male participants who complete the HSQ.	1,040	1	5/60	87
Medication Use Questionnaire (MUQ).	Participants who complete the MUQ	77,281	1	15/60	19,320

Dated: June 23, 2015.

Karla Bailey,

NCI Project Clearance Liaison, National Institutes of Health.

[FR Doc. 2015–17340 Filed 7–14–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Special Emphasis Panel, July 22, 2015, 11:00 a.m. to 04:00 p.m., National Cancer Institute Shady Grove, 9609 Medical Center Drive, 2W194, Rockville, MD, 20850 which was published in the **Federal Register** on June 23, 2015, 80 FR 35964.

The meeting notice is amended to change the date of the meeting from July

22, 2015 to August 19, 2015 and room number to 1E030. The meeting is closed to the public.

Dated: July 10, 2015.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–17342 Filed 7–14–15; 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; Member Conflict: Neurodegeration and Cognition.

Date: August 4, 2015.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Inese Z. Beitins, MD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6152, MSC 7892, Bethesda, MD 20892, 301–435–1034, *beitinsi@csr.nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Project: Structure and Function of the Arp2/3 Complex.

Date: August 7, 2015.

Time: 2:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Noni Byrnes, Ph.D., Division Director, DBIB, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5130, MSC 7840, Bethesda, MD 20892, (301) 435–1023, *byrnesn@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: July 10, 2015.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–17359 Filed 7–14–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, July 30, 2015, 2 p.m. to July 30, 2015, 4 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on July 08, 2015, 80 FR 39140.

The meeting will start at 3 p.m. and end at 5 p.m. on July 30, 2015. The meeting location remains the same. The meeting is closed to the public.

Dated: July 10, 2015.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–17360 Filed 7–14–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG–USCG–2015–0628]

Chemical Transportation Advisory Committee

AGENCY: Coast Guard, DHS.

ACTION: Notice of Federal Advisory Committee Meeting.

SUMMARY: The Chemical Transportation Advisory Committee and its subcommittees will meet on August 4, 5, and 6, 2015, in Washington, DC, to discuss the safe and secure marine transportation of hazardous materials. The meetings will be open to the public.

DATES: Subcommittees will meet on Tuesday, August 4, 2015, from 8:30 a.m. to 5 p.m. and on Wednesday, August 5, 2015, from 8:30 a.m. to 5 p.m. The full committee will meet on Thursday, August 6, 2015, from 8:30 a.m. to 5 p.m. Please note that these meetings may close early if the Committee has completed its business.

ADDRESSES: The meetings will be held at the U.S. Department of Transportation, 1200 New Jersey Avenue, Washington, DC 20590. Attendees will be required to pre-register no later than 5 p.m. on July 20, 2015, to be admitted to the meeting. Non-US citizens will be required to pre-register no later than 5 p.m. on July 15, 2015, to be admitted to the meeting. To pre-register contact Lieutenant Cristina Nelson at 202–372–1419 or *Cristina.E.Nelson@uscg.mil.* For non-U.S. citizens a request for pre-registration should include name, country of citizenship, passport and expiration date, or diplomatic ID number and expiration date, and the company or group with which you are affiliated. For U.S. citizens a pre-registration should include your name, telephone number, and company or group with which you are affiliated. Attendees will be required to provide a government-issued picture identification card in order to gain admittance to the building.

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** as soon as possible.

To facilitate public participation, we are inviting public comment on the issues to be considered by the Committee as listed in the ''Agenda'' section below. Written comments for distribution to Committee members must be submitted no later than July 27, 2015, if you want the Committee members to be able to review your comments before the meeting, and must be identified by docket number USCG–2015–0628. Written comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the instructions for submitting comments. (This is the preferred method to avoid delays in processing.)
- *Fax:* 202–493–2252.
- *Mail:* Docket Management Facility (M–30), U.S. Department of Transportation, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.
- *Hand delivery:* Same as mail address above, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The telephone number is 202–366–9329.

Instructions: All submissions received must include the words ''Department of Homeland Security'' and the docket number for this action. Comments received will be posted without alteration at *http://www.regulations.gov,*

including any personal information provided. You may review a Privacy Act notice regarding our public dockets in the January 17, 2008, issue of the **Federal Register** (73 FR 3316).

Docket: For access to the docket to read documents or comments related to this notice, go to *http://www.regulations.gov,* type USCG–2015–0628 in the Search box, press Enter, and then click on the item you wish to view.

FOR FURTHER INFORMATION CONTACT: Commander Evan Hudspeth, Designated Federal Officer of the Chemical Transportation Advisory Committee, 2703 Martin Luther King Jr. Ave. SE., Stop 7509, Washington, DC 20593–7509, telephone 202–372–1420, fax 202–372–8380, or *Evan.D.Hudspeth@uscg.mil.* If you have any questions on viewing or submitting material to the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone 202–366–9826 or 1–800–647–5527.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the *Federal Advisory Committee Act,* 5 United States Code Appendix.

The Chemical Transportation Advisory Committee is an advisory committee authorized under section 871 of the Homeland Security Act of 2002, 6 United States Code 451, and is chartered under the provisions of the Federal Advisory Committee Act. The committee acts solely in an advisory capacity to the Secretary of the Department of Homeland Security through the Commandant of the Coast Guard and the Deputy Commandant for Operations on matters relating to safe and secure marine transportation of hazardous materials activities insofar as they relate to matters within the United States Coast Guard's jurisdiction. The Committee advises, consults with, and makes recommendations reflecting its independent judgment to the Secretary.

Agendas of Meetings

Subcommittee Meetings on August 4 and 5, 2015

The subcommittee meetings will separately address the following tasks:

(1) Harmonization of Response and Carriage Requirements for Biofuels and Biofuel Blends.

(2) Recommendations on Safety Standards for the Design of Vessels Carrying Natural Gas or Using Natural Gas as Fuel.

(3) Recommendations for Safety Standards for Ship to Ship Transfer of Hazardous Material Outside of the Baseline.

(4) Recommendations for Guidance on the Implementation of Revisions to MARPOL Annex II and the International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk (commonly known as the IBC Code).

(5) Improving Implementation of and Education about MARPOL Discharge Requirements under MARPOL Annex II and V.

(6) Vapor Control System Regulation supplementation, corrections and improvements. The task statements from the last committee meeting are located at Homeport at the following address: *https://homeport.uscg.mil.* Go to: Missions > Ports and Waterways > Safety Advisory Committees > CTAC Subcommittees and Working Groups.

The agenda for each subcommittee will include the following:

1. Review task statements of the agenda for the August 6, 2015, meeting.
2. Work on tasks assigned in task statements mentioned above.
3. Discuss and prepare proposed recommendations for the Chemical Transportation Advisory Committee meeting on August 6, 2015, on tasks assigned in detailed task statements mentioned above.
4. Public comment period.

Full Committee Meeting on August 6, 2015

The agenda for the Chemical Transportation Advisory Committee meeting on August 6, 2015, is as follows:

1. Introductions and opening remarks.
2. Marine Transportation System Presentation.
3. Coast Guard Leadership Remarks.
4. Committee will review, discuss, and formulate recommendations on the following tasks:

a. Harmonization of Response and Carriage Requirements for Biofuels and Biofuel Blends.

b. Recommendations on Safety Standards for the Design of Vessels Carrying Natural Gas or Using Natural Gas as Fuel.

c. Recommendations for Safety Standards for Ship to Ship Transfer of Hazardous Material Outside of the Baseline.

d. Recommendations for Guidance on the Implementation of Revisions to MARPOL Annex II and the International Code for the Construction and Equipment of Ships Carrying Dangerous Chemicals in Bulk (commonly known as the IBC Code).

e. Improving Implementation of and Education about MARPOL Discharge Requirements under MARPOL Annex II and V.

f. Vapor Control System Regulation supplementation, corrections and improvements.

5. USCG presentations on the following items of interest:

a. Update on International Maritime Organization activities as they relate to the marine transportation of hazardous materials.

b. Update on U.S. regulations and policy initiatives as they relate to the marine transportation of hazardous materials.

6. Public comment period.
7. Set next meeting date and location.
8. Set subcommittee meeting schedule.

A public comment period will be held during each Subcommittee meeting and the full committee meeting concerning matters being discussed. Public comments will be limited to 3 minutes per speaker. Please note that the public comment period will end following the last call for comments. Please contact Commander Evan Hudspeth, listed in the **FOR FURTHER INFORMATION CONTACT** section, to register as a speaker.

Dated: July 8, 2015.

J.G. Lantz,

Director of Commercial Regulations and Standards, United States Coast Guard.

[FR Doc. 2015–17358 Filed 7–14–15; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5882–N–01]

Notice of Single Family Loan Sales (SFLS 2015–1)

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice of sales of mortgage loans.

SUMMARY: This notice announces HUD's intention to competitively sell certain unsubsidized single family mortgage loans in a sealed bid sale offering called SFLS 2015–1, without Federal Housing Administration (FHA) mortgage insurance. This notice also generally describes the bidding process for the sale and certain persons who are ineligible to bid. This is the second sale offering of Fiscal Year (FY) 2015 and the sale will be held on July 15, 2015.

DATES: For this sale action, the Bidder's Information Package (BIP) was made available to qualified bidders on or about June 15, 2015. Bids for the 2015–1 sale will be accepted on the Bid Date of July 15, 2015 (Bid Date). HUD anticipates that award(s) will be made on or about July 16, 2015 (the Award Date).

ADDRESSES: To become a qualified bidder and receive the BIP, prospective bidders must complete, execute, and submit a Confidentiality Agreement and a Qualification Statement acceptable to HUD. Both documents are available on the HUD Web site at: *http://www.hud.gov/sfloansales* or via: *http://www.verdiassetsales.com.*

Please mail and fax executed documents to Verdi Consulting, Inc.: Verdi Consulting, Inc., 8400 Westpark Drive, 4th Floor, McLean, VA 22102, *Attention:* HUD SFLS Loan Sale Coordinator, *Fax:* 1–703–584–7790.

FOR FURTHER INFORMATION CONTACT: John Lucey, Director, Asset Sales Office, Room 3136, Department of Housing and Urban Development, 451 Seventh Street SW., Room 3136, Washington, DC 20410–8000; telephone number 202–708–2625, extension 3927. Hearing- or speech-impaired individuals may call 202–708–4594 (TTY). These are not toll-free numbers.

SUPPLEMENTARY INFORMATION: HUD announces its intention to sell in SFLS 2015–1 certain unsubsidized non-performing mortgage loans (Mortgage Loans) secured by single family properties located throughout the United States. A listing of the Mortgage Loans is included in the due diligence materials made available to qualified bidders. The Mortgage Loans will be sold without FHA insurance and with servicing released. HUD will offer qualified bidders an opportunity to bid competitively on the Mortgage Loans.

The Loans will be offered in two pool types. The Department will offer national loan pools for bid and will also offer regionally-based pools, with additional purchaser requirements, that are called the Neighborhood Stabilization Outcome pools. One of these Neighborhood Stabilization Outcome pools, in the Detroit Metropolitan Statistical Area, is designated for bidding by qualified non-profit or unit of local government entities only.

The Bidding Process

The BIP describes in detail the procedure for bidding in SFLS 2015–1. The BIP also includes a standardized non-negotiable Conveyance, Assignment and Assumption Agreement (CAA Agreement). Qualified bidders will be required to submit a deposit with their bid. Deposits are calculated based upon each qualified bidder's aggregate bid price.

HUD will evaluate the bids submitted and determine the successful bid, in terms of the best value to HUD, in its sole and absolute discretion. If a qualified bidder is successful, the qualified bidder's deposit will be non-refundable and will be applied toward the purchase price. Deposits will be returned to unsuccessful bidders. For SFLS 2015–1, settlements are expected to take place on or about August 14, 2015, and September 18, 2015.

This notice provides some of the basic terms of sale. The CAA Agreement, which is included in the BIP, provides comprehensive contractual terms and conditions. To ensure a competitive bidding process, the terms of the bidding process and the CAA Agreement are not subject to negotiation.

Due Diligence Review

The BIP describes how qualified bidders may access the due diligence materials remotely via a high-speed Internet connection.

Mortgage Loan Sale Policy

HUD reserves the right to remove Mortgage Loans from SFLS 2015–1 at any time prior to the Award Date. HUD also reserves the right to reject any and all bids, in whole or in part, and include any Mortgage Loans in a later sale. Deliveries of Mortgage Loans will occur in at least two monthly settlements and the number of Mortgage Loans delivered will vary depending upon the number of Mortgage Loans the Participating Servicers have submitted for the payment of an FHA insurance claim. The Participating Servicers will not be able to submit claims on loans that are not included in the Mortgage Loan Portfolio set forth in the BIP. There can be no assurance that any Participating Servicer will deliver a minimum number of Mortgage Loans to HUD or that a minimum number of Mortgage Loans will be delivered to the Purchaser.

The SFLS 2015–1 Mortgage Loans are assigned to HUD pursuant to section 204(a)(1)(A) of the National Housing Act as amended under Title VI of the Departments of Veterans Affairs and Housing and Urban Development and Independent Agencies Appropriations Act, 1999. The sale of the Mortgage Loans is pursuant to section 204(g) of the National Housing Act.

Mortgage Loan Sale Procedure

HUD selected an open competitive whole-loan sale as the method to sell the Mortgage Loans for this specific sale transaction. For SFLS 2015–1, HUD has determined that this method of sale optimizes HUD's return on the sale of these Mortgage Loans, affords the greatest opportunity for all qualified bidders to bid on the Mortgage Loans, and provides the quickest and most efficient vehicle for HUD to dispose of the Mortgage Loans.

Bidder Ineligibility

In order to bid in SFLS 2015–1 as a qualified bidder, a prospective bidder must complete, execute and submit both a Confidentiality Agreement and a Qualification Statement acceptable to HUD and applicable to the loan pool being purchased. In the Qualification Statement, the prospective bidder must provide certain representations and warranties regarding (i) a prospective bidder, (ii) a prospective bidder's board of directors, (iii) a prospective bidder's direct parent, (iii) a prospective bidder's subsidiaries, and (iv) any related entity with which the prospective bidder shares a common officer, director, subcontractor or sub-contractor who has access to Confidential Information as defined in the Confidentiality Agreement or is involved in the formation of a bid transaction (''Related Entities''), and (v) a prospective bidder's repurchase lenders. The prospective bidder is ineligible to bid on any of the Mortgage Loans included in SFLS 2015–1 if the prospective bidder, its Related Entities or its repurchase lenders, is any of the following, unless other exceptions apply as provided for in the Qualification Statement.

1. An individual or entity that is currently debarred, suspended, or excluded from doing business with HUD pursuant to the Governmentwide Suspension and Debarment regulations at Title 2 of the Code of Federal Regulations, parts 180 and 2424;

2. An individual or entity that is currently suspended, debarred or otherwise restricted by any department or agency of the federal government or of a state government from doing business with such department or agency;

3. An individual or entity that is currently debarred, suspended, or excluded from doing mortgage related business, including having a business license suspended, surrendered or revoked, by any federal, state or local government agency, division or department;

4. An entity that has had its right to act as a Government National Mortgage Association (''Ginnie Mae'') issuer terminated and its interest in mortgages backing Ginnie Mae mortgage-backed securities extinguished by Ginnie Mae;

5. An individual or entity that is in violation of its neighborhood stabilizing outcome obligations or post-sale reporting requirements under a Conveyance, Assignment and

Assumption Agreement executed for a past sale;

6. An employee of HUD's Office of Housing, a member of such employee's household, or an entity owned or controlled by any such employee or member of such an employee's household with household to be inclusive of the employee's father, mother, stepfather, stepmother, brother, sister, stepbrother, stepsister, son, daughter, stepson, stepdaughter, grandparent, grandson, granddaughter, father-in-law, mother-in-law, brother-in-law, sister-in-law, son-in-law, daughter-in-law, first cousin, the spouse of any of the foregoing, and the employee's spouse;

7. A contractor, subcontractor and/or consultant or advisor (including any agent, employee, partner, director, or principal of any of the foregoing) who performed services for or on behalf of HUD in connection with the sale;

8. An individual or entity that knowingly acquired or will acquire prior to the sale date material non-public information, other than that information which is made available to Bidder by HUD pursuant to the terms of this Qualification Statement, about Mortgage Loans offered in the sale;

9. An individual or entity that knowingly uses the services, directly or indirectly, of any person or entity ineligible under 1 through 11 to assist in preparing any of its bids on the Mortgage Loans;

10. An individual or entity which knowingly employs or uses the services of an employee of HUD's Office of Housing (other than in such employee's official capacity); or

11. A Participating Servicer that contributed Mortgage Loans to a pool on which the Bidder is placing a bid.

The Qualification Statement has additional representations and warranties which the prospective bidder must make, including but not limited to the representation and warranty that the prospective bidder or its Related Entities are not and will not knowingly use the services, directly or indirectly, of any person or entity that is, any of the following (and to the extent that any such individual or entity would prevent Bidder from making the following representations, such individual or entity has been removed from participation in all activities related to this sale and has no ability to influence or control individuals involved in formation of a bid for this sale):

(1) An entity or individual is ineligible to bid on any included Mortgage Loan or on the pool containing such Mortgage Loan because it is an entity or individual that:

(a) Serviced or held any Mortgage Loan at any time during the two-year period prior to the bid, or

(b) is any principal of any entity or individual described in the preceding sentence;

(c) any employee or subcontractor of such entity or individual during that two-year period; or

(d) any entity or individual that employs or uses the services of any other entity or individual described in this paragraph in preparing its bid on such Mortgage Loan.

Freedom of Information Act Requests

HUD reserves the right, in its sole and absolute discretion, to disclose information regarding SFLS 2015–1, including, but not limited to, the identity of any successful qualified bidder and its bid price or bid percentage for any pool of loans or individual loan, upon the closing of the sale of all the Mortgage Loans. Even if HUD elects not to publicly disclose any information relating to SFLS 2015–1, HUD will disclose any information that HUD is obligated to disclose pursuant to the Freedom of Information Act and all regulations promulgated thereunder.

Scope of Notice

This notice applies to SFLS 2015–1 and does not establish HUD's policy for the sale of other mortgage loans.

Dated: July 1, 2015.

Edward L. Golding,

Principal Deputy Assistant Secretary for Housing.

[FR Doc. 2015–17271 Filed 7–14–15; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF THE INTERIOR

Geological Survey

[GX15EN05ESB0500]

Reopening of Nomination Period for State Government Members of the Advisory Committee on Climate Change and Natural Resource Science

AGENCY: U.S. Geological Survey, Interior.

ACTION: Notice.

SUMMARY: The U.S. Department of the Interior published a notice inviting nominations for non-Federal members of the Advisory Committee on Climate Change and Natural Resource Science (Committee). The initial closing date for nominations was June 1, 2015, and this nomination period was extended to July 8. This Federal Register Notice reopens the nomination and comment period for an additional 30 days, for state government nominees only. If you have already submitted information to be considered for appointment to the Committee you do not have to resubmit it.

DATES: Written nominations must be received by August 14, 2015.

ADDRESSES: Send nominations to: Robin O'Malley, Policy and Partnership Coordinator, National Climate Change and Wildlife Science Center, U.S. Geological Survey, 12201 Sunrise Valley Drive, Mail Stop 516, Reston, VA 20192, *romalley@usgs.gov*.

FOR FURTHER INFORMATION CONTACT: Robin O'Malley, Policy and Partnership Coordinator, National Climate Change and Wildlife Science Center, U.S. Geological Survey, 12201 Sunrise Valley Drive, Mail Stop 516, Reston, VA 20192, *romalley@usgs.gov*.

SUPPLEMENTARY INFORMATION: On March 30, 2015, the U.S. Department of the Interior (DOI) published a notice inviting nominations for the Advisory Committee on Climate Change and Natural Resource Science (Committee). On June 8, 2015, the DOI published a notice extending this comment period for an additional 30 days, with a closing date of July 8, 2015. The Committee provides advice on matters and actions relating to the establishment and operations of the U.S. Geological Survey National Climate Change and Wildlife Science Center and the DOI Climate Science Centers. See: *https://nccwsc.usgs.gov/acccnrs* for more information.

Contacts with potential nominees from state government have indicated that additional time to secure management approval of their nomination is required. Because state governments are a key partner, the Department is reopening the nomination period, for state government nominees only.

Nominations should include a resume that describes the nominee's qualifications in enough detail to enable us to make an informed decision regarding meeting the membership requirements of the Committee and to contact a potential member.

The Committee will be composed of approximately 25 members from the Federal Government, and the following interests: (1) State and local governments, including state membership entities; (2) Non-governmental organizations, including those whose primary mission is professional and scientific and those whose primary mission is conservation and related scientific and advocacy activities; (3) American Indian tribes

and other Native American entities; (4) Academia; (5) Landowners, businesses, and organizations representing landowners or businesses.

In addition, the Committee may include scientific experts, and will include rotating representation from one or more of the institutions that host the DOI Climate Science Centers.

The Committee will meet approximately 2–4 times annually, and at such times as designated by the DFO. The Secretary of the Interior will appoint members to the Committee. Members appointed as special Government employees are required to file on an annual basis a confidential financial disclosure report.

No individual who is currently registered as a Federal lobbyist is eligible to serve as a member of the Committee.

Robin O'Malley,

Designated Federal Officer, ACCCNRS.

[FR Doc. 2015–17251 Filed 7–14–15; 8:45 am]

BILLING CODE 4311–MP–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–961]

Certain Lip Balm Products, Containers for Lip Balm and Components Thereof; Institution of Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on June 12, 2015, under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of eos Products, LLC of New York, New York and The Kind Group LLC of New York, New York. A supplement to the complaint was filed on June 30, 2015. The complaint alleges violations of section 337 based upon the importation into the United States, the sale for importation, and the sale within the United States after importation of certain lip balm products, containers for lip balm, and components thereof by reason of infringement of certain claims of U.S. Patent No. 8,888,391 (''the '391 patent''). The complaint further alleges that an industry in the United States exists or is in the process of being established as required by subsection (a)(2) of section 337.

The complainants request that the Commission institute an investigation and, after the investigation, issue a limited exclusion order and cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, is 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., Room 112, Washington, DC 20436, telephone (202) 205–2000. Hearing impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at (202) 205–2000. General information concerning the Commission may also be obtained by accessing its internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

FOR FURTHER INFORMATION CONTACT: The Office of Unfair Import Investigations, U.S. International Trade Commission, telephone (202) 205–2560.

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.10 of the Commission's Rules of Practice and Procedure, 19 CFR 210.10 (2015).

Scope of Investigation: Having considered the complaint, the U.S. International Trade Commission, on July 9, 2015, *ordered that*—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain lip balm products, containers for lip balm, and components thereof by reason of infringement of one or more of claims 1–3, 5–7, 10–18, 20–22, and 25–30 of the '391 patent, and whether an industry in the United States exists or is in the process of being established as required by subsection (a)(2) of section 337;

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainants are:

eos Products, LLC, 19 West 44th Street, Suite 811, New York, NY 10036

The Kind Group LLC, 19 West 44th Street, Suite 811, New York, NY 10036

(b) The respondents are the following entities alleged to be in violation of section 337, and are the parties upon which the complaint is to be served:

OraLabs, Inc., 18685 East Plaza Drive, Parker, CO 80134

CVS Health Corporation, 1 CVS Drive, Woonsocket, RI 02895–6146

CVS Pharmacy, Inc., 1 CVS Drive, Woonsocket, RI 02895–6195

Walgreens Boots Alliance, Inc., 108 Wilmot Road, Deerfield, IL 60015

Walgreen Co., 108 Wilmot Road, Deerfield, IL 60015

Dollar Tree, Inc., 500 Volvo Parkway, Chesapeake, VA 23320–1604

Dollar Tree Stores, Inc., 500 Volvo Parkway, Chesapeake, VA 23320

Five Below Inc., 1818 Market Street, Suite 1900, Philadelphia, PA 19103

Wuxi Sunmart Science and Technology Co., Ltd., a/k/a Wuxi Sunmart Group Co., Ltd., a/k/a Wuxi Shengma Science & Technology Co., Ltd., No. 268 Huandong Road, Huangtang Industrial Park, Wuxi, Jiangsu 214407 China

Wuxi Sunmart Plastic Co., Ltd., No. 268 Huandong Road, Huangtang Industrial Park, Wuxi, Jiangsu 214407 China

(c) The Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street SW., Suite 401, Washington, DC 20436; and

(3) For the investigation so instituted, the Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondents in accordance with section 210.13 of the Commission's Rules of Practice and Procedure, 19 CFR 210.13. Pursuant to 19 CFR 201.16(e) and 210.13(a), such responses will be considered by the Commission if received not later than 20 days after the date of service by the Commission of the complaint and the notice of investigation. Extensions of time for submitting responses to the complaint and the notice of investigation will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondent, to find the facts to be as alleged in the complaint and this notice and to enter an initial determination and a final determination containing

such findings, and may result in the issuance of an exclusion order or a cease and desist order or both directed against the respondent.

By order of the Commission.

Issued: July 10, 2015.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2015–17371 Filed 7–14–15; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Water Act

On July 8, 2015 the Department of Justice lodged a proposed Consent Decree with the United States District Court for the District of Wyoming in the lawsuit entitled *United States* v. *Cottonwood Creek, Inc.,* Civil Action No. 2:15-cv-00108–SWS.

In this matter the United States file a Complaint which alleges violations of sections 301(a) and 311(b)(3) of the Clean Water Act (''CWA''), 33 U.S.C. 1311(a) and 1321(b)(3), arising in part from a March 2010 discharge of approximately 162 barrels of oil into an unnamed tributary of the Nowood River from a leak in a pipeline at Cottonwood Creek, Inc.'s onshore pumping facility located in Big Horn County, Wyoming. The Complaint further alleges that Cottonwood Creek had an inadequate Spill Prevention Control and Countermeasure Plan in violation of CWA section 311(b)(7)(C), 33 U.S.C. 1321(b)(7)(C), and 40 CFR part 112, and also lacked a Facility Response Plan in violation of CWA sections 311(j)(5)(A)(i) and (C)(iv), 33 U.S.C. 1321(j)(5)(A)(i) and (C)(iv), and 40 CFR part 112. The proposed Consent Decree resolves all matters alleged in the Complaint for a civil penalty payment of $170,000. Cottonwood Creek Inc. no longer owns the facility. Because the cause of the discharge was promptly corrected and the discharge was adequately remediated, and since the Environmental Protection Agency approved a FRP for the facility, no injunctive relief is required under the proposed settlement.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States* v. *Cottonwood Creek, Inc.,* D.J. Ref. No. 90–5–1–1–11197. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By email	*pubcomment-ees.enrd@usdoj.gov.*
By mail	Assistant Attorney General, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department Web site: *http://www.justice.gov/enrd/consent-decrees.* We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ—ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for $4.75 (25 cents per page reproduction cost) payable to the United States Treasury. There are no exhibits attached to the Consent Decree.

Bob Brook,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2015–17350 Filed 7–14–15; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Office of Workers' Compensation Programs

Division of Longshore and Harbor Workers' Compensation Proposed Extension of Existing Collection; Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995 (PRA95) [44 U.S.C. 3506(c)(2)(A)] This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Office of Workers' Compensation (OWCP) is soliciting comments concerning the proposed collection: Waiver of Service by Registered or Certified Mail for Employers and/or Insurance Carriers (LS–801) and Waiver of Service by Registered or Certified Mail for Claimants and Authorized Representatives (LS–802). A copy of the proposed information collection request can be obtained by contacting the office listed below in the address section of this Notice.

DATES: Written comments must be submitted to the office listed in the addresses section below on or before September 14, 2015.

ADDRESSES: Ms. Yoon Ferguson, U.S. Department of Labor, 200 Constitution Ave. NW., Room S–3323, Washington, DC 20210, telephone/fax (202) 354–9647, Email *ferguson.yoon@dol.gov.* Please use only one method of transmission for comments (mail or Email).

SUPPLEMENTARY INFORMATION:

I. Background

The Office of Workers' Compensation Programs (OWCP) administers the Longshore and Harbor Workers' Compensation Act (LHWCA). The Act provides benefits to workers' injured in maritime employment on the navigable waters of the United States or in an adjoining area customarily used by an employer in loading, unloading, repairing, or building a vessel. In addition, several acts extend the Longshore Act's coverage to certain other employees.

The Longshore and Harbor Workers' Compensation Act (LHWCA), at 33 U.S.C. 919(e), requires that any order rejecting or making an LHWCA award (the compensation order) be filed in the appropriate district director's office of the Office of Workers' Compensation Programs (OWCP), and that copies be sent by registered or certified mail to the claimant and the employer. The implementing regulations at 20 CFR 702.349(b) allow parties and their representatives to waive certified mail service and consent to electronic service instead. The compensation order notifies Employers/Carriers that payment of LHWCA compensation is due within 10 days of filing. If compensation is not paid within that time frame, an additional 20% in compensation must be paid [see LHWCA § 914(f)].

The information collected will be used by OWCP to more efficiently serve compensation orders by email instead of by registered or certified mail. Form LS–801 will be completed by the employer/

insurance carrier and/or an authorized representative and forwarded to the District Director indicating waiver of service by registered or certified mail and designation of receipt by email instead. The LS–802 will be completed by the claimants and/or an authorized representative and forwarded to the District Director indicating waiver of service by registered or certified mail and designation of receipt by email instead. This information collection is currently approved for use through November 30, 2015.

II. Review Focus

The Department of Labor is particularly interested in comments which:

* 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 submissions of responses.

III. Current Actions

The Department of Labor seeks the extension of approval of this information collection in order to carry out its responsibility to meet the statutory requirements to provide compensation or death benefits under the Act to workers covered by the Act.

Agency: Office of Workers' Compensation Programs.

Type of Review: Extension.

Title: Request for Electronic Service of Orders—Waiver of Certified Mail Requirements.

OMB Number: 1240–0053.

Agency Number: LS–801 and LS–802.

Affected Public: Claimants, employers, large insurance companies, and representatives.

Total Respondents: 9,240.

Total Annual Responses: 9,240.

Estimated Total Burden Hours: 770.

Estimated Time per Response: 5 minutes.

Frequency: On occasion.

Total Burden Cost (capital/startup): $0.

Total Burden Cost (operating/maintenance): $0.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: July 9, 2015.

Yoon Ferguson,

Agency Clearance Officer, Office of Workers' Compensation Programs US Department of Labor.

[FR Doc. 2015–17311 Filed 7–14–15; 8:45 am]

BILLING CODE 4510–CF–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: (15–058)]

NASA Advisory Council; Meeting

AGENCY: National Aeronautics and Space Administration.

ACTION: Notice of meeting.

SUMMARY: In accordance with the Federal Advisory Committee Act, Public Law 92–463, as amended, the National Aeronautics and Space Administration announces a meeting of the NASA Advisory Council (NAC).

DATES: Wednesday, July 29, 2015, 1:30 p.m.–4:30 p.m., Local Time; Thursday, July 30, 2015, 9:00 a.m.–5:00 p.m., Local Time; and Friday, July 31, 2015, 9:00 a.m.–11:30 a.m., Local Time.

ADDRESSES: Jet Propulsion Laboratory, Von Karman Auditorium, 4800 Oak Grove Drive, Pasadena, CA 91009.

FOR FURTHER INFORMATION CONTACT: Ms. Marla King, NAC Administrative Officer, NASA Headquarters, Washington, DC 20546, (202) 358–1148.

SUPPLEMENTARY INFORMATION: The meeting will be open to the public up to the seating capacity of the room. This meeting is also available telephonically and by WebEx. You must use a touch tone phone to participate in this meeting. Any interested person may dial 1–888–989–9827, Passcode: ''NAC Meeting'' for all three days. NOTE: If dialing in, please ''mute'' your telephone. To join via WebEx, the link is *https://nasa.webex.com/;* the meeting number is: 998 473 358 and the password is NACJULY2015! for all three days (password is case sensitive).

The agenda for the meeting will include the following:

—Aeronautics Committee Report
—Human Exploration and Operations Committee Report
—Institutional Committee Report
—Science Committee Report
—Technology, Innovation and Engineering Committee Report

Attendees will be required sign a register and to comply with Jet Propulsion Laboratory (JPL) security requirements including presentation of a valid picture ID (such as a driver's license for U.S. Citizens; Permanent Resident green card; or passport/visa for non-U.S. Citizens) before receiving admittance to JPL. Due to the Real ID Act, Public Law 109–13, any attendees with driver's licenses issued from non-compliant states/territories must present a second form of identification: [Federal employee badge; passport; active military identification card; enhanced driver's license; U.S. Coast Guard Merchant Mariner card; Native American tribal document; school identification accompanied by an item from LIST C (documents that establish employment authorization) from the ''List of the Acceptable Documents'' on Form I–9]. Non-compliant states/territories are: American Samoa, Arizona, Idaho, Louisiana, Maine, Minnesota, New Hampshire, and New York. Individuals without proper identification will not be admitted to the JPL. Members of the public interested in attending this meeting must contact Ms. Helen N. Paley of JPL at phone number 818–354–6427 or *helen.n.paley@jpl.nasa.gov* to receive a listing of the information required prior to admittance to JPL. Completed information spreadsheet must be emailed to Ms. Paley by no later than Tuesday, July 21, 2015. It is imperative that this meeting be held on these dates to accommodate the scheduling priorities of the key participants.

Patricia D. Rausch,

Advisory Committee Management Officer, National Aeronautics and Space Administration.

[FR Doc. 2015–17364 Filed 7–14–15; 8:45 am]

BILLING CODE 7510–13–P

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2015–66 and CP2015–97; Order No. 2574]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning the addition of Priority Mail Contract 132 to the competitive product list. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* July 16, 2015.

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:

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I. Introduction
II. Notice of Commission Action
III. Ordering Paragraphs

I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.,* the Postal Service filed a formal request and associated supporting information to add Priority Mail Contract 132 to the competitive product list.[1]

The Postal Service contemporaneously filed a redacted contract related to the proposed new product under 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. *Id.* Attachment B.

To support its Request, the Postal Service filed a copy of the contract, a copy of the Governors' Decision authorizing the product, proposed changes to the Mail Classification Schedule, a Statement of Supporting Justification, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

II. Notice of Commission Action

The Commission establishes Docket Nos. MC2015–66 and CP2015–97 to consider the Request pertaining to the proposed Priority Mail Contract 132 product and the related contract, respectively.

The Commission invites comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than July 16, 2015. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Lyudmila Y. Bzhilyanskaya to serve as Public Representative in these dockets.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2015–66 and CP2015–97 to consider the matters raised in each docket.
2. Pursuant to 39 U.S.C. 505, Lyudmila Y. Bzhilyanskaya is appointed to serve as an officer of the Commission to represent the interests of the general public in these proceedings (Public Representative).
3. Comments are due no later than July 16, 2015.
4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Shoshana M. Grove,

Secretary.

[FR Doc. 2015–17254 Filed 7–14–15; 8:45 am]

BILLING CODE 7710–FW–P

[1] Request of the United States Postal Service to Add Priority Mail Contract 132 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data, July 8, 2015 (Request).

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2015–65 and CP2015–96; Order No. 2573]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning the addition of Priority Mail Contract 131 to the competitive product list. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* July 16, 2015.

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:

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I. Introduction
II. Notice of Commission Action
III. Ordering Paragraphs

I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.,* the Postal Service filed a formal request and associated supporting information to add Priority Mail Contract 131 to the competitive product list.[1]

The Postal Service contemporaneously filed a redacted contract related to the proposed new product under 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. *Id.* Attachment B.

To support its Request, the Postal Service filed a copy of the contract, a copy of the Governors' Decision authorizing the product, proposed changes to the Mail Classification Schedule, a Statement of Supporting Justification, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

II. Notice of Commission Action

The Commission establishes Docket Nos. MC2015–65 and CP2015–96 to consider the Request pertaining to the proposed Priority Mail Contract 131 product and the related contract, respectively.

The Commission invites comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than July 16, 2015. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Cassie D'Souza to serve as Public Representative in these dockets.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2015–65 and CP2015–96 to consider the matters raised in each docket.
2. Pursuant to 39 U.S.C. 505, Cassie D'Souza is appointed to serve as an officer of the Commission to represent the interests of the general public in these proceedings (Public Representative).
3. Comments are due no later than July 16, 2015.
4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Shoshana M. Grove,

Secretary.

[FR Doc. 2015–17253 Filed 7–14–15; 8:45 am]

BILLING CODE 7710–FW–P

[1] Request of the United States Postal Service to Add Priority Mail Contract 131 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data, July 8, 2015 (Request).

POSTAL REGULATORY COMMISSION

[Docket Nos. MC2015–64 and CP2015–95; Order No. 2575]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning the addition of Priority Mail Contract 130 to the competitive product list. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* July 16, 2015.

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:

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I. Introduction
II. Notice of Commission Action
III. Ordering Paragraphs

I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.,* the Postal Service filed a formal request and associated supporting information to add Priority Mail Contract 130 to the competitive product list.[1]

The Postal Service contemporaneously filed a redacted contract related to the proposed new product under 39 U.S.C. 3632(b)(3) and 39 CFR 3015.5. *Id.* Attachment B.

To support its Request, the Postal Service filed a copy of the contract, a copy of the Governors' Decision authorizing the product, proposed changes to the Mail Classification Schedule, a Statement of Supporting Justification, a certification of compliance with 39 U.S.C. 3633(a), and an application for non-public treatment of certain materials. It also filed supporting financial workpapers.

II. Notice of Commission Action

The Commission establishes Docket Nos. MC2015–64 and CP2015–95 to consider the Request pertaining to the proposed Priority Mail Contract 130 product and the related contract, respectively.

The Commission invites comments on whether the Postal Service's filings in the captioned dockets are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR part 3015, and 39 CFR part 3020, subpart B. Comments are due no later than July 16, 2015. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Kenneth R. Moeller to serve as Public Representative in these dockets.

III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2015–64 and CP2015–95 to consider the matters raised in each docket.

2. Pursuant to 39 U.S.C. 505, Kenneth R. Moeller is appointed to serve as an officer of the Commission to represent the interests of the general public in these proceedings (Public Representative).

3. Comments are due no later than July 16, 2015.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Shoshana M. Grove,

Secretary.

[FR Doc. 2015–17277 Filed 7–14–15; 8:45 am]

BILLING CODE 7710–FW–P

[1] Request of the United States Postal Service to Add Priority Mail Contract 130 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data, July 8, 2015 (Request).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75412; File No. SR–BX–2015–039]

Self-Regulatory Organizations; NASDAQ OMX BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change to SPY Position Limits

July 9, 2015.

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 July 8, 2015, NASDAQ OMX BX, Inc. (''BX'' 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.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange's [sic] proposes to extend for another twelve (12) month time period the pilot program to eliminate position limits for options on the SPDR® S&P 500® exchange-traded fund (''SPY ETF'' or ''SPY''),[3] which list and trade under the symbol SPY (''SPY Pilot Program'').

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqomxbx.cchwallstreet.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 amend the Supplementary Material at the end of Chapter III, Section 7 (Position Limits) to extend the current pilot which expires on July 12, 2015 for an additional twelve (12) month time period to July 12, 2016 (''Extended Pilot''). This filing does not propose any substantive changes to the SPY Pilot Program. In proposing to extend the SPY Pilot Program, the Exchange reaffirms its consideration of several factors that supported the original proposal of the SPY Pilot Program, including (1) the availability of economically equivalent products and their respective position limits; (2) the

[3] ''SPDR®,'' ''Standard & Poor's®,'' ''S&P®,'' ''S&P 500®,'' and ''Standard & Poor's 500'' are registered trademarks of Standard & Poor's Financial Services LLC. The SPY ETF represents ownership in the SPDR S&P 500 Trust, a unit investment trust that generally corresponds to the price and yield performance of the SPDR S&P 500 Index.

liquidity of the option and the underlying security; (3) the market capitalization of the underlying security and the related index; (4) the reporting of large positions and requirements surrounding margin; and (5) the potential for market on close volatility.

The Exchange submitted a report to the Commission on June 11, 2015, which report reflects, during the time period from May 2014 through May 2015, the trading of standardized SPY options with no position limits consistent with option exchange provisions.[4] The report was prepared in the manner specified in BX's prior rule filing extending the SPY Pilot Program.[5] The Exchange 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. The proposed extension will allow the Exchange and the Commission additional time to further evaluate the pilot program and its effect on the market.

As with the original proposal to establish the SPY Pilot Program, the Exchange represents that a SPY Pilot Report will be submitted at least thirty (30) days before the end of the Extended Pilot and would analyze that period. The Pilot Report will detail the size and different types of strategies employed with respect to positions established as a result of the elimination of position limits in SPY. In addition, the report will note whether any problems resulted due to the no limit approach and any other information that may be useful in evaluating the effectiveness of the Extended Pilot. The Pilot Report will compare the impact of the SPY Pilot Program, if any, on the volumes of SPY options and the volatility in the price of the underlying SPY shares, particularly at expiration during the Extended Pilot. In preparing the report the Exchange will utilize various data elements such as volume and open interest. In addition the Exchange will make available to Commission staff data elements relating to the effectiveness of the SPY Pilot Program. Conditional on the findings in the SPY Pilot Report, the Exchange will file with the Commission a proposal to extend the pilot program, adopt the pilot program on a permanent basis or terminate the pilot. If the SPY Pilot Program is not extended or adopted on a permanent basis by the expiration of the Extended Pilot, the position limits for SPY options would revert to limits in effect prior to the commencement of the SPY Pilot Program.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act[6] in general, and furthers the objectives of Section 6(b)(5) of the Act[7] 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 mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change would be beneficial to market participants, including market makers, institutional investors and retail investors, by permitting them to establish greater positions when pursuing their investment goals and needs. The Exchange also believes that economically equivalent products should be treated in an equivalent manner so as to avoid regulatory arbitrage, especially with respect to position limits. Treating SPY and SPX options differently by virtue of imposing different position limits is inconsistent with the notion of promoting just and equitable principles of trade and removing impediments to perfect the mechanisms of a free and open market. At the same time, 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 proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. In this regard, the Exchange notes that the rule change is being proposed as a competitive response to similar filings that the Exchange expects to be filed by other options exchanges. The Exchange believes this proposed rule change is necessary to permit fair competition among the options exchanges and to establish uniform position limits for a multiply listed options class.

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

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.[8]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act[9] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[10] 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 so that the proposal may become operative immediately upon filing. The Exchange believes that waiver of the operative delay is consistent with the protection of investors and the public interest because it will permit the SPY Pilot Program to continue without interruption. 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.[11]

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

[4] The report is attached as Exhibit 3.

[5] *See* Securities Exchange Act Release No. 72143 (May 9, 2014), 79 FR 27963 (May 15, 2014) (SR–BX–2014–025).

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

[8] 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.

[9] 17 CFR 240.19b–4(f)(6).

[10] 17 CFR 240.19b–4(f)(6)(iii).

[11] 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).

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–BX–2015–039 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–BX–2015–039. 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–BX–2015–039, and should be submitted on or before August 5, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Brent J. Fields,

Secretary.

[FR Doc. 2015–17300 Filed 7–14–15; 8:45 am]

BILLING CODE 8011–01–P

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75413; File No. SR–NASDAQ–2015–072]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change to SPY Position Limits

July 9, 2015.

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 July 8, 2015, The NASDAQ Stock Market LLC (''Nasdaq'' 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 the Substance of the Proposed Rule Change

The Exchange proposes to extend for another twelve (12) month time period the pilot program to eliminate position limits for options on the SPDR® S&P 500® exchange-traded fund (''SPY ETF'' or ''SPY''),[3] which list and trade under the symbol SPY (''SPY Pilot Program'').

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaq.cchwallstreet.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 amend the Supplementary Material at the end of Chapter III, Section 7 (Position Limits) to extend the current pilot which expires on July 12, 2015 for an additional twelve (12) month time period to July 12, 2016 (''Extended Pilot''). This filing does not propose any substantive changes to the SPY Pilot Program. In proposing to extend the SPY Pilot Program, the Exchange reaffirms its consideration of several factors that supported the original proposal of the SPY Pilot Program, including (1) the availability of economically equivalent products and their respective position limits; (2) the liquidity of the option and the underlying security; (3) the market capitalization of the underlying security and the related index; (4) the reporting of large positions and requirements surrounding margin; and (5) the potential for market on close volatility.

The Exchange submitted a report to the Commission on June 11, 2015, which report reflects, during the time period from May 2014 through May 2015, the trading of standardized SPY options with no position limits consistent with option exchange provisions.[4] The report was prepared in the manner specified in the Exchange's prior filing extending the SPY Pilot Program.[5] The Exchange 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. The proposed extension will allow the Exchange and the Commission additional time to further evaluate the pilot program and its effect on the market.

As with the original proposal to establish the SPY Pilot Program, the Exchange represents that a SPY Pilot Report will be submitted at least thirty (30) days before the end of the Extended Pilot and would analyze that period.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] ''SPDR®,'' ''Standard & Poor's®,'' ''S&P®,'' ''S&P 500®,'' and ''Standard & Poor's 500'' are registered trademarks of Standard & Poor's Financial Services LLC. The SPY ETF represents ownership in the SPDR S&P 500 Trust, a unit investment trust that generally corresponds to the price and yield performance of the SPDR S&P 500 Index.

[4] The report is attached as Exhibit 3.

[5] *See* Securities Exchange Act Release No. 72142 (May 9, 2014), 79 FR 27961 (May 15, 2014) (SR–NASDAQ–2014–052).

The Pilot Report will detail the size and different types of strategies employed with respect to positions established as a result of the elimination of position limits in SPY. In addition, the report will note whether any problems resulted due to the no limit approach and any other information that may be useful in evaluating the effectiveness of the Extended Pilot. The Pilot Report will compare the impact of the SPY Pilot Program, if any, on the volumes of SPY options and the volatility in the price of the underlying SPY shares, particularly at expiration during the Extended Pilot. In preparing the report the Exchange will utilize various data elements such as volume and open interest. In addition the Exchange will make available to Commission staff data elements relating to the effectiveness of the SPY Pilot Program. Conditional on the findings in the Pilot Report, the Exchange will file with the Commission a proposal to extend the pilot program, adopt the pilot program on a permanent basis or terminate the pilot. If the SPY Pilot Program is not extended or adopted on a permanent basis by the expiration of the Extended Pilot, the position limits for SPY options would revert to limits in effect prior to the commencement of the SPY Pilot Program.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act [6] in general, and furthers the objectives of Section 6(b)(5) of the Act [7] 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 mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change would be beneficial to market participants, including market makers, institutional investors and retail investors, by permitting them to establish greater positions when pursuing their investment goals and needs. The Exchange also believes that economically equivalent products should be treated in an equivalent manner so as to avoid regulatory arbitrage, especially with respect to position limits. Treating SPY and SPX options differently by virtue of imposing different position limits is inconsistent with the notion of promoting just and equitable principles of trade and removing impediments to perfect the mechanisms of a free and open market. At the same time, 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 proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. In this regard, the Exchange notes that the rule change is being proposed as a competitive response to similar filings that the Exchange expects to be filed by other options exchanges. The Exchange believes this proposed rule change is necessary to permit fair competition among the options exchanges and to establish uniform position limits for a multiply listed options class.

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

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.[8]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act [9] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[10] 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 so that the proposal may become operative immediately upon filing. The Exchange believes that waiver of the operative delay is consistent with the protection of investors and the public interest because it will permit the SPY Pilot Program to continue without interruption. 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.[11]

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–NASDAQ–2015–072 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–NASDAQ–2015–072. 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

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

[8] 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.

[9] 17 CFR 240.19b–4(f)(6).

[10] 17 CFR 240.19b–4(f)(6)(iii).

[11] 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).

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–NASDAQ–2015–072, and should be submitted on or before August 5, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Brent J. Fields,

Secretary.

[FR Doc. 2015–17301 Filed 7–14–15; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75416; File No. SR–NYSEMKT–2015–49]

Self-Regulatory Organizations; NYSE MKT LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Commentary .07 to Rule 904 To Extend the Pilot Program That Eliminated the Position Limits for Options on SPDR S&P 500 ETF

July 9, 2015.

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 July 8, 2015, NYSE MKT LLC (the ''Exchange'' or ''NYSE MKT'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend Commentary .07 to Rule 904 to extend the pilot program that eliminated the position limits for options on SPDR S&P 500 ETF (''SPY'') (''SPY Pilot Program''). The text of 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.

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 Commentary .07 to Rule 904 to extend the time period of the SPY Pilot Program,[4] which is currently scheduled to expire on July 12, 2015, through July 12, 2016.

This filing does not propose any substantive changes to the SPY Pilot Program. In proposing to extend the SPY Pilot Program, the Exchange reaffirms its consideration of several factors that supported the original proposal of the SPY Pilot Program, including (1) the availability of economically equivalent products and their respective position limits, (2) the liquidity of the option and the underlying security, (3) the market capitalization of the underlying security and the related index, (4) the reporting of large positions and requirements surrounding margin, and (5) the potential for market on close volatility.

As part of the December 2014 Extension, the Exchange submitted a report providing an analysis of the SPY Pilot Program covering the prior ten (10) months from January 2014 to October 2014 during which the SPY Pilot Program was in effect (the ''Pilot Report''). In the December 2014 Extension, the Exchange also stated that if it were to propose an extension, permanent approval or termination of the program, the Exchange would submit, along with any filing proposing such amendments to the program, another Pilot Report covering the period since the previous extension. Accordingly, the Exchange is submitting another Pilot Report detailing the Exchange's experience with the SPY Pilot Program for the period covering six (6) months from November 2014 to April 2015. The Pilot Report is attached as Exhibit 3 to this filing. The Exchange 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 it were to propose another extension, permanent approval or termination of the program, the Exchange would submit another Pilot Report covering the period since the previous extension, which would 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, 2016, the position limits for SPY would revert to limits in effect at the commencement of the pilot program. The proposed extension will allow the Exchange and the Commission additional time to further evaluate the SPY Pilot Program and its effect on the market.

2. Statutory Basis

The Exchange believes that its proposal 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 remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Exchange believes that extending the SPY Pilot Program promotes just and equitable principles of trade by permitting market

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[12] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Securities Exchange Act Release No. 67672 (August 15, 2012), 77 FR 50750 (August 22, 2012). The SPY Pilot Program was subsequently extended. *See* Securities Exchange Release Nos. 70734 (October 22, 2013), 78 FR 64255 (October 28, 2013); and 73847 (December 16, 2014), 79 FR 76426 (December 22, 2014) (the ''December 2014 Extension'').

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(5).

participants, including market makers, institutional investors and retail investors, to establish greater positions when pursuing their investment goals and needs.

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 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 uninterrupted. Additionally, the Exchange expects all other SROs that currently have rules regarding the SPY Pilot Program to also extend the pilot program for an additional year.

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

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 so that the proposal may become operative immediately upon filing. The Exchange believes that waiver of the operative delay is consistent with the protection of investors and the public interest because it will allow the SPY Pilot Program to continue without interruption. 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–NYSEMKT–2015–49 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–NYSEMKT–2015–49. 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–NYSEMKT–2015–49, and should be submitted on or before August 5, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Brent J. Fields,

Secretary.

[FR Doc. 2015–17304 Filed 7–14–15; 8:45 am]

BILLING CODE 8011–01–P

[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. 34–75406; File No. SR–BATS–2015–48]

Self-Regulatory Organizations; BATS Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Market Data Section of Its Fee Schedule

July 9, 2015.

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 July 1, 2015, BATS Exchange, Inc. (the ''Exchange'' or ''BATS'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange has designated the proposed rule change as one establishing or changing a member due, fee, or other charge imposed by the Exchange under Section 19(b)(3)(A)(ii) of the Act[3] and Rule 19b–4(f)(2) thereunder,[4] which

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

renders the proposed rule change effective upon filing with 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 the Substance of the Proposed Rule Change

The Exchange filed a proposal to amend the Market Data section of its fee schedule to: (i) Adopt User fees, an Enterprise fee, and a Digital Media Enterprise fee for the BZX Top and BZX Last Sale feeds; and (ii) make a non-substantive change to the description of the BATS One Feed Enterprise Fee as well as correct a cross-reference within the definition of ''Non-Professional User''.

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.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 parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Market Data section of its fee schedule to: (i) Adopt User fees, an Enterprise fee, and a Digital Media Enterprise fee for the BZX Top and BZX Last Sale feeds; and (ii) make a non-substantive change to the description of the BATS One Feed Enterprise Fee as well as correct a cross-reference within the definition of ''Non-Professional User''.

BZX Top and Last Sale Fees

BZX Top is a market data feed that includes top of book quotations and execution information for all equity securities traded on the Exchange.[5] BZX Last Sale is a market data feed that includes last sale information for all equity securities traded on Exchange.[6]

Currently, the Exchange only charges fees for both internal and external distribution of the BZX Last Sale and BZX Top feeds. The cost of BZX Last Sale for an Internal Distributor[7] is $500 per month. Likewise, the cost of BZX Top for an Internal Distributor is also $500 per month. The Exchange currently does not charge per User[8] fees for either BZX Last Sale or BZX Top. Therefore, the Exchange does not currently require an External Distributor[9] of BZX Last Sale or BZX Top to count, classify (*e.g.,* professional or non-professional), or report to the Exchange information regarding the customers to which they provide the data. Instead, the Exchange charges an External Distributor of BZX Last Sale a flat fee of $2,500 per month. The Exchange also separately charges an External Distributor of BZX Top a flat fee of $2,500 per month. End Users currently do not pay the Exchange for BZX Last Sale or BZX Top, nor are End Users required to enter into contracts with the Exchange.

Subscribers to either BZX Top or BZX Last Sale are able to receive, upon request and at no additional cost, BZX Last Sale or BZX Top, as applicable. The Exchange also offers a New External Distributor Credit under which new External Distributors of BZX Top or BZX Last Sale will not be charged a Distributor Fee for their first three (3) months.

The Exchange now proposes to amend its fee schedule to incorporate additional fees related to the BZX Top or BZX Last Sale feeds.[10] These fees include the following, each of which are described in detail below: (i) Usage Fees for both Professional[11] and Non-Professional[12] Users;[13] (ii) Enterprise Fees;[14] and (iii) a Digital Media Enterprise Fee.

User Fees. The Exchange proposes to charge those who receive either BZX Top or BZX Last Sale from External Distributors different fees for both their Professional Users and Non-Professional Users. The Exchange will assess a monthly fee for Professional Users of $4.00 per User. Non-Professional Users will be assessed a monthly fee of $0.10 per User.[15] The Exchange does not

[5] *See* Exchange Rule 11.22(d).

[6] *See* Exchange Rule 11.22(g).

[7] An ''Internal Distributor'' is defined as ''a Distributor that receives the Exchange Market Data product and then distributes that data to one or more Users within the Distributor's own entity.'' *See* the Exchange Fee Schedule *available at http://batstrading.com/support/fee_schedule/bzx/.* A ''Distributor'' is defined as ''any entity that receives the Exchange Market Data product directly from the Exchange or indirectly through another entity and then distributes it internally or externally to a third party.'' *Id.*

[8] A ''User'' is defined as ''a natural person, a proprietorship, corporation, partnership, or entity, or device (computer or other automated service), that is entitled to receive Exchange data.'' *Id.*

[9] An ''External Distributor'' is defined as ''a Distributor that receives the Exchange Market Data product and then distributes that data to a third party or one or more Users outside the Distributor's own entity.'' *Id.*

[10] The Exchange notes that EDGA Exchange, Inc. (''EDGA''), EDGX Exchange, Inc. (''EDGX'') and BATS Y-Exchange, Inc. (''BYX'', together with the Exchange, EDGA and EDGX, the ''BATS Exchanges'') also filed proposed rule changes with Commission to adopt similar fees for their respective Top and Last Sale market data product. *See* File Nos. SR–EDGA–2015–25, SR–EDGX–2015–28, and SR–BYX–2015–30. The Exchange represents that the proposed fees will not cause the combined cost of subscribing to each of the BATS Exchanges' individual Top and Last Sale feeds to be greater than those currently charged to subscribe to the BATS One Feed. *See* Securities Exchange Act Release Nos. 74285 (February 18, 2015), 80 FR 9828 (February 24, 2015) (SR–BATS–2015–11); 74283 (February 18, 2015), 80 FR 9809 (February 24, 2015) (SR–EDGA–2015–09); 74282 (February 17, 2015), 80 FR 9487 (February 23, 2015) (SR–EDGX–2015–09); *and* 74284 (February 18, 2015), 80 FR 9792 (February 24, 2015) (SR–BYX–2015–09) (''Initial BATS One Feed Fee Filings''). In these filings, the Exchange represented that the cost of subscribing to each of the underlying individual feeds necessary to create the BATS One Feed would not be greater than the cost of subscribing to the BATS One Feed. *Id.*

[11] A ''Professional User'' is defined as ''any User other than a Non-Professional User.'' *See* the Exchange Fee Schedule *available at http://batstrading.com/support/fee_schedule/bzx/.*

[12] A ''Non-Professional User'' is defined as ''a natural person who is not: (i) Registered or qualified in any capacity with the Commission, the Commodity Futures Trading Commission, any state securities agency, any securities exchange or association, or any commodities or futures contract market or association; (ii) engaged as an ''investment adviser'' as that term is defined in Section [202(a)(11)] of the Investment Advisers Act of 1940 (whether or not registered or qualified under that Act); or (iii) employed by a bank or other organization exempt from registration under federal or state securities laws to perform functions that would require registration or qualification if such functions were performed for an organization not so exempt.'' *Id.*

[13] The Exchange notes that User fees as well as the distinctions based on professional and non-professional users have been previously filed with or approved by the Commission by the BATS Exchanges and the Nasdaq Stock Market LLC (''Nasdaq''). *See* Securities Exchange Act Release No. 59582 (March 16, 2009), 74 FR 12423 (March 24, 2009) (Order approving SR–Nasdaq–2008–102). *See also* the Initial BATS One Feed Fee Filings, *supra* note 11 [sic].

[14] The Exchange notes that Enterprise fees have been previously filed with or approved by the Commission by the Exchange, EDGA, EDGX, BYX, Nasdaq, NYSE, and the CTA/CQ Plans. *See* Nasdaq Rule 7047. Securities Exchange Act Release Nos. 71507 (February 7, 2014), 79 FR 8763 (February 13, 2014) (SR–NASDAQ–2014–011); 70211 (August 15, 2013), 78 FR 51781 (August 21, 2013) (SR–NYSE–2013–58); *and* 70010 (July 19, 2013) (File No. SR–CTA/CQ–2013–04). *See also* the Initial BATS One Feed Fee Filings, *supra* note 11 [sic].

[15] The Exchange notes that EDGA, EDGX and BYX also filed proposed rule changes with Commission to adopt User fees for their respective Top and Last Sale market data product. *See* File

Continued

propose to charge per User fees to Internal Distributors.

External Distributors would be required to count every Professional User and Non-Professional User to which they provide BZX Top and/or BZX Last Sale, the requirements for which are identical to that currently in place for the BATS One Feed.[16] Thus, the External Distributor's count will include every person and device that accesses the data regardless of the purpose for which the individual or device uses the data. External Distributors must report all Professional and Non-Professional Users in accordance with the following:

- In connection with an External Distributor's distribution of BZX Top or BZX Last Sale, the Distributor should count as one User each unique User that the Distributor has entitled to have access to BZX Top or BZX Last Sale. However, where a device is dedicated specifically to a single individual, the Distributor should count only the individual and need not count the device.
- The External Distributor should identify and report each unique User. If a User uses the same unique method to gain access to BZX Top or BZX Last Sale, the Distributor should count that as one User. However, if a unique User uses multiple methods to gain access to BZX Top or BZX Last Sale (*e.g.,* a single User has multiple passwords and user identifications), the External Distributor should report all of those methods as an individual User.
- External Distributors should report each unique individual person who receives access through multiple devices as one User so long as each device is dedicated specifically to that individual.
- If an External Distributor entitles one or more individuals to use the same device, the External Distributor should include only the individuals, and not the device, in the count.

Each External Distributor will receive a credit against its monthly Distributor Fee for BZX Top or BZX Last Sale equal to the amount of its monthly Usage Fees up to a maximum of the Distributor Fee for BZX Top or BZX Last Sale. For example, an External Distributor will be subject to a $2,500 monthly Distributor Fee where they elect to receive BZX Top. If that External Distributor reports User quantities totaling $2,500 or more of monthly usage of BZX Top, it will pay no net Distributor Fee, whereas if that same External Distributor were to report User quantities totaling $1,500 of monthly usage, it will pay a net of $1,000 for the Distributor Fee. External Distributors will remain subject to the per User fees discussed above. The same would apply to receipt of BZX Last Sale.

Enterprise Fee. The Exchange also proposes to establish a $15,000 per month Enterprise Fee that will permit a recipient firm who receives BZX Top or BZX Last Sale from an External Distributor to receive the data for an unlimited number of Professional and Non-Professional Users.[17] For example, if a recipient firm had 15,000 Professional Users who each receive BZX Top or BZX Last Sale at $4.00 per month, then that recipient firm will pay $60,000 per month in Professional Users fees. Under the proposed Enterprise Fee, the recipient firm will pay a flat fee of $15,000 for an unlimited number of Professional and Non-Professional Users for BZX Top or BZX Last Sale. A recipient firm must pay a separate Enterprise Fee for each External Distributor that controls display of BZX Top or BZX Last Sale if it wishes such User to be covered by an Enterprise Fee rather than by per User fees. A recipient firm that pays the Enterprise Fee will not have to report its number of such Users on a monthly basis. However, every six months, a recipient firm must provide the Exchange with a count of the total number of natural person users of each product, including both Professional and Non-Professional Users. Lastly, the proposed Enterprise Fee would be counted towards the Distributor Fee credit described above, under which an External Distributor receives a credit towards its Distributor Fee equal to the amount of its monthly BZX Top or BZX Last Sale usage fees.

Digital Media Enterprise Fee. The Exchange proposes to adopt a Digital Media Enterprise Fee of $2,500 per month for BZX Top and BZX Last Sale.[18] As an alternative to proposed User fees discussed above, a recipient firm may purchase a monthly Digital Media Enterprise license to receive BZX Top and BZX Last Sale from an External Distributor to distribute to an unlimited number of Professional and Non-Professional Users for viewing via television, Web sites, and mobile devices for informational and non-trading purposes only without having to account for the extent of access to the data or the report the number of Users to the Exchange. Lastly, the proposed Digital Media Enterprise Fee would be counted towards the Distributor Fee credit described above, under which an External Distributor receives a credit towards its Distributor Fee equal to the amount of its monthly BZX Top and/or BZX Last Sale usage fees.

Non-Substantive, Corrective Changes

The Exchange proposes to make a non-substantive change to the description of the BATS One Feed Enterprise Fee as well as correct a cross-reference within the definition of ''Non-Professional User''.

First, the proposed change to the description of the BATS One Feed[19]

Nos. SR–EDGA–2015–25, SR–EDGX–2015–28 and SR–BYX–2015–30 (proposing a monthly fee of $2.00 per Professional User and of $0.05 per Non-Professional User). A vendor that wishes to create a product like the BATS One Summary Feed could subscribe to each of the BATS Exchanges' Top and Last Sale feeds. *See* the Initial BATS One Feed Fee Filings, *supra* note 11 [sic]. Should a vendor subscribe to each of the BATS Exchanges' Top and Last Sale feeds, it would be charged a total of $10.00 per month per Professional User and $0.25 per month per Non-Professional User. This amount is equal to, and not greater than the User Fees charged for the BATS One Summary Feed. *Id.* (adopting fees of $10.00 per month per Professional User and $0.25 per month per Non-Professional User as well as a separate $1,000 per month Data Consolidation Fee for the BATS One Summary Feed).

[16] *See* the Initial BATS One Feed Fee Filings, *supra* note 11 [sic].

[17] The Exchange notes that EDGA, EDGX and BYX also filed proposed rule changes with Commission to adopt Enterprise Fees for their respective Top and Last Sale market data product. *See* File Nos. SR–EDGA–2015–25, SR–EDGX–2015–28 and SR–BYX–2015–30 (proposing a monthly Enterprise Fee of $15,000 for EDGX Top and EDGX Last Sale and $10,000 for EDGA Top and Last Sale as well as BYX Top and Last Sale). A vendor that wishes to create a product like the BATS One Summary Feed could subscribe to each of the BATS Exchanges' Top and Last Sale feeds. *See* the Initial BATS One Feed Fee Filings, *supra* note 11 [sic]. Should a vendor subscribe to each of the BATS Exchanges' Top and Last Sale feeds, it would be charged a total monthly Enterprise Fee of $50,000. This amount is equal to, and not greater than the Enterprise Fee charged for the BATS One Summary Feed. *Id.* (adopting a monthly Enterprise Fee of $50,000 as well as a separate $1,000 per month Data Consolidation Fee for the BATS One Summary Feed).

[18] The Exchange notes that EDGA, EDGX and BYX also filed proposed rule changes with Commission to adopt a Digital Media Enterprise Fee for their respective Top and Last Sale market data product. *See* File Nos. SR–EDGA–2015–25, SR–EDGX–2015–28 and SR–BYX–2015–30 (proposing a monthly Digital Media Enterprise Fee of $2,500 for their respective Top and Last Sale feeds). A vendor that wishes to create a product like the BATS One Summary Feed could subscribe to each of the BATS Exchanges' Top and Last Sale feeds. *See* the Initial BATS One Feed Fee Filings, *supra* note 11 [sic]. Should a vendor subscribe to each of the BATS Exchanges' Top and Last Sale feeds, it would be charged a total monthly Digital Media Enterprise Fee of $10,000. This amount is less than the Digital Media Enterprise Fee charged for the BATS One Summary Feed. *See* Securities Exchange Act Release Nos. 74598 (March 27, 2015), 80 FR 17791 (April 2, 2015) (SR–BATS–2015–24); 74599 (March 27, 2015), 80 FR 17812 (April 2, 2015) (SR–BYX–2015–19); 74600 (March 27, 2014), 80 FR 17797 (April 2, 2015) (SR–EDGA–2015–14); *and* 74601 (March 27, 2015), 80 FR 17804 (April 2, 2015) (SR–EDGX–2015–14) (adopting a monthly Digital Media Enterprise Fee of $15,000 for the BATS One Summary Feed).

[19] In sum, the BATS One Feed is a data feed that disseminates, on a real-time basis, the aggregate best

Enterprise Fee is intended to align with the descriptions of the Enterprise Fees for BZX Top and BZX Last Sale proposed above. The fee schedule currently states that:

[a]s an alternative to User fees, a recipient firm may purchase a monthly Enterprise license to receive the BATS One Feed from an External Distributor to an unlimited number of Professional and Non-Professional Users. A recipient firm must pay a separate Enterprise Fee for each External Distributor that controls the display of the BATS One Feed if it wishes such User to be covered by the Enterprise Fee. The Enterprise Fee is in addition to the Distributor Fee.

The Exchange proposes to delete the last sentence of the above description stating that the Enterprise Fee is in addition to the Distributor Fee. The original purpose of this sentence was to clarify that the Distributor Fee and Enterprise Fee were separate fees. However, the Exchange understands that this sentence has led to confusion for the following reason. As is the case for the proposed Enterprise Fees for BZX Top and BZX Last Sale described above, the BATS One Feed Enterprise Fee is counted towards the Distributor Fee credit, under which an External Distributor receives a credit towards its Distributor Fee equal to the amount of its monthly BATS One Feed Usage Fees. Stating that the Enterprise and Distributor fees were separate fees has caused confusion regarding the application of the Distributor Fee Usage Fee credit. Therefore, the Exchange proposes to delete the last sentence stating that the Enterprise Fee is in addition to the Distributor Fee. Deleting this sentence does not alter the manner in which the Enterprise Fee is charged. Rather, it is intended to avoid confusion and align the description with that of the proposed Enterprise Fees for BZX Top and BZX Last Sale described above.

Second, the Exchange proposes to correct a cross-reference within the definition of ''Non-Professional User''. In part, a ''Non-Professional User'' is currently defined as ''a natural person who is not: . . . engaged as an ''investment adviser'' as that term is defined in Section 201(11) of the Investment Advisers Act of 1940 (whether or not registered or qualified under that Act) . . .'' The definition incorrectly states that the term ''investment adviser is defined under Section 201(11) of the Investment Advisers Act of 1940, when it is, in fact, defined under Section 202(a)(11) of the Investment Advisers Act of 1940. Therefore, the Exchange proposes to replace the reference to Section 201(11) with Section 202(a)(11) within the definition of Non-Professional User.

Implementation Date

The Exchange proposes to implement the proposed changes to its fee schedule on July 1, 2015.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,[20] in general, and furthers the objectives of Section 6(b)(4),[21] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its members and other recipients of Exchange data. The Exchange believes that the proposed rates are equitable and non-discriminatory in that they apply uniformly to all recipients of Exchange data. The Exchange believes the proposed fees are competitive with those charged by other venues and, therefore, reasonable and equitably allocated to recipients. Lastly, the Exchange also believes that the proposed fees are reasonable and non-discriminatory because they will apply uniformly to all recipients of Exchange data.

The Exchange also believes that the proposed rule change is consistent with Section 11(A) of the Act[22] in that it supports (i) fair competition among brokers and dealers, among exchange markets, and between exchange markets and markets other than exchange markets and (ii) the availability to brokers, dealers, and investors of information with respect to quotations for and transactions in securities. Furthermore, the proposed rule change is consistent with Rule 603 of Regulation NMS,[23] which provides that any national securities exchange that distributes information with respect to quotations for or transactions in an NMS stock do so on terms that are not unreasonably discriminatory. In adopting Regulation NMS, the Commission granted self-regulatory organizations and broker-dealers increased authority and flexibility to offer new and unique market data to the public. It was believed that this authority would expand the amount of data available to consumers, and also spur innovation and competition for the provision of market data.

In addition, the proposed fees would not permit unfair discrimination because all of the Exchange's customers and market data vendors will be subject to the proposed fees on an equivalent basis. BZX Last Sale and BZX Top are distributed and purchased on a voluntary basis, in that neither the Exchange nor market data distributors are required by any rule or regulation to make this data available. Accordingly, Distributors and Users can discontinue use at any time and for any reason, including due to an assessment of the reasonableness of fees charged. Firms have a wide variety of alternative market data products from which to choose, such as similar proprietary data products offered by other exchanges and consolidated data. Moreover, the Exchange is not required to make any proprietary data products available or to offer any specific pricing alternatives to any customers.

In addition, the fees that are the subject of this rule filing are constrained by competition. As explained below in the Exchange's Statement on Burden on Competition, the existence of alternatives to BZX Top and BZX Last Sale further ensures that the Exchange cannot set unreasonable fees, or fees that are unreasonably discriminatory, when vendors and subscribers can elect such alternatives. That is, the Exchange competes with other exchanges (and their affiliates) that provide similar market data products. If another exchange (or its affiliate) were to charge less to consolidate and distribute its similar product than the Exchange charges to consolidate and distribute BZX Top or BZX Last Sale, prospective Users likely would not subscribe to, or would cease subscribing to, the BZX Top or BZX Last Sale.

The Exchange notes that the Commission is not required to undertake a cost-of-service or rate-making approach. The Exchange believes that, even if it were possible as a matter of economic theory, cost-based pricing for non-core market data would

bid and offer (''BBO'') of all displayed orders for securities traded on BZX and its affiliated exchanges and for which the BATS Exchanges report quotes under the Consolidated Tape Association (''CTA'') Plan or the Nasdaq/UTP Plan. The BATS One Feed also contains the individual last sale information for the BATS Exchanges (collectively with the aggregate BBO, the ''BATS One Summary Feed''). In addition, the BATS One Feed contains optional functionality which enables recipients to receive aggregated two-sided quotations from the BATS Exchanges for up to five (5) price levels (''BATS One Premium Feed''). *See* Securities Exchange Act Release No. 73918 (December 23, 2014), 79 FR 78920 (December 31, 2014) (File Nos. SR–EDGX–2014–25; SR–EDGA–2014–25; SR–BATS–2014–055; SR–BYX–2014–030) (Notice of Amendments No. 2 and Order Granting Accelerated Approval to Proposed Rule Changes, as Modified by Amendments Nos. 1 and 2, to Establish a New Market Data Product called the BATS One Feed) (''BATS One Approval Order'').

[20] 15 U.S.C. 78f.

[21] 15 U.S.C. 78f(b)(4).

[22] 15 U.S.C. 78k–1.

[23] *See* 17 CFR 242.603.

be so complicated that it could not be done practically.[24]

User Fees. The Exchange believes that implementing the Professional and Non-Professional User fees for BZX Top and BZX Last Sale is equitable and reasonable because it will result in greater availability to Professional and Non-Professional Users. Moreover, introducing a modest Non-Professional User fee for BZX Top and BZX Last Sale is reasonable because it provides an additional method for retail investors to access BZX Top and BZX Last Sale data by providing the same data that is available to Professional Users. The Exchange believes that the proposed fees are equitable and not unfairly discriminatory because they will be charged uniformly to recipient firms and Users. The fee structure of differentiated Professional and Non-Professional fees is utilized by the Exchange for the BATS One Feed and has long been used by other exchanges for their proprietary data products, and by the Nasdaq UTP and the CTA and CQ Plans in order to reduce the price of data to retail investors and make it more broadly available.[25] Offering BZX Top and BZX Last Sale to Non-Professional Users with the same data available to Professional Users results in greater equity among data recipients.

In addition, the proposed fees are reasonable when compared to similar fees for comparable products offered by the NYSE. Specifically, NYSE offers NYSE BBO, which includes best bid and offer for NYSE traded securities, for a monthly fee of $4.00 per professional subscriber and $0.20 per non-professional subscriber.[26] NYSE also offers NYSE Trades, which is a data feed that provides the last sale information for NYSE traded securities, for the same price as NYSE BBO. The Exchange's proposed per User Fees for BZX Top and BZX Last Sale are comparable with the NYSE's fees for NYSE Trades and NYSE BBO.

Enterprise Fee. The proposed Enterprise Fee for BZX Top and BZX Last Sale are equitable and reasonable as the fees proposed are less than the enterprise fees currently charged for NYSE Trades and NYSE BBO. The NYSE charges a separate enterprise fee of $190,000 per month for NYSE Trades and NYSE BBO.[27] In addition, the Enterprise Fee proposed by the Exchange could result in a fee reduction for recipient firms with a large number of Professional and Non-Professional Users. If a recipient firm has a smaller number of Professional Users of BZX Top or BZX Last Sale, then it may continue using the per User structure and benefit from the per User Fee reductions. By reducing prices for recipient firms with a large number of Professional and Non-Professional Users, the Exchange believes that more firms may choose to receive and to distribute the BZX Top or BZX Last Sale, thereby expanding the distribution of this market data for the benefit of investors.

The Exchange further believes that the proposed Enterprise Fee is reasonable because it will simplify reporting for certain recipients that have large numbers of Professional and Non-Professional Users. Firms that pay the proposed Enterprise Fee will not have to report the number of Users on a monthly basis as they currently do, but rather will only have to count natural person users every six months, which is a significant reduction in administrative burden. Finally, the Exchange believes that it is equitable and not unfairly discriminatory to establish an Enterprise Fee because it reduces the Exchange's costs and the Distributor's administrative burdens in tracking and auditing large numbers of Users.

Digital Media Enterprise Fee. The Exchange believes that the proposed Digital Media Enterprise Fee for BZX Top and BZX Last Sale provides for an equitable allocation of reasonable fees among recipients of the data and is not designed to permit unfair discrimination among customers, brokers, or dealers. In establishing the Digital Media Enterprise Fee, the Exchange recognizes that there is demand for a more seamless and easier-to-administer data distribution model that takes into account the expanded variety of media and communication devices that investors utilize today. The Exchange believes the Digital Media Enterprise Fee will be easy to administer because data recipients that purchase it would not be required to differentiate between Professional and Non-Professional Users, account for the extent of access to the data, or report the number of Users. This is a significant reduction on a recipient firm's administrative burdens and is a significant value to investors. For example, a television broadcaster could display BZX Top and/or BZX Last Sale data during market-related programming and on its Web site or allow viewers to view the data via their mobile devices, creating a more seamless distribution model that will allow investors more choice in how they receive and view market data, all without having to account for and/or measure who accesses the data and how often they do so.

The proposed Digital Media Enterprise Fee is equitable and reasonable because it will also enable recipient firms to more widely distribute data from BZX Top and BZX Last Sale to investors for informational purposes at a lower cost than is available today. For example, a recipient firm may purchase an Enterprise license in the amount of $15,000 per month for to receive BZX Top and/or BZX Last Sale from an External Distributor for an unlimited number of Professional and Non-Professional Users, which is greater than the proposed Digital Media Enterprise Fee. The Exchange also believes the amount of the Digital Media Enterprise Fee is reasonable as compared to the existing enterprise fees discussed above because the distribution of BZX Top and BZX Last Sale data is limited to television, Web sites, and mobile devices for informational purposes only, while distribution of BZX Top and BZX Last Sale data pursuant to an Enterprise license contains no such limitation. The Exchange also believes that the proposed Digital Media Enterprise Fee

[24] The Exchange believes that cost-based pricing would be impractical because it would create enormous administrative burdens for all parties, including the Commission, to cost-regulate a large number of participants and standardize and analyze extraordinary amounts of information, accounts, and reports. In addition, it is impossible to regulate market data prices in isolation from prices charged by markets for other services that are joint products. Cost-based rate regulation would also lead to litigation and may distort incentives, including those to minimize costs and to innovate, leading to further waste. Under cost-based pricing, the Commission would be burdened with determining a fair rate of return, and the industry could experience frequent rate increases based on escalating expense levels. Even in industries historically subject to utility regulation, cost-based ratemaking has been discredited. As such, the Exchange believes that cost-based ratemaking would be inappropriate for proprietary market data and inconsistent with Congress's direction that the Commission use its authority to foster the development of the national market system, and that market forces will continue to provide appropriate pricing discipline. *See* Appendix C to NYSE's comments to the Commission's 2000 Concept Release on the Regulation of Market Information Fees and Revenues, which can be found on the Commission's Web site at *http://www.sec.gov/rules/concept/s72899/buck1.htm. See also* Securities Exchange Act Release No. 73816 (December 11, 2014), 79 FR 75200 (December 17, 2014) (SR–NYSE–2014–64) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Establish an Access Fee for the NYSE Best Quote and Trades Data Feed, Operative December 1, 2014).

[25] *See* the Initial BATS One Feed Fee Filings, *supra* note 11 [sic]. *See also, e.g.,* Securities Exchange Act Release No. 20002, File No. S7–433 (July 22, 1983) (establishing nonprofessional fees for CTA data); Nasdaq Rules 7023(b), 7047.

[26] *See* NYSE Market Data Pricing dated May 2015 *available at http://www.nyxdata.com/.*

[27] *Id.*

is equitable and reasonable because it is less than similar fees charged by other exchanges.[28]

Non-Substantive, Corrective Changes. The Exchange believes that the proposed non-substantive, corrective changes are consistent with Section 6(b) of the Act,[29] in general, and Section 6(b)(4) of the Act,[30] in particular, in that they provide for an equitable allocation of reasonable fees among recipients of the data and is not designed to permit unfair discrimination among customers, brokers, or dealers. These proposed changes are equitable and reasonable because the changes are designed to clarify the fee schedule and avoid potential investor confusion. The amendment to the BATS One Enterprise Fee is also intended to align the description with that of the proposed Enterprise Fees for BZX Top and BZX Last Sale described above. The proposed changes are also non-discriminatory as they would apply to all recipient firms uniformly.

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.

BZX Top and BZX Last Sale

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 Exchange's ability to price BZX Last Sale and BZX Top are constrained by: (i) Competition among exchanges, other trading platforms, and Trade Reporting Facilities (''TRF'') that compete with each other in a variety of dimensions; (ii) the existence of inexpensive real-time consolidated data and market-specific data and free delayed data; and (iii) the inherent contestability of the market for proprietary data.

The Exchange and its market data products are subject to significant competitive forces and the proposed fees represent responses to that competition. To start, the Exchange competes intensely for order flow. It competes with the other national securities exchanges that currently trade equities, with electronic communication networks, with quotes posted in FINRA's Alternative Display Facility, with alternative trading systems, and with securities firms that primarily trade as principal with their customer order flow.

In addition, BZX Last Sale and BZX Top compete with a number of alternative products. For instance, BZX Last Sale and BZX Top do not provide a complete picture of all trading activity in a security. Rather, the other national securities exchanges, the several TRFs of FINRA, and Electronic Communication Networks (''ECN'') that produce proprietary data all produce trades and trade reports. Each is currently permitted to produce last sale information products, and many currently do, including Nasdaq and NYSE. In addition, market participants can gain access to BZX last sale prices and top-of-book quotations, though integrated with the prices of other markets, on feeds made available through the SIPs.

In sum, the availability of a variety of alternative sources of information imposes significant competitive pressures on Exchange data products and the Exchange's compelling need to attract order flow imposes significant competitive pressure on the Exchange to act equitably, fairly, and reasonably in setting the proposed data product fees. The proposed data product fees are, in part, responses to that pressure. The Exchange believes that the proposed fees would reflect an equitable allocation of its overall costs to users of its facilities.

In addition, when establishing the proposed fees, the Exchange considered the competitiveness of the market for proprietary data and all of the implications of that competition. The Exchange believes that it has considered all relevant factors and has not considered irrelevant factors in order to establish fair, reasonable, and not unreasonably discriminatory fees and an equitable allocation of fees among all Users. The existence of alternatives to BZX Last Sale and BZX Top, including existing similar feeds by other exchanges, consolidated data, and proprietary data from other sources, ensures that the Exchange cannot set unreasonable fees, or fees that are unreasonably discriminatory, when vendors and subscribers can elect these alternatives or choose not to purchase a specific proprietary data product if its cost to purchase is not justified by the returns any particular vendor or subscriber would achieve through the purchase.

Non-Substantive, Corrective Changes

The proposed non-substantive, corrective changes to the fee schedule will not have any impact on completion. The proposed changes are designed to clarify the fee schedule and avoid potential investor confusion.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

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) of the Act[31] and paragraph (f) of Rule 19b–4 thereunder.[32] 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.

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–BATS–2015–48 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–BATS–2015–48. 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

[28] The Nasdaq Stock Market offers proprietary data products for distribution over the internet and television under alternative fee schedules that are subject to maximum fee of $50,000 per month. *See* Nasdaq Rule 7039(b). The NYSE charges a Digit Media Enterprise fee of $40,000 per month for the NYSE Trade Digital Media product. *See* Securities Exchange Act Release No. 69272 (April 2, 2013), 78 FR 20983 (April 8, 2013) (SR–NYSE–2013–23).

[29] 15 U.S.C. 78f.

[30] 15 U.S.C. 78f(b)(4).

[31] 15 U.S.C. 78s(b)(3)(A).

[32] 17 CFR 240.19b–4(f).

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–BATS–2015–48, and should be submitted on or before August 5, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[33]

Brent J. Fields,

Secretary.

[FR Doc. 2015–17294 Filed 7–14–15; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75409; File No. SR–BX–2015–038]

Self-Regulatory Organizations; NASDAQ OMX BX, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule 7018

July 9, 2015.

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 30, 2015, NASDAQ OMX BX, Inc. (''BX'' or ''Exchange'') filed with the Securities and Exchange Commission (''SEC'' or ''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend BX Rule 7018(a) and to eliminate the Excess Order Fee in BX Rule 7018(d).

While the changes proposed herein are effective upon filing, the Exchange has designated that the amendments be operative on July 1, 2015.

The text of the proposed rule change is also available on the Exchange's Web site at *http://nasdaqomxbx.cchwallstreet.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 Exchange is proposing to amend BX Rule 7018(a) and to eliminate the Excess Order Fee in BX Rule 7018(d).

Specifically, BX Rule 7018(a) defines the criteria for a firm to become a Qualified Market Maker (''QMM'') as by being a member that provides through one or more of its NASDAQ OMX BX Equities System (''System'') market participant identifiers (''MPIDs'') more than 0.15% of consolidated volume (''Consolidated Volume'') during the month. For a member qualifying under this method, the member must have at least one qualified MPID (''Qualified MPID''), that is, an MPID through which, for at least 200 securities, the QMM quotes at the national best bid and offer (''NBBO'') an average of at least 50% of the time during regular market hours (9:30 a.m. through 4:00 p.m. ET) during the month. Currently, the member must also provide an average daily volume of 1.5M shares or more using orders with midpoint pegging during the month.

The Exchange proposes to modify this last part of the criteria such that the member must also provide an average daily volume of 1.5M shares or more of non-displayed liquidity (rather than using orders with midpoint liquidity) during the month. BX believes that by expanding the type of liquidity that allows firms to qualify as a QMM will improve the market by incentivizing firms to provide more liquidity and meet the other QMM criteria. Non-displayed orders, which include midpoint liquidity, can provide price improvement and improve the experience of members trading on the Exchange and thus provide a benefit to all other Exchange members.

The Exchange also proposes to delete BX Rule 7018(d), which is the Excess Order Fee. The Excess Order Fee was designed to provide a disincentive to member organizations to engage in order entry practices that are inefficient and thereby burdensome on the systems of BX by assessing a fee on member organizations if they reach a threshold of order activity based on an Order Entry Ratio calculation.[3] Although not a pervasive characteristic of the market, the fee was adopted to encourage member organizations with such practices to enhance the efficiency of their systems and modify their order entry practices, thus improving the market for all participants.[4] An unwanted consequence of the rule has been to capture beneficial, liquidity providing order flow and thereby dissuade member organizations from participating in BX in an effort to avoid triggering the fee. Moreover, the Exchange has observed that the fee is not assessed on a significant number of member organizations nor is it triggered every month, leading the Exchange to conclude that the small number of member organizations that may have been affected by the fee because of their inefficient order practices have taken the steps necessary to avoid such practices. The Exchange believes that, in light of the lack of consistent order activity that triggers the fee and the negative effect it has had on beneficial order flow, the Excess Order Fee should be eliminated. The Exchange notes that, should the inefficient order entry practices that gave rise to the fee once again arise, it may adopt the fee once again or take other steps to provide a disincentive for such practices.

2. Statutory Basis

BX believes that the proposed rule change is consistent with the provisions

[33] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* BX Rule 7018(d)(2) for a definition of ''Order Entry Ratio.''

[4] *See* Securities Exchange Act Release No. 67272 (June 27, 2012), 77 FR 39530 (July 3, 2012) (SR–BX–2012–042) (adopting the Excess Order Fee).

of Section 6 of the Act,[5] in general, and with Sections 6(b)(4) and 6(b)(5) of the Act,[6] 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 or system which the Exchange operates or controls, and 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 proposes to amend the criteria for a firm to become a QMM. The criteria currently states that a member may become a QMM by providing through one or more of its System MPIDs more than 0.15% of Consolidated Volume during the month. For a member qualifying under this method, the member must have at least one Qualified MPID, that is, an MPID through which, for at least 200 securities, the QMM quotes at the NBBO an average of at least 50% of the time during regular market hours (9:30 a.m. through 4:00 p.m.) during the month. Currently, the member must also provide an average daily volume of 1.5M shares or more using orders with midpoint pegging during the month.

[sic] Exchange believes it is reasonable to modify this last part of the criteria such that the member must provide an average daily volume of 1.5M shares or more of non-displayed liquidity (rather than using orders with midpoint liquidity) during the month because non-displayed orders can provide price improvement and improve the experience of members trading on the Exchange and thus provide a benefit to all other Exchange members. Also, BX believes the proposed change is reasonable because it expands the opportunity for firms to qualify as a QMM.

The Exchange also believes that the proposed change is equitably allocated and not unfairly discriminatory because modifying the criteria, as stated above, applies uniformly to all members that seek to become a QMM. Additionally, the Exchange believes that the proposed change further perfects the mechanism of a free and open market by refining and making more effective the means by which a member firm may become a QMM. Furthermore firms that currently qualify as a QMM will not need to change behavior under the new qualification method as midpoint liquidity is considered non-displayed liquidity.

The Exchange believes that elimination of the Excess Order Fee is reasonable because the fee is not triggered by a significant number of member organizations nor is it triggered every month; however, the Exchange believes that certain member organizations are disincentivized from providing order activity that is beneficial to market participants. Moreover, the Exchange may adopt the fee once again should the issues that gave rise to it reemerge. The Exchange believes that the proposed change is consistent with an equitable allocation of fees and is not unfairly discriminatory because it eliminates a fee, which applies to all member organizations and which has served as a disincentive to certain market participants in providing beneficial order activity while also not being assessed significantly on member organizations. The Exchange believes that elimination of the Excess Order Fee will not unfairly burden competition because the fee is not relevant to competition. The Exchange notes that the fee was adopted to deter member organizations from using inefficient order practices that place excessive burdens on the systems of BX and, as a consequence, was not designed to impact competition among member organizations.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule changes will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended.[7] BX notes that it operates in a highly competitive market in which market participants can readily favor dozens of different competing exchanges and alternative trading systems 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, BX 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, BX believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited.

In this instance, the modification to part of the criteria to become a QMM does not impose a burden on competition because it is optional and is the subject of competition from other exchanges. The Exchange does not believe that the proposed change will impair the ability of members or competing order execution venues to maintain their competitive standing in the financial markets. Moreover, because there are numerous competitive alternatives to the use of the Exchange, it is likely that BX will lose market share as a result of the changes if they are unattractive to market participants.

As noted above, the Exchange believes that elimination of the Excess Order Fee will not unfairly burden competition because the fee is not relevant to competition as it was adopted to deter member organizations from using inefficient order practices that place excessive burdens on the systems of BX. Moreover, other exchanges' fee schedules do not restrict order activity by using a fee like the Excess Order Fee. As noted, the practices that prompted the Exchange to adopt the rule have subsided and, consequently, the change does not impact the ability of any market participant or trading venue to compete.

Accordingly, BX does not believe that the proposed rule change will impair the ability of members or competing order execution venues 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 change has become effective pursuant to Section 19(b)(3)(A) of the Act[8] and paragraph (f) of Rule 19b–4[9] 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

[5] 15 U.S.C. 78f.

[6] 15 U.S.C. 78f(b)(4) and (5).

[7] 15 U.S.C. 78f(b)(8).

[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFR 240.19b–4(f).

investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BX–2015–038 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–BX–2015–038. 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 offices 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–BX–2015–038, and should be submitted on or before August 5, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Brent J. Fields,

Secretary.

[FR Doc. 2015–17297 Filed 7–14–15; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75408; File No. SR–MIAX–2015–45]

Self-Regulatory Organizations; Miami International Securities Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Its Fee Schedule

July 9, 2015.

Pursuant to the provisions of 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 July 7, 2015, Miami International Securities Exchange LLC (''MIAX'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend the MIAX Options Fee Schedule.

The text of the proposed rule change is available on the Exchange's Web site at *http://www.miaxoptions.com/filter/wotitle/rule_filing,* at MIAX's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Fee Schedule to modify the transaction fees for Members that participate in the price improvement auction (''PRIME Auction'' or ''PRIME'') pursuant to Rule 515A.[3] Specifically, the Exchange proposes: (i) Increase the fee for a PRIME AOC Response from $0.45 per contract to $0.49 per contract for standard options in Penny Pilot classes; (ii) increase the fee for a PRIME AOC Response from $0.90 per contract to $0.94 per contract for standard options in non-Penny Pilot classes; and (iii) provide for additional incentives for achieving certain Priority Customer Rebate Program volume tiers.

Currently, the Exchange assesses PRIME AOC Responses $0.45 per contract for standard options in Penny Pilot classes and $0.90 per contract in non-Penny Pilot classes. The Exchange now proposes to modify these fees that apply to PRIME AOC Responses. Specifically, the Exchange proposes: (i) Increase the fee for a PRIME AOC Response from $0.45 per contract to $0.49 per contract for standard options in Penny Pilot classes; and (ii) increase the fee for a PRIME AOC Response from $0.90 per contract to $0.94 per contract for standard options in non-Penny Pilot classes. The Exchange will continue to assess the standard transaction fees to a PRIME AOC Response if they execute against unrelated orders.

The Exchange proposes to offer Members that submit PRIME AOC Responses the opportunity to reduce transaction fees by $0.04 per contract in standard options if the Member or its affiliates of at least 75% common ownership between the firms as reflected on each firm's Form BD, Schedule A, qualifies in a given month for Priority Customer Rebate Program volume tiers 3, 4, or 5 in the Fee Schedule. Specifically, any Member or its affiliates of at least 75% common ownership between the firms as reflected on each firm's Form BD, Schedule A, that qualifies for Priority Customer Rebate Program volume tiers 3, 4, or 5 will be assessed a PRIME AOC Response fee of $0.45 per contract for standard options in Penny Pilot classes. In addition, any Member or its affiliates of at least 75% common ownership

[10] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Exchange Rule 515A. *See also* Securities Exchange Act Release No.) 72943 (August 28, 2014), 79 FR 52785 (September 4, 2014) (SR–MIAX–2014–45); MIAX Options Fee Schedule, Section 1)a)iv).

between the firms as reflected on each firm's Form BD, Schedule A, that qualifies for Priority Customer Rebate Program volume tiers 3, 4, or 5 will be assessed a PRIME AOC Response fee of $0.90 per contract for standard options in non-Penny Pilot classes. The Exchange believes that these incentives will encourage Members to transact a greater number of contracts on the Exchange. The Exchange notes that these incentives will operate identically to the Priority Customer Rebate Program incentives that apply to any Member or its affiliates of at least 75% common ownership between the firms as reflected on each firm's Form BD, Schedule A, that qualifies for Priority Customer Rebate Program volume tiers 3, 4, or 5 in other types of transaction fees.[4]

The Exchange proposes to implement the proposed changes beginning July 1, 2015.

2. Statutory Basis

The Exchange believes that its proposal to amend its fee schedule is consistent with Section 6(b) of the Act[5] in general, and furthers the objectives of Section 6(b)(4) of the Act[6] in particular, in that it is an equitable allocation of reasonable fees and other charges among Exchange members.

The Exchange's proposal to increase the transaction fees for Members that submit PRIME AOC Responses is reasonable because the Exchange's fees will remain competitive with fees at other options exchanges.[7] The Exchange's proposal to increase the transaction fees for Members that submit PRIME AOC Responses is equitable and not unfairly discriminatory because the increase applies equally to all such market participants. The Exchange believes that the transaction fees for responding to the auction will not deter market participants from providing price improvement. In addition, the Exchange believes that it is reasonable to continue to assess lower transaction fees in penny option classes than non-penny option classes in a manner similar to the current fees.[8]

The Exchange's proposal to offer Members or its affiliates of at least 75% common ownership between the firms as reflected on each firm's Form BD, Schedule A, that qualifies for Priority Customer Rebate Program volume tiers 3, 4, or 5, that submit PRIME AOC Responses the opportunity to reduce transaction fees by $0.04 per contract in standard options, provided certain criteria are met, is reasonable because the Exchange desires to offer all such market participants an opportunity to lower their transaction fees. The Exchange's proposal to offer Members or its affiliates of at least 75% common ownership between the firms as reflected on each firm's Form BD, Schedule A, that qualifies for Priority Customer Rebate Program volume tiers 3, 4, or 5, that submit PRIME AOC Responses the opportunity to reduce transaction fees by $0.04 per contract in standard options, provided certain criteria are met, is equitable and not unfairly discriminatory because the Exchange will offer all market participants a means to reduce transaction fees by qualifying for volume tiers in the Priority Customer Rebate Program. The Exchange believes that offering all such market participants the opportunity to lower transaction fees by incentivizing them to transact Priority Customer order flow in turn benefits all market participants. To the extent that there is higher transaction fees assessed on market participants without Priority Customer order flow, the Exchange believes that this is appropriate because the proposal should incent Members to direct additional order flow to the Exchange and thus provide additional liquidity that enhances the quality of its markets and increases the volume of contracts traded here. To the extent that this purpose is achieved, all the Exchange's market participants should benefit from the improved market liquidity. Enhanced market quality and increased transaction volume that results from the anticipated increase in order flow directed to the Exchange will benefit all market participants and improve competition on the Exchange.

The Exchange believes that the proposal to allow the aggregation of trading activity of separate Members or its affiliates for purposes of the fee reduction is fair, equitable and not unreasonably discriminatory. The Exchange believes the proposed rule change is reasonable because it would allow aggregation of the trading activity of separate Members or its affiliates for purposes of the fee reduction only in very narrow circumstances, namely, where the firm is an affiliate, as defined herein. Furthermore, other exchanges, as well as MIAX, have rules that permit the aggregation of the trading activity of affiliated entities for the purposes of calculating and assessing certain fees. The Exchange believes that offering all such market participants the opportunity to lower transaction fees by incentivizing them to transact Priority Customer order flow 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 believes that the proposed change will enhance the competiveness of the Exchange relative to other exchanges that offer their own electronic crossing mechanism. The Exchange believes that the proposed fees are not going to have an impact on intra-market competition based on the total cost for participants to transact as respondents to the Auction as compared to the cost for participants to engage in non-Auction electronic transactions on the Exchange. As noted above, the Exchange believes that the proposed pricing for the PRIME Auction is comparable to that of other exchanges offering similar electronic price improvement mechanisms, and the Exchange believes that market participants understand that the price-improving benefits, based on their experience with electronic price improvement crossing mechanisms on other markets, offered by the Auction justify and offset the transaction costs associated with Auction. To the extent that there is a difference between non-Auction transactions fees and Auction transactions fees, the Exchange does not believe this difference will cause participants to refrain from responding to Auctions. In addition, the Exchange does not believe that the proposed transaction fees and credits burden competition by creating a disparity of transaction fees between the PRIME Order and the transaction fees that a responder pays would result in certain participants being unable to compete with the Contra-side Order. The Exchange expects to see robust competition within the PRIME Auction, despite the apparent differences in non-Auction fees versus Auction response fees.

To the extent that there is additional competitive burden on market participants without Priority Customer order flow, the Exchange believes that this is appropriate because the proposal should incent Members to direct additional order flow to the Exchange and thus provide additional liquidity

[4] *See* MIAX Options Fee Schedule.

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(4).

[7] *See e.g.,* NYSE Amex Options Fee Schedule; International Securities Exchange LLC Schedule of Fees; BOX Options Exchange Fee Schedule.

[8] *See* Securities Exchange Act Release No. 72989 (September 4, 2014), 79 FR 53792 (September 10, 2014) (SR–MIAX–2014–47).

that enhances the quality of its markets and increases the volume of contracts traded here. To the extent that this purpose is achieved, all the Exchange's market participants should benefit from the improved market liquidity. Enhanced market quality and increased transaction volume that results from the anticipated increase in order flow directed to the Exchange will benefit all market participants and improve competition on the Exchange.

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. In such an environment, the Exchange must continually adjust its fees to remain competitive with other exchanges and to attract order flow to the Exchange. The Exchange believes that the proposed rule change reflects this competitive environment because it establishes a fee structure in a manner that encourages market participants to direct their order flow, to provide liquidity, and to attract additional transaction volume to the Exchange.

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.[9] 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–2015–45 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–2015–45. 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–2015–45, and should be submitted on or before August 5, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Brent J. Fields,

Secretary.

[FR Doc. 2015–17296 Filed 7–14–15; 8:45 am]

BILLING CODE 8011–01–P

[9] 15 U.S.C. 78s(b)(3)(A)(ii).

[10] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75407; File No. SR–BYX–2015–30]

Self-Regulatory Organizations; BATS Y-Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Market Data Section of Its Fee Schedule

July 9, 2015.

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 July 1, 2015, BATS Y-Exchange, Inc. (the ''Exchange'' or ''BYX'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange has designated the proposed rule change as one establishing or changing a member due, fee, or other charge imposed by the Exchange under Section 19(b)(3)(A)(ii) of the Act[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposed rule change effective upon filing with 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 the Substance of the Proposed Rule Change

The Exchange filed a proposal to amend the Market Data section of its fee schedule to: (i) Adopt User fees, an Enterprise fee, and a Digital Media Enterprise fee for the BYX Top and BYX Last Sale feeds; and (ii) make a non-substantive change to the description of the BATS One Feed Enterprise Fee as well as correct a cross-reference within the definition of ''Non-Professional User''.

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.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

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

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 parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Market Data section of its fee schedule to: (i) Adopt User fees, an Enterprise fee, and a Digital Media Enterprise fee for the BYX Top and BYX Last Sale feeds; and (ii) make a non-substantive change to the description of the BATS One Feed Enterprise Fee as well as correct a cross-reference within the definition of ''Non-Professional User''.

BYX Top and Last Sale Fees

BYX Top is a market data feed that includes top of book quotations and execution information for all equity securities traded on the Exchange.[5] BYX Last Sale is a market data feed that includes last sale information for all equity securities traded on Exchange.[6]

Currently, the Exchange only charges fees for both internal and external distribution of the BYX Last Sale and BYX Top feeds. The cost of BYX Last Sale for an Internal Distributor[7] is $500 per month. Likewise, the cost of BYX Top for an Internal Distributor is also $500 per month. The Exchange currently does not charge per User[8] fees for either BYX Last Sale or BYX Top. Therefore, the Exchange does not currently require an External Distributor[9] of BYX Last Sale or BYX Top to count, classify (*e.g.,* professional or non-professional), or report to the Exchange information regarding the customers to which they provide the data. Instead, the Exchange charges an External Distributor of BYX Last Sale a flat fee of $1,250 per month. The Exchange also separately charges an External Distributor of BYX Top a flat fee of $1,250 per month. End Users currently do not pay the Exchange for BYX Last Sale or BYX Top, nor are End Users required to enter into contracts with the Exchange.

Subscribers to either BYX Top or BYX Last Sale are able to receive, upon request and at no additional cost, BYX Last Sale or BYX Top, as applicable. The Exchange also offers a New External Distributor Credit under which new External Distributors of BYX Top or BYX Last Sale will not be charged a Distributor Fee for their first three (3) months.

The Exchange now proposes to amend its fee schedule to incorporate additional fees related to the BYX Top or BYX Last Sale feeds.[10] These fees include the following, each of which are described in detail below: (i) Usage Fees for both Professional[11] and Non-Professional[12] Users;[13] (ii) Enterprise Fees;[14] and (iii) a Digital Media Enterprise Fee.

User Fees. The Exchange proposes to charge those who receive either BYX Top or BYX Last Sale from External Distributors different fees for both their Professional Users and Non-Professional Users. The Exchange will assess a monthly fee for Professional Users of $2.00 per User. Non-Professional Users will be assessed a monthly fee of $0.05 per User.[15] The Exchange does not propose to charge per User fees to Internal Distributors.

External Distributors would be required to count every Professional User and Non-Professional User to

[5] *See* Exchange Rule 11.22(d).

[6] *See* Exchange Rule 11.22(g).

[7] An ''Internal Distributor'' is defined as ''a Distributor that receives the Exchange Market Data product and then distributes that data to one or more Users within the Distributor's own entity.'' *See* the Exchange Fee Schedule *available at http://batstrading.com/support/fee_schedule/byx/.* A ''Distributor'' is defined as ''any entity that receives the Exchange Market Data product directly from the Exchange or indirectly through another entity and then distributes it internally or externally to a third party.'' *Id.*

[8] A ''User'' is defined as ''a natural person, a proprietorship, corporation, partnership, or entity, or device (computer or other automated service), that is entitled to receive Exchange data.'' *Id.*

[9] An ''External Distributor'' is defined as ''a Distributor that receives the Exchange Market Data product and then distributes that data to a third party or one or more Users outside the Distributor's own entity.'' *Id.*

[10] The Exchange notes that EDGA Exchange, Inc. (''EDGA''), EDGX Exchange, Inc. (''EDGX'') and BATS Exchange, Inc. (''BZX'', together with the Exchange, EDGA and EDGX, the ''BATS Exchanges'') also filed proposed rule changes with Commission to adopt similar fees for their respective Top and Last Sale market data product. *See* File Nos. SR–EDGA–2015–25, SR–EDGX–2015–28, and SR–BATS–2015–48. The Exchange represents that the proposed fees will not cause the combined cost of subscribing to each of the BATS Exchanges' individual Top and Last Sale feeds to be greater than those currently charged to subscribe to the BATS One Feed. *See* Securities Exchange Act Release Nos. 74285 (February 18, 2015), 80 FR 9828 (February 24, 2015) (SR–BATS–2015–11); 74283 (February 18, 2015), 80 FR 9809 (February 24, 2015) (SR–EDGA–2015–09); 74282 (February 17, 2015), 80 FR 9487 (February 23, 2015) (SR–EDGX–2015–09); *and* 74284 (February 18, 2015), 80 FR 9792 (February 24, 2015) (SR–BYX–2015–09) (''Initial BATS One Feed Fee Filings''). In these filings, the Exchange represented that the cost of subscribing to each of the underlying individual feeds necessary to create the BATS One Feed would not be greater than the cost of subscribing to the BATS One Feed. *Id.*

[11] A ''Professional User'' is defined as ''any User other than a Non-Professional User.'' *See* the Exchange Fee Schedule *available at http://batstrading.com/support/fee_schedule/byx/.*

[12] A ''Non-Professional User'' is defined as ''a natural person who is not: (i) Registered or qualified in any capacity with the Commission, the Commodity Futures Trading Commission, any state securities agency, any securities exchange or association, or any commodities or futures contract market or association; (ii) engaged as an ''investment adviser'' as that term is defined in Section [202(a)(11)] of the Investment Advisers Act of 1940 (whether or not registered or qualified under that Act); or (iii) employed by a bank or other organization exempt from registration under federal or state securities laws to perform functions that would require registration or qualification if such functions were performed for an organization not so exempt.'' *Id.*

[13] The Exchange notes that User fees as well as the distinctions based on professional and non-professional users have been previously filed with or approved by the Commission by the BATS Exchanges and the Nasdaq Stock Market LLC (''Nasdaq''). *See* Securities Exchange Act Release No. 59582 (March 16, 2009), 74 FR 12423 (March 24, 2009) (Order approving SR–Nasdaq–2008–102). *See also* the Initial BATS One Feed Fee Filings, *supra* note 11 [sic].

[14] The Exchange notes that Enterprise fees have been previously filed with or approved by the Commission by the Exchange, EDGA, EDGX, BZX, Nasdaq, NYSE, and the CTA/CQ Plans. *See* Nasdaq Rule 7047. Securities Exchange Act Release Nos. 71507 (February 7, 2014), 79 FR 8763 (February 13, 2014) (SR–NASDAQ–2014–011); 70211 (August 15, 2013), 78 FR 51781 (August 21, 2013) (SR–NYSE–2013–58); *and* 70010 (July 19, 2013) (File No. SR–CTA/CQ–2013–04). *See also* the Initial BATS One Feed Fee Filings, *supra* note 11 [sic].

[15] The Exchange notes that EDGA, EDGX and BZX also filed proposed rule changes with Commission to adopt User fees for their respective Top and Last Sale market data product. *See* File Nos. SR–EDGA–2015–25, SR–EDGX–2015–28 and SR–BATS–2015–48 (proposing a monthly fee of $2.00 per Professional User and of $0.05 per Non-Professional User for EDGA and EDGX and a monthly fee of $4.00 per Professional User and of $0.10 per Non-Professional User for BZX). A vendor that wishes to create a product like the BATS One Summary Feed could subscribe to each of the BATS Exchanges' Top and Last Sale feeds. *See* the Initial BATS One Feed Fee Filings, *supra* note 11 [sic]. Should a vendor subscribe to each of the BATS Exchanges' Top and Last Sale feeds, it would be charged a total of $10.00 per month per Professional User and $0.25 per month per Non-Professional User. This amount is equal to, and not greater than the User Fees charged for the BATS One Summary Feed. *Id.* (adopting fees of $10.00 per month per Professional User and $0.25 per month per Non-Professional User as well as a separate $1,000 per month Data Consolidation Fee for the BATS One Summary Feed).

which they provide BYX Top and/or BYX Last Sale, the requirements for which are identical to that currently in place for the BATS One Feed.[16] Thus, the External Distributor's count will include every person and device that accesses the data regardless of the purpose for which the individual or device uses the data. External Distributors must report all Professional and Non-Professional Users in accordance with the following:

- In connection with an External Distributor's distribution of BYX Top or BYX Last Sale, the Distributor should count as one User each unique User that the Distributor has entitled to have access to BYX Top or BYX Last Sale. However, where a device is dedicated specifically to a single individual, the Distributor should count only the individual and need not count the device.
- The External Distributor should identify and report each unique User. If a User uses the same unique method to gain access to BYX Top or BYX Last Sale, the Distributor should count that as one User. However, if a unique User uses multiple methods to gain access to BYX Top or BYX Last Sale (*e.g.,* a single User has multiple passwords and user identifications), the External Distributor should report all of those methods as an individual User.
- External Distributors should report each unique individual person who receives access through multiple devices as one User so long as each device is dedicated specifically to that individual.
- If an External Distributor entitles one or more individuals to use the same device, the External Distributor should include only the individuals, and not the device, in the count.

Each External Distributor will receive a credit against its monthly Distributor Fee for BYX Top or BYX Last Sale equal to the amount of its monthly Usage Fees up to a maximum of the Distributor Fee for BYX Top or BYX Last Sale. For example, an External Distributor will be subject to a $1,250 monthly Distributor Fee where they elect to receive BYX Top. If that External Distributor reports User quantities totaling $1,250 or more of monthly usage of BYX Top, it will pay no net Distributor Fee, whereas if that same External Distributor were to report User quantities totaling $1,000 of monthly usage, it will pay a net of $250 for the Distributor Fee. External Distributors will remain subject to the per User fees discussed above. The same would apply to receipt of BYX Last Sale.

Enterprise Fee. The Exchange also proposes to establish a $10,000 per month Enterprise Fee that will permit a recipient firm who receives BYX Top or BYX Last Sale from an External Distributor to receive the data for an unlimited number of Professional and Non-Professional Users.[17] For example, if a recipient firm had 15,000 Professional Users who each receive BYX Top or BYX Last Sale at $2.00 per month, then that recipient firm will pay $30,000 per month in Professional Users fees. Under the proposed Enterprise Fee, the recipient firm will pay a flat fee of $10,000 for an unlimited number of Professional and Non-Professional Users for BYX Top or BYX Last Sale. A recipient firm must pay a separate Enterprise Fee for each External Distributor that controls display of BYX Top or BYX Last Sale if it wishes such User to be covered by an Enterprise Fee rather than by per User fees. A recipient firm that pays the Enterprise Fee will not have to report its number of such Users on a monthly basis. However, every six months, a recipient firm must provide the Exchange with a count of the total number of natural person users of each product, including both Professional and Non-Professional Users. Lastly, the proposed Enterprise Fee would be counted towards the Distributor Fee credit described above, under which an External Distributor receives a credit towards its Distributor Fee equal to the amount of its monthly BYX Top or BYX Last Sale usage fees.

Digital Media Enterprise Fee. The Exchange proposes to adopt a Digital Media Enterprise Fee of $2,500 per month for BYX Top and BYX Last Sale.[18] As an alternative to proposed User fees discussed above, a recipient firm may purchase a monthly Digital Media Enterprise license to receive BYX Top and BYX Last Sale from an External Distributor to distribute to an unlimited number of Professional and Non-Professional Users for viewing via television, Web sites, and mobile devices for informational and non-trading purposes only without having to account for the extent of access to the data or the report the number of Users to the Exchange. Lastly, the proposed Digital Media Enterprise Fee would be counted towards the Distributor Fee credit described above, under which an External Distributor receives a credit towards its Distributor Fee equal to the amount of its monthly BYX Top and/or BYX Last Sale usage fees.

Non-Substantive, Corrective Changes

The Exchange proposes to make a non-substantive change to the description of the BATS One Feed Enterprise Fee as well as correct a cross-reference within the definition of ''Non-Professional User''.

First, the proposed change to the description of the BATS One Feed[19] Enterprise Fee is intended to align with the descriptions of the Enterprise Fees

[16] *See* the Initial BATS One Feed Fee Filings, *supra* note 11 [sic].

[17] The Exchange notes that EDGA, EDGX and BZX also filed proposed rule changes with Commission to adopt Enterprise Fees for their respective Top and Last Sale market data product. *See* File Nos. SR–EDGA–2015–25, SR–EDGX–2015–28 and SR–BATS–2015–48 (proposing a monthly Enterprise Fee of $10,000 for EDGA Top and EDGA Last Sale and $15,000 for EDGX Top and Last Sale as well as BZX Top and Last Sale). A vendor that wishes to create a product like the BATS One Summary Feed could subscribe to each of the BATS Exchanges' Top and Last Sale feeds. *See* the Initial BATS One Feed Fee Filings, *supra* note 11 [sic]. Should a vendor subscribe to each of the BATS Exchanges' Top and Last Sale feeds, it would be charged a total monthly Enterprise Fee of $50,000. This amount is equal to, and not greater than the Enterprise Fee charged for the BATS One Summary Feed. *Id.* (adopting a monthly Enterprise Fee of $50,000 as well as a separate $1,000 per month Data Consolidation Fee for the BATS One Summary Feed).

[18] The Exchange notes that EDGA, EDGX and BATS also filed proposed rule changes with Commission to adopt a Digital Media Enterprise Fee for their respective Top and Last Sale market data product. *See* File Nos. SR–EDGA–2015–25, SR–EDGX–2015–28 and SR–BATS–2015–48 (proposing a monthly Digital Media Enterprise Fee of $2,500 for their respective Top and Last Sale feeds). A vendor that wishes to create a product like the BATS One Summary Feed could subscribe to each of the BATS Exchanges' Top and Last Sale feeds. *See* the Initial BATS One Feed Fee Filings, *supra* note 11 [sic]. Should a vendor subscribe to each of the BATS Exchanges' Top and Last Sale feeds, it would be charged a total monthly Digital Media Enterprise Fee of $10,000. This amount is less than the Digital Media Enterprise Fee charged for the BATS One Summary Feed. *See* Securities Exchange Act Release Nos. 74598 (March 27, 2015), 80 FR 17791 (April 2, 2015) (SR–BATS–2015–24); 74599 (March 27, 2015), 80 FR 17812 (April 2, 2015) (SR–BYX–2015–19); 74600 (March 27, 2014), 80 FR 17797 (April 2, 2015) (SR–EDGA–2015–14); *and* 74601 (March 27, 2015), 80 FR 17804 (April 2, 2015) (SR–EDGX–2015–14) (adopting a monthly Digital Media Enterprise Fee of $15,000 for the BATS One Summary Feed).

[19] In sum, the BATS One Feed is a data feed that disseminates, on a real-time basis, the aggregate best bid and offer (''BBO'') of all displayed orders for securities traded on BYX and its affiliated exchanges and for which the BATS Exchanges report quotes under the Consolidated Tape Association (''CTA'') Plan or the Nasdaq/UTP Plan. The BATS One Feed also contains the individual last sale information for the BATS Exchanges (collectively with the aggregate BBO, the ''BATS One Summary Feed''). In addition, the BATS One Feed contains optional functionality which enables recipients to receive aggregated two-sided quotations from the BATS Exchanges for up to five (5) price levels (''BATS One Premium Feed''). *See* Securities Exchange Act Release No. 73918 (December 23, 2014), 79 FR 78920 (December 31, 2014) (File Nos. SR–EDGX–2014–25; SR–EDGA–2014–25; SR–BATS–2014–055; SR–BYX–2014–030) (Notice of Amendments No. 2 and Order Granting Accelerated Approval to Proposed Rule Changes, as Modified by Amendments Nos. 1 and 2, to Establish a New Market Data Product called the BATS One Feed) (''BATS One Approval Order'').

for BYX Top and BYX Last Sale proposed above. The fee schedule currently states that:

[a]s an alternative to User fees, a recipient firm may purchase a monthly Enterprise license to receive the BATS One Feed from an External Distributor to an unlimited number of Professional and Non-Professional Users. A recipient firm must pay a separate Enterprise Fee for each External Distributor that controls the display of the BATS One Feed if it wishes such User to be covered by the Enterprise Fee. The Enterprise Fee is in addition to the Distributor Fee.

The Exchange proposes to delete the last sentence of the above description stating that the Enterprise Fee is in addition to the Distributor Fee. The original purpose of this sentence was to clarify that the Distributor Fee and Enterprise Fee were separate fees. However, the Exchange understands that this sentence has led to confusion for the following reason. As is the case for the proposed Enterprise Fees for BYX Top and BYX Last Sale described above, the BATS One Feed Enterprise Fee is counted towards the Distributor Fee credit, under which an External Distributor receives a credit towards its Distributor Fee equal to the amount of its monthly BATS One Feed Usage Fees. Stating that the Enterprise and Distributor fees were separate fees has caused confusion regarding the application of the Distributor Fee Usage Fee credit. Therefore, the Exchange proposes to delete the last sentence stating that the Enterprise Fee is in addition to the Distributor Fee. Deleting this sentence does not alter the manner in which the Enterprise Fee is charged. Rather, it is intended to avoid confusion and align the description with that of the proposed Enterprise Fees for BYX Top and BYX Last Sale described above.

Second, the Exchange proposes to correct a cross-reference within the definition of ''Non-Professional User''. In part, a ''Non-Professional User'' is currently defined as ''a natural person who is not: . . . engaged as an ''investment adviser'' as that term is defined in Section 201(11) of the Investment Advisers Act of 1940 (whether or not registered or qualified under that Act) . . .'' The definition incorrectly states that the term ''investment adviser is defined under Section 201(11) of the Investment Advisers Act of 1940, when it is, in fact, defined under Section 202(a)(11) of the Investment Advisers Act of 1940. Therefore, the Exchange proposes to replace the reference to Section 201(11) with Section 202(a)(11) within the definition of Non-Professional User.

Implementation Date

The Exchange proposes to implement the proposed changes to its fee schedule on July 1, 2015.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the objectives of Section 6 of the Act,[20] in general, and furthers the objectives of Section 6(b)(4),[21] in particular, as it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its members and other recipients of Exchange data. The Exchange believes that the proposed rates are equitable and non-discriminatory in that they apply uniformly to all recipients of Exchange data. The Exchange believes the proposed fees are competitive with those charged by other venues and, therefore, reasonable and equitably allocated to recipients. Lastly, the Exchange also believes that the proposed fees are reasonable and non-discriminatory because they will apply uniformly to all recipients of Exchange data.

The Exchange also believes that the proposed rule change is consistent with Section 11(A) of the Act[22] in that it supports (i) fair competition among brokers and dealers, among exchange markets, and between exchange markets and markets other than exchange markets and (ii) the availability to brokers, dealers, and investors of information with respect to quotations for and transactions in securities. Furthermore, the proposed rule change is consistent with Rule 603 of Regulation NMS,[23] which provides that any national securities exchange that distributes information with respect to quotations for or transactions in an NMS stock do so on terms that are not unreasonably discriminatory. In adopting Regulation NMS, the Commission granted self-regulatory organizations and broker-dealers increased authority and flexibility to offer new and unique market data to the public. It was believed that this authority would expand the amount of data available to consumers, and also spur innovation and competition for the provision of market data.

In addition, the proposed fees would not permit unfair discrimination because all of the Exchange's customers and market data vendors will be subject to the proposed fees on an equivalent basis. BYX Last Sale and BYX Top are distributed and purchased on a voluntary basis, in that neither the Exchange nor market data distributors are required by any rule or regulation to make this data available. Accordingly, Distributors and Users can discontinue use at any time and for any reason, including due to an assessment of the reasonableness of fees charged. Firms have a wide variety of alternative market data products from which to choose, such as similar proprietary data products offered by other exchanges and consolidated data. Moreover, the Exchange is not required to make any proprietary data products available or to offer any specific pricing alternatives to any customers.

In addition, the fees that are the subject of this rule filing are constrained by competition. As explained below in the Exchange's Statement on Burden on Competition, the existence of alternatives to BYX Top and BYX Last Sale further ensures that the Exchange cannot set unreasonable fees, or fees that are unreasonably discriminatory, when vendors and subscribers can elect such alternatives. That is, the Exchange competes with other exchanges (and their affiliates) that provide similar market data products. If another exchange (or its affiliate) were to charge less to consolidate and distribute its similar product than the Exchange charges to consolidate and distribute BYX Top or BYX Last Sale, prospective Users likely would not subscribe to, or would cease subscribing to, the BYX Top or BYX Last Sale.

The Exchange notes that the Commission is not required to undertake a cost-of-service or rate-making approach. The Exchange believes that, even if it were possible as a matter of economic theory, cost-based pricing for non-core market data would be so complicated that it could not be done practically.[24]

[20] 15 U.S.C. 78f.

[21] 15 U.S.C. 78f(b)(4).

[22] 15 U.S.C. 78k–1.

[23] *See* 17 CFR 242.603.

[24] The Exchange believes that cost-based pricing would be impractical because it would create enormous administrative burdens for all parties, including the Commission, to cost-regulate a large number of participants and standardize and analyze extraordinary amounts of information, accounts, and reports. In addition, it is impossible to regulate market data prices in isolation from prices charged by markets for other services that are joint products. Cost-based rate regulation would also lead to litigation and may distort incentives, including those to minimize costs and to innovate, leading to further waste. Under cost-based pricing, the Commission would be burdened with determining a fair rate of return, and the industry could experience frequent rate increases based on escalating expense levels. Even in industries historically subject to utility regulation, cost-based ratemaking has been discredited. As such, the Exchange believes that cost-based ratemaking would be inappropriate for proprietary market data and inconsistent with Congress's direction that the

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User Fees. The Exchange believes that implementing the Professional and Non-Professional User fees for BYX Top and BYX Last Sale is equitable and reasonable because it will result in greater availability to Professional and Non-Professional Users. Moreover, introducing a modest Non-Professional User fee for BYX Top and BYX Last Sale is reasonable because it provides an additional method for retail investors to access BYX Top and BYX Last Sale data by providing the same data that is available to Professional Users. The Exchange believes that the proposed fees are equitable and not unfairly discriminatory because they will be charged uniformly to recipient firms and Users. The fee structure of differentiated Professional and Non-Professional fees is utilized by the Exchange for the BATS One Feed and has long been used by other exchanges for their proprietary data products, and by the Nasdaq UTP and the CTA and CQ Plans in order to reduce the price of data to retail investors and make it more broadly available.[25] Offering BYX Top and BYX Last Sale to Non-Professional Users with the same data available to Professional Users results in greater equity among data recipients.

In addition, the proposed fees are reasonable when compared to similar fees for comparable products offered by the NYSE. Specifically, NYSE offers NYSE BBO, which includes best bid and offer for NYSE traded securities, for a monthly fee of $4.00 per professional subscriber and $0.20 per non-professional subscriber.[26] NYSE also offers NYSE Trades, which is a data feed that provides the last sale information for NYSE traded securities, for the same price as NYSE BBO. The Exchange's proposed per User Fees for BYX Top and BYX Last Sale are less than the NYSE's fees for NYSE Trades and NYSE BBO.

Enterprise Fee. The proposed Enterprise Fee for BYX Top and BYX Last Sale are equitable and reasonable as the fees proposed are less than the enterprise fees currently charged for NYSE Trades and NYSE BBO. The NYSE charges a separate enterprise fee of $190,000 per month for NYSE Trades and NYSE BBO.[27] In addition, the Enterprise Fee proposed by the Exchange could result in a fee reduction for recipient firms with a large number of Professional and Non-Professional Users. If a recipient firm has a smaller number of Professional Users of BYX Top or BYX Last Sale, then it may continue using the per User structure and benefit from the per User Fee reductions. By reducing prices for recipient firms with a large number of Professional and Non-Professional Users, the Exchange believes that more firms may choose to receive and to distribute the BYX Top or BYX Last Sale, thereby expanding the distribution of this market data for the benefit of investors.

The Exchange further believes that the proposed Enterprise Fee is reasonable because it will simplify reporting for certain recipients that have large numbers of Professional and Non-Professional Users. Firms that pay the proposed Enterprise Fee will not have to report the number of Users on a monthly basis as they currently do, but rather will only have to count natural person users every six months, which is a significant reduction in administrative burden. Finally, the Exchange believes that it is equitable and not unfairly discriminatory to establish an Enterprise Fee because it reduces the Exchange's costs and the Distributor's administrative burdens in tracking and auditing large numbers of Users.

Digital Media Enterprise Fee. The Exchange believes that the proposed Digital Media Enterprise Fee for BYX Top and BYX Last Sale provides for an equitable allocation of reasonable fees among recipients of the data and is not designed to permit unfair discrimination among customers, brokers, or dealers. In establishing the Digital Media Enterprise Fee, the Exchange recognizes that there is demand for a more seamless and easier-to-administer data distribution model that takes into account the expanded variety of media and communication devices that investors utilize today. The Exchange believes the Digital Media Enterprise Fee will be easy to administer because data recipients that purchase it would not be required to differentiate between Professional and Non-Professional Users, account for the extent of access to the data, or report the number of Users. This is a significant reduction on a recipient firm's administrative burdens and is a significant value to investors. For example, a television broadcaster could display BYX Top and/or BYX Last Sale data during market-related programming and on its Web site or allow viewers to view the data via their mobile devices, creating a more seamless distribution model that will allow investors more choice in how they receive and view market data, all without having to account for and/or measure who accesses the data and how often they do so.

The proposed Digital Media Enterprise Fee is equitable and reasonable because it will also enable recipient firms to more widely distribute data from BYX Top and BYX Last Sale to investors for informational purposes at a lower cost than is available today. For example, a recipient firm may purchase an Enterprise license in the amount of $10,000 per month for to receive BYX Top and/or BYX Last Sale from an External Distributor for an unlimited number of Professional and Non-Professional Users, which is greater than the proposed Digital Media Enterprise Fee. The Exchange also believes the amount of the Digital Media Enterprise Fee is reasonable as compared to the existing enterprise fees discussed above because the distribution of BYX Top and BYX Last Sale data is limited to television, Web sites, and mobile devices for informational purposes only, while distribution of BYX Top and BYX Last Sale data pursuant to an Enterprise license contains no such limitation. The Exchange also believes that the proposed Digital Media Enterprise Fee is equitable and reasonable because it is less than similar fees charged by other exchanges.[28]

Non-Substantive, Corrective Changes. The Exchange believes that the proposed non-substantive, corrective changes are consistent with Section 6(b) of the Act,[29] in general, and Section 6(b)(4) of the Act,[30] in particular, in that they provide for an equitable allocation

Commission use its authority to foster the development of the national market system, and that market forces will continue to provide appropriate pricing discipline. *See* Appendix C to NYSE's comments to the Commission's 2000 Concept Release on the Regulation of Market Information Fees and Revenues, which can be found on the Commission's Web site at *http://www.sec.gov/rules/concept/s72899/buck1.htm. See also* Securities Exchange Act Release No. 73816 (December 11, 2014), 79 FR 75200 (December 17, 2014) (SR–NYSE–2014–64) (Notice of Filing and Immediate Effectiveness of Proposed Rule Change to Establish an Access Fee for the NYSE Best Quote and Trades Data Feed, Operative December 1, 2014).

[25] *See* the Initial BATS One Feed Fee Filings, *supra* note 11 [sic]. *See also, e.g.,* Securities Exchange Act Release No. 20002, File No. S7–433 (July 22, 1983) (establishing nonprofessional fees for CTA data); Nasdaq Rules 7023(b), 7047.

[26] *See* NYSE Market Data Pricing dated May 2015 *available at http://www.nyxdata.com/.*

[27] *Id.*

[28] The Nasdaq Stock Market offers proprietary data products for distribution over the internet and television under alternative fee schedules that are subject to maximum fee of $50,000 per month. *See* Nasdaq Rule 7039(b). The NYSE charges a Digit Media Enterprise fee of $40,000 per month for the NYSE Trade Digital Media product. *See* Securities Exchange Act Release No. 69272 (April 2, 2013), 78 FR 20983 (April 8, 2013) (SR–NYSE–2013–23).

[29] 15 U.S.C. 78f.

[30] 15 U.S.C. 78f(b)(4).

of reasonable fees among recipients of the data and is not designed to permit unfair discrimination among customers, brokers, or dealers. These proposed changes are equitable and reasonable because the changes are designed to clarify the fee schedule and avoid potential investor confusion. The amendment to the BATS One Enterprise Fee is also intended to align the description with that of the proposed Enterprise Fees for BYX Top and BYX Last Sale described above. The proposed changes are also non-discriminatory as they would apply to all recipient firms uniformly.

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.

BYX Top and BYX Last Sale

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 Exchange's ability to price BYX Last Sale and BYX Top are constrained by: (i) Competition among exchanges, other trading platforms, and Trade Reporting Facilities (''TRF'') that compete with each other in a variety of dimensions; (ii) the existence of inexpensive real-time consolidated data and market-specific data and free delayed data; and (iii) the inherent contestability of the market for proprietary data.

The Exchange and its market data products are subject to significant competitive forces and the proposed fees represent responses to that competition. To start, the Exchange competes intensely for order flow. It competes with the other national securities exchanges that currently trade equities, with electronic communication networks, with quotes posted in FINRA's Alternative Display Facility, with alternative trading systems, and with securities firms that primarily trade as principal with their customer order flow.

In addition, BYX Last Sale and BYX Top compete with a number of alternative products. For instance, BYX Last Sale and BYX Top do not provide a complete picture of all trading activity in a security. Rather, the other national securities exchanges, the several TRFs of FINRA, and Electronic Communication Networks (''ECN'') that produce proprietary data all produce trades and trade reports. Each is currently permitted to produce last sale information products, and many currently do, including Nasdaq and NYSE. In addition, market participants can gain access to BYX last sale prices and top-of-book quotations, though integrated with the prices of other markets, on feeds made available through the SIPs.

In sum, the availability of a variety of alternative sources of information imposes significant competitive pressures on Exchange data products and the Exchange's compelling need to attract order flow imposes significant competitive pressure on the Exchange to act equitably, fairly, and reasonably in setting the proposed data product fees. The proposed data product fees are, in part, responses to that pressure. The Exchange believes that the proposed fees would reflect an equitable allocation of its overall costs to users of its facilities.

In addition, when establishing the proposed fees, the Exchange considered the competitiveness of the market for proprietary data and all of the implications of that competition. The Exchange believes that it has considered all relevant factors and has not considered irrelevant factors in order to establish fair, reasonable, and not unreasonably discriminatory fees and an equitable allocation of fees among all Users. The existence of alternatives to BYX Last Sale and BYX Top, including existing similar feeds by other exchanges, consolidated data, and proprietary data from other sources, ensures that the Exchange cannot set unreasonable fees, or fees that are unreasonably discriminatory, when vendors and subscribers can elect these alternatives or choose not to purchase a specific proprietary data product if its cost to purchase is not justified by the returns any particular vendor or subscriber would achieve through the purchase.

Non-Substantive, Corrective Changes

The proposed non-substantive, corrective changes to the fee schedule will not have any impact on completion. The proposed changes are designed to clarify the fee schedule and avoid potential investor confusion.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received written comments on the proposed rule change.

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) of the Act [31] and paragraph (f) of Rule 19b–4 thereunder.[32] 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.

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–BYX–2015–30 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–BYX–2015–30. 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

[31] 15 U.S.C. 78s(b)(3)(A).

[32] 17 CFR 240.19b–4(f).

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–BYX–2015–30, and should be submitted on or before August 5, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[33]

Brent J. Fields,

Secretary.

[FR Doc. 2015–17295 Filed 7–14–15; 8:45 am]

BILLING CODE 8011–01–P

[33] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

In the Matter of Smart Ventures, Inc.; Order of Suspension of Trading

July 13, 2015.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Smart Ventures, Inc. (''Smart Ventures'') because of questions regarding the accuracy and completeness of assertions by Smart Ventures in reports posted on the OTC Link operated by OTC Markets Group, Inc. and in press releases. This includes questions about the accuracy of a report issued by Smart Ventures for the quarterly period ended March 31, 2015 and a press release issued on June 30, 2015 with respect to the company's business plans and activities, control persons, related party transactions and financial statements.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above-listed company.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of the above-listed company is suspended for the period from 9:30 a.m. EDT, on July 13, 2015 through 11:59 p.m. EDT, on July 24, 2015.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2015–17445 Filed 7–13–15; 4:15 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75414; File No. SR–Phlx–2015–60]

Self-Regulatory Organizations; NASDAQ OMX PHLX LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change to SPY Position Limits

July 9, 2015.

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 July 8, 2015, NASDAQ OMX PHLX LLC (''Phlx'' 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 the Substance of the Proposed Rule Change

The Exchange proposes to extend for another twelve (12) month time period the pilot program to eliminate position limits for options on the SPDR® S&P 500® exchange-traded fund (''SPY ETF'' or ''SPY''),[3] which list and trade under the symbol SPY (''SPY Pilot Program'').

The text of the proposed rule change is available on the Exchange's Web site at *http://nasdaqomxphlx.cchwallstreet.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.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] ''SPDR®,'' ''Standard & Poor's®,'' ''S&P®,'' ''S&P 500®,'' and ''Standard & Poor's 500'' are registered trademarks of Standard & Poor's Financial Services LLC. The SPY ETF represents ownership in the SPDR S&P 500 Trust, a unit investment trust that generally corresponds to the price and yield performance of the SPDR S&P 500 Index.

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 amend Rule 1001, entitled ''Position Limits,'' to extend the current pilot, which expires on July 12, 2015 for an additional twelve (12) month time period to July 12, 2016 (''Extended Pilot''). This filing does not propose any substantive changes to the SPY Pilot Program. In proposing to extend the SPY Pilot Program, the Exchange reaffirms its consideration of several factors that supported the original proposal of the SPY Pilot Program, including (1) the availability of economically equivalent products and their respective position limits; (2) the liquidity of the option and the underlying security; (3) the market capitalization of the underlying security and the related index; (4) the reporting of large positions and requirements surrounding margin; and (5) the potential for market on close volatility.

The Exchange submitted a report to the Commission on June 11, 2015, which report reflects, during the time period from December 2014 through May 2015, the trading of standardized SPY options with no position limits consistent with option exchange provisions.[4] The report was prepared in the manner specified in Phlx's prior filing extending the SPY Pilot Program.[5] The Exchange 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. The proposed extension will allow the Exchange and the Commission additional time to further evaluate the pilot program and its effect on the market.

As with the original proposal, related to the SPY Pilot Program, the Exchange represents that a Pilot Report will be submitted at least thirty (30) days before the end of the Extended Pilot and would analyze that period. The Pilot Report will detail the size and different types of strategies employed with respect to positions established as a result of the elimination of position limits in SPY. In addition, the report will note whether any problems resulted due to the no limit approach and any other information that may be useful in evaluating the effectiveness of the Extended Pilot. The Pilot Report will

[4] The report is attached as Exhibit 3.

[5] *See* Securities Exchange Act Release No. 74099 (January 20, 2015), 80 FR 4021 (January 26, 2015) (SR–Phlx–2015–07).

compare the impact of the SPY Pilot Program, if any, on the volumes of SPY options and the volatility in the price of the underlying SPY shares, particularly at expiration during the Extended Pilot. In preparing the report the Exchange will utilize various data elements such as volume and open interest. In addition the Exchange will make available to Commission staff data elements relating to the effectiveness of the SPY Pilot Program.

Conditional on the findings in the Pilot Report, the Exchange will file with the Commission a proposal to extend the pilot program, adopt the pilot program on a permanent basis or terminate the pilot. If the SPY Pilot Program is not extended or adopted on a permanent basis by the expiration of the Extended Pilot, the position limits for SPY options would revert to limits in effect prior to the commencement of the SPY Pilot Program.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act [6] in general, and furthers the objectives of Section 6(b)(5) of the Act [7] 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 mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change would be beneficial to market participants, including market makers, institutional investors and retail investors, by permitting them to establish greater positions when pursuing their investment goals and needs. The Exchange also believes that economically equivalent products should be treated in an equivalent manner so as to avoid regulatory arbitrage, especially with respect to position limits. Treating SPY and SPX options differently by virtue of imposing different position limits is inconsistent with the notion of promoting just and equitable principles of trade and removing impediments to perfect the mechanisms of a free and open market. At the same time, 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 proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. In this regard, the Exchange notes that the rule change is being proposed as a competitive response to similar filings that the Exchange expects to be filed by other options exchanges. The Exchange believes this proposed rule change is necessary to permit fair competition among the options exchanges and to establish uniform position limits for a multiply listed options class.

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

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.[8]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act [9] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii) [10] 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 so that the proposal may become operative immediately upon filing. The Exchange believes that waiver of the operative delay is consistent with the protection of investors and the public interest because it will permit the SPY Pilot Program to continue without interruption. 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.[11]

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–Phlx–2015–60 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–Phlx–2015–60. 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

[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(5).

[8] 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.

[9] 17 CFR 240.19b–4(f)(6).

[10] 17 CFR 240.19b–4(f)(6)(iii).

[11] 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).

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–Phlx–2015–60, and should be submitted on or before August 5, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Brent J. Fields,

Secretary.

[FR Doc. 2015–17302 Filed 7–14–15; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75410; File No. SR–BOX–2015–25]

Self-Regulatory Organizations; BOX Options Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend IM–3120–2 To Rule 3120 To Extend the Pilot Program That Eliminated the Position Limits for Options on SPDR S&P 500 ETF

July 9, 2015.

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 July 7, 2015, BOX Options Exchange LLC (the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the 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 the Substance of the Proposed Rule Change

The Exchange proposes to amend IM–3120–2 to Rule 3120 to extend the pilot program that eliminated the position limits for options on SPDR S&P 500 ETF (''SPY'') (''SPY Pilot Program''). The text of the proposed rule change is available from the principal office of the Exchange, at the Commission's Public Reference Room and also on the Exchange's Internet Web site at *http://boxexchange.com*.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend IM–3120–2 to Rule 3120 to extend the time period of the SPY Pilot Program,[3] which is currently scheduled to expire on July 12, 2015, through July 12, 2016.[4]

This filing does not propose any substantive changes to the SPY Pilot Program. In proposing to extend the SPY Pilot Program, the Exchange reaffirms its consideration of several factors that supported the original proposal of the SPY Pilot Program, including (1) the availability of economically equivalent products and their respective position limits, (2) the liquidity of the option and the underlying security, (3) the market capitalization of the underlying security and the related index, (4) the reporting of large positions and requirements surrounding margin, and (5) the potential for market on close volatility.

In the proposal to extend the SPY Pilot Program, the Exchange stated that if it were to propose an extension, permanent approval or termination of the program, the Exchange would submit, along with any filing proposing such amendments to the program, a report providing an analysis of the SPY Pilot Program covering the period since the previous extension (the ''Pilot Report'').[5] Accordingly, the Exchange is submitting the Pilot Report detailing the Exchange's experience with the SPY Pilot Program. The Pilot Report is attached as Exhibit 3 to this filing. The Exchange 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 it were to propose another extension, permanent approval or termination of the 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, 2016, position limits in SPY will revert to their Pre-Pilot levels. Extending the SPY Pilot Program will give the Exchange and Commission additional time to evaluate the pilot and its effect on the market.

2. Statutory Basis

The Exchange believes that the proposal is consistent with the requirements of Section 6(b) of the Act, in general, and Section 6(b)(5) of the Act, in particular, in that it is 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. 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.

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 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 without interruption. Additionally, the Exchange expects other SROs will propose similar extensions.

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[12] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 67936 (September 27, 2012), 77 FR 60491 (October 3, 2012) (Notice of Filing and Immediate Effectiveness of SR–BOX–2012–013).

[4] *See* Securities Exchange Act Release No. 74196 (February 3, 2015), 80 FR 7064 (February 9, 2015) (Notice of Filing and Immediate Effectiveness of SR–BOX–2015–07).

[5] *Id.*

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6) thereunder.[6]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act[7] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[8] 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 so that the proposal may become operative immediately upon filing. The Exchange believes that waiver of the operative delay is consistent with the protection of investors and the public interest because it will allow the SPY Pilot Program to continue without interruption. 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.[9]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–BOX–2015–25 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–BOX–2015–25. 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 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–BOX–2015–25, and should be submitted on or before August 5, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Brent J. Fields,

Secretary.

[FR Doc. 2015–17298 Filed 7–14–15; 8:45 am]

BILLING CODE 8011–01–P

[6] 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.

[7] 17 CFR 240.19b–4(f)(6).

[8] 17 CFR 240.19b–4(f)(6)(iii).

[9] 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).

[10] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75415; File No. SR–NYSEArca–2015–61]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Commentary .06 to Rule 6.8 To Extend the Pilot Program That Eliminated the Position Limits for Options on SPDR S&P 500 ETF

July 9, 2015.

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 July 8, 2015, NYSE Arca, Inc. (the ''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (the ''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend Commentary .06 to Rule 6.8 to extend the pilot program that eliminated the position limits for options on SPDR S&P 500 ETF (''SPY'') (''SPY Pilot Program''). The text of 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

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Commentary .06 to Rule 6.8 to extend the time period of the SPY Pilot Program,[4] which is currently scheduled to expire on July 12, 2015, through July 12, 2016.

This filing does not propose any substantive changes to the SPY Pilot Program. In proposing to extend the SPY Pilot Program, the Exchange reaffirms its consideration of several factors that supported the original proposal of the SPY Pilot Program, including (1) the availability of economically equivalent products and their respective position limits, (2) the liquidity of the option and the underlying security, (3) the market capitalization of the underlying security and the related index, (4) the reporting of large positions and requirements surrounding margin, and (5) the potential for market on close volatility.

As part of the January 2015 Extension, the Exchange submitted a report providing an analysis of the SPY Pilot Program covering prior ten (10) months from January 2014 to October 2014 during which the SPY Pilot Program was in effect (the ''Pilot Report''). In the January 2015 Extension, the Exchange also stated that if it were to propose an extension, permanent approval or termination of the program, the Exchange would submit, along with any filing proposing such amendments to the program, another Pilot Report covering the period since the previous extension. Accordingly, the Exchange is submitting another Pilot Report detailing the Exchange's experience with the SPY Pilot Program for the period covering six (6) months from November 2014 to April 2015. The Pilot Report is attached as Exhibit 3 to this filing. The Exchange 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 it were to propose another extension, permanent approval or termination of the program, the Exchange would submit another Pilot Report covering the period since the previous extension, which would 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, 2016, the position limits for SPY would revert to limits in effect at the commencement of the pilot program. The proposed extension will allow the Exchange and the Commission additional time to further evaluate the SPY Pilot Program and its effect on the market.

2. Statutory Basis

The Exchange believes that its proposal 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 remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. The Exchange believes that 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.

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 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 uninterrupted. Additionally, the Exchange expects all other SROs that currently have rules regarding the SPY Pilot Program to also extend the pilot program for an additional year.

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

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 so that the proposal may become operative immediately upon filing. The Exchange believes that waiver of the operative delay is consistent with the protection of investors and the public interest because it will allow the SPY Pilot Program to continue without interruption. 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

[4] *See* Securities Exchange Act Release No. 68001 (October 5, 2012), 77 FR 62303 (October 12, 2012). The SPY Pilot Program was subsequently extended. *See* Securities Exchange Act Release Nos. 70968 (December 3, 2013), 78 FR 73899 (December 9, 2013); and 74029 (January 9, 2015), 80 FR 2161 (January 15, 2015) (the ''January 2015 Extension'').

[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).

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–NYSEArca–2015–61 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–NYSEArca–2015–61. 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–NYSEArca–2015–61, and should be submitted on or before August 5, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Brent J. Fields,

Secretary.

[FR Doc. 2015–17303 Filed 7–14–15; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–75411; File No. SR–ISE–2015–22]

Self-Regulatory Organizations; International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Extend the SPY Pilot Program

July 9, 2015.

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 July 6, 2015, the International Securities Exchange, LLC (the ''Exchange'' or the ''ISE'') 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 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 the Substance of the Proposed Rule Change

The ISE proposes to amend its rules to extend the pilot program that eliminated position and exercise limits for physically-settled options on the SPDR S&P ETF Trust (''SPY'') (''SPY Pilot Program''). The text of the proposed rule change is available on the Exchange's Web site (*http://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 self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Supplementary Material .01 to Rule 412 and Supplementary Material .01 to Rule 414 to extend the duration of the SPY Pilot Program through July 12, 2016. This filing does not propose any substantive changes to the SPY Pilot Program. In proposing to extend the SPY Pilot Program, the Exchange reaffirms its consideration of several factors that supported the original proposal of the SPY Pilot Program, including (1) the liquidity of the option and the underlying security, (2) the market capitalization of the underlying security and the related index, (3) the reporting of large positions and requirements surrounding margin, and (4) financial requirements imposed by ISE and the Commission.

With this proposed extension to the SPY Pilot Program, the Exchange has submitted a report to the Commission reflecting the trading of standardized SPY options without position limits from January through May 2015. The report was prepared in the manner specified in the filing extending the SPY Pilot Program to the current pilot end date of July 12, 2015. The Exchange 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. The proposed extension will allow the Exchange and the Commission to further evaluate the SPY Pilot Program and the effect it has on the market.

The Exchange represents that, should the Exchange propose to extend the pilot program, adopt on a permanent basis the pilot program or terminate the pilot program, it will submit a new pilot report at least thirty (30) days before the end of the extended SPY Pilot Program, which will cover the extended pilot period. The Pilot Report will detail the size and different types of strategies employed with respect to positions established as a result of the elimination of position limits in SPY. In addition, the Pilot Report will note whether any problems resulted due to the no limit approach and any other information that may be useful in evaluating the effectiveness of the SPY Pilot Program. The Pilot Report will compare the impact of the SPY Pilot Program, if any,

[11] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

on the volumes of SPY options and the volatility in the price of the underlying SPY shares, particularly at expiration. In preparing the report the Exchange will utilize various data elements such as volume and open interest. In addition the Exchange will make available to Commission staff data elements relating to the effectiveness of the SPY Pilot Program.

Conditional on the findings in the Pilot Report, the Exchange will file with the Commission a proposal to extend the pilot program, adopt the pilot program on a permanent basis or terminate the pilot. If the SPY Pilot Program is not extended or adopted on a permanent basis by the expiration of the extended pilot, the position limits for SPY would revert to limits that were in effect prior to the commencement of the SPY Pilot Program.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b) of the Act.[3] In particular, the proposal is consistent with Section 6(b)(5) of the Act,[4] because it is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

The Exchange believes that 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 also believes that economically equivalent products should be treated in an equivalent manner so as to avoid regulatory arbitrage, especially with respect to position limits. Treating SPY and SPX options differently by virtue of imposing different position limits is inconsistent with the notion of promoting just and equitable principles of trade and removing impediments to perfect the mechanisms of a free and open market. At the same time, 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.

[3] 15 U.S.C. 78f(b).

[4] 15 U.S.C. 78f(b)(5).

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes the proposal is consistent with Section 6(b)(8) of the Act[5] in that it does not 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 all other self-regulatory organizations currently participating in the SPY Pilot Program are expected to extend it for an additional year.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

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.[6]

A proposed rule change filed pursuant to Rule 19b–4(f)(6) under the Act[7] normally does not become operative for 30 days after the date of its filing. However, Rule 19b–4(f)(6)(iii)[8] 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 believes that waiver of the operative delay is consistent with the protection of investors and the public interest because it will allow the SPY Pilot Program to continue uninterrupted. 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.[9]

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.

[5] 15 U.S.C. 78f(b)(8).

[6] 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.

[7] 17 CFR 240.19b–4(f)(6).

[8] 17 CFR 240.19b–4(f)(6)(iii).

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–ISE–2015–22 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–ISE–2015–22. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet 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

[9] 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).

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–ISE–2015–22, and should be submitted on or before August 5, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Brent J. Fields,

Secretary.

[FR Doc. 2015–17299 Filed 7–14–15; 8:45 am]

BILLING CODE 8011–01–P

[10] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

[Public Notice: 9191]

Culturally Significant Objects Imported for Exhibition Determinations: ''Gauguin to Picasso: Masterworks From Switzerland, The Staechelin & Im Obersteg Collections'' Exhibition

SUMMARY: Notice is hereby given of the following Determinations: Pursuant to the authority vested in me by the Act of October 19, 1965 (79 Stat. 985; 22 U.S.C. 2459), Executive Order 12047 of March 27, 1978, the Foreign Affairs Reform and Restructuring Act of 1998 (112 Stat. 2681, *et seq.;* 22 U.S.C. 6501 note, *et seq.*), Delegation of Authority No. 234 of October 1, 1999, Delegation of Authority No. 236–3 of August 28, 2000 (and, as appropriate, Delegation of Authority No. 257 of April 15, 2003), I hereby determine that the objects to be included in the exhibition ''Gauguin to Picasso: Masterworks from Switzerland, The Staechelin & Im Obersteg Collections,'' imported from abroad for temporary exhibition within the United States, are of cultural significance. The objects are imported pursuant to a loan agreement with the foreign owners or custodians. I also determine that the exhibition or display of the exhibit objects at The Phillips Collection, Washington, District of Columbia, from on or about October 10, 2015, until on or about January 10, 2016, and at possible additional exhibitions or venues yet to be determined, is in the national interest. I have ordered that Public Notice of these Determinations be published in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: For further information, including a list of the imported objects, contact the Office of Public Diplomacy and Public Affairs in the Office of the Legal Adviser, U.S. Department of State (telephone: 202–632–6471; email: *section2459@state.gov*). The mailing address is U.S. Department of State, L/PD, SA–5, Suite 5H03, Washington, DC 20522–0505.

Dated: July 2, 2015.

Kelly Keiderling,

Principal Deputy Assistant Secretary, Bureau of Educational and Cultural Affairs, Department of State.

[FR Doc. 2015–17366 Filed 7–14–15; 8:45 am]

BILLING CODE 4710–05–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Fiscal Year 2016 Tariff-Rate Quota Allocations for Raw Cane Sugar, Refined and Specialty Sugar and Sugar-Containing Products

AGENCY: Office of Agricultural Affairs, Office of the United States Trade Representative.

ACTION: Notice.

SUMMARY: The Office of the United States Trade Representative (USTR) is providing notice of country-by-country allocations of the Fiscal Year (FY) 2016 (Oct. 1, 2015 through Sept. 30, 2016) in-quota quantity of the tariff-rate quotas for imported raw cane sugar, certain sugars, syrups and molasses (also known as refined sugar), specialty sugar, and sugar-containing products.

DATES: *Effective date:* July 15, 2015.

FOR FURTHER INFORMATION CONTACT: Ronald Baumgarten, Office of Agricultural Affairs, telephone: 202–395–9583 or facsimile: 202–395–4579.

SUPPLEMENTARY INFORMATION: Pursuant to Additional U.S. Note 5 to chapter 17 of the Harmonized Tariff Schedule of the United States (HTS), the United States maintains tariff-rate quotas (TRQs) for imports of raw cane sugar and refined sugar. Pursuant to Additional U.S. Note 8 to chapter 17 of the HTS, the United States maintains a TRQ for imports of sugar-containing products.

Section 404(d)(3) of the Uruguay Round Agreements Act (19 U.S.C. 3601(d)(3)) authorizes the President to allocate the in-quota quantity of a TRQ for any agricultural product among supplying countries or customs areas. The President delegated this authority to the United States Trade Representative under Presidential Proclamation 6763 (60 FR 1007).

On June 15, 2015 (80 FR 34129), the Secretary of Agriculture (Secretary) announced the sugar program provisions for Fiscal Year (FY) 2016. The Secretary announced an in-quota quantity of the TRQ for raw cane sugar for FY 2016 of 1,117,195 metric tons * raw value (MTRV), which is the minimum amount to which the United States is committed under the World Trade Organization (WTO) Uruguay Round Agreements. USTR is allocating this quantity (1,117,195 MTRV) to the following countries in the amounts specified below:

Country	FY 2016 raw cane sugar allocations (MTRV)
Argentina	45,281
Australia	87,402
Barbados	7,371
Belize	11,584
Bolivia	8,424
Brazil	152,691
Colombia	25,273
Congo	7,258
Costa Rica	15,796
Cote d'Ivoire	7,258
Dominican Republic	185,335
Ecuador	11,584
El Salvador	27,379
Fiji	9,477
Gabon	7,258
Guatemala	50,546
Guyana	12,636
Haiti	7,258
Honduras	10,530
India	8,424
Jamaica	11,584
Madagascar	7,258
Malawi	10,530
Mauritius	12,636
Mexico	7,258
Mozambique	13,690
Nicaragua	22,114
Panama	30,538
Papua New Guinea	7,258
Paraguay	7,258
Peru	43,175
Philippines	142,160
South Africa	24,220
St. Kitts & Nevis	7,258
Swaziland	16,849
Taiwan	12,636
Thailand	14,743
Trinidad & Tobago	7,371
Uruguay	7,258
Zimbabwe	12,636

These allocations are based on the countries' historical shipments to the United States. The allocations of the in-quota quantities of the raw cane sugar

TRQ to countries that are net importers of sugar are conditioned on receipt of the appropriate verifications of origin, and certificates for quota eligibility must accompany imports from any country for which an allocation has been provided.

On June 15, 2015, the Secretary also announced the establishment of the in-quota quantity of the FY 2016 refined sugar TRQ at 132,000 MTRV for which the sucrose content, by weight in the dry state, must have a polarimeter reading of 99.5 degrees or more. This amount includes the minimum level to which the United States is committed under the WTO Uruguay Round Agreements (22,000 MTRV of which 1,656 MTRV is reserved for specialty sugar) and an additional 110,000 MTRV for specialty sugars. USTR is allocating the refined sugar TRQ as follows: 10,300 MTRV of refined sugar to Canada, 2,954 MTRV to Mexico, and 7,090 MTRV to be administered on a first-come, first-served basis.

Imports of all specialty sugar will be administered on a first-come, first-served basis in five tranches. The Secretary has announced that the total in-quota quantity of specialty sugar will be the 1,656 MTRV included in the WTO minimum plus an additional 110,000 MTRV. The first tranche of 1,656 MTRV will open October 9, 2015. All types of specialty sugars are eligible for entry under this tranche. The second tranche of 27,500 MTRV will open on October 23, 2015. The third, fourth, and fifth tranches of 27,500 MTRV each will open on January 8, 2016, April 8, 2016 and July 8, 2016, 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.

With respect to the in-quota quantity of 64,709 metric tons (MT) of the TRQ for imports of certain sugar-containing products maintained under Additional U.S. Note 8 to chapter 17 of the HTS, USTR is allocating 59,250 MT to Canada. The remainder, 5,459 MT, of the in-quota quantity is available for other countries on a first-come, first-served basis.

Raw cane sugar, refined and specialty sugar and sugar-containing products for FY 2016 TRQs may enter the United States as of October 1, 2015.

* *Conversion factor:* 1 metric ton = 1.10231125 short tons.

Dated: July 7, 2015.

Michael Froman,

United States Trade Representative.

[FR Doc. 2015–17337 Filed 7–14–15; 8:45 am]

BILLING CODE 3290–F5–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Membership in the National Parks Overflights Advisory Group Aviation Rulemaking Committee

AGENCY: Federal Aviation Administration, Transportation.

ACTION: Notice.

SUMMARY: By **Federal Register** notice (See 80 FR 21294, April 17, 2015) the National Park Service (NPS) and the Federal Aviation Administration (FAA) invited interested persons to apply to fill three upcoming openings on the National Parks Overflights Advisory Group (NPOAG) Aviation Rulemaking Committee (ARC). The notice invited interested persons to apply to fill future openings to represent general aviation concerns, air tour operator concerns, and Native American interests. This notice informs the public of the persons selected to fill two of the general aviation and air tour operator future vacancies. No selection has been made for the vacancy representing Native American interests.

FOR FURTHER INFORMATION CONTACT: Keith Lusk, Special Programs Staff, Federal Aviation Administration, Western-Pacific Region Headquarters, P.O. Box 92007, Los Angeles, CA 90009–2007, telephone: (310) 725–3808, email: *Keith.Lusk@faa.gov.,*

SUPPLEMENTARY INFORMATION:

Background

The National Parks Air Tour Management Act of 2000 (the Act) was enacted on April 5, 2000, as Public Law 106–181, and subsequently amended in the FAA Modernization and Reform Act of 2012. The Act required the establishment of the advisory group within 1 year after its enactment. The NPOAG was established in March 2001. The advisory group is comprised of a balanced group of representatives of general aviation, commercial air tour operations, environmental concerns, and Native American tribes. The Administrator of the FAA and the Director of NPS (or their designees) serve as ex officio members of the group. Representatives of the Administrator and Director serve alternating 1-year terms as chairman of the advisory group.

In accordance with the Act, the advisory group provides ''advice, information, and recommendations to the Administrator and the Director—

(1) On the implementation of this title [the Act] and the amendments made by this title;

(2) On commonly accepted quiet aircraft technology for use in commercial air tour operations over a national park or tribal lands, which will receive preferential treatment in a given air tour management plan;

(3) On other measures that might be taken to accommodate the interests of visitors to national parks; and

(4) At the request of the Administrator and the Director, safety, environmental, and other issues related to commercial air tour operations over a national park or tribal lands.''

Membership

The current NPOAG ARC is made up of one member representing general aviation, three members representing the commercial air tour industry, four members representing environmental concerns, and two members representing Native American interests. Current members of the NPOAG ARC are as follows:

Heidi Williams representing general aviation; Alan Stephen, Matt Zuccaro, and Mark Francis representing commercial air tour operators; Mark Belles, Nicholas Miller, Michael Sutton, and Dick Hingson representing environmental interests; and Leigh Kuwanwisiwma and Martin Begaye representing Native American tribes. The 3-year membership terms of Ms. Williams, Mr. Stephen, and Mr. Begaye expire on October 9, 2015.

Selection

The person selected to fill the upcoming open seat representing general aviation concerns is Melissa Rudinger and the person selected to fill the upcoming open seat representing air tour operator concerns is Alan Stephen. Mr. Stephen is a current member and will serve another term. Their 3-year terms will begin on October 10, 2015. No persons expressed interest in filling the upcoming opening to represent Native American interests. The FAA and NPS will solicit interest for this opening in another **Federal Register** notice in the near future.

Issued in Hawthorne, CA, on July 9, 2015.

Keith Lusk,

Program Manager, Special Programs Staff, Western-Pacific Region.

[FR Doc. 2015–17383 Filed 7–14–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Rule on Request To Release Property at the Arnold Palmer Regional Airport, Latrobe, PA

AGENCY: Federal Aviation Administration (FAA) DOT.

ACTION: Notice of request to release airport property.

SUMMARY: The FAA proposes to rule and invite public comment on the land release at the Arnold Palmer Regional Airport, Latrobe, PA under the provision 49 U.S.C. 47125(a).

DATES: Comments must be received on or before August 14, 2015.

ADDRESSES: Comments on this application may be mailed or delivered to the following address:

Gabe Monzo, Manager, Arnold Palmer Regional Airport, 148 Aviation Lane, Suite 103, Latrobe, PA, 724–539–8100

and at the FAA Harrisburg Airports District Office:

Lori K. Pagnanelli, Manager, Harrisburg Airports District Office, 3905 Hartzdale Dr., Suite 508, Camp Hill, PA 17011, (717) 730–2830.

FOR FURTHER INFORMATION CONTACT: Charles Sacavage, Project Manager, Harrisburg Airports District Office, location listed above.

The request to release airport 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 Arnold Palmer Regional Airport under the provisions of Section 47125(a) of Title 49 U.S.C. On July 7, 2015, the FAA determined that the request to release property at the Arnold Palmer Regional Airport (LBE), PA, submitted by the Westmoreland County Airport Authority, met the procedural requirements.

The following is a brief overview of the request:

The Airport Authority requests the release of a total of 4.271 acres of required Right-of-Way for the SR 981 widening project and 0.785 acres for a Temporary Construction Easement. The purpose of the project is to address geometric deficiencies of the roadway, reduce the number of crashes at the SR 0981/SR 2027 intersection, and reduce route confusion utilizing current smart transportation criteria. The project is being coordinated by the Pennsylvania Department of Transportation. There are seventeen parcels included in the proposed 4.271 acre land release, which are sliver takes, that were originally purchased using local funds and/or utilizing Airport Improvement Program (AIP) funding. Three of the parcels (0.610 acres) were purchased using local funds for non-aviation use. The existing property use (remaining 3.661 acres) consists of dedicated airport property. As shown on the Airport Layout Plan, the property is not needed now or in the future for airport development. Proceeds from sale of the property that was purchased with federal funds will be utilized toward future Airport Improvement Program (AIP) eligible capital improvement projects at LBE.

Any person may inspect the request by appointment at the FAA office address listed above.

Interested persons are invited to comment on the proposed lease. All comments will be considered by the FAA to the extent practicable.

Issued in Camp Hill, Pennsylvania, July 7, 2015.

Lori K. Pagnanelli,

Manager, Harrisburg Airports District Office.

[FR Doc. 2015–17381 Filed 7–14–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2001–9258; FMCSA–2005–21254; FMCSA–2009–0121]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew the exemptions from the vision requirement in the Federal Motor Carrier Safety Regulations for 5 individuals. FMCSA has statutory authority to exempt individuals from the vision requirement if the exemptions granted will not compromise safety. The Agency has concluded that granting these exemption renewals will provide a level of safety that is equivalent to or greater than the level of safety maintained without the exemptions for these commercial motor vehicle (CMV) drivers.

DATES: This decision is effective August 10, 2015. Comments must be received on or before August 14, 2015.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) numbers: Docket No. [Docket No. FMCSA–2001–9258; FMCSA–2005–21254; FMCSA–2009–0121], using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov*. Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* 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.
- *Fax:* 1–202–493–2251.

Instructions: Each submission must include the Agency name and the docket number for this notice. Note that DOT posts all comments received without change to *http://www.regulations.gov,* including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Federal Docket Management System (FDMS) is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: 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 *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy*.

FOR FURTHER INFORMATION CONTACT: Charles A. Horan, III, Director, Carrier, Driver and Vehicle Safety Standards, 202–366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m. Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

I. Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may renew an exemption from the vision requirements in 49 CFR 391.41(b)(10), which applies to drivers of CMVs in interstate commerce, for a two-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' The procedures for requesting an exemption (including renewals) are set out in 49 CFR part 381.

II. Exemption Decision

This notice addresses 5 individuals who have requested renewal of their exemptions in accordance with FMCSA procedures. FMCSA has evaluated these 5 applications for renewal on their merits and decided to extend each exemption for a renewable two-year period. They are:

Donald M. Jenson (SD)
Dennis D. Lesperance (OR)
Dean A. Maystead (MI)
Carl V. Murphy, Jr. (TX)
Mark A. Pirl (NC)

The exemptions are extended subject to the following conditions: (1) That each individual has a physical examination every year (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the requirements in 49 CFR 391.41(b)(10), and (b) by a medical examiner who attests that the individual is otherwise physically qualified under 49 CFR 391.41; (2) that each individual provides a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (3) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file and retains a copy of the certification on his/her person while driving for presentation to a duly authorized Federal, State, or local enforcement official. Each exemption will be valid for two years unless rescinded earlier by FMCSA. The exemption will be rescinded if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315.

III. Basis for Renewing Exemptions

Under 49 U.S.C. 31315(b)(1), an exemption may be granted for no longer than two years from its approval date and may be renewed upon application for additional two year periods. In accordance with 49 U.S.C. 31136(e) and 31315, each of the 5 applicants has satisfied the entry conditions for obtaining an exemption from the vision requirements (66 FR 17743; 66 FR 33990; 68 FR 35772; 70 FR 30999; 70 FR 33937; 70 FR 46567; 72 FR 32705; 72 FR 40359; 74 FR 26461; 74 FR 26464; 74 FR 34074; 74 FR 34620; 76 FR 44653; 79 FR 4531). Each of these 5 applicants has requested renewal of the exemption and has submitted evidence showing that the vision in the better eye continues to meet the requirement specified at 49 CFR 391.41(b)(10) and that the vision impairment is stable. In addition, a review of each record of safety while driving with the respective vision deficiencies over the past two years indicates each applicant continues to meet the vision exemption requirements.

These factors provide an adequate basis for predicting each driver's ability to continue to drive safely in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each renewal applicant for a period of two years is likely to achieve a level of safety equal to that existing without the exemption.

IV. Public Participation and Request for Comments

FMCSA encourages you to participate by submitting comments and related materials.

Submitting Comments

If you submit a comment, please include the docket number for this notice (FMCSA–2001–9258; FMCSA–2005–21254; FMCSA–2009–0121), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, got to *http://www.regulations.gov* and put the docket number, ''FMCSA–2001–9258; FMCSA–2005–21254; FMCSA–2009–0121'' in the ''Keyword'' box, and click ''Search.'' When the new screen appears, click on ''Comment Now!'' button and type your comment into the text box in the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope. FMCSA will consider all comments and material received during the comment period and may change this notice based on your comments.

Viewing Comments and Documents

To view comments, as well as any documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov* and in the search box insert the docket number, ''FMCSA–2001–9258; FMCSA–2005–21254; FMCSA–2009–0121'' in the ''Keyword'' box and click ''Search.'' Next, click ''Open Docket Folder'' button choose the document listed to review. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

Issued on: July 7, 2015.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2015–17331 Filed 7–14–15; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2011–0140]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew the exemptions from the vision requirement in the Federal Motor Carrier Safety Regulations for 9 individuals. FMCSA has statutory authority to exempt individuals from the vision requirement if the exemptions granted will not compromise safety. The Agency has concluded that granting these exemption renewals will provide a level of safety that is equivalent to or greater than the level of safety maintained without the exemptions for these

commercial motor vehicle (CMV) drivers.

DATES: This decision is effective August 12, 2015. Comments must be received on or before August 14, 2015.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) numbers: Docket No. [Docket No. FMCSA–2011–0140], using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* 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.
- *Fax:* 1–202–493–2251.

Instructions: Each submission must include the Agency name and the docket number for this notice. Note that DOT posts all comments received without change to *http://www.regulations.gov,* including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Federal Docket Management System (FDMS) is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: 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 *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

FOR FURTHER INFORMATION CONTACT: Charles A. Horan, III, Director, Carrier, Driver and Vehicle Safety Standards, 202–366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m. Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

I. Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may renew an exemption from the vision requirements in 49 CFR 391.41(b)(10), which applies to drivers of CMVs in interstate commerce, for a two-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' The procedures for requesting an exemption (including renewals) are set out in 49 CFR part 381.

II. Exemption Decision

This notice addresses 9 individuals who have requested renewal of their exemptions in accordance with FMCSA procedures. FMCSA has evaluated these 9 applications for renewal on their merits and decided to extend each exemption for a renewable two-year period. They are:

Danny F. Burnley (KY)
Ronald J. Claud (NY)
Sean R. Conorman (MI)
Jackie R. Frederick (AL)
Robert E. Graves (NE)
Terrence F. Ryan (FL)
Dennis W. Stubrich (PA)
Stephen W. Verrette (MI)
Leslie H. Wylie (ID)

The exemptions are extended subject to the following conditions: (1) That each individual has a physical examination every year (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the requirements in 49 CFR 391.41(b)(10), and (b) by a medical examiner who attests that the individual is otherwise physically qualified under 49 CFR 391.41; (2) that each individual provides a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (3) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file and retains a copy of the certification on his/her person while driving for presentation to a duly authorized Federal, State, or local enforcement official. Each exemption will be valid for two years unless rescinded earlier by FMCSA. The exemption will be rescinded if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315.

III. Basis for Renewing Exemptions

Under 49 U.S.C. 31315(b)(1), an exemption may be granted for no longer than two years from its approval date and may be renewed upon application for additional two year periods. In accordance with 49 U.S.C. 31136(e) and 31315, each of the 9 applicants has satisfied the entry conditions for obtaining an exemption from the vision requirements (76 FR 37169; 76 FR 50318; 79 FR 4531). Each of these 9 applicants has requested renewal of the exemption and has submitted evidence showing that the vision in the better eye continues to meet the requirement specified at 49 CFR 391.41(b)(10) and that the vision impairment is stable. In addition, a review of each record of safety while driving with the respective vision deficiencies over the past two years indicates each applicant continues to meet the vision exemption requirements.

These factors provide an adequate basis for predicting each driver's ability to continue to drive safely in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each renewal applicant for a period of two years is likely to achieve a level of safety equal to that existing without the exemption.

IV. Public Participation and Request for Comments

FMCSA encourages you to participate by submitting comments and related materials.

Submitting Comments

If you submit a comment, please include the docket number for this notice (FMCSA–2011–0140), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, got to *http://www.regulations.gov* and put the docket number, ''FMCSA–2011–0140'' in the ''Keyword'' box, and click ''Search.'' When the new screen

appears, click on ''Comment Now!'' button and type your comment into the text box in the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope. FMCSA will consider all comments and material received during the comment period and may change this notice based on your comments.

Viewing Comments and Documents

To view comments, as well as any documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov* and in the search box insert the docket number, ''FMCSA–2011–0140'' in the ''Keyword'' box and click ''Search.'' Next, click ''Open Docket Folder'' button choose the document listed to review. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12–140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

Issued on: July 7, 2015.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2015–17330 Filed 7–14–15; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2015–0063]

Qualification of Drivers; Exemption Applications; Diabetes Mellitus

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of applications for exemptions; request for comments.

SUMMARY: FMCSA announces receipt of applications from 58 individuals for exemption from the prohibition against persons with insulin-treated diabetes mellitus (ITDM) operating commercial motor vehicles (CMVs) in interstate commerce. If granted, the exemptions would enable these individuals with ITDM to operate CMVs in interstate commerce.

DATES: Comments must be received on or before August 14, 2015.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) Docket No. FMCSA–2015–0063 using any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.
- *Mail:* Docket Management Facility; U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery:* 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.
- *Fax:* 1–202–493–2251.

Instructions: Each submission must include the Agency name and the docket numbers for this notice. Note that all comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. Please see the Privacy Act heading below for further information.

Docket: For access to the docket to read background documents or comments, go to *http://www.regulations.gov* at any time or Room W12–140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Federal Docket Management System (FDMS) is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: 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 *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.*

FOR FURTHER INFORMATION CONTACT: Charles A. Horan, III, Director, Carrier, Driver and Vehicle Safety Standards, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

I. Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the Federal Motor Carrier Safety Regulations for a 2-year period if it finds ''such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.'' The statute also allows the Agency to renew exemptions at the end of the 2-year period. The 58 individuals listed in this notice have recently requested such an exemption from the diabetes prohibition in 49 CFR 391.41(b) (3), which applies to drivers of CMVs in interstate commerce. Accordingly, the Agency will evaluate the qualifications of each applicant to determine whether granting the exemption will achieve the required level of safety mandated by statute.

II. Qualifications of Applicants

James D. Acker

Mr. Acker, 43, has had ITDM since 2012. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Acker understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Acker meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2014 and certified that he does not have diabetic retinopathy. He holds an operator's license from Oregon.

Henry Andreoli

Mr. Andreoli, 65, has had ITDM since 2010. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Andreoli understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Andreoli meets the

requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Massachusetts.

Jonathan A. Boston

Mr. Boston, 50, has had ITDM since 2013. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Boston understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Boston meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from New York.

James G. Bracegirdle

Mr. Bracegirdle, 52, has had ITDM since 2013. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Bracegirdle understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Bracegirdle meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Georgia.

Richard T. Bray

Mr. Bray, 61, has had ITDM since 2013. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Bray understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Bray meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Texas.

Joseph C. Brewster

Mr. Brewster, 21, has had ITDM since 2011. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Brewster understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Brewster meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Virginia.

Bradley R. Brown

Mr. Brown, 64, has had ITDM since 2013. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Brown understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Brown meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2014 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from New Hampshire.

Steven G. Brown

Mr. Brown, 35, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Brown understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Brown meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Minnesota.

Annette F. Bryant

Ms. Bryant, 52, has had ITDM since 2013. Her endocrinologist examined her in 2015 and certified that she has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. Her endocrinologist certifies that Ms. Bryant understands diabetes management and monitoring has stable control of her diabetes using insulin, and is able to drive a CMV safely. Ms. Bryant meets the requirements of the vision standard at 49 CFR 391.41(b)(10). Her optometrist examined her in 2013 and certified that she does not have diabetic retinopathy. She holds an operator's license from California.

Brian G. Carter

Mr. Carter, 50, has had ITDM since 2013. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Carter understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Carter meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Georgia.

Daniel B. Craig

Mr. Craig, 46, has had ITDM since 2009. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or

more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Craig understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Craig meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Oregon.

Willie L. Davis

Mr. Davis, 65, has had ITDM since 2015. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Davis understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Davis meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Mississippi.

Sean W. Dempsey

Mr. Dempsey, 31, has had ITDM since 1992. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Dempsey understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Dempsey meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class B CDL from Ohio.

Patrick L. Feely

Mr. Feely, 68, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Feely understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Feely meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Minnesota.

Garry W. Garrison

Mr. Garrison, 52, has had ITDM since 2011. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Garrison understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Garrison meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Wisconsin.

James Genello

Mr. Genello, 50, has had ITDM since 2009. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Genello understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Genello meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from New Jersey.

John T. Gorman

Mr. Gorman, 40, has had ITDM since 1984. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Gorman understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Gorman meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he has stable nonproliferative diabetic retinopathy. He holds an operator's license from New Jersey.

Gabriel L. Grooms

Mr. Grooms, 44, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Grooms understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Grooms meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Washington.

Joel K. Hawkins

Mr. Hawkins, 37, has had ITDM since 2000. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Hawkins understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Hawkins meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Illinois.

William H. Hudgens, Jr.

Mr. Hudgens, 64, has had ITDM since 2012. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Hudgens understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Hudgens meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Texas.

Gary L. Hulslander

Mr. Hulslander, 64, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Hulslander understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Hulslander meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2014 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Pennsylvania.

Daniel E. Jackowski

Mr. Jackowski, 36, has had ITDM since 1982. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Jackowski understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Jackowski meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Wisconsin.

Alan J. Jeffrey

Mr. Jeffrey, 25, has had ITDM since 1992. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Jeffrey understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Jeffrey meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Connecticut.

John W. Johnson

Mr. Johnson, 54, has had ITDM since 2015. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Johnson understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Johnson meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Tennessee.

Samuel S. Johnson

Mr. Johnson, 21, has had ITDM since 2007. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Johnson understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Johnson meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Wisconsin.

Thomas R. Keaton

Mr. Keaton, 62, has had ITDM since 2013. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Keaton understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Keaton meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Missouri.

Charles A. Kelley

Mr. Kelley, 57, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Kelley understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Kelley meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Iowa.

Omer E. King

Mr. King, 71, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. King understands diabetes management and monitoring, has stable control of his diabetes using

insulin, and is able to drive a CMV safely. Mr. King meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Pennsylvania.

Eric R. Knutson

Mr. Knutson, 40, has had ITDM since 2015. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Knutson understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Knutson meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Minnesota.

Bruce E. Koehn

Mr. Koehn, 32, has had ITDM since 2015. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Koehn understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Koehn meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2014 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Kansas.

Douglas L. Kugler

Mr. Kugler, 63, has had ITDM since 2012. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Kugler understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Kugler meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Minnesota.

John G. Leutze, Jr.

Mr. Leutze, 62, has had ITDM since 2005. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Leutze understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Leutze meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from New York.

Hershel McIntosh

Mr. McIntosh, 61, has had ITDM since 2013. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. McIntosh understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. McIntosh meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Kentucky.

Andrew S. McKinney

Mr. McKinney, 26, has had ITDM since 1997. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. McKinney understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. McKinney meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Minnesota.

Michael L. Medina

Mr. Medina, 50, has had ITDM since 2012. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Medina understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Medina meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Colorado.

Douglas D. Miller

Mr. Miller, 57, has had ITDM since 2010. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Miller understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Miller meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Wyoming.

Dallas W. Minton

Mr. Minton, 71, has had ITDM since 2012. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the

assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Minton understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Minton meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a chauffeur's license from Indiana.

Ronnie R. Parker

Mr. Parker, 31, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Parker understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Parker meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Maine.

Robert F. Perez

Mr. Perez, 50, has had ITDM since 2013. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Perez understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Perez meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class C CDL from Pennsylvania.

Ray E. Phipps

Mr. Phipps, 53, has had ITDM since 2012. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Phipps understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Phipps meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Illinois.

Bruce F. Sanderson

Mr. Sanderson, 62, has had ITDM since 2015. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Sanderson understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Sanderson meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Louisiana.

Raymond Santiago

Mr. Santiago, 48, has had ITDM since 2015. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Santiago understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Santiago meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from New Jersey.

Travis D. Shadden

Mr. Shadden, 37, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Shadden understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Shadden meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Indiana.

Randy S. Steinbach

Mr. Steinbach, 63, has had ITDM since 2003. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Steinbach understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Steinbach meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Washington.

Bradley D. Stillman

Mr. Stillman, 46, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Stillman understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Stillman meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that

he does not have diabetic retinopathy. He holds a Class A CDL from Arizona.

Paul R. Thorkelson

Mr. Thorkelson, 64, has had ITDM since 2012. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Thorkelson understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Thorkelson meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class C CDL from Minnesota.

Michael J. Toth

Mr. Toth, 61, has had ITDM since 1965. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Toth understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Toth meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class B CDL from Pennsylvania.

Christopher O. Trent

Mr. Trent, 46, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Trent understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Trent meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Kansas.

Charles H. Turner

Mr. Turner, 44, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Turner understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Turner meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Wisconsin.

Jesse W. Turner

Mr. Turner, 52, has had ITDM since 2008. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Turner understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Turner meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds an operator's license from Michigan.

Donavan A. Van Houten

Mr. Van Houten, 38, has had ITDM since 2013. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Van Houten understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Van Houten meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Washington.

Matt S. Volk

Mr. Volk, 56, has had ITDM since 2014. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Volk understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Volk meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Nebraska.

Daniel M. Waldner

Mr. Waldner, 57, has had ITDM since 2015. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Waldner understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Waldner meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from North Dakota.

Carlton G. Watson

Mr. Watson, 59, has had ITDM since 2015. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist

certifies that Mr. Watson understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Watson meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class B CDL from Maryland.

Timothy L. Wilkinson

Mr. Wilkinson, 63, has had ITDM since 2009. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Wilkinson understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Wilkinson meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class C CDL from Ohio.

Catherine A. Willcox

Ms. Willcox, 51, has had ITDM since 2015. Her endocrinologist examined her in 2015 and certified that she has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. Her endocrinologist certifies that Ms. Willcox understands diabetes management and monitoring has stable control of her diabetes using insulin, and is able to drive a CMV safely. Ms. Willcox meets the requirements of the vision standard at 49 CFR 391.41(b)(10). Her optometrist examined her in 2015 and certified that she does not have diabetic retinopathy. She holds a Class A CDL from Connecticut.

Kenneth P. Wing

Mr. Wing, 55, has had ITDM since 2012. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Wing understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CMV safely. Mr. Wing meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His ophthalmologist examined him in 2015 and certified that he has stable nonproliferative diabetic retinopathy. He holds a Class A CDL from Michigan.

Timothy W. Young

Mr. Young, 51, has had ITDM since 1994. His endocrinologist examined him in 2015 and certified that he has had no severe hypoglycemic reactions resulting in loss of consciousness, requiring the assistance of another person, or resulting in impaired cognitive function that occurred without warning in the past 12 months and no recurrent (2 or more) severe hypoglycemic episodes in the last 5 years. His endocrinologist certifies that Mr. Young understands diabetes management and monitoring, has stable control of his diabetes using insulin, and is able to drive a CVM safely. Mr. Young meets the requirements of the vision standard at 49 CFR 391.41(b)(10). His optometrist examined him in 2015 and certified that he does not have diabetic retinopathy. He holds a Class A CDL from Pennsylvania.

III. Request for Comments

In accordance with 49 U.S.C. 31136(e) and 31315, FMCSA requests public comment from all interested persons on the exemption petitions described in this notice. We will consider all comments received before the close of business on the closing date indicated in the date section of the notice.

FMCSA notes that section 4129 of the Safe, Accountable, Flexible and Efficient Transportation Equity Act: A Legacy for Users requires the Secretary to revise its diabetes exemption program established on September 3, 2003 (68 FR 52441).[1] The revision must provide for individual assessment of drivers with diabetes mellitus, and be consistent with the criteria described in section 4018 of the Transportation Equity Act for the 21st Century (49 U.S.C. 31305).

Section 4129 requires: (1) Elimination of the requirement for 3 years of experience operating CMVs while being treated with insulin; and (2) establishment of a specified minimum period of insulin use to demonstrate stable control of diabetes before being allowed to operate a CMV.

In response to section 4129, FMCSA made immediate revisions to the diabetes exemption program established by the September 3, 2003 notice. FMCSA discontinued use of the 3-year driving experience and fulfilled the requirements of section 4129 while continuing to ensure that operation of CMVs by drivers with ITDM will achieve the requisite level of safety required of all exemptions granted under 49 U.S.C. 31136(e).

Section 4129(d) also directed FMCSA to ensure that drivers of CMVs with ITDM are not held to a higher standard than other drivers, with the exception of limited operating, monitoring and medical requirements that are deemed medically necessary.

The FMCSA concluded that all of the operating, monitoring and medical requirements set out in the September 3, 2003 notice, except as modified, were in compliance with section 4129(d). Therefore, all of the requirements set out in the September 3, 2003 notice, except as modified by the notice in the **Federal Register** on November 8, 2005 (70 FR 67777), remain in effect.

IV. Submitting Comments

You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so that FMCSA can contact you if there are questions regarding your submission.

To submit your comment online, go to *http://www.regulations.gov* and in the search box insert the docket number FMCSA–2015–0063 and click the search button. When the new screen appears, click on the blue ''Comment Now!'' button on the right hand side of the page. On the new page, enter information required including the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope.

We will consider all comments and material received during the comment period and may change this proposed

[1] Section 4129(a) refers to the 2003 notice as a ''final rule.'' However, the 2003 notice did not issue a ''final rule'' but did establish the procedures and standards for issuing exemptions for drivers with ITDM.

rule based on your comments. FMCSA may issue a final rule at any time after the close of the comment period.

V. Viewing Comments and Documents

To view comments, as well as any documents mentioned in this preamble, to submit your comment online, go to *http://www.regulations.gov* and in the search box insert the docket number FMCSA–2015–0063 and click ''Search.'' Next, click ''Open Docket Folder'' and you will find all documents and comments related to the proposed rulemaking.

Issued on: July 7, 2015.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2015–17328 Filed 7–14–15; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA–2015–0054]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of denials.

SUMMARY: FMCSA announces its denial of 120 applications from individuals who requested an exemption from the Federal vision standard applicable to interstate truck and bus drivers and the reasons for the denials. FMCSA has statutory authority to exempt individuals from the vision requirement if the exemptions granted will not compromise safety. The Agency has concluded that granting these exemptions does not provide a level of safety that will be equivalent to, or greater than, the level of safety maintained without the exemptions for these commercial motor vehicle (CMV) drivers.

FOR FURTHER INFORMATION CONTACT: Charles A. Horan, III, Director, Carrier, Driver and Vehicle Safety Standards, (202) 366–4001, *fmcsamedical@dot.gov,* FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64–224, Washington, DC 20590–0001. Office hours are from 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the Federal vision standard for a renewable 2-year period if it finds ''such an exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such an exemption.'' The procedures for requesting an exemption are set forth in 49 CFR part 381.

Accordingly, FMCSA evaluated 120 individual exemption requests on their merit and made a determination that these applicants do not satisfy the criteria eligibility or meet the terms and conditions of the Federal exemption program. Each applicant has, prior to this notice, received a letter of final disposition on the exemption request. Those decision letters fully outlined the basis for the denial and constitute final Agency action. The list published in this notice summarizes the Agency's recent denials as required under 49 U.S.C. 31315(b)(4) by periodically publishing names and reasons for denial.

The following applicant, Gregory J. Karkos, did not have sufficient driving experience over the past three years under normal highway operating conditions.

The following 21 applicants had no experience operating a CMV:

Paul M. A. Bobick
Ethan W. Boze
Russell B. Cochran
Harold L. Coleman
Logan B. Dix
Terry L. Dockall
Charles M. Edmonds
Pedro T. Espinal
Ronald A. Francis
William R. Hand
Kristopher M. Heitmeier
Alan L. Kershisnik
Nuru D. Mehammed
Kevin R. Murphy
Eduardo Ortiz
Christopher E. Robles
Jonathan R. Rogers
Joseph D. Sirlin
Maxwell W. Tanner
Charles Wheeler
Haitham N. Zegar

The following 15 applicants did not have three years of experience driving a CMV on public highways with their vision deficiencies:

Clairmont Boston
John R. Boudreaux
James A. Bullock, Jr.
James L. Crain
James W. Faber
Joseph F. Giacometto
Elmer G. Godwin, Jr.
Randall L. Hall
Alexander D. Harry
Clyde M. Lange III
Aveland E. Munroe
Jorge M. Rios
Canute O. Robinson
James R. Sadlow
Thomas A. Schwarz

The following nine applicants did not have three years of recent experience driving a CMV with the vision deficiency:

Kyle J. Bailey
Charles W. Bradley
Jeremy W. Culberson
Albert Goodman, Jr.
Jimmy R. Holman
Ronald L. Irwin
Wayne S. Peisert
Donald L. Pons
Dawn K. Waybill

The following two applicants did not have sufficient driving experience during the past three years under normal highway operating conditions:

Michael Garnys
Edward P. Schrader II

The following applicant, Marsden A. Cummings, was unable to obtain a statement from an optometrist or ophthalmologist stating that he was able to operate a commercial vehicle from a vision standpoint.

The following 19 applicants were denied for multiple reasons:

Shawn B. Blanton
Lorena G. Booker
Gaylon W. Bumpus
Teddy E. Cole
David R. Ford
Joseph R. Fritz
Alan G. Hicks
Tony B. Johnson
Raymond W. Lytle, Sr.
William E. Montanari, Sr.
Donald H. Nelson
Delbert L. Priddle
James D. Simental
Dennis L. Smith
Patrick L. Stansell
Dustin L. Stone
Barron A. Story
Samuel M. Washington
Gary E. Williams

The following two applicants did not have stable vision for the entire three-year period:

Jeffrey L. Jones
Carl A. Shaner

The following 21 applicants met the current federal vision standards. Exemptions are not required for applicants who meet the current regulations for vision:

David D. Bond
Nicholas J. Carbone
Harold C. Darden
Douglas J. Davis
Whitney R. Everhart
Craig T. Gerroll
Darren E. Giles

Sukmindier S. Grewal
Derek Griffin
Bobby L. Hunter
Dennis Johnson
Dennis D. Kahle
Enoc D. Lopez
Michael D. Minchew
Armont S. Nash
Osvaldo Negron
Charles E. Rhodes
Michael C. Schaffer Jr.
Brian D. Sharp
Yancy D. Stone
Charles R. Wulf

The following 24 applicants were denied because they will not be driving interstate, interstate commerce, or are not required to carry a DOT medical card:

Scott W. Andreason
Michael J. Benedict
Ronald R. Campbell
Richard A. Cornejo
Willie J. Evans Jr.
Domenic L. Germano
Robert L. Hodge
John L. Johnson Sr.
Raymond Long
Evaristo Z. Martinez
James C. Mcnee
Jere L. Messersmith
Michael D. Meyer
Jeffrey R. Miller
Anna M. Miller
George S. Moore
Steven J. Mulligan
Robert Noonan
Myron E. Olson
Jerry W. Rufsvold
Elmer F. Silcott
Thomas E. Smith
Anthony E. Smith
Manuel Ulloa-Mendez

Finally, the following five applicants perform transportation for the federal government, state, or any political sub-division of the state.

Michael W. Henderson
Nicholas J. Marchesani
Christopher M. Pannelli
Anthony J. Santi
Todd W. Woronik

Issued on: July 7, 2015.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2015–17329 Filed 7–14–15; 8:45 am]

BILLING CODE 4910–EX–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2009–0078]

Petition for Waiver of Compliance

In accordance with Part 211 of Title 49 Code of Federal Regulations (CFR), this provides the public notice that by a document dated April 14, 2015, the American Short Line and Regional Railroad Association (ASLRRA)—on behalf of Baltimore Industrial Railroad, Cloquet Terminal Railroad Company, Incorporated, and East Erie Commercial Railroad—petitioned the Federal Railroad Administration (FRA) for an amended waiver of compliance from certain provisions of the Federal hours of service laws contained at 49 U.S.C. 21103(a)(4), which, in part, require a train employee to receive 48 hours off duty after initiating an on-duty period for 6 consecutive days. FRA assigned the petition Docket Number FRA–2009–0078.

In its petition, ASLRRA seeks to amend its existing waiver to add the three railroads referenced above, which did not participate in ASLRRA's prior waiver petition. FRA granted ASLRRA's petition for a waiver extension in a letter dated February 27, 2012. The waiver allows a train employee to initiate an on-duty period each day for 6 consecutive days followed by 24 hours, rather than 48 hours, off duty.

Each railroad that seeks to be added to the waiver executed a compliance letter, attesting that it complies with all of the employee consent requirements that FRA set forth in its initial decision letter, dated March 5, 2010. Additionally, each railroad will maintain the underlying employee consent or employee representative consent documents in its files for FRA inspection.

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's Docket Operations Facility, 1200 New Jersey Ave. SE., W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number and may be submitted by any of the following methods:

- Web site: *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- Fax: 202–493–2251.
- Mail: Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590.
- Hand Delivery: 1200 New Jersey Avenue SE., Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

Communications received by August 31, 2015 will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable.

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.* See also *http://www.regulations.gov/#!privacyNotice* for the privacy notice of regulations.gov.

Issued in Washington, DC on July 10, 2015.

Ron Hynes,

Director, Office of Technical Oversight.

[FR Doc. 2015–17341 Filed 7–14–15; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF THE TREASURY

Bureau of the Fiscal Service

Proposed Collection of Information: Application for Disposition of Retirement Plan and/or Individual Retirement Bonds Without Administration of Deceased Owner's Estate

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A). Currently

the Bureau of the Fiscal Service within the Department of the Treasury is soliciting comments concerning the ''Application For Disposition Of Retirement Plan and/or Individual Retirement Bonds Without Administration Of Deceased Owner's Estate.''

DATES: Written comments should be received on or before September 14, 2015 to be assured of consideration.

ADDRESSES: Direct all written comments and requests for further information to Bureau of the Fiscal Service, Bruce A. Sharp, 200 Third Street A4–A, Parkersburg, WV 26106–1328, or *bruce.sharp@fiscal.treasury.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to Ron Lewis; 200 Third Street Room 515, Parkersburg, WV 26106–1328, or *ron.lewis@fiscal.treasury.gov.*

SUPPLEMENTARY INFORMATION:

Title: Application For Disposition Of Retirement Plan and/or Individual Retirement Bonds Without Administration Of Deceased Owner's Estate.

OMB Number: 1530–0032 (Previously approved as 1535–0032 as a collection conducted by Department of the Treasury/Bureau of the Public Debt.)

Transfer of OMB Control Number: The Bureau of Public Debt (BPD) and the Financial Management Service (FMS) have consolidated to become the Bureau of the Fiscal Service (Fiscal Service). Information collection requests previously held separately by BPD and FMS will now be identified by a 1530 prefix, designating Fiscal Service.

Form Number: FS Form 3565.

Abstract: The information is used to support a request for recognition as a person entitled to United States Retirement Plan and/or Individual Retirement bonds which belonged to a deceased owner when a legal representative has not been appointed for the estate and no such appointment is pending.

Current Actions: Extension of a currently approved collection.

Type of Review: Regular.

Affected Public: Individuals or Households.

Estimated Number of Respondents: 350.

Estimated Time per Respondent: 20 minutes.

Estimated Total Annual Burden Hours: 117.

Request For Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Dated: July 9, 2015.

Bruce A. Sharp,

Bureau Clearance Officer.

[FR Doc. 2015–17345 Filed 7–14–15; 8:45 am]

BILLING CODE 4810–AS–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

Unblocking of Specially Designated Nationals and Blocked Persons Pursuant to Executive Order 13310 and Executive Order 13448

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Notice.

SUMMARY: The Treasury Department's Office of Foreign Assets Control (OFAC) is removing the names of three individuals whose property and interests in property have been unblocked pursuant to Executive Order 13310 and Executive Order 13448.

DATES: OFAC's actions described in this notice are effective July 9, 2015.

FOR FURTHER INFORMATION CONTACT: Associate Director for Global Targeting, tel.: 202/622–2420, Associate Director for Sanctions Policy & Implementation, tel.: 202/622–2480, Office of Foreign Assets Control, or Chief Counsel (Foreign Assets Control), tel.: 202/622–2410, Office of the General Counsel, Department of the Treasury (not toll free numbers).

SUPPLEMENTARY INFORMATION:

Electronic and Facsimile Availability

The list of Specially Designated Nationals and Blocked Persons (SDN List) and additional information concerning OFAC sanctions programs are available from OFAC's Web site (*www.treasury.gov/ofac*). Certain general information pertaining to OFAC's sanctions programs is also available via facsimile through a 24-hour fax-on-demand service, tel.: 202/622–0077.

Notice of OFAC Action

On July 9, 2015, OFAC, in consultation with the Department of State, determined that circumstances no longer warrant the inclusion of the following individual in the Annex to Executive Order 13448 of October 18, 2007, ''Blocking Property and Prohibiting Certain Transactions Related to Burma'' (E.O. 13448), and on OFAC's SDN list, and that this individual is no longer subject to the blocking provisions of Section 1(a) of E.O. 13448.

Individual

ZAW, Thidar (a.k.a. ZAW, Daw Thidar; a.k.a. ZAW, Thida), Burma; 6 Cairnhill Circle, Number 18–07, Cairnhill Crest 229813, Singapore; DOB 24 Feb 1962; citizen Burma; nationality Burma; Wife of Tay ZA (individual) [BURMA].

On July 9, 2015, OFAC, in consultation with the Department of State, pursuant to Executive Order 13310 of July 28, 2003, ''Blocking Property of the Government of Burma and Prohibiting Certain Transactions'' (E.O. 13310), determined that circumstances no longer warrant the inclusion of the individuals identified below on the SDN List, and that these individuals are no longer subject to the blocking provisions of Section 1(b) of E.O. 13310.

Individuals

BO, Maung; DOB 16 Feb 1945; citizen Burma; nationality Burma; Lieutenant-General; Chief of Bureau of Special Operation 4; Member, State Peace and Development Council (individual) [BURMA].

WIN, Soe; DOB 10 May 1947; citizen Burma; nationality Burma; Lieutenant-General; Prime Minister; Member, State Peace and Development Council (individual) [BURMA].

Dated: July 9, 2015.

John E. Smith,

Acting Director, Office of Foreign Assets Control.

[FR Doc. 2015–17265 Filed 7–14–15; 8:45 am]

BILLING CODE 4810–AL–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8883

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 8883, Asset Allocation Statement Under Section 338.

DATES: Written comments should be received on or before September 14, 2015 to be assured of consideration.

ADDRESSES: Direct all written comments to Christie A. Preston, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Martha R. Brinson, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the Internet at *Martha.R.Brinson@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Asset Allocation Statement Under Section 338.

OMB Number: 1545–1806.

Form Number: 8883.

Abstract: Form 8883 is used to report information regarding transactions involving the deemed sale of corporate assets under section 338.

Current Actions: There are no changes being made to this form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 243.

Estimated Time per Respondent: 23 hours, 40 minutes.

Estimated Total Annual Burden Hours: 5,755.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: July 6, 2015.

Christie A. Preston,

IRS Reports Clearance Officer.

[FR Doc. 2015–17319 Filed 7–14–15; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Regulation Project

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Hedging Transactions.

DATES: Written comments should be received on or before September 14, 2015 to be assured of consideration.

ADDRESSES: Direct all written comments to Christie A. Preston, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulation should be directed to Martha. R. Brinson, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the Internet at *Martha.R.Brinson@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Hedging Transactions.

OMB Number: 1545–1480.

Regulation Project Number: TD 8985.

Abstract: This document contains final regulations relating to the character of gain or loss from hedging transactions. The regulations reflect changes to the law made by the Ticket to Work and Work Incentives Improvement Act of 1999. The regulations affect businesses entering into hedging transactions.

Current Actions: There is no change to this existing regulation.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 127,100.

Estimated Time per Respondent: 1 hour, 20 minutes.

Estimated Total Annual Burden Hours: 171,050.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request For Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: July 6, 2015.

Christie A. Preston,

IRS Reports Clearance Officer.

[FR Doc. 2015–17320 Filed 7–14–15; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 4461, 4461–A, and 4461–B

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 4461, Application for Approval of Master or Prototype Defined Contribution Plan; Form 4461–A, Application for Approval of Master or Prototype Defined Benefit Plan; Form 4461–B, Application for Approval of Master or Prototype Plan, Mass Submitter Adopting Sponsor.

DATES: Written comments should be received on or before September 14, 2015 to be assured of consideration.

ADDRESSES: Direct all written comments to Christie A. Preston, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to Martha. R. Brinson, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the Internet at *Martha.R.Brinson@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Form 4461, Application for Approval of Master or Prototype or Volume Submitter Defined Contribution Plans; Form 4461–A, Application for Approval of Master or Prototype or Volume Submitter Defined Benefit Plan; Form 4461–B, Application for Approval of Master or Prototype or Volume Submitter Plans Mass Submitter Adopting Sponsor or Practitioner.

OMB Number: 1545–0169.

Form Number: Forms 4461, 4461–A, and 4461–B.

Abstract: The IRS uses these forms to determine from the information submitted whether the applicant plan qualifies under section 401(a) of the Internal Revenue Code for plan approval. The application is also used to determine if the related trust qualifies for tax exempt status under Code section 501(a).

Current Actions: There are no changes being made to these forms at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations.

Estimated Number of Responses: 5,250.

Estimated Number of Respondent: 12 hours, 31 minutes.

Estimated Total Annual Burden Hours: 65,765.

The following paragraph applies to all of the collections of information covered by this notice:

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number. Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record.

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (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; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: July 6, 2015.

Christie A. Preston,

IRS Reports Clearance Office.

[FR Doc. 2015–17313 Filed 7–14–15; 8:45 am]

BILLING CODE 4830–01–P

UNITED STATES SENTENCING COMMISSION

Requests for Applications; Practitioners Advisory Group

AGENCY: United States Sentencing Commission.

ACTION: Notice.

SUMMARY: In view of upcoming vacancies in the voting membership of the Practitioners Advisory Group, the United States Sentencing Commission hereby invites any individual who is eligible to be appointed to succeed such a voting member to apply. The voting memberships covered by this notice are two circuit memberships (for the First Circuit and the Ninth Circuit). Application materials should be received by the Commission not later than September 1, 2015. An applicant for voting membership of the Practitioners Advisory Group should apply by sending a letter of interest and resume to the Commission as indicated in the addresses section below.

DATES: Application materials for voting membership of the Practitioners Advisory Group should be received not later than September 1, 2015.

ADDRESSES: An applicant for voting membership of the Practitioners Advisory Group should apply by sending a letter of interest and resume to the Commission by electronic mail or regular mail. The email address is *pubaffairs@ussc.gov.* The regular mail address is United States Sentencing Commission, One Columbus Circle NE., Suite 2–500, South Lobby, Washington, DC 20002–8002, Attention: Public Affairs.

FOR FURTHER INFORMATION CONTACT: Jeanne Doherty, Public Affairs Officer, 202–502–4502, *jdoherty@ussc.gov.* More information about the Practitioners Advisory Group is available on the Commission's Web site at *www.ussc.gov/advisory-groups.*

SUPPLEMENTARY INFORMATION: The Practitioners Advisory Group of the United States Sentencing Commission is a standing advisory group of the United States Sentencing Commission pursuant to 28 U.S.C. 995 and Rule 5.4 of the Commission's Rules of Practice and Procedure. Under the charter for the advisory group, the purpose of the advisory group is (1) to assist the Commission in carrying out its statutory responsibilities under 28 U.S.C. 994(o); (2) to provide to the Commission its views on the Commission's activities and work, including proposed priorities and amendments; (3) to disseminate to defense attorneys, and to other

professionals in the defense community, information regarding federal sentencing issues; and (4) to perform other related functions as the Commission requests. The advisory group consists of not more than 17 voting members, each of whom may serve not more than two consecutive three-year terms. Of those 17 voting members, one shall be Chair, one shall be Vice Chair, 12 shall be circuit members (one for each federal judicial circuit other than the Federal Circuit), and three shall be at-large members.

To be eligible to serve as a voting member, an individual must be an attorney who (1) devotes a substantial portion of his or her professional work to advocating the interests of privately-represented individuals, or of individuals represented by private practitioners through appointment under the Criminal Justice Act of 1964, within the federal criminal justice system; (2) has significant experience with federal sentencing or post-conviction issues related to criminal sentences; and (3) is in good standing of the highest court of the jurisdiction or jurisdictions in which he or she is admitted to practice. Additionally, to be eligible to serve as a circuit member, the individual's primary place of business or a substantial portion of his or her practice must be in the circuit concerned. Each voting member is appointed by the Commission.

The Commission invites any individual who is eligible to be appointed to a voting membership covered by this notice (*i.e.,* the circuit memberships for the First Circuit and the Ninth Circuit) to apply by sending a letter of interest and a resume to the Commission as indicated in the **ADDRESSES** section above.

Authority: 28 U.S.C. 994(a), (o), (p), 995; USSC Rules of Practice and Procedure 5.4.

Patti B. Saris,

Chair.

[FR Doc. 2015–17323 Filed 7–14–15; 8:45 am]

BILLING CODE 2210–40–P

FEDERAL REGISTER

Vol. 80 Wednesday,

No. 135 July 15, 2015

Part II

Environmental Protection Agency

40 CFR Parts 280 and 281

Revising Underground Storage Tank Regulations—Revisions to Existing Requirements and New Requirements for Secondary Containment and Operator Training; Final Rule

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 280 and 281

[EPA–HQ–UST–2011–0301; FRL 9913–64–OSWER]

RIN 2050–AG46

Revising Underground Storage Tank Regulations—Revisions to Existing Requirements and New Requirements for Secondary Containment and Operator Training

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA or the Agency) is making certain revisions to the 1988 underground storage tank (UST) regulation and to the 1988 state program approval (SPA) regulation. These changes establish Federal requirements that are similar to key portions of the Energy Policy Act of 2005 (EPAct); they also update the 1988 UST and SPA regulations. Changes to the regulations include: Adding secondary containment requirements for new and replaced tanks and piping; adding operator training requirements; adding periodic operation and maintenance requirements for UST systems; addressing UST systems deferred in the 1988 UST regulation; adding new release prevention and detection technologies; updating codes of practice; making editorial corrections and technical amendments; and updating state program approval requirements to incorporate these new changes. EPA thinks these changes will protect human health and the environment by reducing the number of releases to the environment and quickly detecting releases, if they occur.

DATES: This rule is effective October 13, 2015.

ADDRESSES: EPA established a docket for this action under Docket ID No. EPA–HQ–UST–2011–0301. All documents in the docket are listed on the *www.regulations.gov* Web site. 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 *www.regulations.gov* or in paper copy at the OSWER Docket, EPA/DC, WJC West Building, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. The telephone number for the Public Reading Room is 202–566–1744, and the telephone number for the OSWER Docket is 202–566–0270.

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I. General Information

Does this action apply to me?

In the table below, EPA is providing a list of potentially affected entities using North American Industry Classification System (NAICS) codes. However, this final action may affect other entities not listed below. The Agency's goal with this section is to provide a guide for readers to consider regarding entities that potentially could be affected by this action. If you have questions regarding the applicability of this action to a particular entity, consult the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

INDUSTRY SECTORS POTENTIALLY AFFECTED BY THE FINAL REGULATION

Industry sector	NAICS code
Retail Motor Fuel Sales	447.
Commercial (wholesale trade, retail trade, accommodation, and food services)	42, 44–45, 72 (excluding 447).
Institutional (hospitals only)	622.
Manufacturing	31–33.
Transportation (air, water, truck, transit, pipeline, and airport operations)	481, 483–486, 48811.
Communications And Utilities (wired telecommunications carriers; and electric power generation, transmission, and distribution).	5171, 2211.
Agriculture (crop and animal production)	111, 112.

II. Authority

EPA is revising these regulations under the authority of sections 2002, 9001, 9002, 9003, 9004, 9005, 9006, 9007, 9010, and 9012 of the Solid Waste Disposal Act (SWDA) of 1965, as amended (commonly known as the Resource Conservation and Recovery Act (RCRA)) [42 U.S.C. 6912, 6991, 6991(a), 6991(b), 6991(c), 6991(d), 6991(e), 6991(f), 6991(i), and 6991(k)].

III. Background

A. Changes to the UST Regulations

After reviewing and incorporating comments received during the five month public comment period, EPA is finalizing certain changes to the 1988 UST regulation in 40 CFR part 280. EPA is also revising its SPA regulation in 40 CFR part 281 to incorporate the changes in 40 CFR part 280.

These revisions strengthen the 1988 UST regulation by increasing the emphasis on properly operating and maintaining equipment. The 1988 UST regulation required owners and operators to have spill, overfill, and release detection equipment in place for their UST systems, but did not require proper operation and maintenance for some of that equipment. For example, EPA required spill prevention equipment to capture drips and spills when the delivery hose is disconnected from the fill pipe, but did not require periodic testing of that equipment. These revisions require that UST equipment is operated and maintained properly, which will improve environmental protection. These revisions also acknowledge improvements in technology over the last 26 years, including the ability to detect releases from UST systems deferred in the 1988 UST regulation.

EPA is revising the 1988 UST regulation to:

- Establish federal requirements that are similar to certain key provisions of the Energy Policy Act of 2005;
- Ensure owners and operators properly operate and maintain their UST systems;
- Address UST systems deferred in the 1988 UST regulation;
- Include updates to current technology and codes of practices;
- Make technical and editorial corrections; and
- Update the SPA regulation to address the changes listed above.

In 1988, EPA first promulgated the UST regulation (40 CFR part 280) to prevent, detect, and clean up petroleum releases into the environment. The 1988 UST regulation required new UST systems to be designed, constructed, and installed to prevent releases; existing UST systems had to be upgraded to prevent releases. In addition, owners and operators were required to perform release detection, demonstrate financial responsibility, and clean up releases.

The Energy Policy Act of 2005 amended Subtitle I of SWDA, the statute that authorized the UST program. Key Energy Policy Act provisions (such as secondary containment and operator training) apply to all states and United States' territories, hereafter referred to as states, receiving federal Subtitle I money under SWDA, regardless of their state program approval status, but do not apply in Indian country. The United States has a unique legal relationship with federally recognized Indian tribes. This government to government relationship includes recognizing the rights of tribes as sovereign governments with the right to self-determination and acknowledging the federal government's trust responsibility to tribes. As a result, EPA directly implements the UST program in Indian country.

In order to establish federal UST requirements that are similar to the UST secondary containment and operator training requirements of the Energy Policy Act, EPA decided to revise the 1988 UST regulation. These revisions also fulfill objectives in EPA's August 2006 UST Tribal Strategy,[1] where both EPA and tribes recognized the importance of requirements that ensure parity in program implementation among states and in Indian country. Secondary containment will reduce releases to the environment by containing them within a secondary area and detecting them before they reach the environment. Operator training will educate UST system operators and help them prevent releases by complying with the regulation and performing better operation and maintenance of their UST systems.

Since the beginning of the UST program, preventing petroleum and hazardous substance releases from UST systems into the environment has been one of the primary goals of the program. Although EPA and our partners have made significant progress in reducing the number of new releases, approximately 6,000 releases are discovered each year as of FY 2013.[2] Lack of proper operation and maintenance of UST systems is the main cause of new releases. Information on sources and causes of releases shows that releases from tanks are less common than they once were. However, releases from piping and spills and overfills associated with deliveries have emerged as more common problems. In addition, releases at the dispenser are one of the leading sources of releases. Finally, data show that release detection equipment is only detecting approximately 50 percent of releases it is designed to detect. These problems are partly due to improper operation and maintenance. See section IV.B, Additional Requirements for Operation and Maintenance for a more detailed discussion of problems.

EPA relied on two draft causes of releases studies to help support this final UST regulation. *Petroleum Releases at Underground Storage Tank Facilities in Florida* contains release data on 512 releases from new and

[1] 2006 Tribal Strategy, *http://epa.gov/oust/fedlaws/tribalst.htm.*

[2] Semi-Annual Report Of UST Performance Measures, End Of Fiscal Year 2013, *http://epa.gov/oust/cat/camarchv.htm.*

upgraded tanks in Florida.[3] The second draft study, *Evaluation of Releases from New and Upgraded Underground Storage Tank Systems,* contains release data on 580 releases from new and upgraded tanks in 23 states across the Northeast, South, and Central parts of the United States.[4] Taken together, these draft studies provide information on 1,092 releases in 24 of 50 states. The data in the two studies generally provide a representative sampling of releases across the United States, because nearly half of the states contributed to the studies. Both drafts were peer reviewed but never finalized because passage of the Energy Policy Act of 2005 required a reallocation of personnel and resources. Even though these studies were never finalized, the underlying data and calculations can be used to support this final UST regulation because that information did not change as a result of the peer review process. These studies are available in the docket for this final action.

Many USTs currently in the ground were upgraded to meet the spill, overfill, corrosion protection, and release detection requirements in the 1988 UST regulation. As these USTs continue to age, it is vital that we ensure they are still working as intended. These revisions to the 1988 UST regulation focus on ensuring equipment is working, rather than requiring UST owners and operators to replace or upgrade equipment already in place. The 1988 UST regulation requires owners and operators to use equipment that could help prevent releases. These revisions highlight the importance of operating and maintaining UST equipment so releases to the environment are prevented or quickly detected.

This final UST regulation addresses UST systems deferred in the 1988 UST regulation by removing the deferral and regulating UST systems with field-constructed tanks, airport hydrant fuel distribution systems that meet the UST definition, and UST systems storing fuel solely for use by emergency power generators. Note that aboveground storage tanks associated with UST systems with field-constructed tanks and airport hydrant fuel distribution systems that meet the UST definition are partially excluded in this final UST regulation. EPA is partially excluding wastewater treatment tank systems that are not part of a wastewater treatment facility regulated under sections 402 or 307(b) of the Clean Water Act, USTs containing radioactive material, and emergency generator UST systems at nuclear power generation facilities regulated by the Nuclear Regulatory Commission. See section IV.C, Addressing Deferrals, for more information.

EPA is revising the 1988 SPA regulation (40 CFR part 281) to address the changes to 40 CFR part 280. By doing so, states will generally need to adopt the 40 CFR part 280 changes finalized today in order to obtain or retain SPA.

Please note that, although not a part of this final UST regulation, owners and operators may also be subject to other requirements related to underground storage tank systems. For example, EPA's Office of Air and Radiation has national emission standards for hazardous air pollutants for various source categories, including gasoline dispensing facilities (see 40 CFR part 63). These standards include some testing for UST systems, depending on the monthly throughput of the facility.

Finally, EPA allows owners and operators the flexibility to maintain either paper or electronic records to demonstrate compliance with this final UST regulation. EPA encourages owners and operators to maintain records electronically, which promotes innovation[5] and simplifies compliance by using 21st century technology tools.[6]

B. History of the UST Laws and Regulations

In 1984, Congress responded to the increasing threat to groundwater posed from leaking USTs by adding Subtitle I to SWDA, commonly referred to as RCRA. Subtitle I of SWDA required EPA to develop a comprehensive regulatory program for USTs storing petroleum or certain hazardous substances, ensuring that the environment and human health are protected from UST releases. In 1986, Congress amended Subtitle I of SWDA and created the Leaking Underground Storage Tank Trust Fund to implement a cleanup program and pay for cleanups at sites where the owner or operator is unknown, unwilling, or unable to respond, or which require emergency action.

In 1988, EPA promulgated the UST regulation (40 CFR part 280), which set minimum standards for new UST systems and required owners and operators of existing UST systems to upgrade, replace, or close them. In addition, after 1988 owners and operators were required to report and clean up releases from their USTs. The 1988 UST regulation set deadlines for owners and operators to meet those requirements by December 22, 1998. Owners and operators who chose to upgrade or replace had to ensure their UST systems included spill and overfill prevention equipment and were protected from corrosion. In addition, owners and operators were required to monitor their UST systems for releases using release detection (phased in through 1993, depending on when their UST systems were installed). Finally, owners and operators were required to demonstrate financial responsibility (phased in through 1998), which ensured they have financial resources to pay for cleaning up releases. EPA has not significantly changed the UST regulation since 1988.

In 1988, EPA also promulgated a regulation for state program approval (40 CFR part 281). Since states are the primary implementers of the UST program, EPA established a process where state programs could operate in lieu of the federal program, if states met certain requirements and obtained state program approval from EPA. The state program approval regulation describes minimum requirements states must meet so their programs can be approved and operate in lieu of the federal program.

In 2005, the Energy Policy Act further amended Subtitle I of SWDA. The Energy Policy Act required states receiving Subtitle I money from EPA to meet certain requirements. EPA developed grant guidelines for states regarding: Operator training; inspections; delivery prohibition; secondary containment; financial responsibility for manufacturers and installers; public record; and state compliance reports on government USTs.[7] The operator training and secondary containment requirements are two major pieces of the Energy Policy Act that did not apply in Indian country, but will now apply with publication of this final UST regulation.

C. Potential Impact of This Regulation

This final UST regulation will improve parity in program implementation among states and in Indian country. This regulation is adding to the federal UST regulation

[3] *Petroleum Releases At Underground Storage Tank Facilities In Florida,* Peer Review Draft, US EPA/OUST, March 2005.

[4] *Evaluation Of Releases From New And Upgraded Underground Storage Tanks,* Peer Review Draft, US EPA/OUST, August 2004.

[5] Executive Order 13563, ''Improving Regulation And Regulatory Review,'' Section 3, see *http://www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf.*

[6] EPA Budget in Brief, February 2012, p. 4, see *http://yosemite.epa.gov/sab/sabproduct.nsf/2B686066C751F34A852579A4007023C2/$File/FY2013_BIB.pdf.*

[7] EPA guidelines for the Energy Policy Act can be found at: *http://epa.gov/oust/fedlaws/epact_05.htm.*

certain requirements, which will apply in Indian country. These requirements are similar to the Energy Policy Act's operator training and secondary containment requirements, which apply in states receiving federal Subtitle I money from EPA. This action will also further strengthen protection of human health and the environment from UST releases by increasing the emphasis on proper operation and maintenance of release prevention and release detection equipment. These revisions also reflect improvements in technology that allow for the ability to prevent and quickly detect releases for many tank systems currently deferred from regulation under Subtitle I.

The regulatory changes finalized today impose costs to owners and operators of existing regulated UST systems and owners and operators of USTs deferred in the 1988 UST regulation, as well as costs associated with state review of the changes. EPA prepared an analysis of the potential incremental costs and benefits associated with this action. This analysis is contained in the regulatory impact analysis (RIA) titled *Assessment of The Potential Costs, Benefits, and Other Impacts of the Final Revisions to EPA's Underground Storage Tank Regulations,* which is available in the docket for this action. Numerous commenters submitted input relaying their concerns about the costs and feasibility of specific requirements in the 2011 proposed UST regulation. EPA considered these comments and adjusted this final UST regulation to alleviate some of the burden on owners and operators. For example, EPA is requiring testing of spill prevention equipment every three years instead of annually. EPA also adjusted some of the assumptions underlying the RIA to reflect information received from commenters. For example, several commenters provided water disposal costs associated with spill bucket testing. While the RIA for the 2011 proposed UST regulation assumed these costs were part of the spill prevention testing cost, EPA adjusted this assumption to reflect that, in some cases, owners and operators will incur additional costs to dispose of the water. A summary of these impacts is provided in section VI, Overview of Estimated Costs and Benefits, and in the table below. Note that due to data and resource constraints, EPA was unable to quantify or monetize some of this final UST regulation's benefits, including avoidance of human health risks, groundwater protection, ecological benefits, and mitigation of acute exposure events and large-scale releases (*e.g.,* releases from airport hydrant distribution systems and UST systems with field-constructed tanks).

COSTS AND BENEFITS OF THE UST REGULATION

[2012$ Millions]*

	7% discount rate	3% discount rate
Total Annual Social Costs	$160	$160.
Total Annual Avoided Costs	$310	$360.
	Range: ($120–$530)	Range: ($130–$610).
Net Cost (Savings) To Society	($160)	($200).
	Range: $40–($370)	Range: $25–($450).

*Totals may not add up due to rounding

EPA also prepared a risk assessment for the 2011 proposed UST regulation titled *Risk Analysis to Support Potential Revisions to Underground Storage Tank (UST) Regulations.* The risk assessment examined potential impacts to groundwater and subsequent chemical transport, exposure, and risk. EPA decided not to spend resources to finalize the risk assessment through a formal peer review process, because the results from the risk assessment did not materially impact the RIA. Changes brought about by this final UST regulation are not expected to significantly alter these outcomes. The risk assessment developed for the 2011 proposed UST regulation is available for review in the docket.

D. EPA's Process in Deciding Which Changes To Incorporate in the Regulations

After the Energy Policy Act became law, EPA recognized a need to revise the 1988 UST regulation. The Energy Policy Act required additional measures to protect groundwater (either with secondary containment or financial responsibility for manufacturers and installers) and operator training requirements in states receiving federal Subtitle I money from EPA. However, no similar requirements would apply in Indian country until EPA promulgates a regulation. Both EPA and tribes are committed to ensuring program parity between states and in Indian country, and this final UST regulation achieves this parity.

For the past 26 years, the 1988 UST regulation worked well to provide environmental protection. However, over two decades of experience implementing the UST program have shown there are a number of areas where EPA can improve the UST program and increase environmental protection. For example, updating the UST regulation to reflect current technologies and ensuring release prevention and release detection equipment are properly operated and maintained have surfaced as areas needing improvement and are included as part of this final UST regulation.

Throughout the regulatory development process, EPA embraced an open, inclusive, and transparent process so all UST stakeholders had an opportunity to share their ideas and concerns. EPA recognizes concerns about costs to owners and operators and the importance of limiting requirements for retrofits. In developing this action, EPA reached out to stakeholders involved in all aspects of the tank program, provided multiple opportunities for sharing ideas, and kept stakeholders informed of progress.

As a result of the information collected during our extensive outreach to stakeholders, EPA published proposed regulations in the November 2011 **Federal Register**.[8] In order to ensure all stakeholders had an opportunity to comment, EPA provided a five month public comment period on the proposed UST and SPA regulations.

A number of commenters provided general input on EPA's 2011 proposal to update the UST and SPA regulations. Many commenters appreciated the extensive stakeholder outreach EPA conducted prior to drafting the proposed changes to the UST and SPA

[8] Proposed Rule Revising the Underground Storage Tanks Regulation. **Federal Register**. November 18, 2011. *https://www.federalregister.gov/articles/2011/11/18/2011-29293/revising-underground-storage-tank-regulations-revisions-to-existing-requirements-and-new.*

regulations. A few commenters believed EPA's outreach was not adequate. EPA conducted extensive stakeholder outreach before publishing the proposal; we held more than 100 meetings with stakeholders during the two years prior to issuing the 2011 proposed UST and SPA regulations. To further understand comments and concerns, EPA continued to meet with all interested stakeholders during and after the five month public comment period.

Most commenters expressed support for the general revisions to the 1988 UST and SPA regulations. They supported updating the regulations because technology has changed a great deal since the 1980s. Many commenters provided specific concerns on particular topics in the 2011 proposed UST and SPA regulations. We discuss these comments throughout the preamble for this action. Several commenters opposed the changes to the regulations due to concerns about potential costs on owners, especially small businesses. A few commenters requested EPA withdraw the entire proposal and conduct a small business advocacy review panel under the Regulatory Flexibility Act. EPA carefully considered the potential impacts of the proposal on small businesses and determined that a small business panel was not required. EPA also considered all of the comments submitted during the public comment period, including those concerns regarding the potential costs on small businesses, and worked to minimize those costs by making certain changes to the final regulations. EPA did not change this final UST and SPA regulations when comments were beyond the scope of the regulations or beyond EPA's statutory authority.

E. Implementation Timeframe

This final UST regulation aligns the implementation time frames for the new operator training, operation and maintenance, and previously deferred UST system requirements. The table below provides the implementation time frames for each of the new requirements.

IMPLEMENTATION TIME FRAMES FOR NEW REQUIREMENTS

New requirement	Implementation time frame
Flow restrictors in vent lines may no longer be used to meet the overfill prevention requirement at new installations and when an existing flow restrictor is replaced. Testing following a repair Closure of internally lined tanks that fail the internal lining inspection and cannot be repaired according to a code of practice. Notification of ownership changes. Demonstrating compatibility. For airport hydrant fuel distribution systems and UST systems with field-constructed tanks: • Notification and financial responsibility.[9] • Release reporting. • Closure.	Owners and operators must begin meeting these requirements on the effective date of this final UST regulation.
Operator training For previously deferred UST systems: • Subpart D for UST systems that store fuel solely for use by emergency power generators • Subpart K (except notification, financial responsibility, release reporting, and closure) for airport hydrant fuel distribution systems and UST systems with field-constructed tanks.	Owners and operators must begin meeting these requirements three years after the effective date of this final UST regulation.
Spill prevention equipment testing Overfill prevention equipment inspections Containment sump testing for sumps used for piping interstitial monitoring Release detection equipment testing. Walkthrough inspections.	Owners and operators must conduct the first test or inspection within three years after the effective date of this final UST regulation.

EPA proposed different implementation time frames for the various requirements, and for several requirements, a phased in approach based on tank age. Based on commenter input, EPA is not using the phased in approach and instead is requiring owners and operators to meet the requirements as described in the implementation table above. In addition, with one exception EPA is aligning implementation of the requirements in this final UST regulation to begin on the effective date of the UST regulation or three years after the effective date of the UST regulation. The requirements implemented on the effective date of the final UST regulation are those that either do not require significant education and outreach or apply to new installations, repairs, or releases. EPA is allowing up to three years for owners and operators to implement the requirements that require significant outreach, equipment to be upgraded or installed (such as for previously deferred UST systems), or scheduling and testing. Three years allows ample time for implementing agencies to educate owners and operators about this new requirements and allows owners and operators to schedule testing. The exception to implementing the requirements immediately or in three years is that EPA is implementing the secondary containment requirement 180 days after the effective date of the UST regulation. The 180 day time frame allows flexibility for those owners and operators who have concrete plans but have not yet applied for or obtained approvals or permits for a new UST system installation.

IV. Revisions to the Requirements for Owners and Operators of Underground Storage Tank Systems

The following sections describe this final UST regulation, starting with establishing new requirements for operator training and secondary containment. The next four sections

[9] Note that EPA is requiring owners and operators to also submit a one-time notification of existence for these UST systems within 3 years of the effective date of this final UST regulation. Owners and operators must demonstrate financial responsibility when they submit the one-time notification form

address changes to the 1988 UST regulation, organized by topic: Additional requirements for operation and maintenance; addressing UST systems deferred in the 1988 UST regulation; other changes to improve release prevention and release detection; and general updates to the 1988 UST regulation. Finally, there is a section describing alternative options considered.

A. Establishing Federal Requirements for Operator Training and Secondary Containment

1. Operator Training

This final UST regulation adds a new subpart J, which contains operator training requirements to ensure properly trained individuals operate all regulated UST systems. The operator training provision of the Energy Policy Act of 2005 requires implementing agencies, as a condition of receiving federal Subtitle I money, develop state-specific training requirements for three classes of UST system operators. EPA issued grant guidelines that provide minimum requirements state operator training programs must include in order for states to continue receiving federal Subtitle I money.[10] All states are implementing or plan to implement operator training. The EPAct did not specifically require operator training in Indian country. To bring UST systems in Indian country to the same level of protection as UST systems in states, this final UST regulation implements operator training requirements.

This final UST regulation closes the gap in coverage and ensures all operators designated as Class A, B, or C operators are trained according to their level of responsibility. Sufficiently training designated UST operators will increase compliance with regulatory requirements. In addition, operator training should decrease UST system releases by educating Class A, B, and C operators about their UST system requirements and result in greater protection of human health and the environment.

The operator training requirements in this final UST regulation are consistent with the requirements in EPA's operator training grant guidelines for states. In both, EPA establishes minimum operator training requirements, yet allows flexibility to tailor training programs for specific needs. This means that although there may be variations among operator training programs, all Class A, B, and C operators will have a minimum level of knowledge about their UST system requirements.

Definitions

EPA is adding definitions for the three operator classes requiring training to distinguish them from the term operator originally defined in the 1988 UST regulation and maintained in this final UST regulation. Only if Class A, B, or C operators meet the definition of operator will they be subject to the same responsibilities and liabilities as an operator. EPA's definitions of Class A, B, and C operators do not relieve UST system owners and operators from legal responsibility for complying with the UST regulation. EPA based the three operator class definitions on duties each typically perform at UST facilities. Commenters on the 2011 proposed UST regulation indicated this final UST regulation should further differentiate Class A, B, and C operators from EPA's definition of operator. EPA agrees with commenters and is changing the title of § 280.241 to *Designation of Class A, B, and C operators* in the final UST regulation. This change correctly identifies the individuals who must be designated.

With the exception of the definition for the Class C operator, the operator class definitions remain unchanged from the 2011 proposed UST regulation. Several commenters pointed out that UST system owners and operators were, at the time of the 2011 proposed UST regulation, using contractors to perform Class C operator functions. Some commenters believed EPA was restricting the use of a contractor as a Class C operator since the proposal required a Class C operator to be an employee. EPA agrees; we are removing the restriction. EPA does not intend for the operator training requirements to restrict UST system owners and operators who are using contractors to operate their UST systems.

EPA added a definition for training program in the 2011 proposed UST regulation; we are modifying it in this final UST regulation. It is important that training programs for Class A, B, and C operators include both sharing information and evaluating knowledge. Several commenters requested clarification on how EPA expected knowledge to be verified. To address these requests, EPA changed the definition of training program by adding the phrase *''through testing, practical demonstration, or another approach acceptable to the implementing agency.''* This addition clarifies the definition and makes it consistent with how the term is used in this final UST regulation.

How Operators Are Designated

This final UST regulation indicates how UST owners and operators are to designate the three operator classes for their facilities. UST owners and operators must designate at least one Class A and B operator at each facility. Class A and B operators may provide training to Class C operators, which should help UST owners and operators comply with this requirement. The UST owner and operator must ensure Class C operator training is documented.

Because Class C operators' duties typically require them to provide initial responses to emergencies, individuals who meet the Class C operator definition must be designated as such and trained in UST system emergency response—for example response to release detection alarms, spills, or releases. EPA received several comments on the 2011 proposed UST regulation requesting we require only one Class C operator be designated. The final UST regulation requires all individuals who meet the definition of Class C operator be trained. EPA maintains that the initial response to emergencies provided by this operator class is important to environmental protection. Requiring training for all individuals who meet the Class C operator definition will increase the likelihood UST system emergencies are quickly and appropriately addressed. This does not mean all workers need to be trained. For example, numerous workers at convenience stores do not control or monitor dispensing or sale of petroleum products, nor are they responsible for initial alarms. As a result, it is unnecessary to designate and train these individuals to meet Class C operator training requirements.

In addition, EPA acknowledges some readers might misinterpret that control of the dispensing operation described in the definition of the Class C operator applies to anyone fueling a vehicle. The level of UST system control and responsibility of individuals who must be trained excludes customers who are pumping product into their vehicles. For example, police officers using an unmanned facility would not have to meet Class C operator training requirements unless they are responsible, as specifically tasked by UST system owners and operators, to respond to emergencies and alarms caused by spills or releases from the UST system.

In the preamble to the 2011 proposed UST regulation, EPA acknowledged that many UST owners and operators might

[10] Grant Guidelines To States For Implementing The Operator Training Provision Of The Energy Policy Act Of 2005: *www.epa.gov/oust/fedlaws/optraing.htm.*

want to designate one person at an UST facility to fulfill more than one class of operator. This final UST regulation allows one person to serve in multiple operator classes; however, that person must be trained for each class designated.

EPA is aware owners and operators rely on contractors to perform various UST system tasks, including those of Class A, B, and C operators. Because of the current use of contractors, EPA is allowing UST owners and operators to designate contractors as their Class A, B, and C operators, as long as they are trained in all areas for the class of operator designated. UST owners and operators must maintain documentation containing individual names (not just company names) of Class A, B, and C operators. This will allow implementing agencies to use individual names, rather than company names, when verifying training, retraining, and refresher training.

Who Must Be Trained

This final UST regulation requires training for designated Class A, B, and C operators at UST systems regulated under Subtitle I. This includes UST systems at attended and unattended facilities. An unattended UST facility means a Class A, B, or C operator might not be present when a facility is operating. Nonetheless, even for unattended UST facilities, owners and operators must designate and train Class A, B, and C operators.

Requirements for Operator Training

In the operator training grant guidelines for states, EPA based the three operator classes on duties each typically perform at UST facilities. Building on that, this final UST regulation requires each person designated in an operator class to participate in a specific training program or pass an examination comparable to the training program.

- For Class A operators, the training program must teach and evaluate their knowledge to make informed decisions regarding compliance and determine whether appropriate people are performing the operation, maintenance, and recordkeeping requirements for UST systems.
- For Class B operators, the training program must teach and evaluate their knowledge and skills to implement UST regulatory requirements on typical UST system components or site-specific equipment at UST facilities.
- For Class C operators, the training program must teach and evaluate their knowledge to take appropriate action, including notifying appropriate authorities, in response to emergencies or alarms caused by spills or releases from UST systems.
- For all operator classes, the test is based on the training program and evaluates the minimum knowledge required for the operator class.

EPA received several comments on the description of Class C operator training requirements. One commenter suggested EPA should clarify the scope of emergencies a Class C operator is trained on. This final UST regulation requires Class C operators receive training on emergencies or alarms caused by spills or releases from operating UST systems. EPA also agrees with the comment regarding Class C operator training avoiding triggering the Hazardous Waste Operations and Emergency Response (HAZWOPER) standard. HAZWOPER is the United States' recognized standard of safety requirements employers and their subcontractors or public sector responders must meet in order to conduct cleanups or emergency response operations. The level of training in this standard is beyond that which EPA intends for Class C operators. This final UST regulation modifies the training requirements for Class C operators and clarifies that appropriate actions Class C operators can take include notifying appropriate authorities.

For each class of operator, EPA considered developing specific training curricula prescribing length of training, topic areas, and trainer qualifications. Instead, this final UST regulation provides general criteria and requirements, because they provide flexibility while ensuring each class of operator is trained in a way that is comparable to EPA's operator training grant guidelines for states. EPA also modified the lists of training requirements for Class A and B operators from those identified in the 2011 proposal. The modifications made it clearer that new operation and maintenance inspection and testing, and compatibility demonstration requirements must be covered by operator training programs and comparable examinations.

EPA received several comments regarding restrictions on who may develop and administer the evaluation component of training, as well as restrictions on who may train Class A and B operators. This final UST regulation removes those restrictions because they could prohibit in-house and other potentially viable training. EPA supports a variety of operator training approaches. However, for retraining, EPA is revising language in § 280.244 to address conflicts of interest. This final UST regulation requires the training program or comparable examination to be developed or administered by an independent organization, the implementing agency, or a recognized authority. These retraining restrictions will help address any ineffective training approaches.

This final UST regulation allows a variety of ways to train operators, including classroom, computer based, hands on, and any combination of these. In lieu of completing a training program, Class A, B, or C operators can pass a comparable examination—such as classroom, Internet, or computer based—that meets the requirements for operator training described in this final UST regulation.

When Designated Operators Must Complete Operator Training

This final UST regulation requires UST owners and operators ensure all Class A, B, and C operators successfully complete a training program or a comparable examination within three years of the effective date of this final UST regulation. EPA proposed a phased in approach over three years, based on UST installation dates because older USTs potentially pose a greater risk to the environment and Class A, B, and C operators of those systems should be trained first. EPA received comments strongly indicating EPA should not phase in the operator training requirements. EPA agrees with commenters that it is less confusing to establish a single compliance date for this requirement. EPA is aligning implementation of operator training with the three year inspection requirement, which will make it easier for UST system owners and operators to comply.

Consistent with EPA's operator training grant guidelines, new operators designated after the three year implementation period must be trained as follows:

- Class A and B operators must be trained within 30 days of assuming duties
- Class C operators must be trained before they assume their duties because they must be able to immediately respond to emergencies

Retraining

Class A and B operators are responsible for ensuring their UST systems are compliant. Generally, Class A and B operators need to be retrained if the UST systems they are responsible for are determined to be out of compliance. At a minimum, retraining must cover those areas the

implementing agency determines are out of compliance. Retraining must be completed within 30 days of the implementing agency's final determination of noncompliance. This final UST regulation allows designated operators to take annual refresher training in lieu of retraining, as long as all training areas required by regulation are covered. Designated operators must be subject to the annual refresher training in place at the time of the violation.

This final UST regulation also allows implementing agencies to waive the retraining requirement. Unless waived, Class A and B operators must complete retraining according to § 280.244. EPA recommends the waiver be in writing. In waiving the requirement, EPA expects the implementing agency to consider factors such as the severity and areas of noncompliance. For example, retraining should not be required for equipment found inoperative during an inspection if one of the following apply: The owner and operator was unaware of the problem and operation and maintenance records indicate the equipment was operating during the most recent test or inspection; or the owner or operator is aware of the problem and has scheduled a timely repair. In those instances where UST system noncompliance violations do not warrant retraining, EPA encourages implementing agencies to provide information about the compliance issue to Class A and B operators so they are able to return their facilities to compliance. This provides greater flexibility for UST owners and operators to meet the retraining requirement. This final UST regulation is consistent with EPA's retraining requirement for noncompliance with significant operational compliance requirements and an annual refresher training allowance in our operator training grant guidelines for states.

This final UST regulation addresses comments about the terms independent trainer and independent organization in the retraining requirement at § 280.244. In this section, EPA is requiring that a training program or comparable examination be developed, administered, or both by an independent organization, the implementing agency, or recognized authority. A recognized authority includes, but is not limited to, tribes recognized by the U.S. Department of Interior Bureau of Indian Affairs. The development, administration, or both by an independent organization applies to all training approaches (classroom, Internet based, testing, etc.) and provides sufficient control for the implementing agency to address conflict of interest and other concerns during retraining.

EPA considered requiring retraining when UST facilities change equipment, but decided this would be a significant burden on both the regulated community and implementing agencies. However, if an UST system is out of compliance because of an equipment change, EPA is requiring that UST owners and operators ensure Class A and B operators are retrained as discussed above.

Documentation

This final UST regulation requires owners and operators maintain records on currently designated Class A, B, and C operators, rather than records on all Class A, B, and C operators for the previous three years, as proposed. EPA is requiring owners and operators maintain basic information to document Class A, B, and C operators and confirm they are appropriately trained. For example, classroom training records must be signed by the trainer and include information about the training company; computer based training records do not require a signature, but must indicate the name of the training program and the Web address, if Internet based. This final UST regulation also modifies § 280.245(b)(1) by clarifying that the requirement for a record of training is also applicable when Class A or B operators train Class C operators. UST owners and operators must document verification of training or retraining for each class of operator. Owners and operators must maintain records verifying training or retraining as long as Class A, B, and C operators are designated at the facility.

2. Secondary Containment

This final UST regulation adds new requirements for secondary containment and interstitial monitoring of new and replaced tanks and piping along with under-dispenser containment (UDC) of new dispenser systems. Data from release sites show a higher number of releases from single walled tanks and piping when compared to secondarily contained systems.[11] [12] These new requirements will prevent regulated substances from reaching the environment and ensure a consistent level of environmental protection for regulated UST systems across the United States.

The Energy Policy Act of 2005 requires implementing agencies, as a condition of receiving federal Subtitle I money, implement additional measures to protect groundwater. Under EPAct, implementing agencies' choices to protect groundwater are: Secondary containment (including UDC); or financial responsibility for manufacturers and installers (and installer certification). All states are implementing or plan to implement secondary containment. The EPAct did not specifically require additional measures to protect groundwater in Indian country. To bring UST systems in Indian country to the same level of environmental protection as UST systems in states, this final UST regulation implements secondary containment requirements for new and replaced tanks and piping along with UDC underneath all new dispenser systems.

The EPAct requires states that receive federal Subtitle I money (and choose the secondary containment option) to have secondary containment and UDC for tanks, piping, and dispensers only if they are installed or replaced within 1,000 feet of an existing community water system or potable drinking water well.[13] However, EPA is requiring all new and replaced tanks and piping to install secondary containment and new dispenser systems to install UDC for these reasons:

- Nearly all new and replaced tanks and piping are installed within 1,000 feet of an existing community water system (CWS) or potable drinking water well (PDWW). An UST listed with a commercial ownership type (*i.e.,* gas station) is typically located within 1,000 feet of an on-site well or public water line because nearly all commercially-owned facilities with USTs require water utilities in order to operate. In addition, privately owned facilities (*i.e.,* fleet fueling for non-marketers) are generally in close proximity to some type of water supply, given that these sites are typically combined with other functional operations (office, maintenance, manufacturing, etc.) and require water for restrooms, water fountains, shops, etc.; [14]
- Some implementing agencies that require secondary containment only

[11] *Petroleum Releases At Underground Storage Tank Facilities In Florida,* Peer Review Draft, US EPA/OUST, March 2005.

[12] *Evaluation Of Releases From New And Upgraded Underground Storage Tanks,* Peer Review Draft, US EPA/OUST, August 2004.

[13] Title XV, Subtitle B, Section 1530 of Energy Policy Act of 2005, Public Law 109–58, August 8, 2005.

[14] E², Incorporated, memoranda and analyses submitted under Contract EP–W–05–018, U.S. Environmental Protection Agency. *Underground Storage Tanks/Leaking Underground Storage Tanks Analytical And Technical Support.* These supporting materials are located in the docket EPA–HQ–UST–2011–0301.

within 1,000 feet of a CWS or PDWW informed EPA that installations of single walled tanks or piping are not occurring; and

• Secondary containment for all new and replaced tanks and piping along with UDC for new dispenser systems will help protect other sensitive areas, such as designated source water protection areas, natural springs, and surface waters.

The EPAct requires under-dispenser containment underneath new motor fuel dispenser systems at UST systems regulated under 40 CFR part 280. However, EPA is aware of a small number of dispenser systems, such as kerosene dispensers, that do not dispense motor fuel. Small releases can occur at these dispensers in the same manner as they occur at motor fuel dispensers.[15] [16] [17] Therefore, this final UST regulation requires owners and operators install UDC underneath new dispenser systems at UST systems regulated under 40 CFR part 280, irrespective of whether they dispense motor fuel.

The secondary containment requirement applies to new or replaced underground tanks and piping regulated under Subtitle I, except those excluded by regulation in § 280.10(b) and those partially excluded by regulation in § 280.10(c). Petroleum and hazardous substance USTs must meet the secondary containment requirement with the corresponding use of interstitial monitoring for release detection. The 1988 UST regulation allowed variances to the use of interstitial monitoring as the method of release detection for hazardous substance USTs. Since these variances are no longer an option, EPA is removing the language allowing variances for new installations from this final UST regulation.

EPA is requiring owners and operators install tank and piping secondary containment that: Will contain regulated substances leaked from the primary containment until they are detected and removed; will prevent the release of regulated substances to the environment at any time during the operational life of the UST system; and is monitored for a leak at least once every 30 days using interstitial monitoring. These requirements are consistent with the requirements for secondarily contained hazardous substance tanks in § 280.42 and are necessary to help prevent releases to the environment.

EPA is not requiring secondary containment for piping that meets the requirements of § 280.41(b)(2)(i) through (v), sometimes called safe suction piping, because such piping is currently not required to meet release detection requirements. Safe suction piping uses a suction pump to deliver regulated substances from the UST to the dispenser. Safe suction piping operates at less than atmospheric pressure, slopes towards the UST so regulated substances drain to the UST if suction is lost, and has only one check valve located close to the suction pump. As discussed in the 1988 UST regulation preamble, these characteristics ensure that little, if any, regulated substances will be released if a break occurs in the line.[18] Similarly, EPA considers piping that manifolds two tanks together, which has characteristics that allow product to drain to the manifolded tanks if the piping loses suction, the same as safe suction piping. In addition, this final UST regulation does not require secondary containment for new and replaced piping associated with field-constructed tanks greater than 50,000 gallons in capacity and airport hydrant fuel distribution systems. See section C–2 for additional information about these types of UST systems.

EPA is not requiring secondary containment and UDC for UST systems where installation began on or before 180 days after the effective date of this final UST regulation. 180 days allows owners and operators who have concrete plans for a new UST system or dispenser installation to move forward with their plans before the secondary containment and UDC requirement takes effect. Similar to the definition of existing tank system in the 1988 UST regulation, EPA considers an installation to have begun after the owner or operator applied for or obtained all federal, state, and local approvals or permits and:

• Physical construction or installation began; or

• The owner or operator entered into a contractual agreement that cannot be cancelled or modified without substantial loss and physical construction or installation will commence within a reasonable time frame.

Requiring retrofits of major components would be a significant financial burden for owners and operators. EPA anticipates owners and operators will replace single walled UST systems as they age. When owners and operators replace single walled UST systems after the effective date of the final UST regulation, tanks and piping must be secondarily contained and new dispensers must have UDC.

To implement secondary containment and UDC, EPA is adding new definitions to this final UST regulation. EPA is defining these terms so they are consistent with the definitions contained in EPA's secondary containment grant guidelines to implementing agencies.[19] New definitions in the final UST regulation are:

• Dispenser—This means equipment located aboveground that dispenses regulated substances from the UST system. The 2011 proposed UST regulation defined dispenser system. However, based on comments received, EPA decided to also add the definition of dispenser to the final UST regulation.

• Dispenser system—This means the dispenser and the equipment necessary to connect the dispenser to the UST system. As described above, EPA decided to add dispenser to the list of definitions in the final UST regulation for clarity. As a result, EPA shortened the definition of dispenser system in the final UST regulation to account for the new definition of dispenser.

• Replaced—For a tank, this means to remove a tank and install another tank. For piping, it means to remove 50 percent or more of piping and install other piping, excluding connectors, connected to a single tank. For tanks with multiple piping runs, this definition applies independently to each piping run. Commenters suggested adding a definition of replaced as it applies to a dispenser system. However, since EPA is only applying the UDC requirement to new dispenser systems, we are not defining the term replaced as it relates to dispenser systems.

• Secondary containment or secondarily contained—This means a release prevention and release detection system for a tank or piping. This system has an inner and outer barrier with an interstitial space that is monitored for leaks. This term includes containment sumps when used for interstitial monitoring of piping. The EPAct defines secondary containment as a release

[15] Petroleum Releases At Underground Storage Tank Facilities In Florida, Peer Review Draft, US EPA/OUST, March 2005.

[16] *Evaluation Of Releases From New And Upgraded Underground Storage Tanks,* Peer Review Draft, US EPA/OUST, August 2004.

[17] *Frequency And Extent Of Dispenser Releases At Underground Storage Tank Facilities In South Carolina* (EPA–510–R–04–004, September 2004). *http://epa.gov/oust/pubs/dispenser.htm.*

[18] Preamble to 40 CFR part 280, 53 FR 37154, September 23, 1988.

[19] Grant Guidelines to States for Implementing the Secondary Containment Provision of the Energy Policy Act of 2005: *http://epa.gov/oust/fedlaws/secondco.htm.*

detection and prevention system that meets the interstitial monitoring requirement in § 280.43(g). Based on this definition, this final UST regulation includes interstitial monitoring as part of the secondary containment definition. Consistent with the 1988 UST regulation release detection requirements, EPA is requiring interstitial monitoring of new and replaced secondarily contained tanks and piping to occur at least once every 30 days. Some commenters expressed concern about whether secondary containment included containment sumps. To clarify the definition, EPA is adding language about containment sumps to the secondary containment definition. In addition, EPA is defining containment sump in this final UST regulation. See section B–4, Secondary Containment Tests, for details about this new definition. Several commenters suggested EPA add to the definition of secondary containment a 360 degree containment requirement for tanks. EPA relies on codes of practice developed by nationally recognized associations or independent testing laboratories to determine the degree of containment necessary to be considered secondarily contained. This final UST regulation continues to rely on these codes of practice for determining when the tanks and piping are considered secondarily contained.

- Under-dispenser containment—This means containment underneath a dispenser system designed to prevent leaks from the dispenser and piping within or above the UDC from reaching soil or groundwater. Based on comments received and to provide clarification, EPA is adding piping in the containment sump to the definition.

EPA's secondary containment grant guidelines provide states with significant flexibility to define replaced as it applies to piping. The guidelines require that states, at a minimum, consider replacing piping when 100 percent of piping, excluding connectors, connected to a single UST is removed and other piping is installed. When deciding how to best define replaced as it applies to piping, EPA analyzed state UST regulations for approximately 40 states that currently require secondary containment and interstitial monitoring.[20] About 75 percent of these states have requirements as stringent as, or more stringent than, the 50 percent threshold in this final UST regulation.

In addition, EPA performed a screening analysis using limited, readily available data to determine when repair cost approached replacement cost (and at what point owners and operators were most likely to replace the entire piping run rather than repair it).[21] The screening analysis suggested replacement cost of an entire piping run became equal to repair cost when about 60 percent of a piping run is repaired. Since 60 percent was an approximate screening number, EPA in this final UST regulation is requiring owners and operators to secondarily contain the entire piping run when 50 percent or more of a piping run is replaced. Fifty percent represents half of a piping run, is consistent with most implementing agency decisions, and provides flexibility for allowing repairs while continuing to protect the environment. Fifty percent also prevents owners and operators from leaving small pipe sections in the ground to avoid this secondary containment requirement. If an UST has multiple piping runs, the secondary containment requirement applies independently to each piping run where 50 percent or more of piping is replaced. Currently installed piping runs, and piping runs where less than 50 percent of the piping is repaired, do not require secondary containment.

For pressurized piping, EPA considers a piping run to be the piping that connects the submersible turbine pump (STP) to all of the dispensers fed by that pump. For example, if a tank has two STPs, EPA considers the piping associated with each STP to be separate piping runs. For suction piping, a piping run is the piping that runs between the tank and the suction pump.

Consistent with EPA's current policy, if an owner or operator chooses to reinstall a secondarily contained tank or piping that was previously installed, that tank or piping must meet new tank and piping standards in § 280.20 at the time of installation.

EPA is requiring owners and operators install UDC underneath new dispenser systems at UST systems regulated by 40 CFR part 280. Data from release sites show dispensers are one of the leading release sources.[22] [23] UDC is located underground and prevents some releases by containing small leaks that occur inside and underneath the dispenser. EPA considers a dispenser system new when owners and operators install both the dispenser and equipment needed to connect the dispenser to an UST system. EPA includes check valves, shear valves, unburied risers or flexible connectors, and other transitional components as equipment that connects a dispenser to an UST system. This equipment is located underneath the dispenser and typically connects underground piping to a dispenser. If an owner or operator replaces a dispenser but uses existing equipment to connect a dispenser to the UST system, then UDC is not required.

To contain small releases from the dispenser, piping, and other equipment, UDC must be liquid tight. This final UST regulation requires UDC be liquid tight on its sides, bottom, and at any penetrations through the containment. EPA is requiring periodic testing of UDC in section B–4, Secondary Containment Tests, if the UDC is used for piping interstitial monitoring. In addition, EPA is requiring annual inspections of containment sumps in section B–1, Walkthrough Inspections, including UDC. Finally, an owner or operator must be able to access and visually inspect the containment. If visual inspection and access are not possible, then owners and operators must periodically monitor UDC (*i.e.,* by electronic monitoring) to ensure it is intact and free of liquids. EPA proposed continuous UDC monitoring if visual inspection and access of the UDC are not possible. However, in guidance to state UST programs about meeting the secondary containment provision of the EPAct, EPA did not require continuous monitoring. Therefore, to provide owners and operators additional flexibility and be consistent with guidance provided to states, this final UST regulation requires periodic monitoring of UDC if access to and visual inspection of the UDC are not possible.

B. Additional Requirements for Operation and Maintenance

The 1988 UST regulation required owners and operators install improved UST system equipment to detect and prevent releases; however, it did not require operation and maintenance for all of that equipment. Owners and operators need to properly operate and maintain their UST system equipment in order to prevent and quickly detect releases. Therefore, this final UST regulation adds requirements for periodic walkthrough inspections, spill prevention equipment testing, overfill

[20] E², Incorporated, memoranda and analyses submitted under Contract EP–W–05–018, U.S. Environmental Protection Agency. *Underground Storage Tanks/Leaking Underground Storage Tanks Analytical And Technical Support.* These supporting materials are located in the docket EPA–HQ–UST–2011–0301.

[21] Industrial Economics Incorporated, Work Assignment #1–19, *Methodology and Calculator for Secondary Containment for Piping,* October 3, 2008.

[22] *Petroleum Releases At Underground Storage Tank Facilities In Florida,* Peer Review Draft, US EPA/OUST, March 2005.

[23] *Evaluation Of Releases From New And Upgraded Underground Storage Tanks,* Peer Review Draft, US EPA/OUST, August 2004.

prevention equipment inspections, containment sump testing, and release detection equipment testing.

When a test or inspection occurs, owners and operators may find problems with the UST system. When a test or inspection indicates a problem, owners and operators must repair the problem to remain in compliance with this final UST regulation. Section 280.33 of this final UST regulation describes repair requirements for UST systems.

1. Walkthrough Inspections

To help EPA determine whether walkthrough inspections will be effective, EPA asked nine states with requirements for periodic walkthrough inspections whether their requirements are effective.[24] Seven states believe their programs are effective. Two states did not provide input because they had not been implementing their walkthrough inspection programs long enough to evaluate effectiveness. States providing input indicated their walkthrough inspections: Identify and resolve problems more quickly; decrease the chance of a potential spill or release; and increase understanding and compliance with the UST regulation. Based on this information and input received from comments on the 2011 proposed UST regulation, EPA thinks walkthrough inspections will be effective in helping prevent and detect releases.

Based on comments EPA received, this final UST regulation requires owners and operators conduct walkthrough inspections as follows:

- Every 30 days:
  - Visually check spill prevention equipment for damage and remove liquid or debris; check for and remove obstructions in the fill pipe; check the fill cap to ensure it is securely on the fill pipe; and, for double walled spill prevention equipment with interstitial monitoring, check for a leak in the interstitial area (exception: Owners and operators of spill prevention equipment at UST systems receiving deliveries at intervals greater than 30 days may check that equipment prior to each delivery)
  - Check release detection equipment to ensure it is operating with no alarms or unusual operating conditions present and ensure release detection records are reviewed and current
- Annually:
  - Visually check containment sumps for damage and leaks to the containment area or releases to the environment; remove liquid (in contained sumps) or debris; and, for double walled containment sumps with interstitial monitoring, check for a leak in the interstitial area
  - Check hand held release detection equipment, such as groundwater bailers and tank gauge sticks, for operability and serviceability

In addition, this final UST regulation allows owners and operators to conduct operation and maintenance walkthrough inspections according to a standard code of practice developed by a nationally recognized association or independent testing laboratory or according to requirements developed by the implementing agency. The inspections must check equipment in a manner comparable to the walkthrough inspection requirements described above.

This final UST regulation requires owners and operators maintain walkthrough inspection records for one year. Most commenters supported a one year recordkeeping requirement for walkthrough inspections. In addition, the one year recordkeeping time frame is consistent with the recordkeeping requirement for 30 day release detection monitoring. The walkthrough inspection record must include a list of each area checked, whether each area checked was acceptable or needed action taken, a description of actions taken to correct an issue, and delivery records if owners and operators check spill prevention equipment less frequently than every 30 days.

In 2011, EPA proposed to implement the walkthrough inspection requirement on the effective date of the final UST regulation. However, based on comments received and to align implementation of all operation and maintenance requirements, owners and operators must begin conducting walkthrough inspections not later than three years after the effective date of this final UST regulation. This change will make compliance easier and allow owners and operators ample time to understand their walkthrough inspection responsibilities.

In 2011, EPA proposed requiring owners and operators inspect containment sumps once every 30 days. Many commenters were concerned about inspecting containment sumps every 30 days because of the physical burdens of lifting heavy lids, the potential to ruin seals that prevent water from entering the sump, and the safety of the people performing the inspection in high traffic areas. While EPA thinks frequent containment sump inspections are a valuable part of UST system operation and maintenance, EPA recognizes the concerns raised by commenters and is moving the requirement to conduct containment sump inspections from once every 30 days to annual, which coincides with when owners and operators must open containment sumps to test release detection equipment.

In the 2011 proposed UST regulation, EPA required that hand held release detection equipment be inspected once every 30 days. Based on commenter input, this final UST regulation requires annual inspections of hand held release detection equipment to coincide with other release detection equipment operation and maintenance requirements.

In the 2011 proposed UST regulation, EPA required 30 day cathodic protection inspections as part of the walkthrough inspection. Several commenters indicated this frequency conflicted with the 60 day requirement already in the 1988 UST regulation. Based on this input, this final UST regulation keeps cathodic protection inspections at the 60 day interval as required in the 1988 UST regulation. Therefore, owners and operators must continue to perform the 60 day impressed current cathodic protection inspections to ensure equipment is running properly and keep the most recent three records of those inspections.

The 2011 proposed UST regulation required checking monitoring and observation wells every 30 days to make sure they are secure. A few commenters questioned the need to perform these inspections because owners and operators seldom access these wells unless they are used for release detection or cleanup. EPA agrees with these commenters and also thinks that owners and operators will secure monitoring wells following each 30 day release detection monitoring event or during cleanups as part of their normal compliance activities. Therefore, EPA is not including monitoring and observation wells as part of the periodic walkthrough inspection requirement in this final UST regulation.

EPA received several comments on the 2011 proposed UST regulation recommending treating nonretail UST systems differently than traditional commercial UST facilities because some nonretail UST systems receive infrequent deliveries. Based on the comments, this final UST regulation allows additional flexibility for inspecting spill prevention equipment at UST systems where filling occurs infrequently. In cases where filling activities occur less often than 30 days, owners and operators may inspect spill

[24] Work Order No. 1004, Task 2, Subtask a—*State Walkthrough Underground Storage Tank Inspections,* SKEO, 1/31/2013

prevention equipment prior to each delivery, instead of at least once every 30 days. This exception to the spill prevention equipment check for the 30 day walkthrough inspection requirement will still provide appropriate environmental protection because the purpose of this equipment is to catch drips and spills that may occur when the delivery hose is disconnected from the fill pipe. For UST systems receiving infrequent deliveries, inspecting spill prevention equipment before each delivery is adequate.

This final UST regulation retains 30 day inspections of release detection equipment and spill prevention equipment. EPA thinks these inspections are needed at least once every 30 days for release detection to ensure the equipment is operating, check release detection records, and determine whether the tank or piping is leaking. Owners and operators who monitor their release detection system remotely may check the release detection equipment and records remotely as long as the release detection system at the UST system location is determined to be in communication with the remote monitoring equipment. In addition, 30 day inspections (or before each delivery) of spill prevention equipment will ensure these devices contain small drips and spills that occur when the delivery hose is disconnected from the fill pipe. Based on commenter input, EPA is adding the requirement to check for and remove obstructions in the fill pipe as part of the walkthrough inspection because obstructions in the fill pipe will cause a shutoff device to operate improperly.

EPA is including Petroleum Equipment Institute's Recommended Practice 900, *Recommended Practices for the Inspection and Maintenance of UST Systems,* as a code of practice that may be used to meet the walkthrough inspection requirement in this final UST regulation.[25] This recommended practice includes daily, monthly, and annual inspections for properly maintaining underground storage tank systems. Owners and operators who use the code of practice option for meeting UST requirements must use the entire code of practice. For example, owners and operators would not meet the walkthrough inspection requirement if they chose to follow only some of the walkthrough inspection areas in the code of practice while ignoring others.

This final UST regulation allows flexibility for owners and operators to conduct walkthrough inspections themselves or hire a third party to conduct walkthrough inspections. Although EPA does not require training for owners and operators who conduct these inspections, operators trained in the Class A or B training requirements (see section A–1) should already have adequate knowledge to perform periodic walkthrough inspections.

EPA received multiple comments suggesting we revise the 30 day inspection requirement to be a monthly requirement. After careful consideration, EPA is keeping the 30 day inspection requirement. Thirty days provides owners and operators with clarity about the inspection time frame by specifying the maximum number of days between walkthrough inspections. EPA is not moving to monthly inspections because owners and operators could misinterpret monthly and go 60 or more days without conducting a walkthrough inspection. For example, an owner or operator could perform a monthly inspection on January 31, then again on February 1, and then not inspect again until March 31. If an owner or operator continued this practice, six inspections would occur one day apart and six inspections would occur about 60 days apart. While this could be considered inspecting monthly, it is not inspecting consistently on or about the same time each month. EPA wants to ensure the walkthrough inspection frequency is consistent, rather than allow the more inconsistent monthly option in this example. Since 30 days is the average length of a month, EPA's intent with requiring 30 days is to ensure owners and operators conduct walkthrough inspections on or about the same time each month.

Some commenters raised concern about disposing of liquids owners and operators discover during the inspection. For spill prevention equipment and containment sumps to operate as intended, those areas must be free of liquids. In the past, when owners and operators found liquids in those areas, they needed to remove the liquids so the equipment would operate properly (and meet the 1988 UST regulation). This final UST regulation is requiring those areas be inspected periodically; as a result, owners and operators may discover the liquid sooner, but the responsibility to remove the liquid remains the same. EPA expects owners and operators to remove, manage, and dispose of the liquid properly (according to federal, state, and local requirements) as soon as practicable after discovery.

2. Spill Prevention Equipment Tests

In this final UST regulation, EPA is adding a three year testing requirement for spill prevention equipment. This action helps ensure spill prevention equipment will contain small drips and spills when the delivery transfer hose is disconnected from the fill pipe. Owners and operators need to properly operate and maintain their spill prevention equipment in order to prevent releases to the environment. If a small release occurs at the fill port and the spill prevention equipment is not liquid tight, then the release can exit the spill prevention equipment and reach the environment. EPA is aware of various problems with spill prevention equipment. Data show that UST spills account for about 15 percent of releases from UST systems.[26] [27] Examples of problems with spill prevention equipment include damage due to: Vehicles driving over the spill prevention equipment; ground movement or freeze and thaw cycles; inadequate installation practices; and normal wear and tear. In addition, the typical life of spill prevention equipment is relatively short—five to eight years according to a South Carolina study.[28] [29] The life span for spill prevention equipment can be even shorter when exposed to more severe weather conditions such as freeze and thaw cycles and plowing following snow events. Because of these factors, periodic spill prevention equipment testing is needed to minimize problems and ensure spill prevention equipment will contain small releases from the delivery hose when disconnected from the fill pipe.

This final UST regulation does not require periodic testing of double walled spill prevention equipment if the integrity of both walls is periodically monitored. Because the integrity of both walls is periodically monitored, this type of spill prevention equipment is periodically checked for tightness. In 2011, EPA proposed to exclude from the periodic testing requirement only double walled spill prevention equipment with continuous interstitial monitoring. Several commenters suggested that monitoring of the

[25] This document is available for purchase at *www.pei.org.*

[26] *Evaluation Of Releases From New And Upgraded Underground Storage Tanks*, Peer Review Draft, US EPA/OUST, August 2004.

[27] *Petroleum Releases At Underground Storage Tank Facilities In Florida,* Peer Review Draft, US EPA/OUST, March 2005.

[28] Spill Bucket Performance Presentation by Dale Stoudemire, 2005 UST National Conference, March 14–15 2005, Seattle, WA.

[29] Spill Buckets: Mistaken Expectations?, LUSTLine Bulletin 48, Dale W. Stoudemire, November 2004.

interstitial area be used in lieu of periodic spill prevention equipment testing. EPA agrees with commenters that double walled spill prevention equipment, where the integrity of both walls is periodically monitored, should not have to undergo testing—as long as owners and operators conduct periodic monitoring of the equipment at a frequency consistent with, or more frequent than, the walkthrough inspection frequency (see section B–1). For example, owners and operators who check vacuum, pressure, or liquid interstitial integrity indicators on double walled spill containment devices as part of their 30 day walkthrough inspections are considered to be periodically monitoring the integrity of both walls.

For spill prevention equipment that must be tested once every three years, this final UST regulation requires owners and operators to conduct testing using vacuum, pressure, or liquid methods. In addition, the test must be conducted in accordance with manufacturer's requirements or a code of practice developed by a nationally recognized association or independent testing laboratory. The manufacturer's requirement is an option only when the manufacturer has developed requirements for testing the tightness of their spill prevention equipment. As of the publication date of this final UST regulation, EPA is aware of one code of practice that contains procedures for testing spill prevention equipment: Petroleum Equipment Institute (PEI) Recommended Practice (RP) 1200, *Recommended Practices for the Testing and Verification of Spill, Overfill, Leak Detection and Secondary Containment Equipment at UST Facilities.*[30] EPA is adding this code of practice to this final UST regulation. In addition, EPA is providing implementing agencies flexibility to allow other methods they determine to be as protective of human health and the environment as the manufacturer's requirements or a code of practice. This option allows alternatives in case codes of practice and manufacturer's requirements are not available for testing spill prevention equipment. Several commenters expressed concern that EPA did not establish specific pass or fail performance criteria for spill prevention equipment testing. EPA thinks the manufacturer, code of practice, or implementing agency are better suited to establish test method criteria because spill prevention devices are manufactured in different shapes and sizes. Therefore, EPA is relying on the test method to establish specific pass or fail performance criteria.

In 2011, EPA proposed a one year implementation time frame for owners and operators to begin conducting spill prevention equipment testing. However, based on commenter input suggesting implementation be consistent with other testing requirements, EPA is requiring owners and operators of spill containment equipment in use as of the effective date of this final UST regulation conduct the first test no later than three years after the effective date of this final UST regulation. EPA thinks aligning implementation dates for the different operation and maintenance testing requirements to the extent possible will provide clarity about the requirements owners and operators must meet. After the first spill prevention equipment test, owners and operators must test spill prevention equipment at least once every three years.

For UST systems brought into use after the effective date of this final UST regulation, the spill prevention equipment testing requirement applies at installation. However, owners and operators must also follow the installation requirements in § 280.20(d) which require manufacturer's instructions and installation standards be followed. These instructions and standards currently address liquid tightness of spill prevention equipment at installation. As long as the spill prevention equipment is tested and liquid tight at installation, the first periodic spill prevention equipment test does not have to be conducted until three years after installation.

In 2011, EPA proposed that owners and operators test spill prevention equipment at least annually. However, based on comments received, EPA is requiring owners and operators test spill prevention equipment at least once every three years. Commenters suggested that all operation and maintenance testing should be aligned so that all tests can be conducted at the same time. EPA agrees. To make it easier for owners and operators to comply, this final UST regulation aligns periodic spill, overfill, and secondary containment testing to the extent possible. Since spill prevention equipment has a relatively short lifespan, EPA thinks a three year testing frequency, when combined with periodic visual checks via the walkthrough inspection (see section B–1), is adequate to ensure spill prevention equipment will contain any drips or spills when the delivery hose is disconnected from the fill pipe.

EPA received significant support for requiring owners and operators to keep records of the spill prevention equipment test for three years. This final UST regulation requires owners and operators maintain records of spill prevention equipment testing for three years for each spill prevention device at the facility. A three year period aligns with the maximum time between on-site UST facility compliance inspections. These records will demonstrate to implementing agencies that the spill prevention equipment was tested and tight at the time of the test.

Owners and operators of UST systems with double walled spill prevention equipment, where the integrity of both walls is periodically monitored and who choose not to conduct spill prevention equipment testing at least once every three years, must maintain documentation showing that spill prevention equipment has two walls and the integrity of both walls is periodically monitored. Owners and operators must maintain this documentation for as long as the equipment is periodically monitored. Owners and operators who discontinue periodic monitoring of their double walled spill prevention equipment must conduct a test within 30 days of discontinuing the periodic monitoring. EPA considers this necessary because discontinuing periodic monitoring of the interstitial area may mean some portion of that area of the spill prevention equipment may no longer have integrity. Owners and operators need to ensure the primary containment of the spill prevention equipment is tight. Alternatively, owners and operators may choose to test double walled spill prevention equipment once every three years, and maintain the test record, in lieu of periodically monitoring this equipment and maintaining these monitoring records.

Several commenters raised concerns about disposal of the spill prevention equipment test liquid following the test. EPA considered test liquid disposal in this final UST regulation and contacted several vendors to determine whether disposal of the test liquid was included as part of spill prevention equipment testing.[31] Some vendors include handling of the test liquid as part of the test; they carry the test liquid with them and reuse it several times before disposal. Others charge a separate cost to dispose of the test liquid or make sure the owner or operator has drums on site to dispose of the test liquid. In addition,

[30] This document is available for purchase at *www.pei.org.*

[31] Spill, Overfill, and Secondary Containment testing Questions and Answers from Three Vendors (11/8/12).

vendors sometimes use vacuum testing for spill prevention equipment testing, which eliminates the liquid from the test.

A few commenters raised concerns about facility down time and replacement costs for spill prevention equipment as a result of testing. EPA acknowledges that, in instances where access to the spill prevention equipment is in the line of traffic, there could be a small amount of facility down time as a result of testing; however EPA thinks the benefit to the environment far outweighs the cost of potential down time. To minimize the effects of down time, owners and operators can also schedule the testing during low traffic times at the facility or when other routine maintenance occurs. EPA expects owners and operators to have properly functioning spill prevention equipment at all times and fix problems when they are discovered. The spill prevention equipment test may uncover a problem earlier, resulting in repair or replacement (and better protection from spills) sooner rather than later, and more quickly detect or prevent releases of regulated substances to the environment.

3. Overfill Prevention Equipment Inspections

In this final UST regulation, EPA is adding periodic operation and maintenance requirements for overfill prevention equipment to help ensure the equipment is operating properly and will activate before an UST is overfilled. Owners and operators need to properly operate and maintain their overfill prevention equipment in order to prevent releases to the environment. If overfill prevention equipment is not working properly, an UST can be overfilled and release product to the environment. EPA is aware that USTs are being overfilled and there are problems with overfill prevention equipment. Data show that tank overfills account for about 15 percent of releases from UST systems.[32] [33] Examples of problems with overfill prevention equipment include: Tampering, improper use, and normal wear and tear. Overfill prevention equipment inspections will minimize problems and ensure overfill prevention equipment is operating properly.

The 2011 proposed UST regulation used the term testing for overfill prevention equipment when describing the periodic functionality checks. However, based on input from commenters about potentially overfilling the tank during testing, EPA is using the term inspections—rather than testing—in this final UST regulation. The procedure to determine whether overfill prevention equipment is operating properly should not overfill the tank. Rather, the equipment must be inspected to determine whether it will operate or activate properly according to requirements in this final UST regulation. For example, the inspection to determine whether an automatic shutoff device in the fill pipe will activate at the correct height might involve removing and inspecting the device to ensure it operates as well as measuring the position of the device in the tank to ensure it activates at the appropriate level in the tank.

For overfill prevention equipment inspections, owners and operators must use manufacturer's requirements or a code of practice developed by a nationally recognized association or independent testing laboratory. Manufacturer's requirements are an option only when manufacturers have developed inspection requirements for their overfill prevention equipment that determines the device is set to activate at the appropriate level in the tank and will activate when the regulated substance reaches that level. As of this final UST regulation, EPA is aware of one code of practice that contains procedures for inspecting overfill prevention equipment: PEI RP 1200, *Recommended Practices for the Testing and Verification of Spill, Overfill, Leak Detection and Secondary Containment Equipment at UST Facilities.*[34] EPA added this code of practice in this final UST regulation. In addition, EPA is providing implementing agencies flexibility to allow other methods they determine to be as protective of human health and the environment as the manufacturer's requirements or a code of practice. This option allows alternatives in case a code of practice and manufacturer's requirements are not available for inspecting overfill prevention equipment.

This final UST regulation requires owners and operators conduct overfill prevention equipment inspections at least once every three years. Commenters generally supported a three year or more frequent inspection cycle. EPA chose the three year time frame because it aligns with three year compliance inspections and is consistent with other operation and maintenance requirements, such as containment sump testing and spill prevention equipment testing.

In 2011, EPA proposed to stagger implementation for overfill prevention equipment inspections over a three year period based on the installation date of the oldest UST at the facility. However, EPA received significant input from commenters opposing the phased in approach and advocating a single implementation date. EPA agrees with the merits of a more simplified approach. Therefore, for overfill prevention equipment installed as of this final UST regulation, owners and operators must conduct the first inspection within three years of the effective date of this final UST regulation. After the first overfill prevention equipment inspection, owners and operators must inspect overfill prevention equipment at least once every three years.

For UST systems brought into use after the effective date of this final UST regulation, the overfill prevention equipment inspection requirement applies at installation. However, owners and operators must also follow the installation requirements in § 280.20(d) which require following manufacturer's instructions and installation standards. These instructions and standards currently address the operability of the overfill equipment at installation. As long as the overfill prevention equipment is inspected for operability at installation, the first periodic overfill prevention equipment inspection does not have to be conducted until three years after installation.

EPA received significant support for requiring owners and operators to keep records of overfill prevention equipment inspections for three years. The three year period aligns with the maximum time between on-site UST facility compliance inspections. Therefore, this final UST regulation requires owners and operators maintain for three years overfill prevention equipment inspection records for each overfill device at the facility. These records will demonstrate to implementing agencies that the overfill prevention equipment has been inspected, is set at the appropriate height in the tank, and will activate when regulated substances reach that height.

Several commenters were concerned about potential damage to overfill prevention equipment during removal for inspection. EPA asked several vendors who perform overfill prevention equipment inspections about the potential for damage during periodic overfill prevention equipment

[32] *Petroleum Releases At Underground Storage Tank Facilities In Florida*, Peer Review Draft, US EPA/OUST, March 2005.

[33] *Evaluation Of Releases From New And Upgraded Underground Storage Tanks,* Peer Review Draft, US EPA/OUST, August 2004.

[34] This document is available for purchase at *www.pei.org.*

inspections.[35] The vendors indicated that seals may need to be replaced when removing the equipment, but that overfill prevention equipment itself would not easily be damaged during removal or reinstallation. The vendors also indicated that replacing these seals will result in little or no additional cost to the owner and operator.

A few commenters raised concerns about facility down time and replacement costs for overfill prevention equipment as a result of periodic inspections. EPA acknowledges that, in instances where access to overfill prevention equipment is in the line of traffic, there could be a small amount of facility down time as a result of inspecting; however EPA thinks the benefit to the environment far outweighs the cost of potential down time. To minimize the effects of down time, owners and operators can also schedule the inspection during low traffic times at the facility or when other routine maintenance occurs. EPA expects owners and operators to have properly functioning overfill prevention equipment at all times and fix problems when they are discovered. The overfill prevention equipment inspection may uncover a problem earlier, resulting in repair or replacement (and better protection from overfills) sooner rather than later.

4. Secondary Containment Tests

The 2011 proposed UST regulation included periodic secondary containment testing requirements for secondary containment areas of tanks and piping and for containment sumps used for monitoring the secondary containment areas of piping. However, based on the significant opposition commenters provided, this final UST regulation is not requiring periodic secondary containment testing of secondarily contained tanks and piping. EPA agrees with commenters who indicated secondarily contained UST systems using interstitial monitoring are more protective of the environment than single walled UST systems. In addition, EPA understands that some secondarily contained UST systems installed before this final UST regulation may not have been designed to have the interstitial areas periodically tested. Finally, EPA does not want to create a disincentive for owners and operators to replace older single walled UST systems with secondarily contained systems or penalize early installers of secondarily contained UST systems. However, this final UST regulation does require testing of these areas following a repair or, as appropriate, in response to a suspected release if they are used for interstitial monitoring. Interstitial areas where interstitial monitoring is used need to be tight following a repair so that the interstitial monitoring will detect a release before it reaches the environment. Likewise, interstitial areas need to be tested in response to a suspected release to determine whether a leak has reached the environment.

EPA disagrees with commenters who suggested periodic testing for containment sumps used for interstitial monitoring of piping is unnecessary. These areas function similar to spill containment equipment, containing leaks from piping and other components in the sump. Containment sumps can degrade over time, resulting in releases to the environment. Information about source and cause of release shows that a significant number of releases occur in containment sump areas.[36] [37] Containment sumps have piping and other components that penetrate through the containment sump walls, increasing the likelihood that these areas are not liquid tight. Containment sumps used for interstitial monitoring of piping need to be liquid tight so they will contain regulated substances released from the primary wall of the piping. Therefore, this final UST regulation includes a three year testing requirement for containment sumps used for interstitial monitoring of piping.

This final UST regulation does not require periodic testing of double walled containment sumps used for interstitial monitoring of piping if the integrity of both walls of the containment sump is periodically monitored. Because the integrity of both walls is periodically monitored, this type of containment sump is periodically checked for tightness. EPA proposed to exclude from the periodic testing requirement only containment sumps with continuous interstitial monitoring. Several commenters suggested that periodic monitoring (rather than continuous monitoring) of the interstitial area of the double walled containment sump would be adequate in lieu of performing the periodic containment sump testing. EPA agrees with commenters that double walled containment sumps, where the integrity of both walls is periodically monitored, should not have to undergo testing—as long as owners and operators conduct periodic monitoring of the equipment at a frequency consistent with, or more frequent than, the walkthrough inspection frequency (see section B–1). For example, owners and operators who check vacuum, pressure, or liquid interstitial integrity indicators on double walled containment sumps as part of their annual walkthrough inspections are considered to be periodically monitoring the integrity of both walls.

This final UST regulation does not require periodic testing of containment sumps used for reasons other than interstitial monitoring of piping. Testing of these areas is not necessary to ensure the release detection will detect a leak because owners and operators are not using the containment sumps for interstitial monitoring. In these cases, owners and operators use another method of release detection and previously installed containment sumps as part of good business practice.

Some commenters suggested EPA add definitions for continuous monitoring and interstitial monitoring. Since this final UST regulation uses the concept of periodic monitoring rather than continuous monitoring, EPA is not defining continuous monitoring. The concept of interstitial monitoring was used in the 1988 UST regulation and remains the same in this final UST regulation (see § 280.43(g)). In addition, this final UST regulation describes interstitial monitoring in detail in subpart D. Therefore, EPA is not further defining interstitial monitoring. Based on commenter input, EPA is adding to this final UST regulation a definition of containment sump, which addresses comments about what constitutes a containment sump. EPA considers a containment sump to be a liquid tight container that protects the environment by containing leaks and spills of regulated substances from piping, dispensers, pumps, and related components in the containment area. Containment sumps may be single walled or secondarily contained and located at the top of tank (tank top or submersible turbine pump sump), underneath the dispenser (under-dispenser containment sump), or at other points in the piping run (transition or intermediate sump).

This final UST regulation requires owners and operators conduct testing of containment sumps used for interstitial monitoring of piping at least once every three years. Commenters generally supported a three year or more frequent inspection cycle. EPA is choosing the three year time frame to: Make

[35] Spill, Overfill, and Secondary Containment testing Questions and Answers from Three Vendors (11/8/12).

[36] *Petroleum Releases At Underground Storage Tank Facilities In Florida,* Peer Review Draft, US EPA/OUST, March 2005.

[37] *Evaluation Of Releases From New And Upgraded Underground Storage Tanks,* Peer Review Draft, US EPA/OUST, August 2004.

compliance easier for owners and operators; align with three year compliance inspections; and be consistent with other operation and maintenance requirements, such as overfill prevention equipment inspections and spill prevention equipment testing.

For containment sumps that require testing at least once every three years, this final UST regulation requires owners and operators conduct testing by using vacuum, pressure, or liquid methods. In addition, the test must be conducted in accordance with manufacturer's requirements or a code of practice developed by a nationally recognized association or independent testing laboratory. The manufacturer's requirement is an option only when the manufacturer has developed testing requirements for their containment sumps that ensure their containment sump is tight. As of this final UST regulation, EPA is aware of one code of practice that contains procedures for testing containment sumps: PEI RP 1200, *Recommended Practices for the Testing and Verification of Spill, Overfill, Leak Detection and Secondary Containment Equipment at UST Facilities,* and is adding this code of practice to the final UST regulation.[38] In addition, EPA is providing implementing agencies flexibility to allow other methods they determine to be as protective of human health and the environment as the manufacturer's requirements or a code of practice. This option allows alternatives in the event that a code of practice and manufacturer's requirements are not available for testing containment sumps. Several commenters expressed concern that EPA did not establish specific pass or fail performance criteria for containment sump testing. However, EPA thinks the test method established by the manufacturer, code of practice, or implementing agency are better suited to establish criteria because containment sumps are made in different shapes and sizes. Therefore, EPA is relying on the test method to establish specific pass or fail performance criteria.

In 2011, EPA proposed to stagger secondary containment testing implementation over a three year period, based on the installation date of the oldest UST at a facility. However, EPA received significant input from commenters opposing a phased in approach and advocating a single implementation date. EPA agrees with the merits of a more simplified approach. Therefore, containment sumps used for interstitial monitoring of piping installed as of the effective date of this final UST regulation must be tested within three years of the effective date of this final UST regulation. After the first test, owners and operators must conduct periodic testing at least once every three years.

For UST systems brought into use after the effective date of this final UST regulation, the containment sump testing requirement applies at installation. However, owners and operators must also follow the installation requirements in § 280.20(d) which require following manufacturer's instructions and installation standards. These instructions and standards currently address liquid tightness of containment sumps at installation. As long as the containment sump is tested and liquid tight at installation, the first periodic containment sump test does not have to be conducted until three years after installation.

EPA received significant support for the three year recordkeeping time frame for secondary containment testing because the three year time period aligns with the maximum time between on-site UST facility compliance inspections. Therefore, this final UST regulation requires owners and operators maintain for three years containment sump testing records for each containment sump used for interstitial monitoring at a facility. These records will demonstrate to implementing agencies that containment sumps were tested and tight at the time of the test.

Owners and operators who have double walled containment sumps where the integrity of both walls is periodically monitored and choose not to conduct containment sump testing at least once every three years must maintain documentation showing their containment sumps have two walls and the integrity of both walls is periodically monitored. Owners and operators must maintain this documentation for as long as the integrity of the two walls of the containment sump is periodically monitored. Owners and operators who discontinue periodic monitoring of their double walled containment sumps must conduct a test within 30 days of discontinuing the periodic monitoring. EPA considers this necessary because discontinuing periodic monitoring of the interstitial area may mean some portion of that area of the containment may no longer have integrity. Therefore, owners and operators need to ensure the primary containment of the containment sump is tight. Alternatively, owners and operators may choose to test double walled containment sumps (and maintain testing records) once every three years in lieu of maintaining these records.

Several commenters raised concern about disposing of containment sump test liquid following the test. EPA considered test liquid disposal in this final UST regulation and contacted several vendors to determine whether they included disposal of test liquid as part of containment sump testing.[39] Some vendors include handling of the test liquid as part of the test; they carry the test liquid with them and reuse it several times before disposal. Others charge a separate cost to dispose of the test liquid or make sure the owner or operator has drums on site to dispose of the test liquid. In addition, vendors could use vacuum testing for containment sump testing, which eliminates the liquid from the test.

A few commenters raised concerns about facility down time and replacement costs for containment sumps as a result of testing. EPA acknowledges that, in instances where access to the containment sump is in the line of traffic, there could be a small amount of facility down time as a result of testing; however EPA thinks the benefit to the environment far outweighs the cost of potential down time. To minimize the effects of down time, owners and operators can also schedule the testing during low traffic times at the facility or when other routine maintenance occurs that requires opening containment sumps. EPA expects owners and operators to have properly functioning containment sumps at all times when those containment sumps are used for interstitial monitoring of piping and fix problems when they are discovered. The containment sump test may uncover a problem earlier than if a test was never conducted, resulting in repair or replacements of the containment sump (and better protection from releases) sooner rather than later.

5. Release Detection Equipment Tests

This final UST regulation requires UST owners and operators perform annual operation and maintenance tests on electronic and mechanical components of their release detection equipment to ensure the equipment is operating properly. Owners and operators are required, at a minimum, to check this equipment:

[38] This document is available for purchase at *www.pei.org.*

[39] Spill, Overfill, and Secondary Containment testing Questions and Answers from Three Vendors (11/8/12).

- Automatic tank gauge (ATG) systems and other controllers
  - Test alarm
  - Verify system configuration
  - Test battery back-up
- Probes and sensors
  - Inspect for residual build-up
  - Ensure floats move freely
  - Ensure shaft is not damaged
  - Ensure cables are free of kinks and breaks
  - Test alarm operability and communication with controller
- Automatic line leak detector (ALLD)
  - Simulate leak which determines capability to detect a leak
- Vacuum pumps and pressure gauges
  - Ensure proper communication with sensors and controller
- Handheld electronic sampling equipment associated with vapor and groundwater monitoring
  - Ensure proper operation

This final UST regulation changes some requirements discussed in the 2011 proposed operation and maintenance for release detection equipment requirements. Changes include:

- Noting that PEI RP 1200 may be used to meet the testing requirements
- Increasing from one year to three years the time allowed for UST system owners and operators to implement the requirements
- Using the term automatic line leak detector instead of line leak detector
- Removing the leak sensing O-ring from the list of components tested
- Adding handheld electronic equipment associated with vapor and groundwater monitoring

EPA is concerned about the performance of release detection equipment. Inspectors routinely find release detection equipment installed on UST systems, but often that equipment is not properly operated or maintained. In addition, information from an analysis in Florida indicates that leak detection successfully detected 26 percent of all releases. Conversely, leak detection was specifically identified as failing to detect 23 percent of releases.[40] To increase the effectiveness of release detection, this final UST regulation targets operation and maintenance.

This final UST regulation requires that release detection is operated and maintained in accordance with manufacturer's instructions, a code of practice, or requirements developed by the implementing agency. To achieve optimal performance from equipment and to meet release detection requirements, it is important for UST system owners and operators to both install the equipment properly and properly operate and maintain it. In the 1988 UST regulation, EPA did not provide specifics on the minimum requirements to ensure adequate operation and maintenance of release detection equipment. As a result, manufacturer operation and maintenance requirements vary greatly, even among similar types of equipment.

Some manufacturer's requirements do not adequately address operation and maintenance. For example, some manufacturers only recommend operation and maintenance testing; but EPA is taking the position that testing should be mandatory instead of optional. In addition, similar release detection components should be tested in a similar manner, which will increase the likelihood all release detection equipment will function at optimal levels for as long as possible. California's in field analysis of sensors used for release detection supports EPA's position.[41]

This final UST regulation improves and standardizes operation and maintenance for all release detection equipment; it provides owners and operators with required equipment tests, which will help ensure equipment is properly operated and maintained. EPA is requiring a set of minimum operation and maintenance criteria that owners and operators must follow for electronic and mechanical based release detection equipment.

The operation and maintenance minimum requirements for release detection established in This final UST regulation are based on common requirements and recommendations by various equipment manufacturers of similar equipment. EPA used the National Work Group On Leak Detection Evaluations' (NWGLDE) list of leak detection equipment to identify commonly used equipment.[42] In addition, EPA's publication, *Operating And Maintaining Underground Storage Tanks Systems: Practical Help And Checklists* and PEI's *Recommended Practices for the Inspection and Maintenance of UST Systems* (RP 900) also helped establish proper operation and maintenance activities.

Owners and operators must meet the release detection operation and maintenance requirements according to one of the following: Manufacturer's instructions; a code of practice developed by a nationally recognized association or independent testing laboratory; or requirements determined by the implementing agency to be no less protective of human health and the environment than the two options listed above. These requirements are consistent with options for other operation and maintenance activities in this final UST regulation. As an example, see section B–2, Spill Prevention Equipment Tests.

At the time of the 2011 proposed UST regulation, PEI was developing a code of practice, which EPA anticipated would address operability testing of release detection equipment. PEI issued the final recommended practice in 2012. EPA reviewed PEI's final *Recommended Practices for the Testing and Verification of Spill, Overfill, Leak Detection and Secondary Containment Equipment at UST Facilities* (RP 1200) and is including it in this final regulation as an option for meeting the annual release detection equipment testing requirements.[43]

This final UST regulation requires owners and operators maintain records of the annual operation tests for three years. At a minimum, records must: List each component tested; indicate whether each component meets the criteria listed or needed to have action taken; and describe any action taken to correct an issue. The requirement to maintain records for three years is consistent with the three year compliance inspection cycle; maintaining records will allow owners and operators to demonstrate compliance with this operation and maintenance requirement.

Based on comments received and EPA's goal to align all implementation dates for consistency and easier compliance, this final UST regulation requires owners and operators meet operation and maintenance for release detection requirements no later than three years after the effective date of the final UST regulation. This is a change from the 2011 proposed UST regulation, which required that owners and operators meet this requirement no later than one year after the effective date of the final UST regulation.

The 2011 proposed UST regulation used the term line leak detector as a component that must be tested. Based on comments received, this final UST regulation uses the term automatic line leak detector. This is consistent with

[40] *Petroleum Releases At Underground Storage Tank Facilities In Florida,* Peer Review Draft, US EPA–OUST, March 2005.

[41] California's *Field Evaluation Of Underground Storage Tank System Leak Detection Sensors,* August 2002. *http://www.waterboards.ca.gov/water_issues/programs/ust/leak_prevention/sensors/index.shtml.*

[42] National Work Group On Leak Detection Evaluations' *List Of Leak Detection Evaluations For Storage Tank Systems. http://www.nwglde.org/.*

[43] This document is available for purchase at *www.pei.org.*

how EPA has historically referenced line leak detectors in the 1988 UST regulation. These devices can be electronic or mechanical and are described in § 280.44(a). Commenters also asked EPA to add the performance criteria of 3 gallons per hour at 10 pounds per square inch line pressure to the simulated ALLD test required for the line leak detector. This is unnecessary since the 2011 proposed UST regulation required this performance standard for the simulated test by referencing § 280.44(a). This final UST regulation maintains that ALLDs, whether electronic or mechanical, must meet the annual simulated leak test of 3 gallons per hour at 10 pounds per square inch line pressure within 1 hour.

One commenter noted his experience with testing release detection equipment, which verified electrical circuitry, but during operation the connected device still did not function to its intended precision. This commenter recommended EPA change the term test to functionality test. EPA thinks this change is unnecessary. The operation and maintenance requirements for release detection feature minimum performance criteria for testing. Each method used to meet the requirement (manufacturer's instructions, a code of practice, or requirements developed by the implementing agency) must, at a minimum, cover each listed component and the stated performance criteria.

EPA disagrees with the commenter who said EPA should allow self-diagnostic equipment. Similar to the commenter in the previous paragraph, EPA is concerned that self-diagnostic equipment might verify electrical circuitry or communication, but not actually test equipment functionality. EPA requires testing to be performed in a manner that verifies equipment operation according to performance standards provided for each piece of release detection equipment. For example, testing ALLDs must involve simulating a system leak not greater than 3 gallons per hour at 10 pounds per square inch line pressure within 1 hour, or equivalent. ALLDs connected to ATG systems or other controllers may themselves be used to test electronic communication, but unless capable of simulating an appropriate leak in the system, do not meet the performance standard and, therefore, cannot be used to meet this requirement.

In this final UST regulation, EPA is deleting language from the 2011 proposed UST regulation about inspecting and testing the leak sensing O-ring. Commenters requested EPA clarify what a leak sensing O-ring is. This O-ring is specific to the functional element of mechanical line leak detectors and is, therefore, only present on certain types of ALLDs. In addition, all functional elements will be tested as part of the simulated leak test conducted at 3 gallons per hour at 10 psi or equivalent for all ALLDs.

This final UST regulation allows use of groundwater and vapor monitoring as methods of release detection, but with some restrictions (see section D–6). For owners and operators choosing groundwater or vapor monitoring as their method of release detection, this final UST regulation requires that hand held electronic devices such as photoionization devices meet the operation and maintenance requirements for release detection equipment. Non electronic hand held devices, such as measuring sticks and groundwater bailers, are covered in section B–1, Walkthrough Inspections.

C. Addressing Deferrals

This final UST regulation addresses airport hydrant fuel distribution systems and USTs with field-constructed tanks. In addition, this final UST regulation removes the release detection deferral for UST systems that store fuel solely for use by emergency power generators. As a result, these UST systems may no longer be subject to Spill Prevention, Control, and Countermeasure (SPCC) requirements. Finally, this final UST regulation partially excludes from Part 280 requirements wastewater treatment tank systems, UST systems containing radioactive material regulated under the Atomic Energy Act, and UST systems that are part of an emergency generator system at nuclear power generation facilities regulated by the Nuclear Regulatory Commission under 10 CFR part 50. To the extent these systems were regulated by the SPCC requirements, they will continue to be regulated by those requirements.

In this final UST regulation, EPA partially excludes from part 280 requirements the aboveground storage tanks associated with airport hydrant fuel distribution systems and USTs with field-constructed tanks. These aboveground storage tanks are part of the UST system, but are excluded from most of this final UST regulation because they are not underground. At the time of the 1988 UST regulation, facilities with an aggregate completely buried storage capacity greater than 42,000 gallons and located near navigable waters of the United States or adjoining shorelines were subject to both UST regulations and SPCC regulations. Since then, the SPCC regulation has been amended and exempts completely buried storage tanks, as well as connected underground piping, underground ancillary equipment, and containment systems when fully subject to the technical requirements of 40 CFR part 280. Partially excluded aboveground storage tanks which are part of the UST system may be subject to SPCC requirements.

1. UST Systems Storing Fuel Solely for Use by Emergency Power Generators—Require Release Detection

This final UST regulation eliminates the deferral for UST systems storing fuel solely for use by emergency power generators (also referred to as emergency generator tanks). This means emergency generator tanks are no longer deferred from release detection requirements in 40 CFR part 280, subpart D and are subject to all UST requirements.

This final UST regulation requires owners and operators of UST systems storing fuel solely for use by emergency power generators begin meeting these requirements:

- For systems installed after the effective date of this final UST regulation, at the time of installation
- For systems installed on or before the effective date of this final UST regulation, within three years of the effective date of this final UST regulation

EPA is regulating UST systems storing fuel solely for use by emergency power generators because the rationale in the 1988 UST regulation for deferring release detection no longer applies. To allow time for developing workable release detection requirements, EPA in the 1988 UST regulation deferred release detection requirements for UST systems storing fuel solely for use by emergency power generators. The 1988 UST regulation preamble indicated that monthly monitoring requirements were unworkable because these tanks often were located at unmanned stations in remote areas and visited infrequently.

EPA always intended for these systems to meet release detection requirements when appropriate release detection methods became available. Since the 1988 UST regulation, release detection technologies have matured greatly. In addition, technology is now available to perform release detection at remote sites. Emergency generator tanks can now be monitored for releases by the majority of methods listed in subpart D. EPA estimates about 30 percent of emergency generator tanks already have release detection.

Effective remote monitoring methods for release detection are now available

and currently used to monitor unmanned UST systems storing fuel solely for emergency generator tanks. Numerous companies perform remote monitoring for releases at these unmanned sites. When there is a suspected release, a remote monitor transmits a visual or audible alarm to a receiving console at a manned location. This provides owners and operators with real-time release detection data so owners and operators can quickly respond to suspected releases at sites with unmanned emergency generator tanks.

Several commenters raised concerns that release detection methods may not properly operate on some emergency generator tanks and suggested changes to the release detection requirement. Commenters reported these issues:

- Looped piping systems, which is piping configured to run continuously with integrated supply and return lines, cannot be properly isolated or does not have a sufficient quiet period to perform a precision test when using automatic tank gauging
- Emergency generator tanks with copper piping may pose issues with meeting the release detection requirement due to system configurations
- Most emergency generator tanks are single walled and are limited to automatic tank gauging as the form of release detection
- Emergency generator tanks with day tanks and aboveground piping may need anti-siphon valves

Other commenters suggested EPA limit the type of release detection, such as statistical inventory reconciliation (SIR), owners and operators may use on emergency generator tanks and that EPA should require owners and operators install electronic line leak detectors, which have a positive system shutdown of any product flow in the event of a leak. Other commenters recommended EPA clarify that automatic line leak detectors can go to alarm mode only and not shut down or restrict product flow when a leak is suspected in emergency generator tanks used during a crisis.

EPA agrees that not all release detection methods may be suitable for all configurations of emergency generator tanks. EPA discussed the applicability of SIR on emergency generator tanks in general with several SIR vendors and received conflicting responses. A challenge to performing release detection is establishing a usage rate of product based on the run time of the system during operation. Although EPA thinks it is difficult to achieve accurate results, we do not have enough information at this time to determine that SIR or other methods that rely on metered data are unacceptable for use on emergency generator tanks. Owners and operators must carefully consider whether these methods meet the release detection requirement for their UST systems. To meet the release detection requirement, some systems may require reconfiguration and addition of components such as anti-siphon valves to separate sections of the system. Some emergency generator tanks use safe suction piping, in which case release detection for piping is not required. However, release detection technologies have advanced since EPA issued the 1988 UST regulation and there are now various options available to meet this requirement. EPA understands some commenters want to require owners and operators to install automatic line leak detectors, which only shut off at the STP or allowing only certain release detection methods for these systems. However, to provide flexibility to owners and operators while continuing to protect human health and the environment, this final UST regulation allows owners and operators to choose the most appropriate release detection methods, including automatic line leak detectors that trigger an alarm only and not necessarily shut down the pump, for their systems. For an unmanned facility, the alarm must be transmitted to a monitoring center where someone can hear or see the alarm and quickly respond to a suspected release.

One commenter suggested EPA define what is mission critical as it relates to emergency generator tanks. While EPA acknowledges the need for operating emergency generator tanks during an emergency, we think it is unnecessary to define the term mission critical or make exceptions for the release detection requirement for these tanks. The concern is that owners and operators of these systems should not have to shut down their systems during an emergency if they encounter a suspected release. EPA understands this concern but thinks owners and operators can perform release detection and respond to suspected releases while continuing to operate the UST system.

Emergency generator tanks are located throughout the country. EPA's review of several state databases revealed these systems are located at hospitals, universities, communication utilities, military installations, and other locations relying on backup power sources. Based on information from these databases, EPA estimates UST systems storing fuel solely for use by emergency power generators represent approximately 3 percent of the active tank population.

Additionally, about 20 states currently require release detection for emergency generator tanks. Automatic tank gauging and secondary containment with interstitial monitoring are the most common release detection methods used for emergency generator tanks. Line tightness testing, automatic line leak detectors, or secondary containment with interstitial monitoring are the most common release detection methods used for piping. With technology now available to detect releases from emergency generator tanks and because they pose a risk to human health and the environment, this final UST regulation removes the deferral from release detection.

The 2011 proposed UST regulation required owners and operators meet the release detection requirement within one year of the effective date of the final UST regulation. Several commenters raised concerns that a one-year time frame to meet this requirement is insufficient for owners and operators to assess, budget, and install release detection. Commenters also wanted EPA to establish a single implementation date, which is consistent with effective dates for release detection on other previously deferred tanks. EPA agrees that extending the time frame will allow owners and operators sufficient time for planning and installing necessary equipment to meet the release detection requirement; but we disagree with commenters who suggested a five to ten year implementation date. EPA also agrees that establishing a single effective date, which is consistent with other effective dates for the release detection requirement, decreases the tracking burden on implementing agencies as well as owners and operators. Based on support for increasing the final implementation date for release detection from one year and EPA's goal of aligning regulatory implementation dates to make compliance easier for owners and operators, EPA is requiring owners and operators of emergency generator tanks installed on or before the effective date of this final UST regulation to meet the release detection requirement within three years of the effective date of this final UST regulation. Emergency generator tanks installed after the effective date of this final UST regulation must meet the release detection requirements when installed.

The 2011 proposed UST regulation required that no later than 30 days after the effective date of the final UST regulation, owners of UST systems storing fuel solely for use by emergency

power generators notify implementing agencies that their systems exist. Commenters stated that this requirement is unnecessary because the 1988 UST regulation excluded emergency generator tanks from only the release detection requirement. EPA agrees with commenters. This final UST regulation does not include this one-time notification requirement for emergency generator tanks.

2. Airport Hydrant Fuel Distribution Systems and UST Systems With Field-Constructed Tanks

This final UST regulation removes the 1988 deferral and requires owners and operators of airport hydrant fuel distribution systems (referred to as airport hydrant systems) comply with applicable requirements. However, EPA is tailoring the requirements to the unique nature of airport hydrant systems. Airport hydrant systems function and are designed differently than conventional USTs. Unlike conventional USTs, airport hydrant systems consist of networks of large diameter underground piping operating at high pressures to deliver fuel to aircraft. In addition, operation and maintenance requirements for airport hydrant systems may differ from those for conventional UST systems.

This final UST regulation removes the 1988 deferral and requires owners and operators of UST systems with field-constructed tanks comply with applicable requirements. Similar to airport hydrant systems, EPA is tailoring the requirements to the unique nature of field-constructed tanks. UST systems with field-constructed tanks (referred to as field-constructed tanks) range from conventional sizes to very large capacities greater than 2 million gallons.

A few commenters suggested EPA write regulations specifically for airport hydrant systems and field-constructed tanks, since they are distinctly different from conventional USTs. EPA agrees that airport hydrant systems and field-constructed tanks are different from conventional USTs. Additionally, EPA thinks it would help owners and operators if the requirements for airport hydrant systems and field-constructed tanks are in a separate subpart of the final UST regulation. In order to help owners and operators of these systems comply, this final UST regulation adds subpart K (*UST Systems with Field-Constructed Tanks and Airport Hydrant Fuel Distribution Systems*) and places most regulatory requirements for both airport hydrant systems and field-constructed tanks in one location. Since 1988, owners and operators of these systems have been required to comply with the requirements for subparts A (*Program Scope and Interim Prohibition*) and F (*Release Response and Corrective Action for UST Systems Containing Petroleum or Hazardous Substances*).

This final UST regulation requires airport hydrant systems and field-constructed tanks installed on or before the effective date of the final UST regulation begin meeting the requirements of subpart K according to the schedule below. Airport hydrant systems and field-constructed tanks installed after the effective date of this final UST regulation must meet the requirements at the time of installation.

Requirement	Effective date
Upgrading UST systems, general operating requirements, and operator training.	Three years after the effective date of this final UST regulation.
Release detection	Three years after the effective date of this final UST regulation.
Release reporting, response, and investigation; closure; financial responsibility and notification, except as provided in § 280.251(2)(b).	On the effective date of this final UST regulation.

This final UST regulation modifies the 2011 proposed UST regulation by revising the definition of airport hydrant fuel distribution system and defining a field-constructed tank.

An airport hydrant fuel distribution system (also called airport hydrant system) is defined as an UST system which fuels aircraft and operates under high pressure with large diameter piping that typically terminates into one or more hydrants (fill stands). The airport hydrant system begins where fuel enters one or more tanks from an external source, such as a pipeline, barge, rail car, or other motor fuel carrier.

A field-constructed tank is defined as a tank constructed in the field. For example, a tank constructed of concrete that is poured in the field, or a steel or fiberglass tank primarily fabricated in the field is considered field-constructed.

Overview of Actions

Release Detection—Tanks

This final UST regulation requires airport hydrant system tanks and field-constructed tanks meet these requirements:

- These tanks must be monitored using release detection methods specified in subpart D:
  - Shop fabricated tanks and
  - Field-constructed tanks with a capacity less than or equal to 50,000 gallons
- Field-constructed tanks with a capacity greater than 50,000 gallons must either be monitored using release detection methods specified in subpart D (except tanks using groundwater and vapor monitoring must combine that method with inventory control as described in the alternatives below) or use one of the alternatives below
  - Conduct an annual tank tightness test that can detect a 0.5 gallon per hour (gph) leak rate
  - At least once every 30 days, use an automatic tank gauging system to perform release detection, which can detect a leak rate of 1 gallon per hour or less; and at least once every three years, use a tank tightness test that can detect a 0.2 gallon per hour leak rate
  - At least once every 30 days, use an automatic tank gauging system to perform release detection, which can detect a leak rate of 2 gallons per hour or less; and at least every two years, use a tank tightness test that can detect a 0.2 gallon per hour leak rate
  - At least every two years, perform vapor monitoring (conducted according to § 280.43(e) for a tracer compound placed in the tank system) capable of detecting a 0.1 gallon per hour leak rate
  - At least every 30 days, perform inventory control, conducted according to Department of Defense (DoD) Directive 4140.25; Air Transport Association (ATA) Airport Fuel Facility Operations and Maintenance Guidance Manual; or equivalent procedures that can detect a leak equal to or less than 0.5 percent of flow through and either
    - At least every two years, perform a tank tightness test that can detect a 0.5 gallon per hour leak rate or
    - At least every 30 days, perform vapor monitoring or groundwater monitoring (conducted according to § 280.43(e) or (f), respectively, for the stored regulated substance)

The implementing agency may approve another method of release detection if the owner or operator can demonstrate the method can detect a release as effectively as any of methods listed above. In comparing methods, the implementing agency shall consider the size of release the method can detect and frequency and reliability of detection.

Release Detection—Piping

Underground piping associated with field-constructed tanks less than or equal to 50,000 gallons must meet the release detection requirements in subpart D of the final UST regulation.

Underground piping associated with airport hydrant systems and field-constructed tanks greater than 50,000 gallons must meet these requirements:

- Piping must be monitored using release detection methods specified in subpart D, except that piping using groundwater and vapor monitoring must combine that method with inventory control as described in the alternatives below, or
- Use one of these alternatives
  - Perform a semiannual or annual line tightness test at or above operating pressure according to the table below

MAXIMUM LEAK DETECTION RATE PER TEST SECTION VOLUME

Test section volume (gallons)	Semiannual test—leak detection rate not to exceed (gallons per hour)	Annual test—leak detection rate not to exceed (gallons per hour)
<50,000	1.0	0.5
≥50,000 to <75,000	1.5	0.75
≥75,000 to <100,000	2.0	1.0
≥100,000	3.0	1.5

Piping segment volumes greater than or equal to 100,000 gallons, which are not capable of meeting the 3 gallons per hour leak rate for semiannual testing, may be tested at a leak rate up to 6 gallons per hour according to this schedule:

PHASE IN FOR PIPING SEGMENTS ≥100,000 GALLONS IN VOLUME

First test	Not later than three years after the effective date of this final UST regulation (may use up to 6 gph leak rate).
Second test	Between three and six years after the effective date of this final UST regulation (may use up to 6 gph leak rate).
Third test	Between six and seven years after the effective date of this final UST regulation (must use 3 gph leak rate).
Subsequent tests	Beginning seven years after the effective date of this final UST regulation, use semiannual or annual line testing according to the Maximum Leak Detection Rate Per Test Section Volume table above.

  - At least every two years, perform vapor monitoring according to § 280.43(e) for a tracer compound placed in the tank system capable of detecting a 0.1 gallon per hour leak rate
  - At least every 30 days, perform inventory control, conducted according to DoD Directive 4140.25, ATA Airport Fuel Facility Operations and Maintenance Guidance Manual, or equivalent procedures, that can detect a leak equal to or less than 0.5 percent of flow through and either
    - At least every two years, perform a line tightness test using the leak detection rate for the semiannual test in § 280.252(d)(2(i) or
    - At least every 30 days, perform vapor monitoring or groundwater monitoring (conducted according to § 280.43(e) or (f), respectively, for the stored regulated substance) or
- The implementing agency may approve another method of release detection if the owner or operator can demonstrate that the method can detect a release as effectively as any of the methods listed above; in comparing methods, the implementing agency shall consider the size of release the method can detect and the frequency and reliability of detection.

Release Prevention

This final UST regulation requires airport hydrant systems and field-constructed tanks meet corrosion protection, spill, overfill, and walkthrough inspection requirements. Corrosion protection installed on airport hydrant systems and field-constructed tanks must meet either:

- New tank and piping standards described in § 280.20, except that new and replaced hydrant piping and piping associated with field-constructed tanks greater than 50,000 gallons need not be secondarily contained or
- Airport hydrant systems and field-constructed tanks installed on or before the effective date of the final UST regulation must either meet the corrosion protection upgrade requirements in § 280.252(b)(1) or the new tank and piping standards described above

Airport hydrant systems and field-constructed tanks installed on or before the effective date of the final UST regulation that are not upgraded according to § 280.252(b) within three years of the effective date of the final UST regulation must be permanently closed according to subpart G. The presence of an internal lining does not meet the corrosion protection upgrade requirement.

Owners and operators of airport hydrant systems and field-constructed tanks must install spill and overfill prevention equipment and meet the

periodic spill testing and overfill inspection requirements of § 280.35. Owners and operators must install the equipment and conduct the first spill test and overfill inspection no later than three years after the effective date of this final UST regulation and every three years thereafter. For airport hydrant systems brought into use after the effective date of this final UST regulation, spill and overfill prevention equipment requirements must be met at installation.

Owners and operators must conduct walkthrough inspections that meet the requirements of § 280.252(c). Owners and operators must conduct the first inspection within three years after the effective date of the final UST regulation. In addition to the items inspected as part of the walkthrough inspection for other regulated UST systems, owners and operators of airport hydrant systems must inspect hydrant pits and hydrant piping vaults every 30 days for areas that do not require confined space entry according to the Occupational Safety and Health Administration (OSHA) and annually for areas that do require confined space entry. Owners and operators must keep documentation of the inspection according to § 280.36(b).

Notification

This final UST regulation requires owners and operators of regulated airport hydrant systems and field-constructed tanks meet these notification requirements:

- For airport hydrant systems and field-constructed tanks currently installed, owners and operators must submit no later than 3 years after the effective date of this final UST regulation a one-time notification to their implementing agency that their systems exist
- For airport hydrant systems and field-constructed tanks installed after the effective date of the final UST regulation, owners and operators must provide their implementing agency a notification of each newly installed system within 30 days of bringing each system into use
- Owners must provide their implementing agency a notification of ownership change for each newly acquired airport hydrant system or field-constructed tank within 30 days of the date on which the new owner assumes ownership

Financial Responsibility

This final UST regulation requires owners and operators of airport hydrant systems and field-constructed tanks that have not been permanently closed meet the financial responsibility requirements in subpart H at the time the one-time notification of existence is submitted to the implementing agency. Owners and operators who install these systems after the effective date of this final UST regulation must meet the financial responsibility requirements at installation. This requirement does not apply to state or federal owners of airport hydrant systems and field-constructed tanks.

Partially Excluded Components

This final UST regulation excludes aboveground storage tanks associated with airport hydrant systems and field-constructed tanks from the requirements of subparts B, C, D, E, G, J, and K. Owners and operators are still required to comply with subparts A (*Program Scope and Installation Requirements for Partially Excluded UST Systems*); and F (*Release Response and Corrective Action for UST Systems Containing Petroleum or Hazardous Substances*) for these tanks.

Operator Training

This final UST regulation requires owners and operators of airport hydrant systems and field-constructed tanks meet the operator training requirements in subpart J.

Closure Requirements for Previously Closed Tanks

When directed by the implementing agency, owners and operators of airport hydrant systems and field-constructed tanks permanently closed before the effective date of this final UST regulation must assess the excavation zone and close the UST system according to subpart G if releases from the UST may, in the judgment of the implementing agency, pose a current or potential threat to human health and the environment.

Background

Tanks and piping associated with airport hydrant systems and field-constructed tanks can store millions of gallons of fuel and handle large volumes of regulated substances on a daily basis. Leaks from these systems can contaminate subsurface soil beneath the airport apron and runways, groundwater, and nearby surface water systems, posing a significant risk to human health and the environment. As a result, EPA is removing the deferral.

Some commenters indicated EPA needed to justify that airport hydrant systems and field-constructed tanks are leaking in order to regulate them. The 1988 UST regulation required owners and operators report only confirmed releases from these tanks to implementing agencies. Owners and operators were not required to report suspected releases to implementing agencies, which sometimes resulted in gaps for ensuring proper site investigations or transmission of sufficient release information. As a result, implementing agencies have little to no available historical records regarding releases of regulated substances from airport hydrant systems and field-constructed tanks.

In the 2011 proposed UST regulation, EPA provided details on several releases that previously occurred at airport hydrant systems. Since that time, EPA identified additional information on releases from both DoD and commercial airport hydrant systems. For example, at Hartsfield Jackson International Airport in Georgia, active remediation and free product recovery is ongoing (as of 2014) due to a 1988 release of an estimated 14,000 gallons of jet fuel.[44] In 2003, an estimated 100,000 gallons of jet fuel leaked from the valves and flanges of an airport hydrant system at Minneapolis-St. Paul International Airport in Minnesota. Some of the jet fuel was released into the sanitary sewer and nearby waterway. During the investigation of the jet fuel release, personnel discovered a second jet fuel leak at a different concourse; this leak impacted the stormwater system and produced oily sheens in the Minnesota River. Responsible parties agreed to pay civil penalties and complete environmental projects, including continued site remediation and fuel recovery.[45] In 1983 at Camp Lejeune, North Carolina, investigators discovered multiple feet of free product while using a hand auger to investigate the cause of a fuel inventory discrepancy.[46] In addition, from the 1960s to the 1980s, thousands of gallons of jet fuel leaked from a former airport hydrant system at Pope Air Force Base, North Carolina. At one time, it was noted that as much as 75,000 gallons of free product was floating on top of the groundwater because of these releases. As of 2014, the site is undergoing remediation.[47] In addition, at Marine Corps Air Station Cherry Point, North Carolina there have been multiple releases from the airport

[44] Corrective Action Plan—Part B: Hartsfield-Jackson International Airport, Concourse Pit. Number 19 Fuel Spill.

[45] *http://www.pca.state.mn.us/index.php/about-mpca/mpca-news/current-news-releases/news-release-archive-2005/airport-agrees-to-pay-$540000-for-environmental-violations.html?nav=0.*

[46] *http://www.tftptf.com/New_ATSDR3/RR_DRAFT_RAO.pdf.*

[47] Federal Remediation Technologies Roundtable Abstracts of Remediation Case Studies, Volume 3 *http://epa.gov/tio/download/frtr/abstractsvol3.pdf.*

hydrant system underground piping. The station was cited twice in the 1990s for contaminating soil and groundwater under this fuel facility due to leaking tanks or fuel spills. An extensive environmental remediation effort is underway in 2014 to clean this site. Contamination from many of the releases combined and migrated to form a single plume.

In the 2011 proposed UST regulation, EPA also provided details on several previous releases that occurred from field-constructed tanks. Since that time, EPA identified additional anecdotal information on releases from field-constructed tanks. At Adak Island, Alaska's Tank Farm A, records show fuel was released at various times from 21,000 to 420,000 gallon field-constructed tanks and piping. As of 2014, all tanks have been removed, but the former fuel farm is still undergoing remediation through long term monitoring and monitored natural attenuation.[48] Also at Adak Island, an overfill during a fuel transfer caused 142,800 gallons of diesel fuel to leak from a 4.8 million gallon underground field-constructed tank into the immediate and surrounding environment, causing harm to native wildlife.[49]

Releases can have a major impact on human health and the environment. Release prevention equipment, regular release detection tests, operator training, periodic walkthrough inspections, and proper operation and maintenance are keys to preventing and quickly identifying releases before they contaminate the surrounding environment. This final UST regulation adds these requirements for airport hydrant systems and field-constructed tanks in order to help prevent and quickly detect leaks from these systems into the environment.

Definition of an Airport Hydrant System

The 1988 UST regulation did not provide a definition for airport hydrant system. In the 2011 proposed UST regulation, EPA provided a definition of an airport hydrant system to clarify what components would be regulated. However, that definition was based on an airport hydrant system that received fuel at a single delivery point, designed with all components operating in tandem, and included only the immediate piping and tank directly feeding the airport hydrant piping. To clarify for owners and operators, EPA presented scenarios of typical airport hydrant systems in a guidance document provided during the public comment period.

After publishing the 2011 proposed UST regulation, EPA met with stakeholders to gather more information on airport hydrant system design and operation.[50] [51] EPA also provided another iteration of the schematics that contained better defined airport hydrant system scenarios. However, some commenters still were confused about which specific components of an airport hydrant system would be regulated.[52]

Many commenters requested that EPA provide guidance on how to perform the calculations to determine whether the airport hydrant system meets the definition of an underground storage tank and requested clarification of system components. In response to these comments, EPA is providing guidance below.

In order for an airport hydrant system to be subject to the final UST regulation, it must first meet the definition of an underground storage tank. Airport hydrant systems are not regulated UST systems under 40 CFR part 280, unless 10 percent or more of the total capacity of the system is beneath the surface of the ground. When performing the calculation, include all tanks and underground piping that are part of the airport hydrant system. An airport hydrant system may have one or more of the following connected together: Aboveground tanks, underground tanks, field-constructed tanks, or factory constructed tanks. Below are two examples. Note that aboveground piping is not included when calculating the total volume.

Example 1: A 1 million gallon aboveground storage tank (AST) connected to underground piping with a capacity of 100,000 gallons does not meet the definition of an UST, as explained below:

1 million gallons (AST) + 100,000 gallons (underground pipe) = 1.1 million gallons total volume

1.1 million gallons × 10% = 110,000 gallons

The volume of the underground piping (100,000 gallons) is less than 10 percent of the total volume of the tanks and underground piping (110,000 gallons).

Example 2: A 2 million gallon AST feeds two 100,000 gallon field-constructed underground storage tanks and two 50,000 gallon underground tanks constructed in the factory which feed 100,000 gallons of underground hydrant piping. Calculating these values yields a total system capacity of 2,400,000 gallons with 400,000 gallons underground. More than 16% of this airport hydrant system is underground making it an UST.

In response to comments on the proposed definition, EPA is clarifying the definition of an airport hydrant system in this final UST regulation. EPA determined that multiple tanks grouped or interconnected together can function as one system to fuel an airport hydrant system. EPA agrees with commenters that it would not be feasible to separate these tanks to define an airport hydrant system. EPA also found that other tanks not directly connected to the underground airport hydrant piping also could feed the airport hydrant system. The Agency is concluding that an airport hydrant system may consist of interconnected aboveground and underground storage tanks (that could be constructed in the factory or field-constructed) and piping that function as integral and interchangeable components of the fueling system. Field-constructed tanks that are part of the airport hydrant system are treated as part of the airport hydrant system and not independent UST systems that are field-constructed. The airport hydrant system begins when regulated substance enters from an external source such as a pipeline, barge, rail car, or other motor vehicle carrier, but does not include the external source. Airport hydrant systems use large diameter piping and operate at pressures higher than those of a conventional UST. This final definition alleviates stakeholder uncertainty on which components of an airport hydrant system must meet the UST regulation by including all integral components that form an airport hydrant system and deliver fuel to the aircraft. These systems include underground piping and ASTs or USTs that hold aircraft fuel (for example, settling tanks or product recovery tanks). They do not include tanks or underground piping not storing aircraft fuel (for example, additive tanks) or tanks and underground piping not connected to the airport hydrant system (for example, a system that fuels an emergency power generator for a pump house). In addition, EPA is aware there may be instances where an airport hydrant system might include permanently installed dispensing

[48] Tank Farm A *http://dec.alaska.gov/Applications/SPAR/CCReports/Site_Report.aspx?Hazard_ID=686.*

[49] *http://www.darrp.noaa.gov/northwest/adak/pdf/ADAK_DARPEA_FINAL_Draft%20PDF.pdf.*

[50] January 28, 2012, March 29, 2012, and October 19, 2012 meetings with representatives from Airlines for America.

[51] February 28, 2013 and March 18, 2013 meetings with DoD's Defense Logistics Agency Energy.

[52] *Airport Hydrant Systems Scenarios Revised,* dated February 28, 2012.

equipment at the end of the hydrant piping instead of a fill stand. However, since these systems still operate under high pressure and contain large diameter piping, we consider them to be airport hydrant systems.

Definition of a Field-Constructed Tank

The preamble to the 1988 UST regulation described a field-constructed tank as a tank usually constructed of steel or concrete and shaped like flat vertical cylinders, with a capacity of greater than 50,000 gallons. Tanks that are primarily factory built, but assembled in the field, are considered factory built tanks. For example, welding two halves of a factory constructed tank together in the field does not qualify the tank as a field-constructed tank. Several commenters requested EPA define field-constructed tank in the final UST regulation in order for implementing agencies and owners and operators to know which tanks are applicable. While EPA thinks this term is self-evident, this final UST regulation defines field-constructed tank as a tank constructed in the field. For example, a tank constructed of concrete that is poured in the field, or a steel or fiberglass tank primarily fabricated in the field is considered field-constructed. Please note this definition excludes those tanks with components primarily manufactured in a factory with minimal assembly in the field. EPA considers those tanks are factory built tanks. Field-constructed tanks vary from sizes smaller than 50,000 gallons to sizes very large in capacity. Large capacity tanks may exceed size or shape limitations that prohibit transportation of the tank in whole to the UST site. Field-constructed tanks present an engineering, design, or transportation concern that cannot be addressed by fabrication in a factory or are more ideally addressed through in-field construction. This definition includes tanks that are mounded or partially buried, such as those defined in 40 CFR part 112, if 10 percent or more of the volume of the system is beneath the ground's surface or otherwise covered with earthen material. EPA considers a field-constructed tank that is part of a wastewater treatment system to be partially excluded from the final UST regulation according to § 280.10(c). See section C–3 for additional information on the partial exclusion for wastewater treatment tank systems.

Universe of Field-Constructed Tanks and Airport Hydrant Systems Affected

UST systems with field-constructed tanks are generally very large and, in the event of a release, pose a substantial threat to human health and the environment. Typical tank sizes range from 20,000 gallons to greater than 2 million gallons. EPA is aware of approximately 330 UST systems with field-constructed tanks owned by the Department of Defense and 12 field-constructed tanks owned by the Department of Energy (DOE).

One commenter objected to EPA regulating airport hydrant systems because the 2011 proposed UST regulation addressed airport hydrant systems at military facilities and did not include systems at commercial airports. When issuing the 2011 proposed UST regulation, EPA thought the universe of these systems was mainly owned by DoD, based on information from DoD and commercial airport representatives. The 2011 proposed UST regulation also assumed the universe included two commercial airports with airport hydrant systems. Airlines for America (A4A, formerly known as Air Transport Association of America, Inc.) provided additional information during the public comment period that suggested nine commercial airports would be affected by the final UST regulation. As a result of the comments received, EPA did extensive research to confirm which commercial airports might be affected by the final UST regulation. EPA met with personnel from DoD and from eight of the nine suggested commercial airport facilities to gather additional information and determine the universe of airport hydrant systems that would have to comply with the final UST regulation.[53] [54] [55] [56] Additionally, EPA listened to concerns and answered questions about the 2011 proposed UST regulation. EPA also met with release detection vendors to determine whether commercial airports and DoD facilities could achieve release detection compliance within the specified time frames.[57] [58] [59] EPA concluded that of the nine airports A4A named, eight would possibly be affected by the final UST regulation. Based on these meetings, EPA found that most of the commercial airport hydrant systems have release prevention and detection equipment currently installed on them and airport personnel are already performing various activities that can be modified to meet the final UST regulation.

Process for Obtaining Public Comment

One commenter suggested that EPA:

- Did not follow all requirements to allow stakeholder input prior to issuing the 2011 proposed UST regulation
- Did not allow stakeholders adequate time to provide comments
- Failed to follow the correct public notice procedures
- Failed to inform stakeholders of two commercial airports that might be affected by the final UST regulation
- May have led commercial airport stakeholders to doubt that any commercial airport hydrant systems would be affected by the final UST regulation

The commenter also suggested EPA should withdraw the 2011 proposed UST regulation because the administrative record and resulting proposal conflicted with Executive Order 13563 (*Improving Regulation and Regulatory Review*).[60]

EPA disagrees with these comments. We performed extensive stakeholder outreach both prior to developing the 2011 proposed UST regulation and during the public comment period. In addition, EPA followed procedures required by the Administrative Procedure Act for providing public notice and requesting public comment through the **Federal Register**. In order to allow additional time for airport authorities to perform a preliminary assessment and respond to the 2011 proposed UST regulation, EPA extended the public comment period by two months as requested by commenters.[61] EPA met with all interested stakeholders who requested meetings, including representatives of commercial airports. EPA carefully researched information provided during the public comment period; this included verifying methods of release detection currently

[53] Discussions With Commercial Airports That May Be Affected By The Final UST Regulation dated February 6, 2013.

[54] Note that EPA did not meet with personnel from Indianapolis International Airport however, A4A and vendors stated that the airport hydrant system is equipped with the necessary equipment to meet requirements in the final UST regulation.

[55] January 28, 2013 and March 29, 2012 meetings with A4A.

[56] February 28, 2013 and March 18, 2013 meetings with DoD's Defense Logistics Agency Energy.

[57] June 20, 2012 and May 19, 2013 meeting with Hansa Consult of North America, LLC.

[58] June 20, 2012 meeting with VISTA Precision Solutions.

[59] August 15, 2012 meeting with Ken Wilcox and Associates.

[60] On January 18, 2011, President Obama issued Executive Order 13563, which directed federal agencies to develop a preliminary plan which outlined the agency's approach for periodically reviewing regulations to determine whether any rules ''should be modified, streamlined, expanded, or repealed so as to make the agency's regulatory program more effective or less burdensome in achieving the regulatory objectives.''

[61] January 5, 2012 request from A4A for a 60-day extension for more time to review and query its membership and potentially affected airports for a more complete understanding of the 2011 proposed UST regulation and potential costs.

in use at commercial airports and DoD facilities, as well as what methods would be technically feasible at those facilities. When issuing the 2011 proposed UST regulation, EPA thought Lambert-St. Louis International Airport and Denver International Airport were the only commercial airports that would be affected by the final UST regulation. EPA identified these airports in a meeting with Airlines for America. During that meeting, the Agency also received additional information on other airports possibly affected by the proposal.[62] While EPA did not specifically identify the two commercial airports that would potentially be affected by the final UST regulation, the 1988 UST regulation has been in effect for over two decades and portions of it have applied to airport hydrant systems since that time. Owners and operators of these systems have been required to comply with those applicable portions of the UST regulation since 1988, and it has been the responsibility of owners and operators to determine whether their airport hydrant systems are regulated since the effective date of the 1988 UST regulation. Nonetheless, EPA stated in the 2011 proposed UST regulation that airport hydrant systems are ''. . . mainly owned by the Department of Defense (DoD) . . .,'' not that DoD is the sole owner of all airport hydrant systems. This statement indicates there are non-DoD owned airport hydrant systems that could be affected by this final UST regulation.

Impacts of Regulating Airport Hydrant Systems and Field-Constructed Tanks

Commenters generally supported removing the deferral for these systems. However, there were some commenters who opposed regulating these systems. A few commenters were concerned about the costs for owners and operators to comply with the release detection requirements of the final UST regulation. EPA acknowledges that some release detection methods may result in additional costs to owners and operators. However, EPA carefully researched current release detection efforts at commercial airports and DoD facilities and used that information to estimate costs. See the RIA, which is available in the docket for this action, for additional information about how we estimated costs.

Other Regulations That Affect Airport Hydrant Systems and Field-Constructed Tanks

To avoid overlapping regulations, several commenters suggested EPA evaluate other requirements that owners and operators of airport hydrant systems and field-constructed tanks perform as part of fuel management programs. One commenter also asserted that this evaluation was necessary to comply with Executive Order No. 13563.[63] After issuing the 2011 proposed UST regulation, EPA performed this evaluation by gathering information on fuel management programs (such as release prevention, repairs, operation and maintenance, inspections, and operator training) owners and operators at these facilities must perform in order to meet other federal, state, and industry regulations.[64] For example, EPA found that requirements administered by the Federal Aviation Authority (FAA), such as 14 CFR part 139 (*Certification of Airports*), and directives, such as ATA 103 and United Facilities Criteria (UFC) 3–460–03, require owners and operators of airport hydrant systems inspect airport hydrant systems and connected components. EPA also found that 14 CFR part 139 (*Certification of Airports*) emphasizes overall airport safety practices.

One commenter asked whether EPA evaluated the SPCC requirements for regulating underground portions of airport hydrant systems. Another commenter suggested that EPA evaluate the effectiveness of existing state requirements for field-constructed tanks.[65] EPA is aware that commercial airports and DoD facilities comply with SPCC requirements for their airport hydrant systems and field-constructed tanks. However, UST and SPCC regulations are complementary. The SPCC regulation focuses on oil discharges that could impact navigable waters, while the UST regulation focuses mainly on day-to-day maintenance and operation to prevent releases to soil and groundwater. For example, the SPCC regulation requires a tank inspection, such as an American Petroleum Institute (API) Standard 653 inspection, which ensures aboveground storage tanks and piping are structurally sound. In addition, regulatory overlap is mitigated by the SPCC regulation, which allows UST release detection as a method to meet its tank inspection requirement. The SPCC regulation requires owners and operators conduct integrity and leak testing of buried piping at the time of installation, modification, construction, relocation, or replacement, but does not specify a method, frequency, or leak rate. The UST regulation is more specific and requires periodic release detection testing of underground piping.

EPA thinks that other regulatory programs (such as SPCC and FAA) lack the necessary specificity or do not meet equivalency criteria we deem are necessary for these UST systems. Additionally, even though some A4A documents provide many recommended practices that owners and operators of airport hydrant systems and field-constructed tanks may follow for their fuel management programs, these practices are not regulatory requirements, and airports have the option of following them. Moreover, EPA developed a final UST regulation that is cost effective to the extent practical and is the least burdensome to owners and operators, yet still protects human health and the environment. This final UST regulation does not impose redundant requirements. Rather, it contains complementary requirements that will protect human health and the environment.

Effect on Airport Operations

One commenter suggested the requirements in the 2011 proposed UST regulation were not legally or technically viable for commercial airports. That commenter said EPA should develop a separate regulation specific to commercial airport hydrant systems. In addition, a few commenters were concerned that removing the deferral for airport hydrant systems would cause service disruptions due to installing release prevention and detection equipment. Those commenters also said performing release prevention and detection would cause massive service delays, affect military missions, and threaten national security and the National Airspace System.

Based on discussions with DoD prior to issuing the 2011 proposed UST regulation and talking to DoD and potentially affected airports after issuing it, EPA concluded that most facilities already have the necessary equipment to meet many of the requirements in the final UST regulation. EPA also concluded from those conversations that release detection is normally performed during service downtimes or when

[62] January 28, 2012 meeting with A4A.

[63] Executive Order 13563 requires federal agencies to avoid implementing unnecessary redundant requirements and promulgate regulations that are less burdensome to the regulated community.

[64] EPA performed an assessment of the following additional requirements that owners and operators follow: 40 CFR part 112 (SPCC); 14 CFR part 139 (FAA); A4A 123; ATA 103; ATA O&M Guidance; UFC 3–460–1 [*Proposed UST Requirements Compared To Existing Facility Requirements And Recommended Practices*].

[65] New York allows owners and operators to perform a modified American Petroleum Institute Standard 653 inspection combined with monitoring well release detection for large field-constructed tanks.

operations are minimal. Some airport hydrant systems have the capability of transferring product flow to other sections of the airport hydrant system to avoid system downtime. DoD stated that leak testing is performed according to prescribed requirements in Florida and California and at least biennially in other states when funding allows. Where feasible, piping is normally tested in segments to meet testing leak rates; piping segments can be isolated to find leaks more efficiently. EPA learned that some airport hydrant systems are capable of bypassing areas when airport hydrant piping is being tested; this avoids total system shutdown and allows continued airport operation. In addition, many airport personnel perform daily operations and maintenance activities, such as hydrant pit inspections and leak monitoring, on airport hydrant system components to avoid product loss, ensure fuel quality, and ensure personnel safety.

This final UST regulation incorporates many of those tasks that operators normally perform regularly to prevent and detect leaks from these systems. However, to meet the final UST regulation, owners and operators may need to make minor modifications to their current activities. Since many airports have mechanisms in place and are already performing release monitoring, meeting requirements in the final UST regulation will not severely affect airport operations or cause service delays severe enough to significantly affect the military mission or disrupt the National Airspace System. EPA concluded that the information we gathered since issuing the 2011 proposed UST regulation supports regulating these systems as required in the final UST regulation. In addition, this final UST regulation includes changes to ensure compliance requirements are less disruptive and further mitigate concerns regarding service disruptions, such as adding options owners and operators may use to meet the release detection requirement.

Implementation Time Frame

EPA is aware that this final UST regulation adds new requirements for owners and operators, as well as implementing agencies which have not fully regulated airport hydrant systems and field-constructed tanks in the past. A few commenters voiced concerns that the proposed implementation time frames would not give owners and operators, or implementing agencies, adequate time to assess these systems and determine the proper course of action. EPA thinks providing a single effective date is important because it reduces the burden on implementing agencies, owners, and operators to track various compliance deadlines. EPA is also allowing owners and operators who use periodic tightness testing for certain piping to phase in release detection requirements up to seven years. Additionally, EPA thinks three years gives owners and operators sufficient time for planning and installing necessary equipment to meet the requirements in this final UST regulation.

Other Comments

Commenters generally supported changing the applicability date for previously closed systems of airport hydrant systems and field-constructed tanks, giving implementing agencies the flexibility to require a site assessment and proper closure of systems closed between the effective date of the 1988 UST regulation and this final UST regulation. EPA agrees with commenters. As a result, this final UST regulation requires owners and operators of field-constructed tanks and airport hydrant systems, which were permanently closed before the effective date of this final UST regulation, to conduct a site assessment and close the UST system according to the closure requirements if directed to do so by the implementing agency.

In the 2011 proposed UST regulation, EPA asked commenters if we should consider alternative options for closing very large UST systems in place. Most commenters recommended that large field-constructed tanks either be removed or filled with an inert solid material to prevent releases of residual contamination to the environment. Others suggested EPA allow some flexibility when closing these UST systems in place. EPA agrees with commenters that implementing agencies may need to have more flexibility in addressing these systems at closure. EPA is modifying the closure requirement in § 280.71(b) of the final UST regulation to allow closure in place in a manner approved by the implementing agency. This addition provides implementing agencies the option to determine that owners and operators may close the UST system in place without filling it with an inert solid material.

One commenter recommended that EPA, in the final UST regulation, directly reference the military construction standard associated with field-constructed tank design and construction discussed in the preamble to the 2011 proposed UST regulation. EPA agrees with the commenter and is adding the military construction criteria *UFC 3–460–01—Petroleum Fuel Facilities* to this final UST regulation.[66] Although design standards are now available for aboveground field-constructed tanks, EPA is not aware of standards written according to a national code of practice developed by a nationally recognized or independent testing laboratory for non-military field-constructed tanks and airport hydrant systems. If demand arises and a commercial standard is not developed to address the need, owners and operators may use the UFC, where applicable.

Release Detection

Background

In the preamble to the 1988 UST regulation, EPA discussed the large volumes of product throughput, large capacities, and long lengths of large diameter piping for airport hydrant systems. At the time, EPA believed release detection was not feasible for airport hydrant systems. These systems were monitored for releases periodically, but no single leak test existed as an industry standard. Inventory control was often used, but its sensitivity was limited due to the large product volumes airport hydrant systems typically handle. To allow more time for gathering information, EPA in the 1988 UST regulation deferred regulating airport hydrant systems from release detection requirements in subpart D. EPA also deferred UST systems with field-constructed tanks from most requirements in the 1988 UST regulation, due to a lack of appropriate release detection methods. At that time, EPA believed the majority of release detection methods applied to factory built tank systems and did not adequately work for UST systems with field-constructed tanks or airport hydrant systems.

Challenges of Conventional Release Detection Methods

Standard release detection methods can successfully test and detect releases on pressurized piping at commercial service stations, but that is not the case for airport hydrant systems and large diameter piping associated with field-constructed tanks. For a variety of reasons, the piping of most airport hydrant systems and field-constructed tanks cannot meet release detection

[66] UFC 3–460–01—*Petroleum Fuel Facilities* is a military construction criteria that includes basic requirements for the design of fueling systems; the design of receiving, dispensing, and storage facilities; ballast treatment and sludge removal; corrosion and fire protection; and environmental requirements.

requirements in the 1988 UST regulation. High product throughput makes it difficult and expensive to achieve the same leak rate thresholds established for traditional UST systems within a reasonable time frame. Product temperature fluctuations present challenges for release detection testing of conventional underground piping. However, release detection for piping of airport hydrant systems and large diameter piping associated with field-constructed tanks poses greater challenges. As temperatures fluctuate, product expands or contracts, increasing or decreasing product volume and pressure. The magnitude of piping associated with these systems creates an even greater temperature fluctuation; there are varying temperature gradients throughout the length of piping. Fluctuating line pressure during a release detection test can mask an existing release or falsely indicate one occurred. In addition, the out of service period needed to test airport hydrant piping could range from one to several days after the last product transfer.

Removing airport hydrant systems from service for extended periods will greatly impede their purpose of rapid and timely delivery of fuel to aircraft. When using pressure based testing methods to produce accurate leak test results, airport hydrant system piping needs to be isolated in appropriately sized segments. Some airport hydrant systems have numerous isolation points with connections for release detection equipment. Others have longer underground piping segments with isolation valves for testing located up to 0.5 miles apart. The greater the volume of a segment, the more time it takes to obtain a valid result at a given leak rate. Although technology is available, it may be cost prohibitive and require significant facility down time for owners and operators to monitor airport hydrant systems for releases at the rates and frequencies required in the 1988 UST regulation.

EPA also recognizes that most release detection methods for factory built tanks are capable of monitoring UST systems with field-constructed tanks up to 50,000 gallons. After evaluating current methods, EPA realized existing release detection options for tanks in subpart D of the 1988 UST regulation are generally not applicable to UST systems greater than 50,000 gallons because most methods are limited by tank capacity. EPA acknowledges the complexities in performing release detection on tanks significantly larger than 50,000 gallons. It is critical to allow sufficient time for a tank to reach a state of equilibrium prior to performing a test. As tank size increases, the time for a tank to reach an equilibrium increases significantly. Based on discussions with release detection vendors, many larger tanks require multiple inactive days to yield an accurate test result.

DoD owns most UST systems with field-constructed tanks. Taking these tanks out of service for multiple days to meet the 1988 release detection requirement would, in some cases, impede DoD's mission, be impractical to sustain, and result in significant costs.

Release Detection Is Now Available

While release detection used for conventional USTs may not work well for airport hydrant systems and field-constructed tanks greater than 50,000 gallons, release detection methods specifically designed for these UST systems are now available. Over the last 25 years, the petroleum services industry has developed release detection technologies for airport hydrant systems and field-constructed tanks. The NWGLDE lists *Large Diameter Line Leak Detection Method (6 Inches Diameter Or Above)* and *Bulk Underground Storage Tank Leak Detection Method (50,000 Gallons Or Greater),* both of which identify methods capable of detecting releases from airport hydrant systems and field-constructed tanks.[67] EPA contacted several vendors to determine the strengths and limitations of release detection methods for these UST systems. EPA also talked with DoD's Defense Logistics Agency (DLA) Energy[68] about challenges in addressing release detection requirements in states, such as California, which do not defer airport hydrant systems from release detection. Because they perform release detection on airport hydrant systems in other states, DLA Energy has significant information about airport hydrant system release detection. As of this final UST regulation, some state UST programs require release detection for UST systems with field-constructed tanks and airport hydrant systems.[69]

Feasibility of Proposed Release Detection Options for Piping

In order to allow owners and operators flexibility to meet the release detection requirement, EPA proposed these four alternatives for underground piping associated with airport hydrant systems and field-constructed tanks greater than 50,000 gallons:

- Pressure based line testing methods
- Continuous interstitial monitoring
- Automatic line leak detector combined with interstitial monitoring and
- Other methods approved by implementing agencies

EPA requested comment or additional data on the proposed release detection requirements to determine their feasibility. Several commenters said the options in the 2011 proposed UST regulation were insufficient and requested EPA provide options that offered owners and operators more choices. A4A provided EPA with the names of nine commercial airports that could be affected by the final UST regulation and the feasibility of applying the release detection methods discussed in the 2011 proposed UST regulation to these airports. This information helped EPA further refine this final airport hydrant system requirements, including release detection.

A4A stated that the only feasible choice EPA provided was pressure based methods and substantial retrofits would be required to meet the requirements at Chicago O'Hare International Airport (ORD), John F. Kennedy International Airport (JFK), and possibly other airports. However, EPA through our analysis and in depth discussions with those airports, thinks the airport hydrant system at JFK, as currently configured, may not meet the definition of an UST in this final UST regulation; this means the requirements would not apply. In addition, if planned capital upgrades are completed on one of ORD's airport hydrant systems, that system may not meet the definition of an UST and would not be subject to this final UST regulation. If configurations for either of these airport hydrant systems change in the future, the owner and operator must re-evaluate the system to determine if it meets the definition of UST in this final UST regulation. Owners and operators are responsible for determining whether their airport hydrant systems meet the definition of an UST and, if necessary, comply with this final UST regulation.

As a result of comments and while developing the final UST regulation, EPA met with DoD, A4A, personnel

[67] National Work Group On Leak Detection Evaluation's List Of Leak Detection Evaluations For Storage Tank Systems. *http://www.nwglde.org/.*

[68] Defense Logistics Agency Energy was formerly known as Defense Energy Support Center.

[69] Tasks 2–4, Work Assignment 1–25: *Preliminary Assessment and Scoping of Data Related to Potential Revisions to the UST Regulations;* Industrial Economics (IEc) Inc. identified 17 state UST programs that regulate airport hydrant systems. EPA's Office of Underground Storage Tanks gathered additional information from seven of nine select state UST programs to identify the extent of the state's release detection requirements and compare those requirements to the release detection requirements in EPA's proposed 2011 UST regulation.

representing potentially impacted commercial airports, and release detection vendors to develop release detection methods for the final UST regulation and determine how or if commercial airports and DoD facilities could achieve compliance within the specified time frames.[70] [71] [72] [73] [74] From those discussions, EPA found that most, if not all, of the potentially affected commercial airports have or will have mechanisms in place to achieve compliance with the release detection requirements in this final UST regulation. In addition, owners and operators already implement release detection according to technical requirements in states where airport hydrant systems are not deferred. EPA found that many of these airport hydrant systems perform a type of inventory management and hydrostatic testing of the piping system to detect pressure changes in the UST system. EPA determined that although the 1988 UST regulation did not require airport hydrant system owners and operators perform these tests, both DoD facilities and commercial airports have already been performing various fuel management methods to monitor and track fuel inventories.

Release Detection Options for Piping in the Final UST Regulation

Based on comments, EPA is providing flexibility for owners and operators of piping associated with airport hydrant systems and field-constructed tanks greater than 50,000 gallons to meet the release detection requirements. This final UST regulation modifies the piping release detection options in the 2011 proposed UST regulation and incorporates some of the methods currently used at commercial airports and DoD facilities. Owners and operators of these systems may use existing piping release detection options provided in subpart D (except for passive groundwater and vapor monitoring, which must be combined with inventory control as described below), or they may use alternative piping release detection methods in § 280.252(d)(2). EPA thinks these options are reasonable and represent an appropriate balance of practicality and protectiveness. Piping associated with field-constructed tanks 50,000 gallons or less in capacity must use the release detection options listed in subpart D.

Pressure Based Testing

The final UST regulation allows owners and operators to perform pressure based testing methods according to performance criteria dependent on volume of the line segment tested. These criteria provide specific performance thresholds for both semiannual and annual testing. Owners and operators may perform semiannual or annual line testing at or above operating pressure with a probability of detection of 0.95 and a probability of false alarm of 0.05. This method allows owners and operators to meet a variable leak rate based on piping test section volume. The leak rate ranges from 1 to 3 gallons per hour, depending on piping volume for semiannual testing and from 0.5 to 1.5 gallons per hour for annual testing. The final UST regulation establishes 3 gallons per hour as the maximum threshold because the majority of available testing methods are capable of meeting this leak rate.

For the first six years (or two test periods), piping segments that cannot meet a 3 gallons per hour threshold are allowed to meet a higher threshold of up to 6 gallons per hour. Available methods are capable of testing segments to a leak rate of 6 gallons per hour. The higher threshold provides for use of existing test methods during the first six year period. Six years will provide owners and operators time to upgrade their piping systems to meet the up to 3 gallons per hour threshold for semiannual testing. Between years six and seven, owners and operators must conduct one additional tightness test that, at a minimum, meets the semiannual testing threshold. In the seventh year, owners and operators must begin meeting the semiannual or annual line tightness testing requirements according to the requirements in § 280.252(d)(2)(i). EPA is providing a three year phase-in period for the remaining release detection options, because these methods will not require significant construction or upgrades for implementation.

EPA asked commenters whether other release detection options should be considered for underground piping associated with airport hydrant systems and field-constructed tanks greater than 50,000 gallons. Based on comments, EPA is adding inventory control, groundwater and vapor monitoring, and other methods for piping as release detection options in this final UST regulation.

Inventory Control

EPA reviewed performance standards for daily inventory control procedures used by DoD and the commercial airports identified by A4A.[75] [76] Based on performance standards for daily inventory control procedures performed by both DoD and A4A, EPA is allowing inventory control as part of a combination method of release detection. EPA chose 0.5 percent of flow through as the performance standard for inventory control because this value represents the maximum tolerance allowed under the performance standard for products typically stored or handled by airport hydrant systems. Owners and operators may conduct inventory control according to DoD Directive 4140.25, ATA's Airport Fuel Facility Operations and Maintenance Guidance Manual, or equivalent procedures. EPA is allowing this method in combination with either a pressure based line tightness test using the leak rates from the semiannual test in § 280.252(d)(2)(i) at least once every two years, or passive groundwater or vapor monitoring once every 30 days as described below.

Groundwater and Vapor Monitoring

EPA proposed to phase out groundwater and vapor monitoring as release detection methods in the 2011 proposed UST regulation. However, this final UST regulation retains these methods with modifications. See section D–6 for more information. These methods are also allowed with some modifications in subpart K. EPA divided vapor monitoring into two categories: Active monitoring for chemical markers or tracers and passive monitoring for stored product in the tank system. Owners and operators of these systems

[70] January 28, 2012 and March 29, 2012 meetings with representatives from Airlines for America.

[71] February 28, 2013 and March 18, 2013 meetings with DoD's Defense Logistics Agency Energy.

[72] June 20, 2012 and May 19, 2013 meeting with Hansa Consult of North America, LLC.

[73] June 20, 2012 meeting with VISTA Precision Solutions.

[74] August 15, 2012 meeting with Ken Wilcox and Associates.

[75] DoD's Bulk Petroleum Management Policy—DoD 4140.25–M, Volume II—*Petroleum Management,* Chapter 10—Accountability (June 22, 1994) is accessible on line at: *http://www.dtic.mil/whs/directives/corres/pdf/414025-m-vol2-chapter10.pdf.* This standard recognizes that petroleum products are subject to losses and gains. The tolerance factor that represents the amount of fuel which might be lost or gained under normal conditions varies by product and status of fuel (*i.e.,* storage or in transit). These values in the policy represent standard tolerances (*i.e.,* system flow-through) for various products in transit and storage: (1) Aviation and motor gas = 0.5 percent and 0.5 percent; (2) JP4 = 0.5 percent and 0.3 percent; (3) Jet Fuel, Distillates, Residuals = 0.5 percent and 0.25 percent; and (4) JP5, JP8, DF2, F76, etc. = varies by individual agreements with airports and 0.5 percent.

[76] EPA reviewed Airlines For America Guidance—*ATA Airport Fuel Facility Operation and Maintenance Guidance Manual,* Revision 2004.1; and ATA Spec 123: *Procedures for the Accounting of Jet Fuel Inventory 2011.2.* The two documents provide guidance for operators to investigate, report, or explain any variances exceeding ±0.1 percent.

may use active vapor monitoring methods characterized by testing or monitoring of chemical markers or a tracer compound placed in the tank system, according to § 280.43(e) to detect a release of at least 0.1 gallon per hour with probabilities of detection and false alarm of 0.95 and 0.05, respectively. Owners and operators choosing this option must conduct this test at least once every two years. This method may be used as a stand-alone method of release detection.

Owners and operators may also combine passive vapor or groundwater monitoring with inventory control, described above, that can detect a release of at least 0.5 percent of flow through at least every 30 days. Passive vapor monitoring or groundwater monitoring must be conducted at least every 30 days according to § 280.43(e) or (f), respectively.

Other Methods for Piping

The final UST regulation maintains the option for owners and operators to use alternative methods of release detection for piping approved by the implementing agency, as discussed in the 2011 proposed UST regulation. This provides flexibility for owners and operators to comply by using methods or a combination of methods equivalent to the requirements in § 280.252(d)(2). EPA recognized that other methods not included in § 280.252(d)(2) could be acceptable, as long as they are as effective and are approved by implementing agencies. The performance criteria for piping release detection methods in § 280.252(d)(2) provide owners and operators with information about how to demonstrate the effectiveness of release detection methods that must be approved by the implementing agency.

Proposed Release Detection Options for Piping Not Included in the Final UST Regulation

Because piping segments associated with airport hydrant systems and field-constructed tanks can contain large volumes of regulated substances, EPA asked commenters if it was feasible to require ALLDs to detect a leak at 3 gallons per hour at 10 pounds per square inch line pressure within one hour or equivalent. EPA anticipated receiving information on the appropriate leak rate for ALLDs on this piping. EPA did not receive any indication that current performance standards of ALLDs could be modified for these systems. Although some portions of existing systems may be able to use this option, EPA agrees it is not feasible to use an ALLD with interstitial monitoring on piping associated with airport hydrant systems and field-constructed tanks.

This final UST regulation modifies the 2011 proposed UST regulation; owners and operators of airport hydrant systems or piping associated with field-constructed tanks greater than 50,000 gallons are not provided specific requirements in this final UST regulation for using continuous interstitial monitoring and the combination of automatic line leak detectors with interstitial monitoring for piping. Many of these systems lack secondary containment and automatic line leak detectors cannot adapt to the operating pressures of these systems. In the 2011 proposed UST regulation, EPA asked if testing the piping for airport hydrant systems and field-constructed tanks at operating pressure was sufficient. The 1988 UST regulation requires owners and operators test conventional systems at one and a half times operating pressure. EPA is aware that airport hydrant system piping operates at high pressures and agrees with commenters who stated that testing above operating pressure might be infeasible. This final UST regulation requires owners and operators to test these systems at least at operating pressure, because these large piping systems operate at pressures much higher than conventional gasoline stations. However, EPA is allowing testing at or above operating pressure, but is not providing a set value. Professional testers can decide the appropriate pressure to test these systems, as long as the pressure is at least the operating pressure of the system.

Release Detection Requirements for Tanks Associated With Airport Hydrant Systems and Field-Constructed Tanks

This final UST regulation establishes release detection requirements for tanks associated with airport hydrant systems and field-constructed tanks. Airport hydrant systems may consist of a series of large capacity shop fabricated tanks, although some airport hydrant systems use field-constructed tanks. Shop fabricated tanks and field-constructed tanks with a capacity less than or equal to 50,000 gallons must meet the requirements in subpart D. Field-constructed tanks with capacity greater than 50,000 gallons must either be monitored using release detection methods in subpart D (except for passive groundwater and vapor monitoring which must be combined with inventory control as described below) or use one of the alternative methods for tanks listed at § 280.252(d)(1).

Feasibility of Proposed Release Detection Options for Field-Constructed Tanks

To allow owners and operators more flexibility in meeting the release detection requirement, EPA proposed these four alternatives for UST systems with field-constructed tanks greater than 50,000 gallons:

- Annual tank tightness test
- Automatic tank gauging system that can detect a 1 gph leak combined with a tank tightness test every three years
- Automatic tank gauging system that can detect a 2 gph leak combined with a tank tightness test every two years and
- Other methods approved by the implementing agency

EPA requested comment or additional data on the proposed release detection options to determine their feasibility. Most commenters thought the release detection options were appropriate and sufficient. One commenter thought EPA should include chemical marker or tracer testing. Another commenter thought EPA should expand the types of release detection methods specified in the final UST regulation to include use of sensors, probes, monthly visual inspections, or other methods approved by the implementing agency.

EPA met with and obtained information from DoD and release detection vendors throughout the regulatory process. EPA researched suggested release detection options and standard practices conducted by DoD following the public comment period for the 2011 proposed UST regulation. EPA found that these facilities perform inventory management on their UST systems. EPA determined that although not performed as specified in the 1988 UST regulation, some DoD facilities are performing fuel management methods to monitor and track fuel inventories for their field-constructed tanks.[77] [78]

Release Detection Options for Field-Constructed Tanks in the Final UST Regulation

Based on comments and additional information from DoD as well as commercial airports about their operations, EPA is including in this final UST regulation all release

[77] Final Report—*Validation of the Low-Range Differential Pressure (LRDP) Leak Detection System for Small Leaks in Bulk Fuel Tanks Environmental Security Technology Certification Program,* U.S. Department of Defense.

[78] DoD 4140.25–M: *Management of Bulk Petroleum Products, Storage, and Distribution Facilities,* Volume V *http://www.dtic.mil/whs/directives/corres/html/414025m_vol1_3.html.*

detection options discussed in the 2011 proposed UST regulation. EPA is also adding three other options to this final UST regulation. Owners and operators of field-constructed tanks less than or equal to 50,000 gallons must meet the release detection requirements in subpart D. Owners and operators of field-constructed tanks greater than 50,000 gallons must use the alternative release detection methods described in subpart K or the release detection options in subpart D (except that groundwater and vapor monitoring must be used in combination with inventory control as described below). EPA thinks these options are reasonable and will quickly detect releases when they occur.

Tank Tightness Testing

In the 2011 proposed UST regulation, EPA discussed the option of owners and operators performing annual tank tightness testing that can detect a 0.5 gallon per hour leak rate. EPA proposed this performance standard based on information about leaks from several field-constructed tanks. The information indicated leak rates from the tanks ranged from 0.31 gph to 10 gph, with a median leak rate of 0.58 gph. EPA determined that most available methods were capable of meeting the proposed leak rate of 0.5 gph. EPA did not receive comments regarding the performance standard during the public comment period. The final UST regulation retains the option for owners and operators to perform annual underground tank tightness testing that can detect a 0.5 gallon per hour leak rate.

Automatic Tank Gauging Combinations with Tank Tightness Testing

This final UST regulation allows owners and operators to combine an automatic tank gauging system with a tank tightness test that achieves different leak rates during different periods of performance. One combination uses an automatic tank gauging system performing release detection at least every 30 days that can detect a leak rate less than or equal to 1 gallon per hour with a tank tightness test that can detect a 0.2 gallon per hour leak rate performed at least every three years. Another combination couples an automatic tank gauging system performing release detection at least every 30 days that can detect a leak rate less than or equal to 2 gallons per hour with a tank tightness test that can detect a 0.2 gallon per hour leak rate performed at least every two years. This automatic tank gauging requirement is different from the release detection requirement in the 1988 UST regulation for factory built tanks. These leak rates and time frames for release detection testing are appropriate because they will detect releases within a reasonable time frame, given the large tank sizes and time needed to perform testing on these tanks.

Inventory Control

This final UST regulation allows inventory control combined with one of these methods: passive groundwater monitoring every 30 days, passive vapor monitoring every 30 days, or a 0.5 gallon per hour tank tightness test performed at least once every two years. The inventory control option must meet the same requirements as inventory control for piping associated with airport hydrant systems and field-constructed tanks described in the *Release Detection Options for Piping in the Final UST Regulation* section above.

Groundwater and Vapor Monitoring

This final UST regulation allows active vapor monitoring for tanks using the same requirements as described in the *Release Detection Options for Piping in the Final UST Regulation* section above. In addition, owners and operators may also use a combination method incorporating inventory control and passive vapor monitoring or groundwater monitoring using the requirements described in the *Release Detection Options for Piping in the Final UST Regulation* section above.

Other Methods for Field-Constructed Tanks

Implementing agencies may approve another method if the owner and operator demonstrate the method can detect a release as effectively as any of the other five methods described in the *Release Detection Options for Field-Constructed Tanks* section. In comparing methods, an implementing agency shall consider the size of release the method can detect and frequency and reliability of detection. Other methods are described in *Other Methods for Piping.*

Release Detection Recordkeeping

This final UST regulation requires owners and operators maintain records of release detection for field-constructed tanks and airport hydrant systems in accordance with § 280.45. The results of any sampling, testing, or monitoring must be maintained for at least one year except as follows: Tank tightness testing; line tightness testing; and vapor monitoring using a tracer compound placed in the tank system must retain records until the next test is conducted. EPA is requiring owners and operators maintain these records until the next test is conducted because owners and operators can choose different time frames to conduct release detection testing. This additional flexibility results in some testing occurring at frequencies ranging from less than one year to up to three years.

Release Prevention

As with all other regulated UST systems, this final UST regulation requires airport hydrant systems and field-constructed tanks meet corrosion protection, spill, and overfill requirements, as well as walkthrough inspections.

Corrosion Protection

This final UST regulation requires all airport hydrant systems and field-constructed tanks that routinely contain regulated substances and are in contact with the ground to meet corrosion protection requirements in § 280.252(b)(1). Metal tanks and piping which are encased or surrounded by concrete have no metal in contact with the ground and are not subject to the corrosion protection requirements. Because interim prohibition for deferred UST systems in the 1988 UST regulation has been in effect since May 1985, many of these systems are already equipped with corrosion protection (that is, constructed of: Non-corrodible material, coated and cathodically protected steel, fiberglass reinforced plastic, or steel tank clad with fiberglass reinforced plastic). In this final UST regulation, EPA renames § 280.11 *to Installation requirements for partially excluded UST systems.* For corrosion protection, airport hydrant systems and field-constructed tanks must meet the requirements in § 280.252(b)(1). Owners and operators must meet this requirement within three years of the effective date of this final UST regulation.

This final UST regulation does not allow an internal lining as a method for meeting the corrosion protection upgrade requirement. EPA is not allowing an internal lining as corrosion protection because it does not protect steel in contact with the ground from corroding and causing a release to the environment. Field-constructed tanks and tanks associated with airport hydrant systems, which are not upgraded according to § 280.252(b), and are installed on or before the effective date of this final UST regulation must be permanently closed according to § 280.70.

Spill and Overfill Prevention

EPA concludes that using properly functioning equipment, which is

operated according to manufacturer guidelines, is necessary to protect human health and the environment. After discussions with industry, DoD, and commercial airport personnel, EPA understands that existing airport hydrant systems are generally already equipped with spill and overfill prevention equipment to prevent spills and overfills. This final UST regulation requires owners and operators of airport hydrant systems and field-constructed tanks to have spill and overfill prevention equipment and conduct testing or inspections of the equipment. This will ensure the systems and tanks operate properly, contain releases, and decrease the likelihood of a leak into the environment. Owners and operators must install spill and overfill prevention equipment and conduct the first test or inspection within three years of the effective date of this final UST regulation, then at least once every three years thereafter. For more information on spill prevention equipment testing and overfill prevention equipment inspections, see sections B–2 and B–3, respectively.

Walkthrough Inspections

Owners and operators need to properly operate and maintain their UST system equipment in order to prevent and quickly detect releases. Therefore, this final UST regulation adds requirements for owners and operators of airport hydrant systems and field-constructed tanks to perform periodic walkthrough inspections to prevent and quickly detect releases.

EPA found that owners and operators of airport hydrant systems are required to ensure safety and fuel quality, and frequently inspect these systems as part of other requirements and recommendations to ensure system components are operating properly. In addition, EPA understands that airport hydrant systems and some field-constructed tank facilities are already performing operation and maintenance inspections that ensure their systems and associated spill and overfill equipment are operating properly. Thus, EPA found these requirements will impose little, if any, additional burden at these facilities. This final UST regulation requires owners and operators of airport hydrant systems and field-constructed tanks conduct walkthrough inspections according to § 280.36. In addition, EPA is requiring owners and operators inspect hydrant pits and hydrant piping vaults. These areas are unique to airport hydrant systems. It is important to look at hydrant pits and hydrant piping vaults as part of periodic walkthrough inspections to ensure these areas are: Free of liquid and debris, not damaged, and free of leaks. Owners and operators must inspect these areas at least once every 30 days if OSHA confined space entry is not required or at least annually if OSHA confined space entry is required. See 29 CFR part 1910 for information about OSHA confined space entry. Some owners and operators already periodically check these areas using the ATA guidance manual, *Airport Fuel Facility Operations and Maintenance Guidance Manual.* Owners and operators must conduct the first inspection within three years of the effective date of the final UST regulation. For more information on walkthrough inspections, see section B–1.

Secondary Containment

This final UST regulation does not require secondary containment for new and replaced piping associated with field-constructed tanks greater than 50,000 gallons in capacity or piping associated with airport hydrant systems. EPA understands this piping typically is larger diameter and runs for long distances, making it difficult to slope the piping to an interstitial monitoring area. In addition, EPA understands it is difficult to keep water out of the interstitial area of long piping runs. Since nearly all this piping is steel, corrosion can occur in the interstitial area when an electrolyte, such as water, is in the interstitial area. This corrosion can significantly shorten the piping's operational life. Corrosion protection on the outside of the piping protects the part of the piping in contact with the ground from corrosion, but does not protect the inside part of piping from corrosion. To prevent corrosion caused by water in the interstitial area, owners and operators would need to add corrosion protection inside the interstitial area of piping, which EPA realizes would be difficult to do. Given these issues, EPA has determined that requiring secondary containment for these piping runs is not practical.

However, EPA is requiring secondary containment for new and replaced piping associated with field-constructed tanks 50,000 gallons or less that do not feed airport hydrant system piping. EPA understands that new, smaller field-constructed tanks, such as those constructed within tanks following permanent closure of an existing UST, typically have piping similar to that installed at commercial gasoline stations. This piping can effectively meet the secondary containment requirements and better protect the environment. For more information, see section A–2, Secondary Containment.

Notification

The 1988 UST regulation did not require owners of airport hydrant systems or field-constructed tanks to comply with the notification requirements of § 280.22, which included certifying proper installation of airport hydrant systems. The 2011 proposed UST regulation required owners and operators of airport hydrant systems and field-constructed tanks installed prior to the effective date of the final UST regulation provide notification of existence to implementing agencies within 30 days of the effective date of this final UST regulation. This final UST regulation modifies the 2011 proposed UST regulation by requiring owners and operators provide a one-time notification of existence to implementing agencies no later than 3 years after the effective date of this final UST regulation. EPA agrees with commenters that airport hydrant system owners and operators need more than 30 days to provide the one-time notification of existence. This change allows owners and operators, as well as implementing agencies, time to identify airport hydrant systems covered by the final UST regulation and gives implementing agencies time to include these systems in their inventories. The final UST regulation does not consider currently installed tanks, including airport hydrant systems, as new UST systems. Therefore, EPA is requiring owners and operators only certify proper installation for airport hydrant systems and field-constructed tanks installed on or after the effective date of the final UST regulation according to § 280.22. In addition, EPA is requiring owners notify within 30 days of ownership change. See section D–3 for more information on notification requirements.

Financial Responsibility

Because EPA is eliminating the deferral for airport hydrant systems and field-constructed tanks, they are no longer be excluded from the financial responsibility requirements in subpart H. Owners and operators who install these UST systems after the effective date of this final UST regulation must comply with the financial responsibility requirements at installation. Owners and operators of airport hydrant systems and field-constructed tanks in use as of the effective date of this final UST regulation must have financial responsibility when they submit the one-time notification of existence for

these systems. However, subpart H exempts federal and state entities, which means that federal and state owners and operators of airport hydrant systems and field-constructed tanks do not have to meet the financial responsibility requirement.

Operator Training

EPA is aware that commercial airports are required to follow fuel facility training requirements of 14 CFR part 139; however, those requirements do not cover specifics of the UST requirements. This final UST regulation requires owners and operators of airport hydrant systems and field-constructed tanks meet the operator training requirements of subpart J. Owners and operators of some airport hydrant systems that are considered underground storage tanks may have already complied with state operator training requirements. For example, personnel from General Mitchell Field in Wisconsin report that operators have received Wisconsin class A and B operator training certification. All owners and operators must begin meeting this requirement not later than three years after the effective date of this final UST regulation. For more information see section A–1, Operator Training.

Partially Excluded Components

EPA regulates UST systems, including tanks and underground piping, in 40 CFR part 280 and aboveground tanks in 40 CFR part 112 (Oil Pollution Prevention). Facilities with greater than 1,320 gallons of aboveground oil storage capacity that could reasonably be expected to discharge oil into navigable waters or adjoining shorelines are subject to the SPCC regulation under the authority of the Clean Water Act.[79] The SPCC regulation includes requirements for oil spill prevention, preparedness, and response to prevent oil discharges into navigable waters and adjoining shorelines. The SPCC regulation also requires regular inspections of aboveground valves, piping, and appurtenances along with integrity and leak testing of buried piping at the time of installation, modification, construction, relocation, or replacement. Facilities regulated by the SPCC regulation must also prepare and maintain a written SPCC plan that includes measures to prevent, prepare for, and respond to oil discharges that threaten navigable waters or adjoining shorelines.

Aboveground storage tanks associated with airport hydrant systems and field-constructed tanks covered in this final UST regulation do not have to meet many of the requirements in the UST regulation because they are neither beneath the surface of the ground, nor in contact with the ground. For these reasons, the SPCC regulation is the most effective means of addressing the aboveground storage tanks associated with UST systems. Airport hydrant systems that do not meet the definition of UST system because the underground portion is less than 10 percent of the system capacity may be subject to the SPCC regulation for both the aboveground and underground portions of the system. Underground storage tank components such as hydrant pits and piping vaults are considered part of the UST system and subject to the requirements in 40 CFR part 280.

Complementary Regulation of Partially Buried Tanks

Partially buried (also called partially covered) field-constructed tanks may be regulated by both this final UST regulation and the SPCC regulation. The SPCC regulation exempts only completely buried storage tanks subject to all of 40 CFR part 280.[80] Additionally, the SPCC regulation covers tanks situated on top of the ground's surface or partially buried (for example, bunkered, also referred to as mounded tanks) and considers these to be aboveground storage tanks. If 10 percent or more of the total capacity of the tank or tanks and underground piping is underground, the tank system meets the definition of an UST regulated by 40 CFR part 280 or state equivalent program approved under 40 CFR part 281. Therefore, these containers or systems are covered by both SPCC and UST regulations. These regulations are complementary because the SPCC regulation focuses on oil discharges that could impact navigable waters or shorelines, while the UST regulation focuses primarily on day-to-day maintenance and operation to prevent releases that impact soil and groundwater.

Change from Deferred to Partially Excluded

The 2011 proposed UST regulation used the term deferred for aboveground storage tanks associated with airport hydrant systems and field-constructed tanks considered to be UST systems. The proposal indicated that although these aboveground storage tanks would be subject to some parts of the final UST regulation, EPA intended to continue evaluating whether to fully regulate them in the future. EPA reconsidered these aboveground storage tanks and is making the final determination that the SPCC requirements are the most effective means for addressing oil discharges from aboveground storage tanks. This final UST regulation excludes from subparts B, C, D, E, G, J, and K aboveground storage tanks associated with airport hydrant systems and field-constructed tanks. Aboveground storage tanks that are part of an UST system must continue to meet the requirements of subparts A and F.

3. Wastewater Treatment Tank Systems that Are Not Part of a Wastewater Treatment Facility Regulated Under Sections 402 or 307(b) of the Clean Water Act

In the 2011 proposed UST regulation, EPA removed the existing deferral in § 280.10(c)(1) for wastewater treatment tank systems that are not part of a wastewater treatment facility regulated under sections 402 or 307(b) of the Clean Water Act. Since the 1988 UST regulation, owners and operators of these systems (hereafter referred to as wastewater treatment tanks) were deferred from complying with 40 CFR part 280, subparts B (*UST Systems: Design, Construction, Installation and Notification*); C (*General Operating Requirements*); D (*Release Detection*); E (*Release Reporting, Investigation, and Confirmation*); G *(Out-of-Service UST Systems and Closure*); and H (*Financial Responsibility*). Owners and operators have been required to comply with requirements for interim prohibition and release response and corrective action (40 CFR part 280, subparts A and F) since the effective date of the 1988 UST regulation. However, removing the deferral, as discussed in the 2011 proposed UST regulation, would have required owners and operators comply with all subparts of 40 CFR part 280.

Change from Deferred to Partially Excluded

The 1988 UST regulation used the term deferred for wastewater treatment tanks. Although these tanks were subject to some parts of the UST regulation, EPA intended to continue evaluating whether or not to regulate these tanks at a future date. EPA reconsidered these tanks and is making a final determination. EPA is excluding

[79] *http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=b843807afdc641b203ffec44aa671d36&rgn=div5&view=text&node=40:23.0.1.1.7&idno=40.*

[80] 40 CFR 112.2 defines completely buried as any container completely below grade and covered with earth, sand, gravel, asphalt, or other material. Containers in vaults, bunkered tanks, or partially buried tanks are considered aboveground storage containers for purposes of the part.

these tanks from most requirements in this final UST regulation; however, the regulatory requirements in subparts A and F for these systems remain the same.

EPA deferred wastewater treatment tanks in the 1988 UST regulation due to uncertainty about the number of tanks that existed and the appropriateness of release detection for these systems. EPA's intent in removing the deferral for these tanks in the 2011 proposed UST regulation was to regulate them further, which would protect human health and the environment from discharges of regulated substances contained in these systems. EPA used the proposal to obtain additional information on these systems, and determine if there were appropriate release prevention and detection technologies available to fully regulate them according to the UST regulation. According to commenter responses, EPA determined that these tanks are often subject to other environmental regulations; it may not be technically feasible to install release prevention and detection equipment on these systems due to varying designs of these systems; and many of these systems contain mostly water and are not significant sources of contamination.

Installation Requirements for Partially Excluded Tanks

In the 1988 UST regulation, deferred wastewater treatment tanks were required to meet the interim prohibition requirements at § 280.11 (that is, corrosion protected, made of non-corrodible materials, or otherwise designed and constructed to prevent releases during the operating life of the facility due to corrosion or structural failure). Therefore, these tanks are already equipped with corrosion protection if they were installed after the effective date of the 1988 UST regulation. EPA thinks it is appropriate to maintain this requirement, which ensures these tanks are provided with some degree of corrosion protection to prevent releases into the environment. Because EPA is partially excluding these systems, the term interim prohibition no longer applies. Therefore, EPA is rewording the title of § 280.11 to *Installation requirements for partially excluded UST systems.* In addition, EPA is changing § 280.11(a) to reflect that these requirements are installation requirements rather than prohibitions on installation.

Many commenters did not support removing the deferral to regulate these UST systems and were unsure of the universe of wastewater treatment tanks. To address this concern, EPA developed a February 2012 document describing wastewater treatment tanks that would have been regulated under the final UST regulation.[81] Several commenters also voiced concern that regulating these systems may result in unintended consequences (for example, impracticability of technical requirements and dual regulation) for owners and operators and implementing agencies. To help determine the feasibility of the 2011 proposed UST regulation, EPA asked several stakeholders about operating various types of wastewater treatment tanks.[82] [83] [84] EPA also gathered information from commenters about implementing other regulations that apply to these systems.[85] [86] [87] [88] After considering commenters' feedback, EPA concluded that the historic level of regulation for these tanks is appropriate and provides adequate controls to ensure environmental protection.

This final UST regulation excludes owners and operators of wastewater treatment tanks from 40 CFR part 280, subparts B (*UST Systems: Design, Construction, Installation and Notification*); C (*General Operating Requirements*); D (*Release Detection*); E (*Release Reporting, Investigation, and Confirmation*); G *(Out-of-Service UST Systems and Closure*); H (*Financial Responsibility*); J (*Operator Training*); and K (*UST Systems with Field-Constructed Tanks and Airport Hydrant Fuel Distribution Systems*). EPA is basing this decision on maintaining the installation requirement (§ 280.11), other regulatory controls in place, and the additional information gathered. Owners and operators of wastewater treatment tank systems are still required to comply with subparts A (*Program Scope and Installation Requirements for Partially Excluded UST Systems*); and F (*Release Response and Corrective Action for UST Systems Containing Petroleum or Hazardous Substances*).

4. USTs Containing Radioactive Material and Emergency Generator UST Systems at Nuclear Power Generation Facilities Regulated by the Nuclear Regulatory Commission

In the 2011 proposed UST regulation, EPA maintained the existing deferral in § 280.10(c)(2) and (3) for USTs containing radioactive material and for emergency generator UST systems at nuclear power generation facilities regulated by the United States Nuclear Regulatory Commission (NRC). Since the 1988 UST regulation, owners and operators of these tanks were deferred from complying with 40 CFR part 280, subparts B (*UST Systems: Design, Construction, Installation and Notification*); C (*General Operating Requirements*); D (*Release Detection*); E (*Release Reporting, Investigation, and Confirmation*); G *(Out-of-Service UST Systems and Closure*); and H (*Financial Responsibility*). Owners and operators have been required to comply with requirements for interim prohibition and release response and corrective action (40 CFR part 280, subparts A and F) since the effective date of the 1988 UST regulation.

After review of DOE Orders and NRC regulations,[89] EPA determined these requirements are comparable to EPA requirements for new and existing USTs regarding spill and overfill control (§ 280.30); operation and maintenance of corrosion protection (§ 280.31); and release detection (40 CFR part 280, subpart D). DOE established standards for facility operations that: protect the public and environment from exposure to radiation from radioactive

[81] *http://www.epa.gov/oust/fedlaws/wwtts_2-29-12_final.pdf.*

[82] April 2012 telephone conversation with Tom Groves, New England Interstate Water Pollution Control Commission.

[83] April 2012 telephone conversation with Ming Pan, Massachusetts Department of Environmental Protection.

[84] April 2012 telephone conversation with Joe Cerutti, Massachusetts Department of Environmental Protection.

[85] March 2012 telephone conversation with Kevin Brackney, Nez Perce Tribe.

[86] April 2012 telephone conversation with Chris Wiesberg, Missouri Department of Natural Resources.

[87] April 2012 telephone conversation with Mary Hansen, Washington State Department of Ecology.

[88] May 2012 telephone conversation with Candace Cady, Utah Department of Environmental Quality.

[89] Contract No. GS–10F–0309N, EPA Work Order No. EP–G10S–00001, Work Order No. 1004, Task 2, Subtask c, Quick Turnaround Request No. 6, *Release Response and Corrective Action.*

materials;[90] [91] [92] protect workers;[93] provide industrial safety;[94] and ensure compliance with applicable federal, state, and local laws, as well as Executive Orders and other DOE directives. DOE uses orders to regulate radioactive materials at their facilities.

NRC regulations at 10 CFR part 50 require that construction permit applications include a design and safety analysis, health and safety risk assessment of facility operations, and determination of the adequacy of controls for accidental releases into the environment for the life of the operating unit. NRC regulations also require facilities meet minimum design, installation, testing, and performance criteria.[95] Appendix B of 10 CFR part 50 requires a quality assurance report that includes testing of facility structures, systems, and components.[96] NRC also developed guidance documents to assist operators with licensing compliance.[97]

EPA was concerned with whether NRC and DOE cleanup standards for radionuclides adequately protect groundwater[98] [99] [100] and was unfamiliar with how NRC regulates releases of petroleum products or enforces cleanup of releases.

The 1988 UST regulation contains prescriptive procedures UST owners and operators must follow in responding to releases into the environment. NRC regulations are performance-based actions; they identify performance measures that are designed to ensure an adequate safety margin and offer incentives for licensees to improve safety without formal regulatory intervention.[101] Accordingly, DOE created orders to supplement EPA regulations for USTs at DOE facilities already subject to the 1988 UST regulation.[102] NRC requires that facilities perform site remediation as part of the decommissioning process, but there are currently no NRC regulations that require remediation at active facilities, unless dose limits are exceeded.[103]

EPA concludes it is appropriate to continue requiring release response and corrective action for these tanks, if the need arises. Due to the sensitive nature of these facilities, implementing agencies have flexibility to establish appropriate response and remediation requirements for owners and operators at these facilities.

Move from Deferred to Partially Excluded

The 1988 UST regulation used the term deferred for USTs containing radioactive material and for emergency generator UST systems at nuclear power generation facilities regulated by the NRC. This indicated that although these tanks were subject to some parts of the UST regulation, EPA intended to continue evaluating the applicability of full regulation of these tanks at a future date. EPA reconsidered these tanks and is making a final determination. EPA is excluding these tanks from most requirements in this final UST regulation; however, the regulatory requirements in subparts A and F for these systems remain the same.

Installation Requirements for Partially Excluded Tanks

In the 1988 UST regulation, deferred USTs containing radioactive material and emergency generator UST systems at nuclear power generation facilities regulated by NRC were required to meet the interim prohibition requirements of § 280.11 (that is, corrosion protected, made of non-corrodible materials, or otherwise designed and constructed to prevent releases during the operating life of the facility due to corrosion or structural failure). While NRC's regulation addresses design and installation standards, interim prohibition requirements have been in effect since the 1988 UST regulation. Accordingly, owners and operators have had to follow this requirement since the effective date of the 1988 UST regulation. EPA has no information suggesting that maintaining this requirement has been an issue for owners and operators. After considering commenters' feedback, EPA concluded that the historic level of regulation for these tanks is appropriate and provides adequate environmental controls to ensure environmental protection. Therefore, this final UST regulation continues to require that owners and operators of these tanks comply with the requirements of § 280.11. Because EPA is partially excluding these systems, the term interim prohibition no longer applies. Therefore, EPA is rewording the title of § 280.11 to *Installation requirements for partially excluded UST systems.* In addition, EPA is changing § 280.11(a) to reflect that these requirements are installation requirements rather than prohibitions on installation.

After considering comments and additional information, this final UST regulation excludes owners and operators of these tanks from 40 CFR part 280, subparts B (*UST Systems: Design, Construction, Installation and Notification*); C (*General Operating Requirements*); D (*Release Detection*); E (*Release Reporting, Investigation, and Confirmation*); G (*Out-of-Service UST Systems and Closure*); H (*Financial Responsibility*); J (*Operator Training*); and K (*UST Systems with Field-Constructed Tanks and Airport Hydrant Fuel Distribution Systems*). Owners and operators of these tank systems are still required to comply with subparts A (*Program Scope and Installation Requirements for Partially Excluded*

[90] DOE Order 435.1 Chg 1, *Radioactive Waste Management,* ensures management of DOE radioactive waste (*i.e.* high-level, transuranic, low-level, and the radioactive component of mixed waste) is consistent with Atomic Energy Act of 1954 responsibilities, in a manner that provides radiological protection from DOE operations. (see *https://www.directives.doe.gov/directives-documents/400-series/0435.1-BOrder-chg1.*)

[91] DOE M 435.1–1 Admin Chg 2, *Radioactive Waste Management Manual,* further describes the requirements and establishes specific responsibilities for implementing DOE O 435.1, *Radioactive Waste Management.* It prescribes the following requirements and specific responsibilities for new or modified existing systems: Secondary containment designed to detect and contain releases, and compatible with material stored (Chapter II P(2)(b)); spill/overfill control (Chapter II(P)(2)(i)); release detection for tanks (Chapter II(Q)(2)(a)(1)), and other storage components (Chapter II(Q)(2)(c)); release detection for failed containment and/or other abnormal conditions (Chapter II(P)(2)(j)); monitoring and/or leak detection for secondary containment (Chapter IIP(2)(j)); corrosion protection (Chapter II(Q)(2)(a)(2),(3)); monitoring and physical inspections (Chapter II(T)) and corrective action (Chapter I(2)(F)(20)). (see *https://www.directives.doe.gov/directives-documents/400-series/0435.1-DManual-1-admchg2.*)

[92] DOE O 458.1 Admin Chg 3, *Radiation Protection of the Public and the Environment* (see *https://www.directives.doe.gov/directives-documents/400-series/0458.1-BOrder-AdmChg3*).

[93] 10 CFR part 835, *Occupational Radiation Protection* (see *http://www.ecfr.gov/cgi-bin/text-idx?SID=dc937acd7069e30635139ca1ee3a44a0&node=pt10.4.835&rgn=div5*).

[94] DOE O 440.1B Admin Chg 1, *Worker Protection Program for DOE (Including the National Nuclear Security Administration) Federal Employees* (see *https://www.directives.doe.gov/directives-documents/400-series/0440.1-BOrder-b-admchg1*).

[95] see *http://www.nrc.gov/reading-rm/doc-collections/fact-sheets/radwaste.html.*

[96] Ibid.

[97] Ibid.

[98] February 1997 letter from EPA to the NRC expressing concerns over the NRC's proposal for increasing dose limits and eliminating the requirement to protect groundwater that could be used as drinking water.

[99] December 1997 letter from EPA to DOE expressing concerns that DOE's draft rule 10 CFR part 834 (Radiation Protection of the Public and the Environment) needs to be consistent with CERCLA and that inconsistencies exist between the draft rule and CERCLA and NCP guidance.

[100] October 2002 Memorandum of Understanding between EPA and NRC to identify the interactions for only the decommissioning and decontamination of NRC-licensed sites and ensure dual regulation does not occur regarding the cleanup and reuse of NRC-licensed sites.

[101] Contract No. GS–10F–0309N, EPA Work Order No. EP–G10S–00001, Work Order No. 1004, Task 2, Subtask c, Quick Turnaround Request No. 6, *Release Response and Corrective Action.*

[102] Ibid.

[103] Ibid.

UST Systems) and F (*Release Response and Corrective Action for UST Systems Containing Petroleum or Hazardous Substances*).

This final UST regulation also amends § 280.10(c)(4) which refers to facilities licensed under 10 CFR part 50. This change is consistent with the regulatory citation listed in the Spill Prevention, Control, and Countermeasure provision in 40 CFR part 112 and also applies to installation of these tanks at NRC facilities in the future.

D. Other Changes

1. Changes to Overfill Prevention Equipment Requirements

Through extensive stakeholder outreach, EPA identified vent line flow restrictors (also called ball float valves) as a significant concern for operability and safety. As a result, this final UST regulation modifies the 1988 UST regulation by eliminating vent line flow restrictors as an option for meeting the overfill prevention equipment requirement for new tank installations and when overfill prevention equipment is replaced. EPA makes this change to: reduce the frequency of UST releases due to operability issues, address system safety concerns, and address personnel safety concerns. Below are the issues:

- Operability—For a vent line flow restrictor to operate properly, the device must restrict the flow of regulated substance into the UST when the flow restrictor engages. If the tank top is not liquid or vapor tight, flow into the UST is not restricted because vapors continue to escape through non-tight areas. If vapors continue to escape from the UST, there is no pressure buildup in the vapor area of the tank, resulting in no reduced flow rate into the UST. Examples where non-tight tank tops may result in ineffective flow restrictors include: loose tank bungs or other tank top components; tanks with coaxial stage I vapor recovery installed; and tanks with both tank top and remote fill areas.
- System safety—Vent line flow restrictors can create safety concerns when they activate. USTs can become over pressurized and be damaged during deliveries when product is pumped into the tank. PEI's recommended practice for installation, RP 100, advises against using vent restriction devices because the vent line flow restrictor pressurizes the UST, creating a hazardous condition when the device operates as designed.
- Personnel safety—Delivery personnel can be sprayed with regulated substances when they disconnect the delivery hose from the fill pipe because pressure can build up in the tank when the vent line flow restrictor activates.

Owners and operators may continue to use flow restrictors not in vent lines (such as flow restrictors in fill pipes), automatic shutoff devices, and high level alarms to meet the overfill prevention requirement for their UST systems.

Owners and operators using a vent line flow restrictor before the effective date of this final UST regulation may continue using it to meet the overfill prevention requirement, as long as it operates properly by restricting the flow of regulated substances into the UST when the device activates. Flow restrictors in vent lines must be periodically inspected for proper operation according to section B–3, Overfill Prevention Equipment Inspections. This means that the flow restrictor will need to be accessible to the person inspecting the overfill prevention device. In addition, owners and operators may continue to use flow restrictors in UST system vent lines for reasons other than meeting the overfill prevention requirement, as long as the flow restrictors do not interfere with operation of the overfill prevention equipment being used.

Most commenters supported this change to the 1988 UST regulation. Several even suggested requiring retrofits of vent line flow restrictors with another type of overfill prevention equipment. Because EPA is concerned about imposing too many additional costs on owners and operators of existing UST systems, EPA is not requiring retrofits of existing vent line flow restriction devices, as long as they operate properly, alert delivery personnel, and prevent overfills. Some commenters suggested EPA continue to allow the use of vent line flow restrictors if they meet the criteria set forth in PEI's RP 100. EPA reviewed the PEI recommended practice and noted that the code sets criteria for the allowed use of vent line flow restrictors. However, more importantly, the code advises against using vent line flow restrictors for overfill prevention under any circumstance because they pressurize the UST, creating a hazardous condition when the device operates as designed. Consistent with PEI's RP 100 advisory, EPA is not allowing owners and operators to use vent line flow restrictors in new tanks or when overfill prevention equipment is replaced. Finally, several commenters suggested EPA continue to allow the use of vent line flow restrictors, as long as the flow restrictor can be shown to operate effectively. Because it is difficult to determine if flow restrictors in vent lines will effectively restrict flow when the tank is close to being full, EPA is not allowing their use in new UST system installations or when overfill prevention equipment is replaced. However, the final UST regulation allows continued use of vent line flow restrictors installed before the effective date of the final UST regulation, as long as they operate properly, alert delivery personnel, and prevent overfills.

2. Internal Linings that Fail the Periodic Lining Inspection and Cannot Be Repaired

About 3 percent of tanks rely on internal lining as the sole method of corrosion protection to meet the 1988 UST regulation.[104] Tanks that were internally lined to meet the 1988 UST regulation corrosion protection requirement at § 280.21 are typically older, bare steel tanks installed before 1986. The 1988 UST regulation preamble says that internal lining, when used as the sole method for corrosion protection, is not regarded as a permanent upgrade. However, it is adequate if the lining continues to meet original design specifications. If the internal lining no longer meets original design specifications and cannot be repaired according to industry codes, then the lined tank is subject to unprotected tank requirements and must be replaced after 1998. However, this language, which was in the 1988 UST regulation preamble, was inadvertently omitted from the 1988 UST regulation.

This final UST regulation modifies the 1988 UST regulation by requiring owners and operators to permanently close an UST that uses internal lining as the sole method of corrosion protection for the tank when the lining inspection determines the internal lining is no longer performing according to original design specifications and the internal lining cannot be repaired according to a code of practice developed by a nationally recognized association or independent testing laboratory. EPA understands that codes of practice for internal lining inspections in use as of publication of this final UST regulation contain pass or fail criteria for the internal lining and criteria for allowing repairs to an internal lining that fails the internal lining inspection.

[104] E², Incorporated, memoranda and analyses submitted under Contract EP–W–05–018, U.S. Environmental Protection Agency. *Underground Storage Tanks/Leaking Underground Storage Tanks Analytical And Technical Support.* These supporting materials are located in the docket EPA–HQ–UST–2011–0301.

Owners and operators using internal lining as the sole method of corrosion protection for the tank may continue using that method as long as the internal lining is periodically inspected according to § 280.21(b)(1)(ii) and the internal lining passes the inspection or is repaired so it meets original design specifications according to a code of practice developed by a nationally recognized association or independent testing laboratory.

Consistent with current EPA policy,[105] tanks using the combination of cathodic protection and internal lining for corrosion protection are not required to be closed if the internal lining fails and cannot be repaired, as long as the cathodic protection is operated and maintained according to § 280.31 and the tank was assessed and found to be structurally sound and free of corrosion holes when the cathodic protection was added to the tank. In addition, owners and operators may use internal linings for purposes other than meeting EPA's corrosion protection upgrade requirement (for example, internal linings used for compatibility or secondary containment).

Most commenters supported this change to the 1988 UST regulation. Some even suggested more restrictive requirements: either phasing out internal lining as a corrosion protection upgrade or permanently closing an UST if the lining inspection failed. EPA is not requiring these more restrictive approaches because we think internal lining repairs can be appropriate and protect the environment when conducted according to a code of practice developed by a nationally recognized association or independent testing laboratory. In addition, requiring permanent closure under these more restrictive circumstances would place additional financial burdens on UST owners and operators. Several commenters offered adding cathodic protection and relining the tank as alternatives to permanent closure. EPA is not including these options in this final UST regulation because internally lined tanks that fail the lining inspection and cannot be repaired according to a code of practice are generally older and are nearing or past the end of their useful lives.

3. Notification

This final UST regulation adds a one-time notification of existence for UST systems with field-constructed tanks and UST systems identified as airport hydrant fuel distribution systems. In addition, it adds a new notification requirement for ownership changes; provides a new form for making notification of ownership changes; and makes minor changes to the notification language and notification form.

EPA agrees with commenters who opposed requiring one-time notification of existence for emergency power generator UST systems as was proposed. Commenters explained, and EPA agrees, that since the 1988 UST regulation deferred these systems only from the release detection requirements in subpart D, owners should have notified the appropriate implementing agency within 30 days of bringing an UST system into use in accordance with the notification requirements in subpart B. Therefore, in this final UST regulation, the requirement to submit a one-time notification of existence applies only to owners of UST systems with field-constructed tanks and airport hydrant fuel distribution systems. (This one-time notification of existence does not apply to wastewater treatment tank systems, UST systems containing radioactive material that are regulated under the Atomic Energy Act of 1954, and UST systems that are part of an emergency generator system at nuclear power generation facilities regulated by the Nuclear Regulatory Commission under 10 CFR part 50 previously deferred in the 1988 UST regulation and partially excluded in this final UST regulation.)

Furthermore, EPA agrees with commenters' requests to extend the time frame of 30 days in the 2011 proposed UST regulation for owners of UST systems with field-constructed tanks and airport hydrant fuel distribution systems to submit their one-time notification of existence. To provide owners more time for identifying and gathering information about these previously deferred systems, EPA is allowing owners of existing UST systems with field-constructed tanks and airport hydrant fuel distribution systems to submit a one-time notification of existence within 3 years of the effective date of this final UST regulation. EPA is requiring owners of UST systems with field-constructed tanks and airport hydrant fuel distribution systems brought into use after the effective date of the final UST regulation to submit notification forms; this notification requirement has been in place since 1986 for all UST owners bringing new USTs into use. See subpart K for other requirements related to UST systems with field-constructed tanks and airport hydrant fuel distribution systems.

Several commenters requested EPA allow 60 days instead of 30 days to submit a notification of ownership change, noting that the 30-day requirement is too stringent. One commenter stated that the time frame should be relaxed to account for large organizations where paperwork could involve a significant amount of time to process. Another stated that 30 days would be too short and unduly burdensome on small businesses. While EPA fully considered these comments, EPA thinks it is important for the ownership change notification requirement to be consistent with the new tank notification requirement (within 30 days of bringing an UST into use) in place since 1988. In addition, the ownership change notification form is shorter and takes less time to complete than the new tank notification form. As a result, this final UST regulation requires owners to submit a notification of ownership change within 30 days of assuming ownership of regulated UST systems.

In this final UST regulation, EPA provides a new notification form titled *Notification of Ownership Change for Underground Storage Tanks* under appendix II. This form supplants the *List of Agencies Designated to Receive Notifications* in appendix II of the 1988 UST regulation. The list, published in 1988, contained agency names, addresses, and phone numbers, many of which are no longer accurate. EPA considered updating the list, but given the frequency with which contact information changes, decided it is pointless to publish information in the final UST regulation since it will quickly become obsolete. Rather, owners can obtain current agency contact information on EPA's Web site at *www.epa.gov/oust*.

Two commenters indicated it was unclear who the implementing agency is and whether owners and operators need to notify both the state and EPA. In this final UST regulation, EPA is clarifying that owners must submit notification forms to the appropriate implementing agency. The term implementing agency is defined in the UST regulation and owners can obtain current contact and other information regarding their implementing agency on EPA's Web site at *www.epa.gov/oust*. In practice, EPA expects most owners will submit notification forms only to their respective state as their implementing agency, except in instances where the implementing agency is EPA. For example, EPA is the implementing agency for USTs located in Indian country; thus, owners with USTs in Indian country will submit their

[105] EPA UST Technical Compendium Question And Answer # 14: *www.epa.gov/oust/compend/nus.htm*.

notification forms to EPA. Owners should also be aware that individual states may have state versions of notification forms which owners should use instead when submitting to the implementing agency. EPA is revising the regulatory language in § 280.22(a) and (b) and including language in subpart K to reflect that state forms may be used if the state requires owners to use notification forms that differ from those in appendices I and II.

Lastly, EPA is amending the notification form in appendix I and the ownership change form in appendix II to incorporate comments regarding specific items on these forms. For example, two commenters noted that owners of previously deferred UST systems would be unable to complete the Certification of Installation section of the *Notification for Underground Storage Tanks* form because they were not subject to this requirement when the UST system was brought into use. In addition, records of installation for these previously deferred UST systems are likely to be nonexistent given the passage of time since installation. EPA agrees with these commenters and is revising the notification form to indicate that only owners of UST systems with field-constructed tanks and airport hydrant fuel distribution systems brought into use after the effective date of this final UST regulation need to complete this section.

4. Compatibility

Regulated Substance and Motor Fuel Definitions

This final UST regulation revises the regulated substance definition to clarify that UST systems containing petroleum derived from non-crude oil products are regulated. The preamble to the supplement of the proposed 1988 UST regulation indicates that petroleum products can be derived from other materials, such as biomass, plant material, organic waste, coal, and shale oil.[106] Petroleum is comprised of a complex blend of hydrocarbons regardless of its source material.

Many people applied the definition of regulated substance in the 1988 UST regulation to petroleum UST systems only if the petroleum was derived from crude oil. This final UST regulation clarifies that petroleum derived from non-crude oil based products, such as green gasoline, is a regulated substance under 40 CFR part 280. This clarification is consistent with the preamble to the 1988 UST regulation, which indicates petroleum is not limited to being derived from crude oil.

This final UST regulation also modifies the definition of motor fuel to better accommodate new motor fuels that may be marketed and stored in the future. The definition in the 1988 UST regulation listed motor fuel products. This led to confusion as to whether new fuels, such as petroleum blended with ethanol or biodiesel, are motor fuels. This final UST regulation clarifies the definition of motor fuel and explains that it is any fuel typically used to operate a motor engine. In addition, EPA received comments to change the motor fuel definition from petroleum and petroleum-based substances to a complex blend of hydrocarbons. EPA agrees that using the phrase complex blend of hydrocarbons eliminates ambiguity; it provides a clearer definition of motor fuel by including complex blends of hydrocarbons that may not be petroleum or petroleum-based. EPA is making this change in this final UST regulation.

Compatibility

EPA understands that the chemical and physical properties of ethanol and biodiesel can be more degrading to certain UST system materials than petroleum alone. As the use of ethanol- and biodiesel-blended fuels increases, EPA is concerned that not all UST system equipment or components are compatible with these fuel blends. For purposes of compatibility, EPA uses the term equipment to mean a group of components assembled together by the manufacturer. Compatibility can be determined for all components of a piece of equipment. Compatibility determinations for equipment are typically useful when an UST system is newly installed or when a complete piece of equipment is replaced. Examples of equipment include the piping system, STP assembly, and automatic shutoff device assembly. A component is considered an individual piece of an UST system and is typically a single piece of the equipment. Component compatibility is determined on a piece by piece basis. A component compatibility determination is typically needed when performing repairs on an UST system where only parts of a piece of equipment are replaced. Examples of components include gaskets, seals, and other individual pieces that form a piece of equipment.

Gasoline containing 10 percent or less ethanol (E10) has been used in parts of the United States for many years. UST equipment and component manufacturers accommodated the E10 market by producing compatible equipment and components. According to the Renewable Fuels Association, ethanol is blended into over 90 percent of all gasoline sold in the United States,[107] predominantly as E10. Recently, the United States has been moving toward use of higher blends of ethanol, due in part to federal and state laws encouraging increased use of biofuels. While most UST system equipment and components are compatible with E10, fuel blends containing greater than 10 percent ethanol do not have a long history of storage and may not be compatible with certain materials in existing UST systems. According to a 2011 report published by the U.S. Department of Energy's Oak Ridge National Laboratory,[108] some elastomeric materials are particularly affected by intermediate ethanol blends and certain sealants may not be suitable for any ethanol-blended fuels. A 2007 report from Underwriters Laboratories (UL)[109] evaluated the effect of 85 percent ethanol and 25 percent ethanol blends on dispenser components. Results indicated some materials used in the manufacture of seals degraded more when exposed to 25 percent ethanol test fluid than when exposed to 85 percent ethanol test fluid. Other literature suggests ethanol fuel blends can be more aggressive toward certain materials than independent fuel constituents, with maximum polymer swelling observed at approximately 15 percent ethanol by volume.[110] Based on this information, this final UST regulation clarifies the compatibility requirements for owners and operators storing regulated substances containing greater than 10 percent ethanol.

This final UST regulation also clarifies the compatibility requirements for owners and operators storing regulated substances containing greater than 20 percent biodiesel. Although the total use of biodiesel is significantly less than that of ethanol, biodiesel has

[106] "40 CFR parts 280 and 281 USTs; Supplement to Proposed Rule," 52 FR 48640 (December 23, 1987).

[107] Renewable Fuels Association, *Building Bridges to a More Sustainable Future: 2011 Ethanol Industry Outlook. http://www.ethanolrfa.org/page/-/2011%20RFA%20Ethanol%20Industry%20Outlook.pdf?nocdn=1.*

[108] Oak Ridge National Laboratory, *Intermediate Ethanol Blends Infrastructure Materials Compatibility Study: Elastomers, Metals, and Sealants* (March 2011).

[109] Underwriters Laboratories, Inc., *Underwriters Laboratories Research Program on Material Compatibility and Test Protocols for E85 Dispensing Equipment* (December 2007). Available in the UST Docket under Docket ID No. EPA–HQ–UST–2010–0651.

[110] Westbrook, P.A., *Compatibility and Permeability of Oxygenated Fuels to Materials in Underground Storage and Dispensing Equipment* (January 1999). Available in the UST Docket under Docket ID No. EPA–HQ–UST–2010–0651.

become increasingly available across the United States and may be incompatible with certain materials in UST systems. For example, pure biodiesel (B100) has known compatibility issues with certain materials. According to the U.S. Department of Energy's National Renewable Energy Laboratory (NREL) *Biodiesel Handling and Use Guide, Fourth Edition,*[111] ''B100 will degrade, soften, or seep through some hoses, gaskets, seals, elastomers, glues, and plastics with prolonged exposure. . . . Nitrile rubber compounds, polypropylene, polyvinyl, and Tygon® materials are particularly vulnerable to B100.''

In contrast, the properties of very low blends of biodiesel, such as B5 or less, are so similar to those of petroleum diesel that the American Society for Testing and Materials (ASTM) International considers conventional diesel that contains up to 5 percent biodiesel to meet its *Standard Specification for Diesel Fuel Oils.*[112] For biodiesel blends between 5 and 100 percent, there is very little compatibility information; however, NREL's handling and use guide concludes that biodiesel blends of B20 or less have less of an effect on materials and very low blends of biodiesel, such as B5 and B2, ''. . . have no noticeable effect on materials compatibility.'' [113] In addition, fleet service sites have stored B20 in UST systems for years, and EPA is not aware of compatibility-related releases associated with those UST systems storing B20. Therefore, this final UST regulation requires tank owners and operators who store greater than 20 percent biodiesel in their UST systems demonstrate compatibility of UST equipment or components by one of the options listed in § 280.32.

This final UST regulation retains the requirement for owners and operators to use UST systems made of or lined with materials that are compatible with the substance stored in the UST system. It does not change the compatibility requirement in the 1988 UST regulation, but does add several options for owners and operators to demonstrate that their UST systems are compatible with regulated substances containing greater than 10 percent ethanol, greater than 20 percent biodiesel, or any other regulated substances identified by the implementing agency. Owners and operators of these UST systems must meet one of the following options:

- Use equipment or components that are certified or listed by a nationally recognized, independent testing laboratory for use with the fuel stored
- Use equipment or components approved by the manufacturer to be compatible with the fuel stored

In addition, owners and operators may use another option determined by the implementing agency to be no less protective of human health and the environment than the methods listed above.

These options provide owners and operators flexibility in demonstrating compatibility while still protecting human health and the environment. In the past, owners and operators typically demonstrated compatibility by using equipment or components certified or listed by a nationally recognized, independent testing laboratory, such as UL. Many pieces of UST equipment and components in the ground today were manufactured before regulated substances containing ethanol or biodiesel existed and are not approved by nationally recognized, independent testing laboratories for use with these fuel blends. Currently, certain tanks and piping have been tested and are listed by UL for use with higher-level ethanol blends. However, many other pieces of equipment and components of UST systems, such as leak detection devices, sealants, and containment sumps, may not be listed by UL or another nationally recognized, independent testing laboratory for use with these blends.

In addition, EPA is not aware of any nationally recognized, independent testing laboratory that has performed compatibility testing on UST system equipment or components with biodiesel-blended fuels. Absent certification or listing from a nationally recognized, independent testing laboratory or other verification that the equipment or component may be used with anything other than conventional fuels, the suitability of an UST system for use with biodiesel blends is questionable. As a result, EPA is providing several options for demonstrating compatibility to reduce the risk of releases due to material incompatibility. Owners and operators storing regulated substances blended with greater than 10 percent ethanol or greater than 20 percent biodiesel must meet the compatibility requirements before storing those regulated substances.

For equipment and components tested and approved by a nationally recognized, independent testing laboratory, owners and operators may demonstrate compatibility solely by keeping records of the equipment and components. In this instance, the testing laboratory's listing, labeling, or approval demonstrates the equipment or component's suitability to be used with the regulated substance stored. This means owners and operators will be able to demonstrate compatibility by retaining equipment or component records.

Owners and operators may also demonstrate compatibility by obtaining manufacturer's approval of the equipment or component. The manufacturer's approval must be in writing and include an affirmative statement that the equipment or component is compatible with the fuel blend stored. The manufacturer's approval must also specify the range of fuel blends for which the equipment or component is compatible. The manufacturer's approval must be issued from the equipment or component manufacturer, not another entity, such as the installer or distributor. A manufacturer's approval enables owners and operators to demonstrate compatibility for equipment or components not approved for use by a nationally recognized, independent testing laboratory. It also provides implementing agencies with verification that the equipment or component is compatible with the fuel stored.

Implementing agencies may approve other options for complying with the compatibility requirement for regulated substances containing greater than 10 percent ethanol or greater than 20 percent biodiesel if they are no less protective of human health and the environment than manufacturer's approval or a listing, labeling, or approval by a nationally recognized, independent testing laboratory. This provides implementing agencies with flexibility to consider other approaches they determine to be appropriate. For example, in lieu of an affirmative compatibility determination, implementing agencies may allow secondarily contained UST systems using interstitial monitoring to store regulated substances containing greater than 10 percent ethanol or 20 percent biodiesel. The rationale is that a leak from the primary containment will be contained by secondary containment and detected by interstitial monitoring equipment before regulated substances reach the environment.

Although these options for demonstrating compatibility apply to

[111] National Renewable Energy Laboratory, *Biodiesel Handling and Use Guide, Fourth Edition,* (2009). Available in the UST Docket under Docket ID No. EPA–HQ–UST–2010–0651.

[112] ASTM Standard D975, 2010c, *Standard Specification for Diesel Fuel Oils,* ASTM International, West Conshohocken, PA, 2010, DOI: 10.1520/D0975–10C, *www.astm.org.*

[113] National Renewable Energy Laboratory, *Biodiesel Handling and Use Guide, Fourth Edition,* (2009). Available in the UST Docket under Docket ID No. EPA–HQ–UST–2010–0651.

UST systems storing regulated substances containing greater than 10 percent ethanol and greater than 20 percent biodiesel, this final UST regulation extends the compatibility demonstration requirement to other regulated substances identified by implementing agencies. This provides implementing agencies with the flexibility to require a demonstration of compatibility if there are concerns about other existing regulated substances and when new regulated substances, such as biobutanol, enter the fuel market.

EPA received comments about the difficulty in determining whether some UST system equipment or components currently installed in the ground are compatible with ethanol and biodiesel blended fuels. In fact, EPA thinks there are many cases where some equipment or components of UST systems in the ground as of 2014 are not compatible with newer fuels. Unless owners and operators specifically requested all of the UST system be compatible with higher ethanol or biodiesel blends, installers probably installed lower cost options for certain UST system equipment, such as a STP assembly, which may not be compatible with some newer fuels. Non-compatible equipment or components, such as equipment in containment sumps, are usually easier to upgrade or replace than the tank or piping because they are typically located in areas not requiring excavation. In addition, EPA provides various options for meeting the compatibility requirement. To protect the environment from releases of ethanol blends greater than 10 percent, biodiesel blends greater than 20 percent, or any other regulated substance identified by the implementing agency, owners and operators must do one of the following:

- Demonstrate the UST system is compatible through certification or listing by a nationally recognized, independent testing laboratory or manufacturer approval
- Replace equipment or components not compatible or for which compatibility cannot be determined
- Use another option determined by an implementing agency to be no less protective of human health and the environment
- Not store these regulated substances in the UST system

These options provide owners and operators with adequate flexibility when demonstrating compatibility and determining whether certain regulated substances may be stored in the UST system.

Some commenters suggested adding other options owners and operators could use for determining compatibility. One suggested addition was certification by a professional engineer (P.E.), who would perform an on-site UST system analysis to determine compatibility. In order to perform this analysis, a P.E. would need to know the manufacturer and model of all UST system equipment or components. Because this information cannot be entirely obtained through visual observation, a P.E. would need to obtain records of the equipment to make an assessment and then search for relevant equipment listings or manufacturer certifications. This means a P.E. certification is equivalent to the options in this final UST regulation. EPA does not object to a P.E. performing a records review; however, we think it is impractical for a P.E. to perform a visual assessment of an UST system and make a compatibility determination in the absence of equipment records and certifications. Therefore, EPA is not explicitly allowing a P.E. to make a compatibility determination in the absence of UST system information and compatibility certifications.

Some commenters suggested EPA use a tiered approach to demonstrate compatibility for UST systems storing regulated substances containing greater than 10 percent ethanol and greater than 20 percent biodiesel, and choose one method of determining compatibility. EPA interprets tiered approach to mean requiring the more stringent option first, which is listing by a nationally recognized, independent testing laboratory. If the more stringent option is not available, the second tier would allow manufacturer's approval. This final UST regulation does not include a tiered approach because EPA thinks using this method for demonstrating compatibility makes the final UST regulation too complicated for implementing agencies as well as owners and operators. Even if the UST system equipment or components have a listing from a nationally recognized, independent testing laboratory, we do not always know whether compatibility testing was part of the listing. EPA thinks manufacturers will only issue written claims of compatibility if they have sufficient information to support such claims.

The 2011 proposed UST regulation required owners and operators retain these records:

- For all new and replaced equipment or components—so it is easier to demonstrate whether or not the equipment or component is compatible with the regulated substance stored
- For UST systems storing greater than 10 percent ethanol, greater than 20 percent biodiesel, or other regulated substance identified by the implementing agency—to demonstrate the UST system is compatible with these regulated substances or compliance with alternatives allowed by the implementing agency

However, after careful consideration of comments, this final UST regulation does not require owners and operators maintain records for all new and replaced equipment. EPA decided it is too onerous for owners and operators to maintain this information, which may not transfer when facilities change ownership.

To make it easier for UST owners and operators to comply with the compatibility requirement, this final UST regulation requires that owners and operators notify the implementing agency at least 30 days before switching to a regulated substance containing greater than 10 percent ethanol, greater than 20 percent biodiesel, or any other regulated substance identified by the implementing agency. This notification prior to switching fuels gives the implementing agency an opportunity to inquire about the compatibility of the UST system before owners and operators begin storing the new regulated substance. This notification requirement already exists in some states. For example, Colorado, North Carolina, and South Carolina require UST owners submit a completed compatibility checklist prior to storing some newer fuel blends. To notify, owners and operators may contact implementing agencies via EPA's Web site at *www.epa.gov/oust/*.

This final UST regulation requires owners and operators maintain records that demonstrate compliance with § 280.32(b) for as long as the UST system stores greater than 10 percent ethanol, greater than 20 percent biodiesel, or other regulated substances identified by the implementing agency. Owners and operators must retain records for these regulated substances in order to meet this compatibility requirement.

The 2011 proposed UST regulation preamble included an extensive list of UST system equipment and components that must be compatible but that list was not in the 2011 proposed UST regulation. Based on commenter input, this final UST regulation includes a list of UST system equipment and components that owners and operators

must demonstrate to be compatible when using the manufacturer's approval and certification or listing options. The UST system equipment or components that owners and operators must demonstrate to be compatible are those related to the tank, piping, containment sumps, pumping equipment, release detection equipment, spill prevention equipment, and overfill prevention equipment. These items are a subset of an UST system, as defined by § 280.12, which, if incompatible, could lead to a release.

This changes protect human health and the environment from potential releases from incompatible UST systems. These changes are not overly burdensome, nor do they require costly retrofits. They give owners and operators flexibility, yet provide EPA with confidence that UST systems are compatible with new fuel blends when owners and operators use one or more of the options to determine compatibility. This final UST regulation provides owners and operators with certainty about which options are allowed for demonstrating UST system compatibility with the substances stored.

Finally, EPA is removing from the compatibility section of the 1988 UST regulation API Recommended Practice 1627, which is a code of practice related to methanol-blended fuels. EPA included this code of practice in the 1988 UST regulation to help owners and operators demonstrate compliance with the compatibility requirement for methanol-blended fuels. However, EPA's subsequent review of this code revealed no substantial information about determining compatibility of UST systems with methanol-blended fuels. In August 2010, API published an updated version of API Recommended Practice 1626, which is a code of practice for storing and handling of ethanol-blended fuels. In the 2011 proposed UST regulation, EPA removed this code of practice because the proposed UST regulation provided specific requirements about how owners and operators may demonstrate compatibility for their UST systems. However, because commenters pointed out the code of practice includes requirements for demonstrating compatibility of UST systems with ethanol-blended fuels, EPA is including it as a code of practice that may be useful in complying with the compatibility section in this final UST regulation.

5. Improving Repairs

Changes to the Definition of Repair

This final UST regulation adds these UST system components to the definition of repair: piping; spill prevention equipment; overfill prevention equipment; corrosion protection equipment; and release detection equipment. The 1988 UST regulation definition of repair used the generic term UST system component and provided no detail about what an UST system component is. By adding these UST system components, EPA is making it clear that these specific components are subject to the repairs allowed section of the final UST regulation. This means owners and operators performing repairs on these UST system components must follow the repairs allowed section (§ 280.33).

Owners and operators commonly fix UST components that have not caused a release of regulated substance from the UST system. However, the repair definition in the 1988 UST regulation did not consider these types of fixes as repairs since they were not associated with releases. This final UST regulation removes the link that a repair is only associated with a release, requiring owners and operators meet the repairs allowed section (§ 280.33) when fixing UST system components that have failed to function properly, even if they have not caused a release of product from the UST system. This change means owners and operators must perform repairs in accordance with a code of practice developed by a nationally recognized association or independent testing laboratory and test or inspect the repaired equipment. This change ensures repair activities separate from a release are conducted properly. For example, under the 1988 UST regulation, fixing a cathodic protection system was not considered a repair. In this final UST regulation, this activity is considered a repair that must meet the repair requirements in § 280.33.

EPA proposed adding a suspected release as part of the definition of repair, so repairs associated with suspected releases are covered under the repair definition. However, based on comments received, EPA is not including suspected release as part of the definition of repair in this final UST regulation because that circumstance is already covered under the ''failed to function properly'' language in the repair definition. EPA disagrees with commenters suggesting EPA remove the ''failed to function properly'' language because EPA thinks repairs need to occur both when a release occurs and when UST system equipment fails to function properly.

Finally, based on comments received, EPA is adding clarifying language to the repair definition to ensure UST system component repairs restore components to proper operating condition.

Tests or Inspections After Repairs

This final UST regulation adds new testing or inspection requirements for spill, overfill, and secondary containment equipment following a repair and allows owners and operators up to 30 days following the repair to test or inspect the repaired UST component. EPA acknowledges that some secondary containment can be tested through normal release detection if vacuum, pressure, or liquid-filled methods of interstitial monitoring are used as the method of release detection. In these cases, the secondary containment test occurs automatically, making it unnecessary to perform additional testing.

EPA agrees with commenters about using the term inspecting rather than testing as it relates to the operability of overfill prevention equipment. Performing inspections will avoid potentially overfilling the tank while ensuring the overfill prevention equipment operates properly. EPA is revising the overfill prevention equipment test to be an overfill prevention equipment inspection.

EPA agrees with commenters who indicated that testing or inspection following repair should only apply to the component or components repaired and not to the entire UST system. This final UST regulation requires testing or inspection, as appropriate, following a repair only for those UST system components repaired and not to all components at the UST site. In addition, EPA is requiring owners conduct a test of the secondary containment area (including containment sumps) only if the secondary containment area is repaired and that area is used for interstitial monitoring. Note that all secondary containment areas must use interstitial monitoring for tanks and piping installed 180 days after the effective date of this final UST regulation (see section A–2, Secondary Containment for additional information). Repairs to the primary containment areas of a tank or piping may be tested using other options for tanks and piping listed in the repairs section.

Several commenters expressed concern that replacing UST system components that have not yet failed to function properly would trigger the repair requirements. If owners and

operators choose to replace UST system components, those components must meet the installation requirements in § 280.20(d). Therefore, replaced UST system components do not have to meet the repair requirements in § 280.33.

EPA solicited comments about whether to consider requiring tests or inspections of spill, overfill, and secondary containment areas before returning the UST system to service, rather than within 30 days of the repair. Many commenters were supportive of requiring testing or inspection before bringing the UST system back into service. However, this final UST regulation allows owners and operators up to 30 days following the repair to conduct testing or inspections. EPA thinks owners and operators need to test or inspect the repaired component as soon as possible following the repair. However, EPA understands there are circumstances where testing or inspection before returning the UST system to service may be impractical (for example, weather conditions, remote locations, or the need to schedule a test). In these examples, the UST system would remain out of service until the test or inspection is completed, resulting in unnecessary UST system down time for owners and operators. Thirty days allows some flexibility for completing the test or inspection, while allowing the UST system to return to service.

6. Vapor Monitoring and Groundwater Monitoring

This final UST regulation retains vapor monitoring and groundwater monitoring as methods of release detection for tanks and piping installed before the effective date of this final regulation, as long as owners and operators demonstrate proper installation and performance through a site assessment. In addition, this final UST regulation revises the recordkeeping requirement in § 280.45, which means owners and operators must maintain site assessments according to § 280.43(e)(6) and (f)(7) for as long as these release detection methods are used.

In the 2011 proposed UST regulation, EPA phased out vapor monitoring and groundwater monitoring over a five year time frame. However, EPA received significant comments in support of retaining these release detection methods. Many commenters presented circumstances where EPA should allow owners and operators to use vapor monitoring and groundwater monitoring such as: Until the system is replaced and the secondary containment requirement is triggered; or when the UST implementing agency already has or will establish additional criteria for use. In addition, commenters suggested EPA continue allowing certain UST systems to use vapor monitoring and groundwater monitoring, specifying emergency generator tanks, certain high-throughput UST systems, or specific low-throughput systems. EPA also received numerous requests to expand our proposed release detection options for airport hydrant fuel systems and field-constructed tanks to allow the use of vapor monitoring or groundwater monitoring. Under the 2011 proposed UST regulation, these options are not acceptable release detection options for owners and operators of airport hydrant systems and field-constructed tanks.

EPA agrees with commenters that owners and operators of emergency generator tanks, certain high-throughput UST systems, and specific low-throughput systems could benefit from continued use of vapor monitoring and groundwater monitoring until owners and operators replace their UST systems to meet the secondary containment requirement necessitating interstitial monitoring. EPA thinks that requiring owners and operators to maintain the site assessment will increase environmental protection appreciably beyond the 1988 UST requirements. Implementing agencies have noted that site assessments often do not exist for vapor or groundwater monitoring. Thus, by requiring site assessment records, we will ensure vapor and groundwater monitoring wells are properly located and function as effective release detection. EPA also thinks that allowing these release detection options to be customized and used for airport hydrant systems and field-constructed tanks will make it easier for owners and operators to comply with the release detection requirement.

Therefore, this final UST regulation continues to allow vapor and groundwater monitoring as long as owners and operators maintain a site assessment that demonstrates the release detection method meets the requirements in this final UST regulation. Owners and operators of airport hydrant systems and field-constructed tanks will have to meet the requirements for vapor monitoring and groundwater monitoring described in subpart K (see section C–2 for additional information).

The 1988 UST regulation defined criteria for the use of both release detection methods as explicitly as possible, given the large variation of site-specific conditions at UST sites across the country. EPA supports UST implementing agencies' efforts to better define site assessment criteria specific to their local geology in addition to what is required in the UST regulation. EPA also acknowledges and supports several UST implementing agencies' efforts in conducting construction certification and recertification inspections. However, EPA has not analyzed the economic burden construction certification and recertification inspections would place on UST implementing agencies and potentially UST system owners and operators. Therefore, this final UST regulation does not require installation inspections, certification, or recertification inspections of monitoring wells. EPA expects UST implementing agencies will continue reviewing and accepting site assessments according to their program policies.

In the event of a confirmed release at an UST site, vapor monitoring and groundwater monitoring are no longer acceptable options for release detection unless a new site assessment for the release detection method is conducted. If a release is confirmed, an owner and operator will have to remediate the site according to 40 CFR part 280, subpart F. Following site remediation, and as long as replacement of the UST system does not trigger the secondary containment requirement, an owner and operator must obtain a new site assessment to verify appropriate use of these methods, if the owner and operator chooses to continue using vapor monitoring or groundwater monitoring as the primary release detection method. Otherwise, owners and operators must use another method of release detection according to subpart D or subpart K.

At the time of the 2011 proposed UST regulation, EPA estimated approximately 5 percent of all active UST systems were using vapor monitoring or groundwater monitoring to comply with release monitoring requirements.[114] Commenters confirmed that 5 percent of vapor monitoring and groundwater monitoring was accurate. EPA also confirmed that although the methods are used very infrequently in the majority of jurisdictions, there is considerably high use in certain states. Arkansas, Louisiana, and Mississippi have a significant number of owners and operators using vapor monitoring, groundwater monitoring, or a combination of the two methods.

[114] E², Incorporated, memoranda and analyses submitted under Contract EP–W–05–018, U.S. Environmental Protection Agency. *Underground Storage Tanks/Leaking Underground Storage Tanks Analytical And Technical Support.* These supporting materials are located in the docket EPA–HQ–UST–2011–0301.

Estimated use of both methods in these states is 29 percent, 12 percent, and 65 percent, respectively. Confirmation of high use in one particular geographic area of the country influenced EPA's decision to continue allowing use of these methods.

EPA agrees with comments about major benefits for UST system owners and operators to use backup release detection, whether it is vapor monitoring, groundwater monitoring, or another method. However, neither the 1988 UST regulation nor this final UST regulation requires a secondary 30 day release detection method.

EPA discussed several issues in the 2011 proposed UST regulation that prompted our proposal to no longer allow vapor monitoring and groundwater monitoring as primary methods of release detection. However, the requirement in this final UST regulation for owners and operators to maintain the record of a site assessment for as long as the method is used will address most of these issues.

If the site assessment is available when inspecting USTs, UST implementing agencies can confirm proper installation and use of monitoring wells. For example, if inspectors find what they believe to be insufficient numbers of wells or wells improperly located to sufficiently monitor all portions of the tank or piping that routinely contain product, inspectors will be able to reference the site assessment to determine adequacy of the wells.

The site assessment will also help UST implementing agencies determine whether certain conditions, which allow users to switch between vapor monitoring and groundwater monitoring due to seasonal variations, have been met. Monitoring wells must be properly constructed and installed to meet all criteria in § 280.43(e) and (f). Wells used for vapor monitoring must allow vapors to collect; wells used for groundwater monitoring must be screened to prevent clogging and intercept the water table at both high and low groundwater conditions while being sealed from the ground to the top of the filter pack. Information regarding acceptability of the same wells used for both methods of release detection must be documented in the site assessment.

In the 2011 proposed UST regulation, EPA discussed issues that were specific to vapor monitoring. These issues will be addressed when owners and operators maintain the site assessment for as long as the method is used. The site assessment will contain information on site conditions, such as whether porosity of the surrounding soil is sufficient. The site assessment will confirm that vapors to be monitored will be unaffected by groundwater, rainfall, or soil moisture. Perhaps the most crucial information in the site assessment is the background contamination level at the site. This will allow owners, operators, and implementing agencies to determine whether that level interferes with monitoring methods. It also marks the threshold for determining a release has occurred when monitoring for petroleum hydrocarbons.

Maintaining the site assessment also addresses specific groundwater monitoring issues EPA discussed. Groundwater at times can be more than 20 feet from the ground surface, due to seasonal water table variations. This can result in the depth to groundwater requirement not being met. Unless an analysis is performed and valid documentation regarding use of the wells for vapor monitoring during low water table conditions is included in the site assessment, the wells will be restricted for groundwater monitoring use only.

In cases where there is no site assessment or an assessment does not sufficiently ensure requirements in § 280.43(e) or (f) are met, UST system owners and operators must reassess the site and maintain documentation required in § 280.43(e)(6) and (f)(7) in order to continue using groundwater or vapor monitoring as a method of release detection. At a minimum, a professional engineer or professional geologist, or equivalent licensed professional with experience in environmental engineering, hydrogeology, or other relevant technical discipline acceptable to the UST implementing agency must sign the new site assessment.

EPA understands that in Arkansas, Louisiana, and Mississippi, where the methods are commonly used and account for the majority of use in the country, most UST system owners and operators or the UST implementing agency have sufficient documentation of the site assessment. This means most owners and operators in those states will not need to conduct a new site assessment to comply with this final UST regulation. Owners and operators in other areas of the country may need to conduct a site assessment in order to continue using vapor monitoring or groundwater monitoring.

This final UST regulation also addresses another major aspect associated with vapor monitoring and groundwater monitoring methods. Equipment that is used as part of these release detection methods requires proper operation and maintenance in order to provide optimal monitoring results. Operation and maintenance requirements for electronic and non-electronic equipment are addressed in the release detection equipment testing requirement discussed in section B–5 and the walkthrough inspection requirement in section B–1, respectively.

7. Interstitial Monitoring Results, Including Interstitial Alarms, Under Subpart E

This final UST regulation clarifies UST owners' and operators' responsibilities regarding interstitial monitoring results, including alarms, under 40 CFR part 280, subpart E. Specifically, EPA is making these changes:

- § 280.50(b)—adding liquid in interstitial spaces of secondarily contained UST systems as an example of an unusual operating condition and adding to the list of criteria for not being required to report a suspected release that any liquid in the interstitial space not used as part of the interstitial monitoring method must be removed
- § 280.50(c)—clarifying that an alarm during release detection monitoring is subject to the reporting requirement and describing exceptions to the reporting requirement
- § 280.52(a)—adding owners and operators as appropriate must conduct secondary containment testing, and clarifying actions UST owners and operators must take if a test confirms a leak into the interstitial space or indicates a release to the environment

The 1988 UST regulation implicitly covered interstitial monitoring when reporting suspected releases because it was a method of release detection. This final UST regulation makes changes to explicitly cover interstitial monitoring and reinforce that a leak into an interstitial space of a secondarily contained UST system also indicates a potential threat to the environment; leaks must be investigated, addressed, and as necessary, reported.

This final UST regulation requires interstitial monitoring for all new or replaced tanks and piping (see section A–2, Secondary Containment). As new systems are installed, interstitial monitoring will become more widely used as a method of release detection. With this in mind, EPA wants UST owners and operators to clearly understand how interstitial monitoring results, including interstitial alarms, must be handled.

In the 1988 UST regulation, EPA indicated that product or water in the

interstice, and alarms signifying the presence of those conditions, are unusual operating conditions and must be investigated appropriately. However, EPA did not indicate how UST owners and operators were to address discrepancies with interstitial spaces. As a result, some UST owners and operators were uncertain about how best to respond to interstitial monitoring results and alarms associated with interstitial monitoring that indicate a release may have occurred. To alleviate uncertainty for owners and operators, EPA provides information below about interstitial monitoring and responses to alarms.

This final UST regulation revises § 280.50(b) by adding interstitial spaces of secondarily contained UST systems and clarifying the presence of liquid in this space as an unusual operating condition unless the liquid is used for interstitial monitoring or meets the requirements described in § 280.43(g)(2)(iv). Water in the interstitial space (presumably from a breach in the secondary wall) and product in the interstitial space (presumably from a breach in the primary wall) are the two typically encountered liquids discovered in the interstice. However, EPA is using the broader term liquid to cover water, product, or other substances in the liquid-phase in the interstitial space. Any liquid in this space not used for interstitial monitoring or not meeting the requirements described in § 280.43(g)(2)(iv) indicates there is an UST system problem that needs to be resolved. As a result, EPA is specifying this as an unusual operating condition and is requiring UST owners and operators investigate and address it.

Several commenters suggested changes to § 280.50(b) of the 2011 proposed UST regulation. Suggestions included: Deleting that water or product in the interstice is reportable and clarifying the requirement that the unexplained presence of water or product is an unusual operating condition. Based on comments, EPA in § 280.50(b) of this final UST regulation is using the term liquid, rather than water or product, to address any liquid in the interstitial space. To add clarity to this final UST regulation, EPA is also restructuring the section to provide subsections with separate examples of unusual operating conditions. This final UST regulation also allows owners and operators to not remove or report liquid under two conditions: Within secondary barriers described in § 280.43(g)(2)(iv), as long as interstitial monitoring is not rendered inoperative, or the liquid is used as part of the interstitial monitoring method.

EPA is clarifying in § 280.50(c) that an alarm during release detection monitoring, which indicates a potential release or compromise of the interstitial space, is subject to the reporting requirement. UST owners and operators must appropriately address all release detection monitoring alarms. For example, some interstitial monitoring systems will trigger an alarm, which indicates a potential release or that the interstitial space has been compromised. In subpart E, EPA is adding interstitial monitoring to emphasize its importance because the secondary containment requirement for new and replaced systems in section A–2 will increase the use of interstitial monitoring. UST owners and operators are not required to report alarms from defective system equipment or components or alarms that are investigated and determined to be a non-release. Also, UST owners and operators do not have to report leaks, which are contained in the interstitial space; but owners and operators must investigate and repair problems. Except as provided in § 280.43(g)(2)(iv), any liquid in the interstitial space not used as part of the interstitial monitoring method, such as brine filled, must be removed.

Several commenters misunderstood EPA's discussion regarding reporting alarms. In the 2011 proposed UST regulation, EPA intended that owners and operators need to investigate all alarms, but only report confirmed releases and suspected releases that could not be ruled out by an investigation. Commenters suggested these changes to EPA's 2011 proposed UST regulation at § 280.50(c): Deleting language pertaining to alarms; changing language regarding the time allowed to repair, recalibrate, or replace defective system equipment; and including an exception for reporting alarms that have been confirmed to be false alarms. Based on comments, EPA in § 280.50(c) of this final UST regulation is expanding and describing exceptions to reporting monitoring results, including investigation of an alarm from a release detection method that indicates a release may have occurred.

EPA is adding secondary containment testing, as appropriate, to the release investigation and confirmation steps in § 280.52(a) of the final UST regulation. EPA thinks it is important to clarify actions UST owners and operators must take if a test confirms a leak into the interstitial space or indicates a release has occurred. If a leak into the interstice is confirmed, an UST owner and operator must correct or address the problem. In addition to options listed in the 1988 UST regulation, this final UST regulation includes closure as an option when an owner and operator confirms a release. Nothing in this final UST regulation changes the requirement in subpart F for an UST owner and operator to take corrective action if a release occurred.

In the 2011 proposed UST regulation, EPA suggested that UST owners and operators follow integrity test requirements, now referred to as secondary containment testing, of the interstitial area. Many commenters noted that tank tightness testing or line tightness testing may be more appropriate tests to confirm a suspected release under certain circumstances, and UST system owners and operators should be allowed the choice of determining which test to use. EPA agrees and is revising § 280.52(a) to indicate use of secondary containment testing as appropriate.

EPA received several comments about the terms release and leak used throughout the 2011 proposed UST regulation and the 1988 UST regulation. Historically, EPA used these terms interchangeably. As a result of EPA's new secondary containment and interstitial monitoring requirement (see section A–2, Secondary Containment), there is now a subtle but important distinction between the terms. The term release is defined in the Solid Waste Disposal Act. EPA provides the same definition of release in the UST regulation at § 280.12. Release means any spilling, leaking, emitting, discharging, escaping, leaching or disposing from an UST into groundwater, surface water or subsurface soils. A release always reaches the environment. The term leak in this final UST regulation is a more general term that includes both cases of when a regulated substance enters into a contained area (such as secondary containment) but has not yet reached the environment and when a regulated substance reaches the environment (a release). Therefore, the term release is a subset of the more general term leak. Note that leaks and releases have investigation and reporting requirements in subpart E.

As a result of distinguishing between a leak and a release, EPA is clarifying the definition of release detection. The 1988 UST regulation defined release detection as determining whether a release of a regulated substance occurred from the UST system into the environment or into the interstitial space between the UST system and its secondary barrier or secondary

containment around it. This final UST regulation revises the definition of release detection to clarify regulated substances entering into the interstitial space are leaks instead of releases. This final UST regulation defines release detection as determining whether a release of a regulated substance occurred from the UST system into the environment or a leak occurred into the interstitial space between the UST system and its secondary barrier or secondary containment around it. This change allows EPA to continue to use the term release detection as it applies to both leaks and releases.

E. General Updates

1. Incorporate Newer Technologies

Since EPA promulgated the 1988 UST regulation, newer tank, piping, and release detection technologies have been developed and are being used. EPA is incorporating several of these newer technologies in this final UST regulation. In addition, because the 1988 UST regulation closure requirements unintentionally restrict use of a newer tank within a tank technology, EPA is revising closure requirements to provide additional flexibility for implementing agencies to allow field-constructed tank technologies that construct a tank within an existing closed tank. However, EPA is not specifically including field-constructed tank within a tank technologies in the new tank standards section in § 280.20 of the final UST regulation, because the tank construction technologies currently covered in this section include both factory constructed and field-constructed technologies. Note that § 280.20(d) requires new UST systems, including tank within a tank technologies, to be properly installed according to a code of practice developed by a nationally recognized association or independent testing laboratory and the manufacturer's instructions.

Clad and Jacketed Tanks

This final UST regulation adds steel tanks that are clad or jacketed with a non-corrodible material to the list of specific new tank design and construction options for UST systems. EPA estimates 10 percent of regulated tanks today are jacketed with a non-corrodible material and 18 percent are clad with a non-corrodible material.[115]

The 1988 UST regulation allowed a steel-fiberglass-reinforced-plastic composite tank (also called a fiberglass clad tank), but did not specifically include other non-corrodible claddings. In addition to fiberglass, manufacturers in 2014 are using other non-corrodible materials claddings for steel tanks, which are listed by UL standard 1746, *External Corrosion Protection Systems for Steel Underground Storage Tanks.* These tank technologies are effective at preventing corrosion of the portion of the steel tank shell in contact with the ground. EPA considers a cladding to be a non-corrosive dielectric material, bonded to a steel tank with sufficient durability to prevent external corrosion during the tank's life.

Because they were not commonly used at the time, EPA did not include jacketed tanks in the 1988 UST regulation. These tanks are now: More commonly used; UL 1746 listed for external corrosion protection; and effective in preventing corrosion of the steel tank shell. EPA considers the tank jacket to be a non-corrosive dielectric material that: is constructed as secondary containment or jacketed around a steel tank; has sufficient durability to prevent external corrosion of the steel tank shell during a tank's life; and prevents a regulated substance released from the primary steel tank wall from reaching the environment.

Non-Corrodible Piping

The 1988 UST regulation allowed fiberglass-reinforced plastic piping, but did not specifically include other non-corrodible piping options such as flexible plastic piping. Both fiberglass and flexible plastic piping are listed under the UL 971 standard, *Nonmetallic Underground Piping for Flammable Liquids.* Non-corrodible piping not made of fiberglass-reinforced plastic (in particular, flexible plastic piping) was installed at UST sites beginning in the 1990s and has evolved over the past 20 years. Flexible plastic piping is made of various non-corrodible materials, such as polyethylene and polyurethane. EPA estimates at least 13 percent of regulated piping currently installed is made of non-corrodible materials that are not fiberglass-reinforced plastic.[116] This final UST regulation revises fiberglass-reinforced piping to be non-corrodible piping and allows UST owners and operators to install other types of non-corrodible piping, such as flexible plastic, without requiring implementing agencies to make a determination on the suitability of those materials.

Release Detection Technologies

The 1988 UST regulation allowed UST owners and operators to use other methods that meet release detection performance criteria listed at § 280.43(h). Although continuous in-tank leak detection (CITLD) and SIR were allowed under § 280.43(h), EPA is including both by name and providing specific performance criteria in this final UST regulation for the reasons described below.

CITLD

The 1988 UST regulation allowed ATG systems as a recognized method of release detection. However, ATG systems were generally listed with performance requirements consistent with performing a static test. ATG systems rely on system down time and the absence of product delivery or dispensing activities to perform release detection. In static testing mode, an ATG system analyzes product level and determines whether a leak is present during that down time. UST owners and operators also use ATG systems as a means of continually monitoring tanks for potential releases. CITLD has evolved as a reliable means of providing release detection equivalent to other methods specified in § 280.41. Within this category of methods, this final UST regulation allows continuous in-tank methods where the system incrementally gathers measurements to determine a tank's leak status within the 30-day monitoring period.

One commenter asked EPA to further clarify the term CITLD. That commenter said EPA presented language in the 2011 proposed UST regulation that confused CITLD, continuous statistical leak detection (CSLD), and SIR because each is a statistically based release detection method. EPA agrees with the commenter and is clarifying use of the term CITLD, which encompasses all statistically based methods where the system incrementally gathers measurements on an uninterrupted or nearly uninterrupted basis to determine a tank's leak status. Currently, there are two major groups that fit into this category: CSLD (also referred to as continuous automatic tank gauging methods) and continual reconciliation. Both groups typically use sensors permanently installed in the tank to obtain inventory measurements. They are combined with a microprocessor in

[115] E², Incorporated, memoranda and analyses submitted under Contract EP–W–05–018, U.S. Environmental Protection Agency. *Underground Storage Tanks/Leaking Underground Storage Tanks Analytical And Technical Support.* These supporting materials are located in the docket EPA–HQ–UST–2011–0301.

[116] E², Incorporated, memoranda and analyses submitted under Contract EP–W–05–018, U.S. Environmental Protection Agency. *Underground Storage Tanks/Leaking Underground Storage Tanks Analytical And Technical Support.* These supporting materials are located in the docket EPA–HQ–UST–2011–0301.

the ATG system or other control console that processes the data. Continual reconciliation methods are further distinguished by their connection to dispensing meters that allow for automatic recording and use of dispensing data in analyzing tanks' leak status. SIR, which we describe below, is not a continually operating method that fits into the CITLD category.

This final UST regulation formally recognizes CITLD as a release detection method in § 280.43(d). Per § 280.41, a conclusive pass or fail result must be obtained within the 30-day monitoring period. All monitoring records must be maintained according to § 280.45. Another method of release detection is required in the event of an inconclusive result. For example, in the event of an inconclusive result, UST owners and operators may perform an in-tank static test using an ATG system or use another method of release detection.

SIR

This final UST regulation adds SIR as a release detection method and provides performance criteria for its use. SIR must:

- Report a quantitative result with a calculated leak rate;
- Be capable of detecting a leak rate of at least 0.2 gallon per hour or a release of 150 gallons within a 30-day period with a probability of detection of not less than 0.95 and a probability of false alarm of no greater than 0.05; and
- Use a threshold that does not exceed one-half the minimum detectable leak rate.

A quantitative result with a calculated leak rate is necessary to effectively perform release detection using SIR. Some SIR methods are qualitative based methods that simply provide a result of pass or fail without any additional information for UST owners and operators to gauge the validity of reported results. Based on information in the NWGLDE list,[117] approximately 85 percent of SIR methods listed are quantitative-based methods. Many state UST implementing agencies already only allow quantitative methods. This final UST regulation only allows quantitative SIR as an option for meeting the release detection requirement.

Consistent with the performance criteria described in the other methods option for release detection, this final UST regulation maintains the performance standards of a 0.2 gallon per hour release or a release of 150 gallons within a 30-day period with a probability of detection of 0.95 and a probability of false alarm of 0.05. The 2011 proposed UST regulation did not include the additional standard of 150 gallons within a 30-day period for SIR. EPA agrees with the commenter who noted the importance of the 150 gallons criteria if SIR methods are used for monitoring piping for release detection; as a result, we are retaining this performance standard for SIR in the final UST regulation because EPA and some other implementing agencies allow UST system owners and operators to use SIR for piping release detection.

Like other release detection methods, SIR must be capable of detecting a release of 0.2 gallon per hour or less with a probability of detection (Pd) of at least 0.95 and probability of false alarm (Pfa) of no more than 0.05. In a normal probability distribution, SIR data typically analyzed through the calculation of the reportable values of minimum detectable leak rate (MDL) and the leak declaration threshold (T) are related as follows:

- MDL is always greater than T
- Pd = (1-Pfa), then MDL = 2 times T (*i.e.,* T = ½ MDL)

Any analysis of data indicating a threshold value greater than one-half minimum detectable leak rate should be investigated as a suspected release.

One commenter asked EPA to further clarify SIR. The commenter said EPA presented language in the 2011 proposed UST regulation that confused statistically based release detection methods currently in use. EPA agrees and is modifying the description of SIR in this final UST regulation at § 280.43(h) to narrow the focus of statistically based methods, which fit under this section. SIR encompasses only those statistically based methods where inventory data is gathered over a period and typically provided to a vendor who analyzes the data to determine the leak status of the tank. These methods do not include systems that incrementally gather measurements on an uninterrupted or nearly uninterrupted basis to determine the tank's leak status described in § 280.43(d) under continuous in tank leak detection.

This final UST regulation addresses these issues associated with SIR:

- SIR is not the same as inventory control
  - Historically, users, vendors, and regulators have incorrectly associated SIR with inventory control in § 280.43(a). SIR is more sophisticated than inventory control and not subject to the same requirement to combine it with tank tightness testing and limit its use to 10 years. Section 280.50(c)(3) allows owners and operators to use a second month of inventory control data to confirm initial possible failure results. However, this allowance does not apply to SIR. Therefore, any failed SIR result must be investigated as a suspected release. Also, in the event of an inconclusive result, UST owners and operators must use another method of release detection to determine the leak status of the tank.
- Results for release detection, including SIR, are required within the 30-day monitoring period
  - EPA considered including a requirement in the final UST regulation that UST owners and operators obtain a record of SIR results within 30 days. However, this requirement is already covered in the release detection requirements. As § 280.41(a)(1) states, ''Tanks . . . must be monitored for releases at least every 30 days using one of the methods listed in § 280.43(d) through (i) . . .'' In this final UST regulation, EPA is adding a subsection to formally recognize SIR. A definitive result of pass or fail that identifies the tank's leak status is required within the 30-day monitoring period for all release detection methods, including SIR.
- Owners and operators must use another method of release detection if SIR results are inconclusive
  - For years, implementing agencies have been concerned about inconclusive results when using SIR for release detection. In 1993, EPA issued a policy regarding inconclusive SIR results,[118] which says all methods used to meet release detection requirements in § 280.41 must obtain a conclusive result of pass or fail within the 30-day monitoring period. All monitoring records must be maintained according to § 280.45. For SIR, this means UST owners and operators must obtain a report determining release status within the 30-day monitoring period. Another method of release detection is required when results are inconclusive; prior to sufficient data gathered to generate an initial report at startup; or when a report is not available for any month of

[117] National Work Group On Leak Detection Evaluations' *List Of Leak Detection Evaluations For Storage Tank Systems: http://www.nwglde.org/.*

[118] UST Technical Compendium, question and answer number 21:*http://epa.gov/oust/compend/rd.htm.*

monitoring. Owners and operators have not performed release detection until the release status of the UST system has been conclusively determined.

- Initial SIR report at startup
  - SIR methods need to gather data over a period in order to determine whether the tank is leaking. In some cases, implementing agencies have addressed significant lag times between when data is collected and when a tank status determination is available to owners and operators. NWGLDE's list of third-party evaluated methods indicates the data collection period required for SIR methods ranges from 15 to 90 days. However, most methods require between 23 and 30 days to gather sufficient measurements that provide an accurate result. Any method that goes beyond a 30-day monitoring period is inconsistent with and does not meet the release detection requirement. It is imperative that UST owners and operators determine the status of their tanks within the established monitoring period to avoid increased risk of releases. Therefore, owners and operators must use another release detection method at least once every 30 days until a SIR result is obtained. After that, owners and operators must have a SIR result at least once every 30 days.
- Meeting the 30-day monitoring requirement
  - EPA received several comments regarding the lack of timeliness associated with determining whether a leak exists when using SIR. In many instances, monitoring results are not produced until the next monitoring period or well beyond. These commenters also provided several suggestions for EPA to address the lag time between UST owners and operators collecting leak detection data and receiving late reporting on the leak status of the tank. EPA reiterates its established regulatory requirement that tanks must be monitored for releases at least once every 30 days.
  - Commenters provided other options for how owners and operators can meet the release detection requirement. One possible option is for EPA to require owners and operators perform a SIR analysis every 15 days using the last 30 days of data. This option results in a more frequent analysis of the UST system's leak status. EPA agrees this option would allow owners and operators to meet the release detection requirement. Another option suggested was for EPA to add a requirement that SIR results must be returned to owners within seven days of the end of the data collection period; other commenters indicated various other times. EPA disagrees with this option because it would not meet the requirement to conduct release detection at least once every 30 days. Providing additional time for one method to determine whether a leak has occurred would be both unfair to UST system owners and operators using other release detection methods, as well as result in decreased environmental protection. To meet the release detection requirement for SIR, owners and operators could conduct a more frequent analysis, as one commenter suggested, or send data more expeditiously by electronic means. EPA is retaining the 30-day release detection requirement, which allows owners and operators to use whatever method they choose, as long as the method meets performance standards. UST system owners and operators can discuss changing their methods or data collection procedures with their SIR vendors in order to meet EPA's release detection requirement.

Interstitial Monitoring

The 2011 proposed UST regulation included three methods of continuous interstitial monitoring—vacuum, pressure, and liquid-filled methods—in § 280.43(g). EPA proposed these methods in conjunction with the periodic secondary containment testing requirement. Based on comments, EPA removed references to continuous interstitial monitoring in this final UST regulation. Because continuous interstitial monitoring is not discussed in this final UST regulation, EPA does not include language pertaining to continuous vacuum, pressure, or liquid-filled methods of interstitial monitoring in § 280.43(g). This does not impact release detection methods allowed under § 280.43(g).

2. Updates to Codes of Practice Listed in the UST Regulation

This final UST regulation updates the codes of practice (also called standards or recommended practices) listed in the 1988 UST regulation to reflect new codes, changes to code names, and new nationally recognized associations and independent testing laboratories. The 1988 UST regulation relied on codes of practice developed by nationally recognized associations or independent testing laboratories to implement many of the requirements. EPA will continue to rely on codes of practice in this final UST regulation.

EPA reviewed information from more than 25 code making groups on more than 200 codes of practice, which have been developed or revised since the 1988 UST regulation.[119] As a result, EPA is:

- Updating titles and designations of existing codes of practice;
- Adding applicable codes of practice developed after the 1988 UST regulation was finalized;
- Moving codes of practice that were misplaced in the 1988 UST regulation; and
- Removing codes of practice that:
  - Are out of date, no longer available, withdrawn, or rescinded;
  - No longer provide any information appropriate to or relevant to the final UST regulation where it was referenced; or
  - Are no longer needed.

For example, EPA listed the Association for Composite Tanks ACT–100 tank standard in § 280.20(a)(3) of the 1988 UST regulation as a code of practice for meeting the clad tank requirement. EPA is removing this code of practice from this final UST regulation because both the association and code of practice no longer exist.

In several cases, EPA is moving a code of practice from one section of the final UST regulation to another. For example, EPA is moving Steel Tank Institute Standard F841, *Standard for Dual Wall Underground Steel Storage Tanks* from § 280.43(g)—interstitial monitoring to § 280.20(a)(2), which covers steel tanks. EPA thinks it makes more sense for this to be included under the UST design and construction standards, rather than as a release detection standard. EPA used similar rationale when relocating other codes of practice in this final UST regulation.

As in the preamble to the 1988 UST regulation, this final UST regulation does not require use of a specific version or edition of any code. The consensus codes are frequently revised and updated. EPA recognizes that requiring use of the most recent edition of a code of practice would cause undue confusion in the regulated community. For example, owners and operators install UST systems according to codes

[119] E², Incorporated, memoranda and analyses submitted under Contract EP–W–05–018, U.S. Environmental Protection Agency. *Underground Storage Tanks/Leaking Underground Storage Tanks Analytical And Technical Support.* These supporting materials are located in the docket EPA–HQ–UST–2011–0301.

of practice current at the time of installation, but may not have equipment in the ground that meets codes that are current 10 years later. EPA concludes that the industry codes in effect at the date of publication of this final UST regulation are protective of human health and the environment. Using future editions of codes instead of editions now in effect is not required, but is encouraged; updated codes will probably provide for newer, more effective technologies and practices. Using past codes, which have been replaced by new editions prior to the effective date of this final UST regulation, is not allowed because some past recommended industry practices may not represent current codes of practice or may not adequately cover the regulatory requirement.

Consistent with the preamble to the 1988 UST regulation, this final UST regulation interprets the term nationally recognized organization to mean a technical or professional organization that has issued standards formed by the consensus of its members. The organization should consider all relevant viewpoints and interests, including those of consumers and future or existing potential industry participants. The resulting standards should be widely accepted and based on a broad range of technical information, and performance criteria should be central elements of the resulting standards. EPA regards the following organizations, whose codes of practice are listed in this final UST regulation, as examples of nationally recognized organizations:

American Petroleum Institute (API)
American Society for Testing and Materials (ASTM)
Fiberglass Tank and Pipe Institute (FTPI)
National Association of Corrosion Engineers (NACE)
National Fire Protection Association (NFPA)
National Leak Prevention Association (NLPA)
Petroleum Equipment Institute (PEI)
Steel Tank Institute (STI)
Underwriters Laboratory (UL)

EPA received broad support for updating the codes of practice listed in the final UST regulation. Several commenters pointed out errors to titles or designations in the 2011 proposed UST regulation. This final UST regulation corrects these errors.

EPA received comments on the 2011 proposed UST regulation asking that we add or remove several codes of practice. EPA reviewed PEI's recommended practice for testing and verification of spill, overfill, leak detection, and secondary containment equipment (RP 1200), and in this final UST regulation is including it in areas where testing or inspecting UST equipment is required. EPA also reviewed and is including PEI's recommended practice for the inspection and maintenance of UST systems (RP 900) in the walkthrough inspections portion of this final UST regulation. EPA is not including the Canadian code for installing fiber reinforced plastic linings (ULC/ORD–C58.4–05), because this final UST regulation no longer allows owners and operators to install internal linings to meet the corrosion protection upgrade. Owners may continue using internal linings for other reasons such as compatibility or secondary containment; but EPA determined there are no appropriate areas in this final UST regulation to list lining codes of practice for those purposes. Also, EPA is not including PEI's recommended practice for the inspection and maintenance of motor fuel dispensing equipment (RP 500), because it is a standard for inspecting motor fuel dispensing equipment and Subtitle I of the SWDA does not give EPA the authority to regulate aboveground equipment such as motor fuel dispensing equipment. Finally, EPA is not including STI's storage tank maintenance standard (R–111) as an option for periodic walkthrough inspections because the content of the 2011 version of this code of practice only focused on water and contaminants in the tank along with compatibility. Except for a monthly inspection checklist, this code of practice does not describe how to conduct a periodic walkthrough inspection. If STI changes this code of practice, implementing agencies may determine whether the newer version is adequate for meeting the periodic walkthrough inspection requirement in this final UST regulation.

In the 2011 proposed UST regulation, EPA asked for input on whether the requirement to follow codes of practice and manufacturer's instructions under the installation requirements in § 280.20(d) should apply to just tanks and piping (as stated in the 1988 UST regulation) or apply to the UST system as a whole. Both the 1988 UST regulation and this final UST regulation define UST system as the underground storage tank, connected underground piping, underground ancillary equipment, and containment system, if any. Commenters strongly supported requiring installation of the UST system, rather than just tanks and piping, according to a code of practice developed by a nationally recognized association or independent testing laboratory and according to manufacturer's instructions. For these reasons, this final UST regulation replaces tanks and piping with UST system in § 280.20(d).

3. Updates To Remove Old Upgrade and Implementation Deadlines

This final UST regulation removes references to the 1998 deadline and old phase in schedules, while continuing to allow testing of corrosion protection and release detection. These changes acknowledge that the 1998 deadline for upgrading UST systems with release prevention and the 1990s release detection and financial responsibility deadlines passed more than a decade ago. In addition, as of 2010 implementing agencies have inspected all regulated UST systems at least once for compliance with release detection, release prevention, and financial responsibility requirements.

EPA will no longer allow owners and operators to upgrade UST systems if they never met the 1998 upgrade requirements, unless the implementing agency determines the UST system is acceptable to upgrade. Owners and operators must permanently close non-upgraded UST systems according to the closure requirements in subpart G. Non-upgraded UST systems are older and have been in the ground for more than two decades. In addition, metal USTs and piping without corrosion protection pose a significant risk to human health and the environment, because unprotected metal in contact with soil corrodes. EPA is allowing implementing agencies to make case-by-case determinations on when to allow upgrades. EPA does not expect implementing agencies to allow continued use of tanks or piping not upgraded with corrosion protection. However, some implementing agencies may decide to allow owners and operators of UST systems with corrosion protection, but without spill or overfill prevention, to add spill or overfill prevention instead of requiring permanent closure.

EPA will continue to allow UST systems with field-constructed tanks and airport hydrant systems to be upgraded with spill, overfill, and corrosion protection under subpart K of the UST regulation. See section C–2 for additional information on upgrading these UST systems.

To meet the release detection requirement, § 280.41 of the 1988 UST regulation allowed owners and operators of USTs not upgraded with corrosion protection to use a

combination of monthly inventory control with annual tank tightness testing until December 22, 1998. Since owners and operators no longer have the option to use inventory control and annual tightness testing, EPA is removing this option from this final UST regulation.

In response to comments received, EPA is removing the definition of petroleum marketing firm from subpart H of this final UST regulation. EPA only used the term petroleum marketing firm in the compliance dates section as it related to when these firms needed to meet the financial responsibility requirements. Since the compliance dates for conventional UST systems have passed more than a decade ago, the term no longer needs to be defined.

4. Editorial Corrections and Technical Amendments

This final UST regulation includes editorial corrections and technical amendments to the 1988 UST regulation. Editorial corrections include: Correcting misspellings; capitalizing words; removing unused acronyms; using conventional number formatting; and appropriately referring to parts, subparts, sections, and paragraphs. In addition, this final UST regulation adds technical amendments, which include updating the final UST regulation to incorporate statutory changes that occurred since the 1988 UST regulation was promulgated and clarifying longstanding Agency interpretations and policies. EPA is making the following technical amendments in this final UST regulation:

- § 280.10(c)(4)—EPA is revising the Nuclear Regulatory Commission citation to be consistent with the Spill Prevention Control and Countermeasures requirements in 40 CFR part 112. This final UST regulation partially excludes emergency generator systems at nuclear power generation facilities licensed by the Nuclear Regulatory Commission that are subject to Nuclear Regulatory Commission requirements regarding design and quality criteria, including but not limited to 10 CFR part 50. EPA originally proposed only deleting appendix A from the regulatory citation. However, EPA agrees with commenters that using language consistent with the Spill Prevention Control and Countermeasures requirements in 40 CFR part 112 provides clarity and consistency for owners and operators of emergency generator UST systems at nuclear power generation facilities.
- § 280.12—EPA is revising exclusion (ii) of the definition of UST to incorporate a revision in section 9001 of the Solid Waste Disposal Act.
- This final UST regulation adds a technical amendment to § 280.43(b), which codifies longstanding Agency policy adding additional flexibility for using manual tank gauging. This change updates UST capacity allowances and testing durations when using manual tank gauging. Since 1990, EPA allowed these deviations from the 1988 UST regulation through policy and included them in outreach publications.
- The 2011 proposed UST regulation removed the requirement for inventory control for the automatic tank gauging release detection method in § 280.43(d) because some interpreted the language as requiring both inventory control and automatic tank gauging. However, EPA agrees with commenters who indicated the language is necessary to ensure automatic tank gauging equipment meets inventory control performance standards in § 280.43(a). More specifically, EPA is keeping the regulatory language to ensure owners and operators continue to measure for water as described in the inventory control requirement. This final UST regulation departs from the proposal and retains language established in the 1988 UST regulation that automatic tank gauging equipment also must meet the inventory control requirements. This final UST regulation does not require owners and operators to perform inventory control in addition to automatic tank gauging.
- This final UST regulation expressly states which new operation and maintenance requirements owners and operators do not have to meet for UST systems in temporary closure. Owners and operators of temporarily closed UST systems that are empty do not have to perform the following periodic release detection operation and maintenance testing and inspections in subparts C and D: 30 day release detection checks, annual sump checks, and annual hand-held release detection checks described in the walkthrough inspection section (see section B–1); testing of containment sumps used for interstitial monitoring described in the secondary containment testing section (see section B–4); and testing of release detection equipment described in the release detection equipment testing section (see section B–5). These requirements are unnecessary as long as the temporarily closed UST system is empty because release detection is not required in the first place. In addition, owners and operators of any UST system in temporary closure are not required to conduct the following periodic operation and maintenance testing and inspections for spill prevention equipment and overfill prevention equipment in subpart C: Spill prevention equipment testing (see section B–2); overfill prevention equipment inspections (see section B–3); or spill prevention equipment checks described in walkthrough inspections (see section B–1). Spill and overfill testing or inspections are not required for UST systems in temporary closure because those systems are not receiving deliveries of regulated substances. Finally, as a conforming amendment, this final UST regulation adds subpart K to the release detection citation because new release detection requirements for field-constructed tanks and airport hydrant systems are included in that subpart.
- This final UST regulation amends the definition of the term accidental release in § 280.92 so it matches the definition described in the preamble to the 1988 UST regulation for the financial responsibility requirements (53 FR 43334). EPA intended the definition in the preamble to be included in the 1988 UST regulation, but failed to include the concept of releases as a result of operating the UST. Through this amendment, EPA is clarifying that owners and operators are required to have financial responsibility for releases arising from operating USTs (including releases due to filling USTs and releases occurring at dispensers).
- § 280.94(a)(1)—EPA proposed to include the local government option citations in this section. However, those options are not included in this final UST regulation because they are already included in § 280.94(a)(2).
- § 280.97(b)(1) and (2)—EPA added the local government options as part of the reference since those options are also viable financial responsibility mechanisms.
- To make the local government bond rating test consistent with the requirements of the financial test in § 280.94, this final UST regulation adds a new subsection to § 280.104.
- To ensure the definition of UST technical standards in subpart I, *Lender Liability,* includes all of the preventative and operating requirements in this final UST regulation, EPA revised the definition to include subparts J and K as part of the preventative and operating requirements under 40 CFR part 280.
- To add clarity about the statement for shipping tickets and invoices in appendix III, this final UST regulation revises the appendix.
- Finally, the final UST regulation revises sections that use the terms operating life or properly closed to be permanently closed or when a change-

in-service occurs; this amendment will clearly indicate when the regulated operating life of an UST system ends. This final UST regulation does not define an operating life or proper closure. Rather, it describes permanent closure and change-in-service.

F. Alternative Options EPA Considered

In developing this final UST regulation (hereafter the Selected Option), EPA considered and evaluated variations of a subset of the regulatory requirements using two alternative options (hereafter Option 1 and Option 2). The table below highlights differences between the Selected Option and Options 1 and 2. Some of the regulatory requirements do not vary across the options (for example, notification of ownership changes is required in all three). As a result, regulatory changes discussed earlier in the preamble, but not listed here, mean those changes are in effect in all three options. Overall, Options 1 and 2 consist of regulatory changes that are more and less stringent, respectively, than those of the Selected Option.

COMPARISON OF SELECTED OPTION AND OPTIONS 1 AND 2

Regulatory requirement	Options		
	Selected	1	2
Walkthrough inspections	30 days	30 days (per 2011 proposed UST regulation)*.	Quarterly.
Overfill prevention equipment inspections	3 years	Annual	Not required.
Spill prevention equipment tests	3 years	Annual	3 years.
Containment sump tests	3 years	Annual	Not required.
Elimination of flow restrictors in vent lines for all new tanks and when overfill devices are replaced.	Required	Required	No change from 1988 UST regulation.
Operability checks for release detection equipment	Annual (plus annual check of sumps).	Annual (per 2011 proposed UST regulation)*.	Annual (plus annual check of sumps).
Groundwater and vapor monitoring for release detection	Continue to allow with site assessment.	5-year phase out (per 2011 proposed UST regulation)*.	No change from 1988 UST regulation.
Remove release detection deferral for emergency generator tanks.	Required	Required (per 2011 proposed UST regulation)*.	Required.
Requirements for demonstrating compatibility for fuels containing >E10 and >B20.	Required	Required (per 2011 proposed UST regulation)*.	No change from 1988 UST regulation.
Remove deferrals for airport hydrant fuel distribution systems and UST systems with field-constructed tanks.	Regulate under alternative release detection requirements.	Require airport hydrant systems and field-constructed tanks notify implementing agency and report releases (with no other new requirements).	Maintain deferral.

*In the 2011 proposed UST regulation, these regulatory changes generally consisted of more or stricter requirements than what is in the final UST regulation. For example, the 30-day walkthrough inspections in the 2011 proposed UST regulation included monthly check of sumps. Please see the 2011 proposed UST regulation for details.

Below we explain Options 1 and 2, as well as our rationale for each. (Note that EPA conducted a regulatory impact analysis for all three options. The results are discussed in the RIA document titled *Assessment of the Potential Costs, Benefits, and Other Impacts of the Final Revisions to EPA's Underground Storage Tank Regulations,* which is available in the docket for this action.)

EPA's Rationale for Option 1

EPA considered keeping walkthrough inspections as described in the 2011 proposed UST regulation. However, based on concerns from commenters regarding the proposed walkthrough inspection requirements, EPA decided to revise the components of the walkthrough inspection. See section B–1 for details regarding this final UST regulation on walkthrough inspections.

EPA also considered requiring annual inspections of overfill prevention equipment, annual spill prevention equipment tests, and annual containment sump testing. After reviewing comments, considering the benefits of establishing one consistent implementation time frame across as many regulatory requirements as possible, as well as assessing the cost of requiring annual tests and inspections, EPA is requiring owners and operators inspect overfill prevention equipment and test spill prevention equipment and containment sumps once every three years. This balances the benefits of ensuring properly functioning equipment with the potential administrative burden and costs imposed on owners and operators.

When considering operability checks for release detection equipment, EPA examined the possibility of keeping the operability checks as described in the 2011 proposed UST regulation. However, based on comments, EPA decided to revise some components of the operability checks. This resulted in allowing owners and operators to perform some release detection checks on an annual basis instead of every 30 days. See section B–5 for details regarding release detection equipment testing.

EPA also considered maintaining the 2011 proposed option of a five year phase out of groundwater and vapor monitoring as permissible release detection methods. Based on concerns from states where groundwater and vapor monitoring are used frequently by owners and operators, EPA is retaining groundwater and vapor monitoring as long as owners and operators demonstrate proper installation and performance through a site assessment that must be maintained as long as the methods are used. See section D–6 for details regarding groundwater and vapor monitoring.

EPA also considered maintaining its 2011 proposed requirements for release detection of emergency generator tanks and for demonstrating compatibility. However, as discussed in earlier sections (C–1 for emergency generator tanks and D–4 for compatibility), EPA is

revising these requirements in response to comments. For emergency generator tanks, we are revising the implementation time frame for consistency with other implementation dates. For compatibility, EPA is removing the recordkeeping requirement for new installations to make it easier for owners and operators to be in compliance. EPA is also adding a list of equipment that must demonstrate compatibility with storing ethanol blends greater than 10 percent or biodiesel blends greater than 20 percent, or any other regulated substance identified by the implementing agency. This will help owners and operators understand which UST equipment must be demonstrated to be compatible.

Lastly, EPA considered requiring owners and operators of airport hydrants systems and field-constructed tanks submit a one-time notice of existence in addition to reporting confirmed releases to the implementing agency. Owners and operators of these systems would not be subject to any additional regulatory requirements under Option 1. After weighing the availability of release detection options for these systems, the applicability of other requirements in this final UST regulation, and the potential human health and environmental impact of releases from these systems, EPA is fully regulating these systems. See C–2 for EPA's rationale for regulating airport hydrant systems and field-constructed tanks.

EPA's Rationale for Option 2

In comparing costs with benefits of the final regulatory changes, EPA weighed different frequencies for walkthrough inspections and periodic equipment inspections or tests. EPA assessed quarterly walkthrough inspections, and not requiring overfill prevention equipment inspections and containment sump testing as ways to reduce potential cost impacts on owners and operators. Compared to the 30-day requirement, quarterly walkthrough inspections would reduce costs to owners and operators. However, EPA thinks a period less frequent than 30 days for walkthrough inspections would considerably reduce benefits. High operator turnover and the frequency of deliveries both contribute to the need for 30-day walkthrough inspections. With that in mind, today EPA is requiring 30-day walkthrough inspections so owners and operators can consistently and routinely verify proper spill prevention and release detection performance. This will ensure problems are detected before a release occurs.

EPA also considered not requiring overfill prevention equipment inspections and containment sump testing. However, as explained in sections B–3, Overfill Prevention Equipment Inspections and B–4, Secondary Containment Tests, tank overfills and containment sump areas account for a significant amount of releases from UST systems. As a result, EPA is requiring overfill prevention equipment inspections and containment sump testing (for containment sumps used for interstitial monitoring) once every three years. Overfill prevention equipment inspections will ensure overfill prevention equipment is operating properly. Similarly, containment sump testing will ensure that containment sumps used for interstitial monitoring will be liquid tight.

To reduce total compliance costs of this final UST regulation for owners and operators, EPA considered allowing continued use of flow restrictors in vent lines (that is, ball float valves) as an acceptable form of overfill prevention equipment. After considering public comments, EPA maintains its position that vent line flow restrictors present problems for operability and safety reasons. As described in section D–1, EPA is eliminating ball float valves as an overfill prevention equipment option for all new tanks and when overfill prevention equipment is replaced in existing tanks.

EPA considered maintaining the existing requirements for groundwater and vapor monitoring, in particular retaining the two as permissible release detection methods with no changes to the 1988 UST regulation. However, given the numerous concerns that have arisen over the years regarding these two release detection methods, such as misapplications and improper designs of monitoring wells, EPA is retaining these two release detection methods only if owners and operators demonstrate proper installation and performance through a site assessment. See section D–6 for details regarding groundwater and vapor monitoring.

EPA also considered only retaining the current requirement for owners and operators to use UST systems made of or lined with materials that are compatible with the substance stored in the UST system. However, EPA understands that the chemical and physical properties of ethanol and biodiesel can be more degrading to certain UST materials than petroleum alone. As the use of ethanol- and biodiesel-blended fuels increases, EPA is concerned that not all UST system equipment or components are compatible with these fuels. Therefore, EPA is requiring owners and operators demonstrate compatibility of certain UST system components when storing ethanol blends greater than 10 percent and biodiesel blends greater than 20 percent. Owners and operators can demonstrate compatibility of required components by using one of the three options described in this final UST regulation. See section D–4 for details regarding compatibility.

Finally, EPA considered maintaining deferrals for airport hydrant systems and field-constructed tanks. However, as explained above, after weighing the availability of release detection options for these systems, the applicability of the other requirements in this final UST regulation, and the potential human health and environmental impact of releases from these systems, EPA is fully regulating these systems. See C–2 for EPA's rationale for regulating airport hydrant systems and field-constructed tanks.

V. Updates to State Program Approval Requirements

EPA is making changes to the 1988 SPA regulation (40 CFR part 281) to make it consistent with certain Energy Policy Act requirements and certain revisions to the 1988 UST regulation (40 CFR part 280). Commenters generally supported EPA changing portions of the 1988 SPA regulation and making it consistent with revisions to the 1988 UST regulation. Commenters supported EPA keeping the general format of the 1988 SPA regulation and not making the final SPA regulation as explicit or prescriptive as this final UST regulation.

EPA is making these substantive changes to the 1988 SPA regulation.

- § 281.12(b)—adding definitional exceptions for several Energy Policy Act definitions
- §§ 281.30(a), 281.33(c)(2), and 281.33(d)(3)—require secondary containment for new or replaced tanks and piping and under-dispenser containment for new motor fuel dispenser systems for UST systems located within 1,000 feet of a potable drinking water well or community water system, unless a state requires manufacturer and installer financial responsibility according to section 9003(i)(2) of the Solid Waste Disposal Act
- §§ 281.30(a)(1) and 281.33(d)(3)—exclude safe suction piping, airport hydrant system piping, and field-constructed tank piping from being required to meet the secondary containment and interstitial monitoring requirements

- § 281.30(b)—eliminate flow restrictors for new or replaced overfill prevention
- § 281.30(c)—add notification for ownership changes
- §§ 281.31 and 281.33(b)—delete upgrading requirements and eliminate phase-in schedule; add phase-in schedule for airport hydrant fuel distribution systems and UST systems with field-constructed tanks
- § 281.32(c)—add requirement for states to include provisions for demonstrating compatibility with new and innovative regulated substances or other regulated substances identified by implementing agencies or include other provisions determined by the implementing agency to be no less protective of human health and the environment than the provisions for demonstrating compatibility
- §§ 281.32(e) and (f) and 281.33(a)(3)—add periodic testing or inspection of spill and overfill prevention equipment, containment sumps used for interstitial monitoring of piping, and mechanical and electronic release detection components; and operation and maintenance walkthrough inspections, as well as maintaining associated records
- § 281.33(c)—limit use of monthly inventory control in combination with tank tightness testing conducted every five years for the first ten years after the tank is installed or upgraded, if the tank was installed prior to a state receiving SPA
- § 281.33(e)—require hazardous substance USTs to only use secondary containment with interstitial monitoring
- § 281.34(a)(1)—add interstitial space may have been compromised to suspected releases
- § 281.37—eliminate phase-in requirement for financial responsibility
- § 281.39—require operator training according to § 9010 of the Solid Waste Disposal Act
- § 281.41(a)(4)—add authority to prohibit deliveries

EPA is making these technical changes to the SPA regulation.

- § 281.10—change subpart to part
- §§ 281.11(c), 281.20(d), 281.21(a)(2), 281.23, 281.50(a), and formerly § 281.51—eliminate interim approval
- § 281.12(a)(2)—change Indian lands to Indian country
- Formerly § 281.32(e)—eliminate requirement to maintain upgrade records
- Formerly § 281.38—eliminate reserved section for financial responsibility for USTs containing hazardous substances
- Move § 281.39 to § 281.38—Lender Liability
- §§ 281.50(e) and 281.51(c)(1)—clarify how to provide public notice to attract statewide attention
- § 281.51, formerly § 281.52—add requirement for approved states to submit a revised application within three years of 40 CFR part 281 changes that require a program revision
- § 281.61—move § 281.60(b) to § 281.61(b)(2)

Background Information

The 1988 SPA regulation in 40 CFR part 281 sets criteria state UST programs must meet to receive EPA's approval to operate in lieu of the federal UST program. The 1988 SPA regulation sets performance criteria states must meet to be considered no less stringent than the federal UST regulation (hereafter 40 CFR part 280) and provides requirements for states to have adequate enforcement. It also details the components of a SPA application.

EPA is changing the 1988 SPA regulation and making it consistent with this final UST regulation. By doing so, EPA will require states to adopt requirements similar to the final UST regulation, in order to obtain or retain SPA. Commenters supported maintaining the general format of the 1988 SPA regulation and EPA is keeping that general format. We are not making this final SPA regulation as explicit or prescriptive as this final UST regulation. Finally, EPA is making technical corrections and adding a deadline for states to apply for revised state program approval.

Addressing Energy Policy Act Requirements and 40 CFR Part 280 Changes

How SPA Works

This final UST regulation primarily impacts the 1988 SPA regulation in 40 CFR part 281, subpart C—Criteria for No Less Stringent. As of 2014, 40 states, including the District of Columbia and Puerto Rico, have state program approval and state UST requirements apply in lieu of the federal requirements. To ensure these jurisdictions and any other states or territories obtaining SPA adopt these 40 CFR part 280 changes, EPA must update the 1988 SPA regulations in 40 CFR part 281, subpart C—Criteria for No Less Stringent. To continue providing states with flexibility and not disrupt current state programs, EPA is revising the 1988 SPA regulation to make it consistent with, but not identical to, the 40 CFR part 280 changes. Instead, EPA is making changes to the 1988 SPA regulation in a less prescriptive manner than the changes to 40 CFR part 280. Since 1988, this approach has proven a successful way to implement the UST program and provide environmental protection.

The 1988 SPA regulation developed no less stringent criteria in the form of objectives.[120] EPA is continuing this format so that, taken as a whole, state programs will be no less stringent than the federal requirements, even though state programs may deviate slightly from what is explicitly required in 40 CFR part 280. For example, § 281.30 covers the no less stringent requirement for new UST system design, construction, and installation; it corresponds to § 280.20 of this final UST regulation, but is much less explicit about requirements.

According to § 281.30 and in order to receive SPA, a state must require all new UST systems ''. . . [b]e designed, constructed, and installed in a manner that will prevent releases for their operating life due to manufacturing defects, structural failure, or corrosion . . .''. In contrast, § 280.20 is much more explicit about how tank owners and operators ensure their tanks and piping prevent releases. It states what is required to prevent releases and provides codes of practice to comply. Although § 281.30 is less explicit, it nonetheless ensures owners and operators in approved states install UST systems that prevent releases and provides states flexibility in achieving that goal.

Goal Oriented Changes

EPA is making goal oriented changes to subpart C—Criteria for No Less Stringent. By the term goal oriented changes, EPA means changes in which states have some flexibility as to how they meet the goals of particular sections of the final SPA regulation. These changes reflect certain 40 CFR part 280 changes.

- § 281.30(c)—add notification for ownership changes
- §§ 281.31 and 281.33(b)—add a phase-in schedule for upgrading previously deferred airport hydrant fuel distribution systems and UST systems with field-constructed tanks
- § 281.32(c)—add requirement for states to include provisions for demonstrating compatibility with new and innovative regulated substances or other regulated substances identified by implementing agencies

[120] 53 FR 37216, September 23, 1988.

or include other provisions determined by the implementing agency to be no less protective of human health and the environment than the provisions for demonstrating compatibility

- §§ 281.32(e) and (f) and 281.33(a)(3)—add periodic testing or inspection of spill and overfill prevention equipment, containment sumps used for interstitial monitoring of piping, and mechanical and electronic release detection components; and operation and maintenance walkthrough inspections, as well as maintaining associated records

The ownership change notification in § 280.22 requires anyone who assumes ownership of an UST system to notify the implementing agency within 30 days of assuming ownership and specifies what notification must include. However, the SPA regulation change in § 281.30(c) is much less prescriptive and indicates that states require owners and operators to ''. . . notify the implementing state agency within a reasonable time frame when assuming ownership of an UST system.'' This provides states some flexibility in complying, including allowing them to continue relying on an annual tank registration program to meet this requirement. This is a reasonable way to ensure states know who owns USTs in their jurisdictions. EPA does not have an annual UST registration program, so we specify a time frame in § 280.22 because we want to know who owns tanks in jurisdictions where we are the implementing agency.

EPA is requiring that previously deferred airport hydrant fuel distribution systems and UST systems with field-constructed tanks meet specific upgrade requirements in subpart K. This is one way that states can achieve compliance with § 281.31, which requires states ensure tanks are upgraded to prevent releases due to corrosion, spills, and overfills or be permanently closed. EPA concludes these more general requirements are sufficient for a state program to protect human health and the environment because they require UST systems to ''. . . prevent releases for their operating life. . . .'' EPA thinks it is also adequate to upgrade previously deferred systems to this standard.

Additionally, EPA is requiring airport hydrant systems, field-constructed tanks, and emergency generator tanks be upgraded within three years of the effective date of the state requirements. For states which did not defer these systems or already had their requirements in place before the effective date of this final SPA regulation, the three year requirement does not apply. In the past, EPA experienced issues with requiring states to have a particular requirement by a certain date in order to receive SPA. States applying for SPA after a deadline passed often had difficulty implementing or obtaining a retroactive requirement. EPA understands that states may have given owners and operators of UST systems previously deferred by EPA different time periods than three years to initially meet their requirements.

In § 281.32(c), EPA is adding a requirement for states to include provisions for demonstrating compatibility with new and innovative regulated substances or other regulated substances identified by implementing agencies or include other provisions determined by the implementing agency to be no less protective of human health and the environment than the provisions for demonstrating compatibility. EPA is concerned about the compatibility of new and innovative fuels with the existing UST system infrastructure. We added to § 280.32 methods for demonstrating compatibility of UST systems with certain ethanol and biodiesel blends in response to this concern. State UST implementing agencies also need to ensure owners and operators only store regulated substances compatible with their UST systems. Requiring states have provisions in place for storing new and innovative regulated substances in order to receive SPA ensures states are taking appropriate steps to ensure compatibility of the UST system with a rapidly expanding spectrum of traditional and new and innovative fuels.

This final UST regulation adds various UST operation and maintenance requirements. In 40 CFR part 280, EPA is requiring specific frequencies and procedures for testing or inspecting spill and overfill prevention equipment, testing containment sumps used for interstitial monitoring of piping, testing release detection equipment, and conducting operation and maintenance walkthrough inspections. According to § 281.32, states must require these tests or inspections in a manner and frequency that ensures proper functionality of equipment, includes proper operation and maintenance of the UST system, and prevents releases for the life of the equipment and UST system. EPA thinks this approach allows states that implement these requirements despite different frequencies or manners, to receive SPA, as long as their requirements sufficiently ensure properly functioning non-releasing UST systems. EPA is updating § 281.32(g) by adding these activities to the recordkeeping requirements of SPA.

Energy Policy Act Changes

In this final SPA regulation, EPA is addressing Energy Policy Act requirements more generally than in this final UST regulation; however, the Energy Policy Act requirements are slightly different than the goal oriented approach discussed above. The Energy Policy Act amends the Solid Waste Disposal Act and requires states, which receive federal Subtitle I money, to adopt operator training requirements, delivery prohibition, and additional measures to protect groundwater from contamination. In the additional measures to protect groundwater provision, states must require either secondary containment and interstitial monitoring for new or replaced tanks and piping within 1,000 feet of a potable drinking water well or community water system, *or* manufacturer and installer financial responsibility and installer certification. The secondary containment requirement includes under-dispenser containment on any new motor fuel dispenser system within 1,000 feet of a potable drinking water well or community water system.

EPA developed guidelines for states to implement the Energy Policy Act requirements; many states implemented the Energy Policy Act requirements according to these guidelines. In order to impose similar requirements in Indian country and in states that do not adopt Energy Policy Act requirements, EPA is adding secondary containment and operator training to these 40 CFR part 280 requirements. However, it is not EPA's intent to supersede programs states developed to meet Energy Policy Act requirements.

Several commenters had concerns about the Energy Policy Act provisions. Seven commenters wanted to ensure states only have to meet Energy Policy Act grant guidelines and do not have to change their regulations to mirror the 40 CFR part 280 requirements in order to obtain SPA. These commenters were also concerned that EPA requirements for secondary containment and operator training could be considered more stringent than state requirements that met the grant guidelines. EPA agrees that requiring states to alter newly implemented provisions could cause unnecessary work for states and UST owners. Therefore, this final SPA regulation explicitly addresses the secondary containment, manufacturer and installer financial responsibility

and installer certification, delivery prohibition, and operator training requirements that appear in the Energy Policy Act. EPA agrees that it is not necessary for states already meeting these Energy Policy Act requirements to change their programs in order to receive or retain SPA. EPA was unable to incorporate a similar requirement in 40 CFR part 280, so states will need to obtain SPA in order to ensure there is no difference between state and federal requirements with respect to Energy Policy Act requirements.

EPA is adding definitional exceptions in § 281.12(b). This final SPA regulation allows states to use definitions associated with tank and piping secondary containment and operator training that are different than those in 40 CFR part 280 as long as those definitions are consistent with definitions described in sections 9003 and 9010 of the Solid Waste Disposal Act. This change provides states with additional flexibility in defining key terms.

EPA is adding additional measures to protect groundwater and is adding operator training requirements in subpart C (§§ 281.22(d)(3), 281.30(a), 281.33(c)(2), and 281.39). Delivery prohibition is in subpart D—Adequate Enforcement of Compliance (§ 281.40(a)). Because delivery prohibition is an enforcement option, EPA is requiring states have authority to prohibit deliveries according to the Energy Policy Act and EPA's grant guidelines, rather than make this a no less stringent requirement.

EPA is not adding delivery prohibition to 40 CFR part 280 because delivery prohibition is primarily an enforcement option for implementing agencies; it is not a requirement for owners and operators. Because the Energy Policy Act gives EPA clear delivery prohibition enforcement authority, we do not need to add delivery prohibition to this final UST regulation. However, the only way to ensure states have that same authority is to require states implement delivery prohibition as a prerequisite for SPA, as required in § 281.40(a).

Specific Changes

EPA is making the changes listed below to subpart C—Criteria for No Less Stringent to reflect changes made in 40 CFR part 280. These changes ensure states adopt the changes made in 40 CFR part 280 and are able to receive SPA.

- §§ 281.30(a)(1) and 281.33(d)(3)—exclude safe suction piping, airport hydrant system piping, and field-constructed tank piping from being required to meet the secondary containment and interstitial monitoring requirements
- § 281.30(b)—eliminate flow restrictors for new or replaced overfill prevention
- § 281.31—delete upgrading requirements
- § 281.33(c)—limit use of monthly inventory control in combination with tank tightness testing conducted every five years for the first ten years after the tank is installed or upgraded, if the tank was installed prior to a state receiving SPA
- § 281.33(e)—require hazardous substance USTs to only use secondary containment with interstitial monitoring
- § 281.34(a)(1)—add ''. . . interstitial space may have been compromised . . .'' to suspected releases
- § 281.37—eliminate phase-in requirement for financial responsibility

In §§ 281.30(a)(1) and 281.33(d)(3) EPA is not requiring safe suction piping, airport hydrant system piping, and piping associated with field-constructed tanks greater than 50,000 gallons in capacity to meet the secondary containment and interstitial monitoring requirements. Suction piping that meets the requirements of § 281.33(d)(2)(ii) has characteristics that ensure little, if any, regulated substances will be released if a break occurs in the line. For additional information see section A–2, Secondary Containment. EPA is not requiring secondary containment for piping associated with field-constructed tanks greater than 50,000 gallons in capacity and airport hydrant system piping due to sloping and corrosion concerns. For additional information, see section C–2, Airport Hydrant Fuel Distribution Systems and UST Systems with Field-Constructed Tanks.

In § 281.30(b), EPA is requiring states, which receive SPA, not allow installation of flow restrictors (commonly referred to as ball floats) in vent lines for overfill prevention for new installations or when flow restrictors need to be replaced. The existing goal of § 281.30(b) is for states to require that UST systems have equipment to prevent spills and overfills. In this final UST regulation, EPA maintains the overall goal to prevent spills and overfills; however, owners and operators can no longer install ball floats to achieve that goal.

The deadlines for upgrades and for owners and operators to obtain financial responsibility have passed. As a result, EPA is deleting the 1988 UST regulation deadlines in the final SPA regulation. In §§ 281.31 and 281.33(b), EPA is removing the option for UST upgrades, except for USTs deferred in the 1988 UST regulation. In § 281.37, we are eliminating the financial responsibility phase-in schedule. Please note EPA is allowing states to implement UST requirements, such as upgrades and operation and maintenance, after the deadlines in 40 CFR part 280. EPA is taking this action because experience has shown that some states had difficulties implementing a retroactive requirement when applying for SPA after a federal deadline has passed.

In § 281.33(c), EPA is allowing monthly inventory control in combination with tank tightness testing conducted every five years as a release detection method for the first ten years after a tank is installed or upgraded, only if a tank was installed prior to a state receiving SPA for the 1988 UST regulation. This reflects a change in 40 CFR part 280 and avoids another problem in the 1988 SPA regulation. First, EPA is eliminating this method for new installations. Second, EPA is tying the date for eliminating this method to the effective date of a state's regulations. EPA concludes it is better to tie deadlines in the final SPA regulation to the effective date of states' regulations, rather than dictate specific dates for all states. In the 2011 proposed SPA regulation, we tied the deadlines to the date a state submitted its SPA application or revised application. However, in this final SPA regulation, we realize tying the deadlines to the effective date of a state's regulations is clearer for state regulators as well as owners and operators.

Several commenters were concerned with how release detection requirements were expressed in 40 CFR part 281. One commenter was concerned that the term monthly in § 281.33(c)(1) is not as stringent as the 40 CFR part 280 requirement of completing release detection every 30 days. This commenter wanted EPA to amend the 40 CFR part 281 language so it matches the 30 day wording in 40 CFR part 280. EPA is maintaining the term monthly in 40 CFR part 281. EPA agrees there is variation between the 30 day time frame in 40 CFR part 280 and monthly in 40 CFR part 281. For states receiving SPA, the difference should result in a variation of only a few days, and therefore need not be changed. It is EPA's position that release detection monitoring should be conducted on a consistent and frequently occurring basis. EPA chose the 30 day period in 40 CFR part 280 to represent an average calendar month.

In this final SPA regulation, EPA is requiring states, which wish to receive SPA, no longer allow installation of non-secondarily contained hazardous substance UST systems. This is consistent with EPA's change in § 280.42(e); an equivalent and specific change in the final SPA regulation is the only way to ensure states adopt it. For consistency with changes in this final UST regulation and to ensure states wishing to receive SPA adopt this change, in § 281.34(a)(1), EPA is adding ''. . . interstitial space may have been compromised . . .'' to suspected release conditions.

One commenter expressed concern with the release detection language in § 280.41(b)(2)(ii), which indicates EPA intends to exempt from release detection requirements suction piping that meets the condition of paragraphs (b)(1)(ii)(A) through (E). However § 281.33(d)(3) indicates that in order to be considered no less stringent, states must require new or replaced piping use interstitial monitoring with secondary containment. EPA agrees with the commenter that we need to modify § 281.33(d)(3) to incorporate the concepts of § 280.41(b)(2)(ii). In the final SPA regulation, EPA is modifying § 281.33(d)(3) to indicate that the requirement is applicable to all pressurized piping and suction piping that does not meet standards in § 281.33(d)(2)(ii).

One commenter said that it may be very difficult to achieve compliance with release detection requirements for emergency power generator USTs within one year. This commenter suggested that EPA reword § 281.33(b)(3) to give owners at least three years from the effective date of the final SPA regulation. EPA agrees with the commenter and is extending the date of compliance for this requirement to three years as we are in this final UST regulation; this approach corresponds with EPA's goal of aligning dates of compliance to the extent possible.

Addressing SPA Revision Process

EPA is adding a requirement for approved states to submit a revised application within three years of final SPA regulation changes that require a program revision under § 281.51. Approved states are required to revise their programs and submit revised applications whenever the federal program changes or EPA's Administrator requests a revised application based on changes to a state's program. Given these significant changes, EPA thinks it is necessary to develop a time frame which will ensure approved states meet final SPA regulation changes in a reasonable time. EPA's language in § 281.51 is intended only to require a state program revision within three years if EPA makes changes that necessitate state program changes. For instance, these changes to subpart C—Criteria for No Less Stringent will require state program revision.

Commenters disagreed on the appropriate time frame for states to submit their SPA applications. Some said three years was appropriate, while others preferred a different time frame. EPA maintains that three years is adequate for most states to re-apply for SPA. One commenter expressed concern about what will happen to a state's SPA status if it does not re-apply within the required time frame. While most states will be able to meet the three-year deadline for program revision, EPA is aware that some states may need additional time. EPA will work with states which have not revised their programs within three years. EPA will ask those states to demonstrate their level of effort, show progress to date, and provide dates when they will achieve major milestones for revising their programs and submitting revised applications. EPA will consider these factors before initiating state program approval withdrawal. One commenter was concerned about the cost to states of revising and reapplying for SPA. It is important for states to reapply for SPA to ensure they make appropriate changes to their programs.

Additional Changes to SPA Regulation

EPA is making these additional changes; they are not a direct result of these 40 CFR part 280 changes. Rather, the majority are corrections to the 1988 SPA regulation.

- § 281.10—change subpart to part
- §§ 281.11(c), 281.20(d), 281.21(a)(2), 281.23, and formerly § 281.51—eliminate interim approval
- § 281.12(a)(2)—change Indian lands to Indian country
- § 281.32(e)—eliminate requirement to maintain upgrade records
- Formerly § 281.38—eliminate reserved section for financial responsibility for USTs containing hazardous substances
- Move § 281.39 to § 281.38—Lender Liability
- §§ 281.50(e) and 281.51(c)(1)—clarify how to provide public notice to attract statewide attention
- § 281.61—move § 281.60(b) to § 281.61(b)(2)

The 1988 SPA regulation incorrectly uses the term subpart in § 280.10 and, therefore, EPA is correctly changing this to part. EPA has been using the term Indian country instead of Indian lands for years. We are now incorporating this term in this final SPA regulation; this does not alter the meaning. EPA is removing the reserved financial responsibility for USTs containing hazardous substances section (formerly § 281.38); moving the lender liability section from § 281.39 to § 281.38; and including the new operator training section in § 281.39. Because operator training needs to be in subpart C, which has no section numbers available, this eliminates the need to renumber subpart D. Also, the reserved financial responsibility for hazardous substances section is unnecessary since there is no corresponding requirement in 40 CFR part 280.

EPA is deleting the interim SPA approval language in §§ 281.11(c) and 281.51. In more than 20 years of the UST program, no state applied for interim approval; it is more beneficial to receive full approval all at once, rather than in steps. Also, because 40 states, including the District of Columbia and Puerto Rico, have SPA as of 2014, EPA thinks interim SPA approval is unnecessary at this time.

EPA is eliminating the requirement to maintain upgrade records for the operational life of an UST facility. This requirement in § 281.32(e) of the 1988 SPA regulation does not exist in 40 CFR part 280. In addition, except for airport hydrant systems and field-constructed tanks, EPA is no longer allowing upgrades.

EPA is clarifying how to provide public notice to attract statewide attention in §§ 281.50(e) and 281.51(c)(1). In today's digital age, it is unnecessary to require publication in a state's newspapers. Each state can determine the most appropriate methods for public notice and statewide attention.

EPA is also moving § 281.60(b) to § 281.61(b). This paragraph explains the procedure EPA will follow to withdraw approval after the conclusion of the proceeding to withdraw approval. EPA thinks this paragraph is better suited for § 281.61, which explains the procedures for withdrawing approval, as opposed to § 281.60, which explains the criteria for withdrawal.

VI. Overview of Estimated Costs and Benefits

EPA prepared an analysis of the potential incremental costs and benefits associated with this final UST regulation. This analysis is contained in the regulatory impact analysis document titled *Assessment of the Potential Costs, Benefits, and Other Impacts of the Final Revisions to EPA's*

Underground Storage Tank Regulations, which is available in the docket for this action. The RIA estimated regulatory implementation and compliance costs, as well as benefits for the three regulatory options described in section IV, subsection F. In the RIA, EPA estimated regulatory compliance costs on an annualized basis for the three options: $160 million (Selected Option), $290 million (Option 1), and $70 million (Option 2). Separately, the analysis assessed the potential benefits of the final UST regulation. As discussed in the RIA, a substantial portion of the beneficial impacts associated with the final UST regulation are avoided cleanup costs as a result of preventing releases and reducing the severity of releases. This action is expected to have annual cost savings related to avoided costs of $310 million (range: $120–$530 million) per year under the Selected Option, $450 million (range: $210–$670 million) per year under Option 1, and $230 million (range: $45–$420 million) per year under Option 2. Due to data and resource constraints, EPA was unable to quantify some of the final UST regulation's benefits, including avoidance of human health risks, ecological benefits, and mitigation of acute exposure events and large-scale releases, such as those from airport hydrant systems and field-constructed tanks. EPA was also unable to place a monetary value on the groundwater protected by the final UST regulation, but estimates that this final UST regulation could potentially protect 50 billion to 240 billion gallons of groundwater each year.

VII. Statutory and Executive Orders

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

Under section 3(f)(1) of Executive Order (EO) 12866 (58 FR 51735, October 4, 1993), this action is an economically significant regulatory action because it is likely to have an annual effect on the economy of $100 million or more. Accordingly, EPA submitted this action to the Office of Management and Budget (OMB) for review under EO 12866 and EO 13563 (76 FR 3821, January 21, 2011) and any changes made in response to OMB recommendations are documented in the docket for this action. Also, as part of EO 13563, EPA encourages owners and operators to maintain records electronically which simplifies compliance and recordkeeping by using 21st century technology tools.[121]

B. Paperwork Reduction Act

The information collection requirements (ICR) in this rule will be submitted for approval to the Office of Management and Budget (OMB) under the *Paperwork Reduction Act,* 44 U.S.C. 3501 *et seq.* The information collection requirements are not enforceable until OMB approves them.

The proposed rule ICR was submitted to OMB on 11/18/2011 under OMB number 2050–0068, ICR number 1360.11. On 1/30/2012 OMB released a Notice of Action of comment filed on proposed rule and continue. They also issued this comment: ''Terms of the previous clearance remain in effect. OMB is withholding approval at this time. Prior to publication of the final rule, the agency should provide a summary of any comments related to the information collection and their response, including any changes made to the ICR as a result of comments. In addition, the agency must enter the correct burden estimates. This action has no effect on any current approvals.'' The final rule ICR will be submitted to OMB under a new ICR OMB control number.

This action contains mandatory information collection requirements. The labor burden and associated costs for these requirements are estimated in the ICR supporting statement for this final action. The supporting statement identifies and estimates the burden for each of the changes to the regulation that include recordkeeping or reporting requirements. Changes include: adding secondary containment requirements for new and replaced tanks and piping; adding operator training requirements; adding periodic operation and maintenance requirements for UST systems; regulating certain UST systems deferred in the 1988 UST regulation; adding new release prevention and detection technologies; and updating state program approval requirements to incorporate these new changes.

Based on the same data and cost calculations applied in the RIA for this action, but using the burden estimations for ICRs, the ICR supporting statement estimates an average annual labor hour burden of 344,000 hours and $12 million for the final UST regulation. One time capital and hourly costs are included in these estimates based on a three year annualization period. Burden is defined at 5 CFR 1320.3(b). The total universe of respondents for this ICR is comprised of 211,154 facilities and 56 states and territories. Burden is defined at 5 CFR 1320.3(b).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for EPA's regulations are listed in 40 CFR part 9. When this ICR is approved by OMB, the agency will publish a technical amendment to 40 CFR part 9 in the **Federal Register** to display the OMB control number for the approved information collection requirements contained in this final rule.

C. Regulatory Flexibility Act

The Regulatory Flexibility Act generally requires an agency to prepare a regulatory flexibility analysis of any regulation subject to notice and comment rulemaking requirements under the Administrative Procedure Act or any other statute, unless the agency certifies that the regulation will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small organizations, and small governmental jurisdictions.

For purposes of assessing the impacts of this final UST regulation on small entities, a small entity is defined as: (1) A small business as defined by the Small Business Administration's regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district, or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of this final rule on small entities, I certify that this action will not have a significant economic impact on a substantial number of small entities. The small entities directly regulated by this final rule are small businesses and small governmental jurisdictions. We have determined that less than 1 percent of potentially affected small firms in the retail motor fuel sector (NAICS 447) will experience an impact over 1 percent of revenues, but less than 3 percent of revenues. No small firms have impacts above 3 percent of revenues. In addition, we estimate that no small governmental jurisdictions will be impacted at 1 percent or 3 percent of revenues. This certification is based on the small entities analysis contained in the RIA for this final rule.

[121] Executive Order 13563, *Improving Regulation and Regulatory Review,* Section 3, *http://www.gpo.gov/fdsys/pkg/FR-2011-01-21/pdf/2011-1385.pdf.*

Although this final rule will not have a significant economic impact on a substantial number of small entities, EPA nonetheless sought to reduce the impact of this rule on small entities. EPA conducted extensive outreach to determine how to change the 1988 UST regulation. EPA worked with representatives of owners and operators and reached out specifically to small businesses. In addition, EPA limited changes that would have required major retrofits to UST systems, since this would place a high financial burden on small businesses. Finally, EPA provided numerous options for compliance in order to provide as much flexibility as possible for small entities. EPA also aligned compliance dates to facilitate owner and operator compliance.

D. Unfunded Mandates Reform Act

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531–1538, requires federal agencies, unless otherwise prohibited by law, to assess the effects of their regulatory actions on state, local, and tribal governments and the private sector. This rule contains a federal mandate that may result in expenditures of $100 million or more for state, local, and tribal governments, in the aggregate, or the private sector in any one year. Accordingly, EPA prepared under section 202 of the UMRA a written statement which is summarized below.

As estimated in the RIA, on an annualized basis, the total estimated regulatory compliance costs for the three options in this final action are $160 million (Selected Option), $290 million (Option 1), and $70 million (Option 2). Of this amount, annualized costs to state and local governments total $6.8 million under the Selected Option, $14 million under Option 1, and $3.6 million under Option 2. These costs consist of estimated regulatory compliance costs for state and local governments that currently own or operate UST systems and annualized costs of $120,000 for states to implement the final UST regulation. EPA estimates total annualized costs to owners and operators of tribally-owned UST systems are $0.67 million under the Selected Option. The estimated annualized cost to the private sector is approximately $130 million under the Selected Option, $270 million under Option 1, and $67 million under Option 2. While this final UST regulation may result in expenditures of $100 million or more for the private sector, thereby triggering section 202 of the UMRA, this final UST regulation is not subject to the requirements of section 204 of UMRA because EPA does not think state, local, and tribal governments will incur aggregate costs of over $100 million per year.

Consistent with section 205, EPA identified and considered a reasonable number of regulatory alternatives. This final UST regulation identifies the regulatory options EPA considered. The RIA estimates the annual cost across the three considered options may range between $70 million and $290 million. Section 205 of the UMRA requires federal agencies to select the least costly or most cost-effective regulatory alternative unless EPA publishes with the final regulation an explanation of why such alternative was not adopted. As discussed earlier in the preamble, EPA considered and evaluated variations of a subset of the regulatory requirements using two alternative options (Options 1 and 2). Despite Option 2's lower costs, EPA chose the Selected Option because it provides for greater protection of human health and the environment and better addresses stakeholder concerns.

This rule is not subject to the requirements of section 203 of UMRA because it contains no regulatory requirements that might significantly or uniquely affect small governments.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on states, the relationship between the federal government and states, or the distribution of power and responsibilities among various levels of government, as specified in EO 13132. Under this final action, total costs to all affected states and local governments (including direct compliance costs, notification costs, and state program costs) are approximately $9 million. This is not considered to be a substantial compliance cost under federalism requirements. Thus, Executive Order 13132 does not apply to this action.

In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and State and local governments, EPA specifically solicited comment on the proposed action from State and local officials.

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

Subject to Executive Order 13175 (65 FR 67249, November 9, 2000) EPA may not issue a regulation that has tribal implications, that imposes substantial direct compliance costs, and that is not required by statute, unless the Federal government provides the money necessary to pay the direct compliance costs incurred by tribal governments, or EPA consults with tribal officials early in the process of developing the proposed regulation and develops a tribal summary impact statement.

EPA has concluded that this action will have tribal implications to the extent that tribally-owned entities with UST systems in Indian country will be affected. However, it will neither impose substantial direct compliance costs on tribal governments, nor preempt tribal law. EPA estimated total annualized costs for tribally-owned UST systems in Indian country to be $0.67 million.

EPA consulted with tribal officials early in the process of developing this regulation to permit them to have meaningful and timely input to its development. EPA consulted with tribes on possible changes to the UST regulation shortly after the passage of the Energy Policy Act of 2005. The Energy Policy Act directed EPA to coordinate with tribes in developing and implementing an UST program strategy in Indian country which would supplement the existing approach. EPA and tribes worked collaboratively to develop a tribal strategy.

There are certain key provisions of the Energy Policy Act that apply to states receiving federal Subtitle I money, but do not apply in Indian country. Nonetheless, EPA's goal in this final UST regulation is to establish in Indian country federal requirements similar to the Energy Policy Act provisions; this is an important step in achieving more consistent program results in release prevention. Both EPA and tribes recognize the importance of ensuring parity in program implementation between states and in Indian country.

In addition to early consultation with tribes, EPA also reached out to tribes as we started the official rulemaking process and while developing the 2011 proposed UST regulation. EPA sent letters to leaders of over 500 tribes, as well as to tribal regulatory staff, inviting their participation in developing the 2011 proposed UST regulation. EPA also held conference calls for tribes to provide input. EPA heard from both tribal officials who work as regulators as well as representatives of owners and operators of UST systems in Indian country. The tribal regulators raised concerns about ensuring parity of environmental protection between states and Indian country.

EPA determined that this final UST regulation is needed to ensure parity between UST systems in states and in Indian country. This final UST regulation is also needed to ensure

equipment is both installed and working properly, which will protect the environment from potential releases.

As required by section 7(a), EPA's Tribal Consultation Official certified that the requirements of the Executive Order have been met in a meaningful and timely manner. EPA included a copy of the certification in the docket for this action.

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

This action is not subject to EO 13045 (62 FR 19885, April 23, 1997) because the Agency does not think the environmental health risks or safety risks addressed by this action present a disproportionate risk to children. EPA's risk assessment for this action examines potential impacts to groundwater and subsequent chemical transport, exposure, and risk. While the risk assessment did not specifically measure exposure to children, the general exposure scenarios reflect four exposure pathways that have the most significant potential for human health impacts. They are:

- Ingestion of chemicals in groundwater that have migrated from the source area to residential drinking water wells;
- Inhalation of volatile chemicals when showering with contaminated groundwater;
- Dermal contact with chemicals while bathing or showering with contaminated groundwater; and
- Inhalation of vapors that may migrate upward from contaminated groundwater into overlying buildings.

Adults and children can potentially be exposed through all four exposure pathways considered. For adults, inhalation of vapors while showering is the most significant exposure pathway; for children, ingestion is the most significant pathway, because they are assumed to take baths and are, therefore, not exposed via shower vapor inhalation. As a result of the longer exposure from showering, adults are more sensitive receptors for cancer effects compared to children, particularly those under age 5 who are assumed to take more baths and fewer showers.[122]

While the screening level risk assessment is limited in that it only examines benzene impacts, the final UST regulation will likely reduce other contaminant exposures to children in a similar pattern and will not create significant adverse impacts on children's health.

The screening level population analysis performed to examine EO 12898 shows that children under 18 years and children under 5 years of age are slightly less likely to be found in the vicinity of UST facilities. This suggests that the impacts of this action will not have a disproportionate impact on children's health. Moreover, because all regulatory options in this action will increase regulatory stringency and reduce the number and size of releases, EPA does not expect this action to have any disproportionate adverse impact on children.

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

This action is not a significant energy action as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The following summarizes EPA's assessment of the energy impacts this final UST regulation will have on energy supply, distribution, and use.

This final UST regulation consists of additional regulatory requirements that apply to the owners and operators of underground storage tanks. To the extent that the final UST regulation affects the motor fuel sector, it does so at the retail motor fuel sales level, rather than the level of refineries or distributors, who supply the retail stations with motor fuel. Therefore, we do not expect this final UST regulation to have a significant adverse impact on energy supply or distribution.

The additional regulatory requirements contained in this final UST regulation may increase compliance costs for owners and operators of retail motor fuel stations. If owners and operators of retail motor fuel stations affected by the final UST regulation can pass through their increased compliance costs, energy use may be affected via higher energy prices caused by the final UST regulation. However, we do not expect a significant change in retail gasoline prices to result from this final UST regulation for the following reasons:

- Economic analyses of retail fuel prices revealed that demand for gasoline is highly sensitive to price (elastic) within localized geographic areas—as a result, if one motor fuel retailer in an area passes through increases in compliance costs by increasing gasoline prices, while another does not, the one with higher prices is at a competitive disadvantage; and
- Retail motor fuel stations often have associated stores or services, such as car washes, repair operations, and convenience outlets, on which they can more successfully pass through increases in compliance costs.

Furthermore, when considered in the context of total fuel consumption in the United States, this final UST regulation will represent only a very small fraction of motor fuel prices, even if fully passed through to consumers. According to the Bureau of Transportation Statistics, the United States consumed approximately 169 billion gallons of motor fuel (including gasoline and diesel) in 2011 at an average price of $3.73.[123] This implies that consumers spent $629 billion in 2012 on motor fuel. The overall cost of the final UST regulation is approximately $160 million, less than 0.1 percent of the amount spent by end users on motor fuel in 2012. In comparison, an increase of 1 cent in the average price of motor fuel in 2012 would have increased the total cost to consumers by approximately $1.7 billion. Given these circumstances, this final UST regulation should not measurably impact retail motor fuel prices. As a result, EPA does not expect this final UST regulation to have a significant adverse impact on energy prices or use.

I. National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104–113 (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical

[122] United States Department of Health and Human Services, Public Health Service, Agency for Toxic Substances and Disease Registry, *Toxicological Profile For Polycyclic Aromatic Hydrocarbons,* August 1995.

[123] 2011 is the latest year data available from Bureau of Transportation Statistics for gallons of motor fuel consumed, as reported by: U.S. Department of Transportation, Research and Innovative Technology Administration, Bureau of Transportation Statistics. Accessed at: *http://www.rita.dot.gov/bts/sites/rita.dot.gov.bts/files/publications/national_transportation_statistics/html/table_04_09.html*. The 2012 prices per gallon for all grades of retail motor gasoline and No. 2 diesel fuel (all concentrations of sulfur) were $3.63 and $3.97, respectively, as reported by: U.S. Energy Information Administration. Short-Term Energy Outlook—Real and Nominal Energy Prices for 2012. Accessed at: *http://www.eia.gov/forecasts/steo/realprices/*. We weight these prices according to prime supplier sales volumes in 2012 published by the Energy Information Administration, which summed to 347,234.5 thousands of gallons per day for gasoline and 143,270.6 thousands of gallons per day for all grades of diesel fuel (U.S. Energy Information Administration. Petroleum & Other Liquids. Prime Supplier Sales Volumes. Accessed at: *http://www.eia.gov/dnav/pet/pet_cons_prim_dcu_nus_a.htm.*

standards (*e.g.,* materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through OMB, explanations when EPA decides not to use available and applicable voluntary consensus standards.

This action uses technical standards. EPA has decided to use voluntary consensus standards, called codes of practice, described in section E–2. These codes of practice meet the objectives of this action by establishing criteria for the design, construction, and maintenance of underground storage tanks.

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

Executive Order 12898 (59 FR 7629, Feb. 16, 1994) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA has determined that this action will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations because it increases the level of environmental protection for all affected populations without having any disproportionately high and adverse human health or environmental effects on any population, including any minority or low-income population.

To inform us about the socioeconomic characteristics of communities potentially affected by this final UST regulation, EPA conducted a screening analysis under the 2011 proposed UST regulation to examine whether there is a statistically significant disparity between socioeconomic characteristics of populations located near UST facilities and those that are not.[124] As discussed in the RIA, the results indicate that minority and low-income populations are slightly more likely to be located near UST facilities. An environmental justice analysis would then require an assessment of whether there would be disproportionate and adverse impacts on these populations. However, because all regulatory options considered in this final UST regulation would increase regulatory stringency and reduce the number and size of releases, EPA does not anticipate the final UST regulation will have any disproportionately high and adverse human health or environmental effects on these minority or low-income communities or any community.

K. Congressional Review Act

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this 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**. A Major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is a ''major rule'' as defined by 5 U.S.C. 804(2). This rule is effective September 14, 2015.

List of Subjects

40 CFR Part 280

Environmental protection, Administrative practice and procedures, Confidential business information, Groundwater, Hazardous materials, Petroleum, Reporting and recordkeeping requirements, Underground storage tanks, Water pollution control, Water supply.

40 CFR Part 281

Environmental protection, Administrative practice and procedures, Hazardous substances, Petroleum, State program approval, Underground storage tanks.

Dated: June 19, 2015.

Gina McCarthy,

Administrator.

For the reasons set out in the preamble, parts 280 and 281 of title 40, chapter I of the Code of Federal Regulations are amended as follows:

■ 1. Revise part 280 to read as follows:

PART 280—TECHNICAL STANDARDS AND CORRECTIVE ACTION REQUIREMENTS FOR OWNERS AND OPERATORS OF UNDERGROUND STORAGE TANKS (UST)

Subpart A—Program Scope and Installation Requirements for Partially Excluded UST Systems

Sec.
280.10 Applicability.
280.11 Installation requirements for partially excluded UST systems.
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[124] Note that the affected populations identified in the screening analysis summarized here are simply defined by specific demographics surrounding UST locations. These affected populations are not necessarily equivalent to communities that others have specifically identified as environmental justice communities.

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Appendix II to Part 280—Notification of Ownership Change for Underground Storage Tanks (Form)
Appendix III to Part 280—Statement for Shipping Tickets and Invoices

Authority: 42 U.S.C. 6912, 6991, 6991(a), 6991(b), 6991(c), 6991(d), 6991(e), 6991(f), 6991(g), 6991(h), 6991(i).

Subpart A—Program Scope and Installation Requirements for Partially Excluded UST Systems

§ 280.10 Applicability.

(a) The requirements of this part apply to all owners and operators of an UST system as defined in § 280.12 except as otherwise provided in paragraphs (b) and (c) of this section.

(1) *Previously deferred UST systems.* Airport hydrant fuel distribution systems, UST systems with field-constructed tanks, and UST systems that store fuel solely for use by emergency power generators must meet the requirements of this part as follows:

(i) Airport hydrant fuel distribution systems and UST systems with field-constructed tanks must meet the requirements in subpart K of this part.

(ii) UST systems that store fuel solely for use by emergency power generators installed on or before October 13, 2015 must meet the subpart D requirements on or before October 13, 2018.

(iii) UST systems that store fuel solely for use by emergency power generators installed after October 13, 2015 must meet all applicable requirements of this part at installation.

(2) Any UST system listed in paragraph (c) of this section must meet the requirements of § 280.11.

(b) *Exclusions.* The following UST systems are excluded from the requirements of this part:

(1) Any UST system holding hazardous wastes listed or identified under Subtitle C of the Solid Waste Disposal Act, or a mixture of such hazardous waste and other regulated substances.

(2) Any wastewater treatment tank system that is part of a wastewater treatment facility regulated under Section 402 or 307(b) of the Clean Water Act.

(3) Equipment or machinery that contains regulated substances for operational purposes such as hydraulic lift tanks and electrical equipment tanks.

(4) Any UST system whose capacity is 110 gallons or less.

(5) Any UST system that contains a *de minimis* concentration of regulated substances.

(6) Any emergency spill or overflow containment UST system that is expeditiously emptied after use.

(c) *Partial Exclusions.* Subparts B, C, D, E, G, J, and K of this part do not apply to:

(1) Wastewater treatment tank systems not covered under paragraph (b)(2) of this section;

(2) Aboveground storage tanks associated with:

(i) Airport hydrant fuel distribution systems regulated under subpart K of this part; and

(ii) UST systems with field-constructed tanks regulated under subpart K of this part;

(3) Any UST systems containing radioactive material that are regulated under the Atomic Energy Act of 1954 (42 U.S.C. 2011 and following); and

(4) Any UST system that is part of an emergency generator system at nuclear power generation facilities licensed by the Nuclear Regulatory Commission and subject to Nuclear Regulatory Commission requirements regarding design and quality criteria, including but not limited to 10 CFR part 50.

§ 280.11 Installation requirements for partially excluded UST systems.

(a) Owners and operators must install an UST system listed in § 280.10(c)(1), (3), or (4) storing regulated substances (whether of single or double wall construction) that meets the following requirements:

(1) Will prevent releases due to corrosion or structural failure for the operational life of the UST system;

(2) Is cathodically protected against corrosion, constructed of non-corrodible material, steel clad with a non-corrodible material, or designed in a manner to prevent the release or threatened release of any stored substance; and

(3) Is constructed or lined with material that is compatible with the stored substance.

(b) Notwithstanding paragraph (a) of this section, an UST system without corrosion protection may be installed at a site that is determined by a corrosion expert not to be corrosive enough to cause it to have a release due to corrosion during its operating life. Owners and operators must maintain records that demonstrate compliance with the requirements of this paragraph for the remaining life of the tank.

Note to paragraphs (a) and (b). The following codes of practice may be used as guidance for complying with this section:

(A) NACE International Standard Practice SP 0285, ''External Corrosion Control of

Underground Storage Tank Systems by Cathodic Protection'';

(B) NACE International Standard Practice SP 0169, ''Control of External Corrosion on Underground or Submerged Metallic Piping Systems'';

(C) American Petroleum Institute Recommended Practice 1632, ''Cathodic Protection of Underground Petroleum Storage Tanks and Piping Systems''; or

(D) Steel Tank Institute Recommended Practice R892, ''Recommended Practice for Corrosion Protection of Underground Piping Networks Associated with Liquid Storage and Dispensing Systems''.

§ 280.12 Definitions.

Aboveground release means any release to the surface of the land or to surface water. This includes, but is not limited to, releases from the aboveground portion of an UST system and aboveground releases associated with overfills and transfer operations as the regulated substance moves to or from an UST system.

Ancillary equipment means any devices including, but not limited to, such devices as piping, fittings, flanges, valves, and pumps used to distribute, meter, or control the flow of regulated substances to and from an UST.

Belowground release means any release to the subsurface of the land and to groundwater. This includes, but is not limited to, releases from the belowground portions of an underground storage tank system and belowground releases associated with overfills and transfer operations as the regulated substance moves to or from an underground storage tank.

Beneath the surface of the ground means beneath the ground surface or otherwise covered with earthen materials.

Cathodic protection is a technique to prevent corrosion of a metal surface by making that surface the cathode of an electrochemical cell. For example, a tank system can be cathodically protected through the application of either galvanic anodes or impressed current.

Cathodic protection tester means a person who can demonstrate an understanding of the principles and measurements of all common types of cathodic protection systems as applied to buried or submerged metal piping and tank systems. At a minimum, such persons must have education and experience in soil resistivity, stray current, structure-to-soil potential, and component electrical isolation measurements of buried metal piping and tank systems.

CERCLA means the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended.

Class A operator means the individual who has primary responsibility to operate and maintain the UST system in accordance with applicable requirements established by the implementing agency. The Class A operator typically manages resources and personnel, such as establishing work assignments, to achieve and maintain compliance with regulatory requirements.

Class B operator means the individual who has day-to-day responsibility for implementing applicable regulatory requirements established by the implementing agency. The Class B operator typically implements in-field aspects of operation, maintenance, and associated recordkeeping for the UST system.

Class C operator means the individual responsible for initially addressing emergencies presented by a spill or release from an UST system. The Class C operator typically controls or monitors the dispensing or sale of regulated substances.

Compatible means the ability of two or more substances to maintain their respective physical and chemical properties upon contact with one another for the design life of the tank system under conditions likely to be encountered in the UST.

Connected piping means all underground piping including valves, elbows, joints, flanges, and flexible connectors attached to a tank system through which regulated substances flow. For the purpose of determining how much piping is connected to any individual UST system, the piping that joins two UST systems should be allocated equally between them.

Consumptive use with respect to heating oil means consumed on the premises.

Containment Sump means a liquid-tight container that protects the environment by containing leaks and spills of regulated substances from piping, dispensers, pumps and related components in the containment area. Containment sumps may be single walled or secondarily contained and located at the top of tank (tank top or submersible turbine pump sump), underneath the dispenser (under-dispenser containment sump), or at other points in the piping run (transition or intermediate sump).

Corrosion expert means a person who, by reason of thorough knowledge of the physical sciences and the principles of engineering and mathematics acquired by a professional education and related practical experience, is qualified to engage in the practice of corrosion control on buried or submerged metal piping systems and metal tanks. Such a person must be accredited or certified as being qualified by the National Association of Corrosion Engineers or be a registered professional engineer who has certification or licensing that includes education and experience in corrosion control of buried or submerged metal piping systems and metal tanks.

Dielectric material means a material that does not conduct direct electrical current. Dielectric coatings are used to electrically isolate UST systems from the surrounding soils. Dielectric bushings are used to electrically isolate portions of the UST system (*e.g.,* tank from piping).

Dispenser means equipment located aboveground that dispenses regulated substances from the UST system.

Dispenser system means the dispenser and the equipment necessary to connect the dispenser to the underground storage tank system.

Electrical equipment means underground equipment that contains dielectric fluid that is necessary for the operation of equipment such as transformers and buried electrical cable.

Excavation zone means the volume containing the tank system and backfill material bounded by the ground surface, walls, and floor of the pit and trenches into which the UST system is placed at the time of installation.

Existing tank system means a tank system used to contain an accumulation of regulated substances or for which installation has commenced on or before December 22, 1988. Installation is considered to have commenced if:

(1) The owner or operator has obtained all federal, state, and local approvals or permits necessary to begin physical construction of the site or installation of the tank system; and if,

(2)(i) Either a continuous on-site physical construction or installation program has begun; or,

(ii) The owner or operator has entered into contractual obligations—which cannot be cancelled or modified without substantial loss—for physical construction at the site or installation of the tank system to be completed within a reasonable time.

Farm tank is a tank located on a tract of land devoted to the production of crops or raising animals, including fish, and associated residences and improvements. A farm tank must be located on the farm property. *Farm* includes fish hatcheries, rangeland and nurseries with growing operations.

Flow-through process tank is a tank that forms an integral part of a

production process through which there is a steady, variable, recurring, or intermittent flow of materials during the operation of the process. Flow-through process tanks do not include tanks used for the storage of materials prior to their introduction into the production process or for the storage of finished products or by-products from the production process.

Free product refers to a regulated substance that is present as a nonaqueous phase liquid (*e.g.,* liquid not dissolved in water).

Gathering lines means any pipeline, equipment, facility, or building used in the transportation of oil or gas during oil or gas production or gathering operations.

Hazardous substance UST system means an underground storage tank system that contains a hazardous substance defined in section 101(14) of the Comprehensive Environmental Response, Compensation and Liability Act of 1980 (but not including any substance regulated as a hazardous waste under subtitle C) or any mixture of such substances and petroleum, and which is not a petroleum UST system.

Heating oil means petroleum that is No. 1, No. 2, No. 4—light, No. 4—heavy, No. 5—light, No. 5—heavy, and No. 6 technical grades of fuel oil; other residual fuel oils (including Navy Special Fuel Oil and Bunker C); and other fuels when used as substitutes for one of these fuel oils. Heating oil is typically used in the operation of heating equipment, boilers, or furnaces.

Hydraulic lift tank means a tank holding hydraulic fluid for a closed-loop mechanical system that uses compressed air or hydraulic fluid to operate lifts, elevators, and other similar devices.

Implementing agency means EPA, or, in the case of a state with a program approved under section 9004 (or pursuant to a memorandum of agreement with EPA), the designated state or local agency responsible for carrying out an approved UST program.

Liquid trap means sumps, well cellars, and other traps used in association with oil and gas production, gathering, and extraction operations (including gas production plants), for the purpose of collecting oil, water, and other liquids. These liquid traps may temporarily collect liquids for subsequent disposition or reinjection into a production or pipeline stream, or may collect and separate liquids from a gas stream.

Maintenance means the normal operational upkeep to prevent an underground storage tank system from releasing product.

Motor fuel means a complex blend of hydrocarbons typically used in the operation of a motor engine, such as motor gasoline, aviation gasoline, No. 1 or No. 2 diesel fuel, or any blend containing one or more of these substances (for example: motor gasoline blended with alcohol).

New tank system means a tank system that will be used to contain an accumulation of regulated substances and for which installation has commenced after December 22, 1988. (See also *Existing Tank System.*)

Noncommercial purposes with respect to motor fuel means not for resale.

On the premises where stored with respect to heating oil means UST systems located on the same property where the stored heating oil is used.

Operational life refers to the period beginning when installation of the tank system has commenced until the time the tank system is properly closed under subpart G.

Operator means any person in control of, or having responsibility for, the daily operation of the UST system.

Overfill release is a release that occurs when a tank is filled beyond its capacity, resulting in a discharge of the regulated substance to the environment.

Owner means:

(1) In the case of an UST system in use on November 8, 1984, or brought into use after that date, any person who owns an UST system used for storage, use, or dispensing of regulated substances; and

(2) In the case of any UST system in use before November 8, 1984, but no longer in use on that date, any person who owned such UST immediately before the discontinuation of its use.

Person means an individual, trust, firm, joint stock company, federal agency, corporation, state, municipality, commission, political subdivision of a state, or any interstate body. Person also includes a consortium, a joint venture, a commercial entity, and the United States Government.

Petroleum UST system means an underground storage tank system that contains petroleum or a mixture of petroleum with *de minimis* quantities of other regulated substances. Such systems include those containing motor fuels, jet fuels, distillate fuel oils, residual fuel oils, lubricants, petroleum solvents, and used oils.

Pipe or *Piping* means a hollow cylinder or tubular conduit that is constructed of non-earthen materials.

Pipeline facilities (including gathering lines) are new and existing pipe rights-of-way and any associated equipment, facilities, or buildings.

Regulated substance means:

(1) Any substance defined in section 101(14) of the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) of 1980 (but not including any substance regulated as a hazardous waste under subtitle C); and

(2) Petroleum, including crude oil or any fraction thereof that is liquid at standard conditions of temperature and pressure (60 degrees Fahrenheit and 14.7 pounds per square inch absolute). The term regulated substance includes but is not limited to petroleum and petroleum-based substances comprised of a complex blend of hydrocarbons, such as motor fuels, jet fuels, distillate fuel oils, residual fuel oils, lubricants, petroleum solvents, and used oils.

Release means any spilling, leaking, emitting, discharging, escaping, leaching or disposing from an UST into groundwater, surface water or subsurface soils.

Release detection means determining whether a release of a regulated substance has occurred from the UST system into the environment or a leak has occurred into the interstitial space between the UST system and its secondary barrier or secondary containment around it.

Repair means to restore to proper operating condition a tank, pipe, spill prevention equipment, overfill prevention equipment, corrosion protection equipment, release detection equipment or other UST system component that has caused a release of product from the UST system or has failed to function properly.

Replaced means:

(1) For a tank—to remove a tank and install another tank.

(2) For piping—to remove 50 percent or more of piping and install other piping, excluding connectors, connected to a single tank. For tanks with multiple piping runs, this definition applies independently to each piping run.

Residential tank is a tank located on property used primarily for dwelling purposes.

SARA means the Superfund Amendments and Reauthorization Act of 1986.

Secondary containment or *Secondarily contained* means a release prevention and release detection system for a tank or piping. This system has an inner and outer barrier with an interstitial space that is monitored for leaks. This term includes containment sumps when used for interstitial monitoring of piping.

Septic tank is a water-tight covered receptacle designed to receive or process, through liquid separation or

biological digestion, the sewage discharged from a building sewer. The effluent from such receptacle is distributed for disposal through the soil and settled solids and scum from the tank are pumped out periodically and hauled to a treatment facility.

Storm water or wastewater collection system means piping, pumps, conduits, and any other equipment necessary to collect and transport the flow of surface water run-off resulting from precipitation, or domestic, commercial, or industrial wastewater to and from retention areas or any areas where treatment is designated to occur. The collection of storm water and wastewater does not include treatment except where incidental to conveyance.

Surface impoundment is a natural topographic depression, man-made excavation, or diked area formed primarily of earthen materials (although it may be lined with man-made materials) that is not an injection well.

Tank is a stationary device designed to contain an accumulation of regulated substances and constructed of non-earthen materials (*e.g.,* concrete, steel, plastic) that provide structural support.

Training program means any program that provides information to and evaluates the knowledge of a Class A, Class B, or Class C operator through testing, practical demonstration, or another approach acceptable to the implementing agency regarding requirements for UST systems that meet the requirements of subpart J of this part.

Under-dispenser containment or *UDC* means containment underneath a dispenser system designed to prevent leaks from the dispenser and piping within or above the UDC from reaching soil or groundwater.

Underground area means an underground room, such as a basement, cellar, shaft or vault, providing enough space for physical inspection of the exterior of the tank situated on or above the surface of the floor.

Underground release means any belowground release.

Underground storage tank or *UST* means any one or combination of tanks (including underground pipes connected thereto) that is used to contain an accumulation of regulated substances, and the volume of which (including the volume of underground pipes connected thereto) is 10 percent or more beneath the surface of the ground. This term does not include any:

(1) Farm or residential tank of 1,100 gallons or less capacity used for storing motor fuel for noncommercial purposes;

(2) Tank used for storing heating oil for consumptive use on the premises where stored;

(3) Septic tank;

(4) Pipeline facility (including gathering lines):

(i) Which is regulated under 49 U.S.C. chapter 601; or

(ii) Which is an intrastate pipeline facility regulated under state laws as provided in 49 U.S.C. chapter 601, and which is determined by the Secretary of Transportation to be connected to a pipeline, or to be operated or intended to be capable of operating at pipeline pressure or as an integral part of a pipeline;

(5) Surface impoundment, pit, pond, or lagoon;

(6) Storm water or wastewater collection system;

(7) Flow-through process tank;

(8) Liquid trap or associated gathering lines directly related to oil or gas production and gathering operations; or

(9) Storage tank situated in an underground area (such as a basement, cellar, mineworking, drift, shaft, or tunnel) if the storage tank is situated upon or above the surface of the floor.

Note to the definition of *Underground storage tank* or *UST.* The term *underground storage tank* or *UST* does not include any pipes connected to any tank which is described in paragraphs (1) through (9) of this definition.

Upgrade means the addition or retrofit of some systems such as cathodic protection, lining, or spill and overfill controls to improve the ability of an underground storage tank system to prevent the release of product.

UST system or *Tank system* means an underground storage tank, connected underground piping, underground ancillary equipment, and containment system, if any.

Wastewater treatment tank means a tank that is designed to receive and treat an influent wastewater through physical, chemical, or biological methods.

Subpart B—UST Systems: Design, Construction, Installation and Notification

§ 280.20 Performance standards for new UST systems.

In order to prevent releases due to structural failure, corrosion, or spills and overfills for as long as the UST system is used to store regulated substances, all owners and operators of new UST systems must meet the following requirements. In addition, except for suction piping that meets the requirements of § 280.41(b)(1)(ii)(A) through (E), tanks and piping installed or replaced after April 11, 2016 must be secondarily contained and use interstitial monitoring in accordance with § 280.43(g). Secondary containment must be able to contain regulated substances leaked from the primary containment until they are detected and removed and prevent the release of regulated substances to the environment at any time during the operational life of the UST system. For cases where the piping is considered to be replaced, the entire piping run must be secondarily contained.

(a) *Tanks.* Each tank must be properly designed and constructed, and any portion underground that routinely contains product must be protected from corrosion, in accordance with a code of practice developed by a nationally recognized association or independent testing laboratory as specified below:

(1) The tank is constructed of fiberglass-reinforced plastic; or

Note to paragraph (a)(1). The following codes of practice may be used to comply with paragraph (a)(1) of this section:

(A) Underwriters Laboratories Standard 1316, ''Glass-Fiber-Reinforced Plastic Underground Storage Tanks for Petroleum Products, Alcohols, and Alcohol-Gasoline Mixtures''; or

(B) Underwriter's Laboratories of Canada S615, ''Standard for Reinforced Plastic Underground Tanks for Flammable and Combustible Liquids''.

(2) The tank is constructed of steel and cathodically protected in the following manner:

(i) The tank is coated with a suitable dielectric material;

(ii) Field-installed cathodic protection systems are designed by a corrosion expert;

(iii) Impressed current systems are designed to allow determination of current operating status as required in § 280.31(c); and

(iv) Cathodic protection systems are operated and maintained in accordance with § 280.31 or according to guidelines established by the implementing agency; or

Note to paragraph (a)(2). The following codes of practice may be used to comply with paragraph (a)(2) of this section:

(A) Steel Tank Institute ''Specification STI–P3® Specification and Manual for External Corrosion Protection of Underground Steel Storage Tanks'';

(B) Underwriters Laboratories Standard 1746, ''External Corrosion Protection Systems for Steel Underground Storage Tanks'';

(C) Underwriters Laboratories of Canada S603, ''Standard for Steel Underground Tanks for Flammable and Combustible Liquids,'' and S603.1, ''Standard for External Corrosion Protection Systems for Steel Underground Tanks for Flammable and

Combustible Liquids,'' and S631, ''Standard for Isolating Bushings for Steel Underground Tanks Protected with External Corrosion Protection Systems'';

(D) Steel Tank Institute Standard F841, ''Standard for Dual Wall Underground Steel Storage Tanks''; or

(E) NACE International Standard Practice SP 0285, ''External Corrosion Control of Underground Storage Tank Systems by Cathodic Protection,'' and Underwriters Laboratories Standard 58, ''Standard for Steel Underground Tanks for Flammable and Combustible Liquids''.

(3) The tank is constructed of steel and clad or jacketed with a non-corrodible material; or

Note to paragraph (a)(3). The following codes of practice may be used to comply with paragraph (a)(3) of this section:

(A) Underwriters Laboratories Standard 1746, ''External Corrosion Protection Systems for Steel Underground Storage Tanks'';

(B) Steel Tank Institute ACT–100® Specification F894, ''Specification for External Corrosion Protection of FRP Composite Steel Underground Storage Tanks'';

(C) Steel Tank Institute ACT–100–U® Specification F961, ''Specification for External Corrosion Protection of Composite Steel Underground Storage Tanks''; or

(D) Steel Tank Institute Specification F922, ''Steel Tank Institute Specification for Permatank®''.

(4) The tank is constructed of metal without additional corrosion protection measures provided that:

(i) The tank is installed at a site that is determined by a corrosion expert not to be corrosive enough to cause it to have a release due to corrosion during its operating life; and

(ii) Owners and operators maintain records that demonstrate compliance with the requirements of paragraph (a)(4)(i) of this section for the remaining life of the tank; or

(5) The tank construction and corrosion protection are determined by the implementing agency to be designed to prevent the release or threatened release of any stored regulated substance in a manner that is no less protective of human health and the environment than paragraphs (a)(1) through (4) of this section.

(b) *Piping.* The piping that routinely contains regulated substances and is in contact with the ground must be properly designed, constructed, and protected from corrosion in accordance with a code of practice developed by a nationally recognized association or independent testing laboratory as specified below.

(1) The piping is constructed of a non-corrodible material; or

Note to paragraph (b)(1). The following codes of practice may be used to comply with paragraph (b)(1) of this section:

(A) Underwriters Laboratories Standard 971, ''Nonmetallic Underground Piping for Flammable Liquids''; or

(B) Underwriters Laboratories of Canada Standard S660, ''Standard for Nonmetallic Underground Piping for Flammable and Combustible Liquids''.

(2) The piping is constructed of steel and cathodically protected in the following manner:

(i) The piping is coated with a suitable dielectric material;

(ii) Field-installed cathodic protection systems are designed by a corrosion expert;

(iii) Impressed current systems are designed to allow determination of current operating status as required in § 280.31(c); and

(iv) Cathodic protection systems are operated and maintained in accordance with § 280.31 or guidelines established by the implementing agency; or

Note to paragraph (b)(2). The following codes of practice may be used to comply with paragraph (b)(2) of this section:

(A) American Petroleum Institute Recommended Practice 1632, ''Cathodic Protection of Underground Petroleum Storage Tanks and Piping Systems'';

(B) Underwriters Laboratories Subject 971A, ''Outline of Investigation for Metallic Underground Fuel Pipe'';

(C) Steel Tank Institute Recommended Practice R892, ''Recommended Practice for Corrosion Protection of Underground Piping Networks Associated with Liquid Storage and Dispensing Systems'';

(D) NACE International Standard Practice SP 0169, ''Control of External Corrosion on Underground or Submerged Metallic Piping Systems''; or

(E) NACE International Standard Practice SP 0285, ''External Corrosion Control of Underground Storage Tank Systems by Cathodic Protection''.

(3) The piping is constructed of metal without additional corrosion protection measures provided that:

(i) The piping is installed at a site that is determined by a corrosion expert to not be corrosive enough to cause it to have a release due to corrosion during its operating life; and

(ii) Owners and operators maintain records that demonstrate compliance with the requirements of paragraph (b)(3)(i) of this section for the remaining life of the piping; or

(4) The piping construction and corrosion protection are determined by the implementing agency to be designed to prevent the release or threatened release of any stored regulated substance in a manner that is no less protective of human health and the environment than the requirements in paragraphs (b)(1) through (3) of this section.

(c) *Spill and overfill prevention equipment.* (1) Except as provided in paragraphs (c)(2) and (3) of this section, to prevent spilling and overfilling associated with product transfer to the UST system, owners and operators must use the following spill and overfill prevention equipment:

(i) Spill prevention equipment that will prevent release of product to the environment when the transfer hose is detached from the fill pipe (for example, a spill catchment basin); and

(ii) Overfill prevention equipment that will:

(A) Automatically shut off flow into the tank when the tank is no more than 95 percent full; or

(B) Alert the transfer operator when the tank is no more than 90 percent full by restricting the flow into the tank or triggering a high-level alarm; or

(C) Restrict flow 30 minutes prior to overfilling, alert the transfer operator with a high level alarm one minute before overfilling, or automatically shut off flow into the tank so that none of the fittings located on top of the tank are exposed to product due to overfilling.

(2) Owners and operators are not required to use the spill and overfill prevention equipment specified in paragraph (c)(1) of this section if:

(i) Alternative equipment is used that is determined by the implementing agency to be no less protective of human health and the environment than the equipment specified in paragraph (c)(1)(i) or (ii) of this section; or

(ii) The UST system is filled by transfers of no more than 25 gallons at one time.

(3) Flow restrictors used in vent lines may not be used to comply with paragraph (c)(1)(ii) of this section when overfill prevention is installed or replaced after October 13, 2015.

(4) Spill and overfill prevention equipment must be periodically tested or inspected in accordance with § 280.35.

(d) *Installation.* The UST system must be properly installed in accordance with a code of practice developed by a nationally recognized association or independent testing laboratory and in accordance with the manufacturer's instructions.

Note to paragraph (d). Tank and piping system installation practices and procedures described in the following codes of practice may be used to comply with the requirements of paragraph (d) of this section:

(A) American Petroleum Institute Publication 1615, ''Installation of Underground Petroleum Storage System'';

(B) Petroleum Equipment Institute Publication RP100, ''Recommended Practices for Installation of Underground Liquid Storage Systems''; or

(C) National Fire Protection Association Standard 30, ''Flammable and Combustible

Liquids Code'' and Standard 30A, ''Code for Motor Fuel Dispensing Facilities and Repair Garages''.

(e) *Certification of installation.* All owners and operators must ensure that one or more of the following methods of certification, testing, or inspection is used to demonstrate compliance with paragraph (d) of this section by providing a certification of compliance on the UST notification form in accordance with § 280.22.

(1) The installer has been certified by the tank and piping manufacturers; or

(2) The installer has been certified or licensed by the implementing agency; or

(3) The installation has been inspected and certified by a registered professional engineer with education and experience in UST system installation; or

(4) The installation has been inspected and approved by the implementing agency; or

(5) All work listed in the manufacturer's installation checklists has been completed; or

(6) The owner and operator have complied with another method for ensuring compliance with paragraph (d) of this section that is determined by the implementing agency to be no less protective of human health and the environment.

(f) *Dispenser systems.* Each UST system must be equipped with under-dispenser containment for any new dispenser system installed after April 11, 2016.

(1) A dispenser system is considered new when both the dispenser and the equipment needed to connect the dispenser to the underground storage tank system are installed at an UST facility. The equipment necessary to connect the dispenser to the underground storage tank system includes check valves, shear valves, unburied risers or flexible connectors, or other transitional components that are underneath the dispenser and connect the dispenser to the underground piping.

(2) Under-dispenser containment must be liquid-tight on its sides, bottom, and at any penetrations. Under-dispenser containment must allow for visual inspection and access to the components in the containment system or be periodically monitored for leaks from the dispenser system.

§ 280.21 Upgrading of existing UST systems.

Owners and operators must permanently close (in accordance with subpart G of this part) any UST system that does not meet the new UST system performance standards in § 280.20 or has not been upgraded in accordance with paragraphs (b) through (d) of this section. This does not apply to previously deferred UST systems described in subpart K of this part and where an upgrade is determined to be appropriate by the implementing agency.

(a) *Alternatives allowed.* All existing UST systems must comply with one of the following requirements:

(1) New UST system performance standards under § 280.20;

(2) The upgrading requirements in paragraphs (b) through (d) of this section; or

(3) Closure requirements under subpart G of this part, including applicable requirements for corrective action under subpart F of this part.

(b) *Tank upgrading requirements.* Steel tanks must be upgraded to meet one of the following requirements in accordance with a code of practice developed by a nationally recognized association or independent testing laboratory:

(1) *Interior lining.* Tanks upgraded by internal lining must meet the following:

(i) The lining was installed in accordance with the requirements of § 280.33; and

(ii) Within 10 years after lining, and every 5 years thereafter, the lined tank is internally inspected and found to be structurally sound with the lining still performing in accordance with original design specifications. If the internal lining is no longer performing in accordance with original design specifications and cannot be repaired in accordance with a code of practice developed by a nationally recognized association or independent testing laboratory, then the lined tank must be permanently closed in accordance with subpart G of this part.

(2) *Cathodic protection.* Tanks upgraded by cathodic protection must meet the requirements of § 280.20(a)(2)(ii), (iii), and (iv) and the integrity of the tank must have been ensured using one of the following methods:

(i) The tank was internally inspected and assessed to ensure that the tank was structurally sound and free of corrosion holes prior to installing the cathodic protection system; or

(ii) The tank had been installed for less than 10 years and is monitored monthly for releases in accordance with § 280.43(d) through (i); or

(iii) The tank had been installed for less than 10 years and was assessed for corrosion holes by conducting two tightness tests that meet the requirements of § 280.43(c). The first tightness test must have been conducted prior to installing the cathodic protection system. The second tightness test must have been conducted between three and six months following the first operation of the cathodic protection system; or

(iv) The tank was assessed for corrosion holes by a method that is determined by the implementing agency to prevent releases in a manner that is no less protective of human health and the environment than paragraphs (b)(2)(i) through (iii) of this section.

(3) *Internal lining combined with cathodic protection.* Tanks upgraded by both internal lining and cathodic protection must meet the following:

(i) The lining was installed in accordance with the requirements of § 280.33; and

(ii) The cathodic protection system meets the requirements of § 280.20(a)(2)(ii), (iii), and (iv).

Note to paragraph (b). The following historical codes of practice were listed as options for complying with paragraph (b) of this section:

(A) American Petroleum Institute Publication 1631, ''Recommended Practice for the Interior Lining of Existing Steel Underground Storage Tanks'';

(B) National Leak Prevention Association Standard 631, ''Spill Prevention, Minimum 10 Year Life Extension of Existing Steel Underground Tanks by Lining Without the Addition of Cathodic Protection'';

(C) National Association of Corrosion Engineers Standard RP–02–85, ''Control of External Corrosion on Metallic Buried, Partially Buried, or Submerged Liquid Storage Systems''; and

(D) American Petroleum Institute Recommended Practice 1632, ''Cathodic Protection of Underground Petroleum Storage Tanks and Piping Systems''.

Note to paragraph b(1)(ii). The following codes of practice may be used to comply with the periodic lining inspection requirement of this section:

(A) American Petroleum Institute Recommended Practice 1631, ''Interior Lining and Periodic Inspection of Underground Storage Tanks'';

(B) National Leak Prevention Association Standard 631, Chapter B ''Future Internal Inspection Requirements for Lined Tanks''; or

(C) Ken Wilcox Associates Recommended Practice, ''Recommended Practice for Inspecting Buried Lined Steel Tanks Using a Video Camera''.

(c) *Piping upgrading requirements.* Metal piping that routinely contains regulated substances and is in contact with the ground must be cathodically protected in accordance with a code of practice developed by a nationally recognized association or independent testing laboratory and must meet the requirements of § 280.20(b)(2)(ii), (iii), and (iv).

Note to paragraph (c). The codes of practice listed in the note following § 280.20(b)(2) may be used to comply with this requirement.

(d) *Spill and overfill prevention equipment.* To prevent spilling and overfilling associated with product transfer to the UST system, all existing UST systems must comply with UST system spill and overfill prevention equipment requirements specified in § 280.20(c).

§ 280.22 Notification requirements.

(a) After May 8, 1986, an owner must submit notice of a tank system's existence to the implementing agency within 30 days of bringing the underground storage tank system into use. Owners must use the form in appendix I of this part or a state form in accordance with paragraph (c) of this section.

Note to paragraph (a). Owners and operators of UST systems that were in the ground on or after May 8, 1986, unless taken out of operation on or before January 1, 1974, were required to notify the designated state or local agency in accordance with the Hazardous and Solid Waste Amendments of 1984, Public Law 98–616, on a form published by EPA on November 8, 1985 unless notice was given pursuant to section 103(c) of CERCLA. Owners and operators who have not complied with the notification requirements may use portions I through X of the notification form contained in appendix I of this part.

(b) Within 30 days of acquisition, any person who assumes ownership of a regulated underground storage tank system, except as described in paragraph (a) of this section, must submit a notice of the ownership change to the implementing agency, using the form in appendix II of this part or a state form in accordance with paragraph (c) of this section.

(c) In states where state law, regulations, or procedures require owners to use forms that differ from those set forth in appendix I and appendix II of this part to fulfill the requirements of this section, the state forms may be submitted in lieu of the forms set forth in appendix I and appendix II. If a state requires that its form be used in lieu of the form presented in appendix I and appendix II, such form must, at a minimum, collect the information prescribed in appendix I and appendix II.

(d) Owners required to submit notices under paragraph (a) or (b) of this section must provide notices to the appropriate implementing agency for each tank they own. Owners may provide notice for several tanks using one notification form, but owners who own tanks located at more than one place of operation must file a separate notification form for each separate place of operation.

(e) All owners and operators of new UST systems must certify in the notification form compliance with the following requirements:

(1) Installation of tanks and piping under § 280.20(e);

(2) Cathodic protection of steel tanks and piping under § 280.20(a) and (b);

(3) Financial responsibility under subpart H of this part; and

(4) Release detection under §§ 280.41 and 280.42.

(f) All owners and operators of new UST systems must ensure that the installer certifies in the notification form that the methods used to install the tanks and piping complies with the requirements in § 280.20(d).

(g) Beginning October 24, 1988, any person who sells a tank intended to be used as an underground storage tank must notify the purchaser of such tank of the owner's notification obligations under paragraph (a) of this section. The statement provided in appendix III of this part, when used on shipping tickets and invoices, may be used to comply with this requirement.

Subpart C—General Operating Requirements

§ 280.30 Spill and overfill control.

(a) Owners and operators must ensure that releases due to spilling or overfilling do not occur. The owner and operator must ensure that the volume available in the tank is greater than the volume of product to be transferred to the tank before the transfer is made and that the transfer operation is monitored constantly to prevent overfilling and spilling.

Note to paragraph (a). The transfer procedures described in National Fire Protection Association Standard 385, ''Standard for Tank Vehicles for Flammable and Combustible Liquids'' or American Petroleum Institute Recommended Practice 1007, ''Loading and Unloading of MC 306/DOT 406 Cargo Tank Motor Vehicles'' may be used to comply with paragraph (a) of this section. Further guidance on spill and overfill prevention appears in American Petroleum Institute Recommended Practice 1621, ''Bulk Liquid Stock Control at Retail Outlets''.

(b) The owner and operator must report, investigate, and clean up any spills and overfills in accordance with § 280.53.

§ 280.31 Operation and maintenance of corrosion protection.

All owners and operators of metal UST systems with corrosion protection must comply with the following requirements to ensure that releases due to corrosion are prevented until the UST system is permanently closed or undergoes a change-in-service pursuant to § 280.71:

(a) All corrosion protection systems must be operated and maintained to continuously provide corrosion protection to the metal components of that portion of the tank and piping that routinely contain regulated substances and are in contact with the ground.

(b) All UST systems equipped with cathodic protection systems must be inspected for proper operation by a qualified cathodic protection tester in accordance with the following requirements:

(1) *Frequency.* All cathodic protection systems must be tested within 6 months of installation and at least every 3 years thereafter or according to another reasonable time frame established by the implementing agency; and

(2) *Inspection criteria.* The criteria that are used to determine that cathodic protection is adequate as required by this section must be in accordance with a code of practice developed by a nationally recognized association.

Note to paragraph (b). The following codes of practice may be used to comply with paragraph (b) of this section:

(A) NACE International Test Method TM 0101, ''Measurement Techniques Related to Criteria for Cathodic Protection of Underground Storage Tank Systems'';

(B) NACE International Test Method TM0497, ''Measurement Techniques Related to Criteria for Cathodic Protection on Underground or Submerged Metallic Piping Systems'';

(C) Steel Tank Institute Recommended Practice R051, ''Cathodic Protection Testing Procedures for STI–P3® USTs'';

(D) NACE International Standard Practice SP 0285, ''External Control of Underground Storage Tank Systems by Cathodic Protection''; or

(E) NACE International Standard Practice SP 0169, ''Control of External Corrosion on Underground or Submerged Metallic Piping Systems''.

(c) UST systems with impressed current cathodic protection systems must also be inspected every 60 days to ensure the equipment is running properly.

(d) For UST systems using cathodic protection, records of the operation of the cathodic protection must be maintained (in accordance with § 280.34) to demonstrate compliance with the performance standards in this section. These records must provide the following:

(1) The results of the last three inspections required in paragraph (c) of this section; and

(2) The results of testing from the last two inspections required in paragraph (b) of this section.

§ 280.32 Compatibility.

(a) Owners and operators must use an UST system made of or lined with materials that are compatible with the substance stored in the UST system.

(b) Owners and operators must notify the implementing agency at least 30 days prior to switching to a regulated substance containing greater than 10 percent ethanol, greater than 20 percent biodiesel, or any other regulated substance identified by the implementing agency. In addition, owners and operators with UST systems storing these regulated substances must meet one of the following:

(1) Demonstrate compatibility of the UST system (including the tank, piping, containment sumps, pumping equipment, release detection equipment, spill equipment, and overfill equipment). Owners and operators may demonstrate compatibility of the UST system by using one of the following options:

(i) Certification or listing of UST system equipment or components by a nationally recognized, independent testing laboratory for use with the regulated substance stored; or

(ii) Equipment or component manufacturer approval. The manufacturer's approval must be in writing, indicate an affirmative statement of compatibility, specify the range of biofuel blends the equipment or component is compatible with, and be from the equipment or component manufacturer; or

(2) Use another option determined by the implementing agency to be no less protective of human health and the environment than the options listed in paragraph (b)(1) of this section. (c) Owners and operators must maintain records in accordance with § 280.34(b) documenting compliance with paragraph (b) of this section for as long as the UST system is used to store the regulated substance.

Note to § 280.32. The following code of practice may be useful in complying with this section: American Petroleum Institute Recommended Practice 1626, ''Storing and Handling Ethanol and Gasoline-Ethanol Blends at Distribution Terminals and Filling Stations.''

§ 280.33 Repairs allowed.

Owners and operators of UST systems must ensure that repairs will prevent releases due to structural failure or corrosion as long as the UST system is used to store regulated substances. The repairs must meet the following requirements:

(a) Repairs to UST systems must be properly conducted in accordance with a code of practice developed by a nationally recognized association or an independent testing laboratory.

Note to paragraph (a). The following codes of practice may be used to comply with paragraph (a) of this section:

(A) National Fire Protection Association Standard 30, ''Flammable and Combustible Liquids Code'';

(B) American Petroleum Institute Recommended Practice RP 2200, ''Repairing Crude Oil, Liquified Petroleum Gas, and Product Pipelines'';

(C) American Petroleum Institute Recommended Practice RP 1631, ''Interior Lining and Periodic Inspection of Underground Storage Tanks'';

(D) National Fire Protection Association Standard 326, ''Standard for the Safeguarding of Tanks and Containers for Entry, Cleaning, or Repair'';

(E) National Leak Prevention Association Standard 631, Chapter A, ''Entry, Cleaning, Interior Inspection, Repair, and Lining of Underground Storage Tanks'';

(F) Steel Tank Institute Recommended Practice R972, ''Recommended Practice for the Addition of Supplemental Anodes to STI–P3® Tanks'';

(G) NACE International Standard Practice SP 0285, ''External Control of Underground Storage Tank Systems by Cathodic Protection''; or

(H) Fiberglass Tank and Pipe Institute Recommended Practice T–95–02, ''Remanufacturing of Fiberglass Reinforced Plastic (FRP) Underground Storage Tanks''.

(b) Repairs to fiberglass-reinforced plastic tanks may be made by the manufacturer's authorized representatives or in accordance with a code of practice developed by a nationally recognized association or an independent testing laboratory.

(c) Metal pipe sections and fittings that have released product as a result of corrosion or other damage must be replaced. Non-corrodible pipes and fittings may be repaired in accordance with the manufacturer's specifications.

(d) Repairs to secondary containment areas of tanks and piping used for interstitial monitoring and to containment sumps used for interstitial monitoring of piping must have the secondary containment tested for tightness according to the manufacturer's instructions, a code of practice developed by a nationally recognized association or independent testing laboratory, or according to requirements established by the implementing agency within 30 days following the date of completion of the repair. All other repairs to tanks and piping must be tightness tested in accordance with § 280.43(c) and § 280.44(b) within 30 days following the date of the completion of the repair except as provided in paragraphs (d)(1) through (3) of this section:

(1) The repaired tank is internally inspected in accordance with a code of practice developed by a nationally recognized association or an independent testing laboratory; or

(2) The repaired portion of the UST system is monitored monthly for releases in accordance with a method specified in § 280.43(d) through (i); or

(3) Another test method is used that is determined by the implementing agency to be no less protective of human health and the environment than those listed in paragraphs (d)(1) and (2) of this section.

Note to paragraph (d). The following codes of practice may be used to comply with paragraph (d) of this section:

(A) Steel Tank Institute Recommended Practice R012, ''Recommended Practice for Interstitial Tightness Testing of Existing Underground Double Wall Steel Tanks''; or

(B) Fiberglass Tank and Pipe Institute Protocol, ''Field Test Protocol for Testing the Annular Space of Installed Underground Fiberglass Double and Triple-Wall Tanks with Dry Annular Space''.

(C) Petroleum Equipment Institute Recommended Practice RP1200, ''Recommended Practices for the Testing and Verification of Spill, Overfill, Leak Detection and Secondary Containment Equipment at UST Facilities''.

(e) Within 6 months following the repair of any cathodically protected UST system, the cathodic protection system must be tested in accordance with § 280.31(b) and (c) to ensure that it is operating properly.

(f) Within 30 days following any repair to spill or overfill prevention equipment, the repaired spill or overfill prevention equipment must be tested or inspected, as appropriate, in accordance with § 280.35 to ensure it is operating properly.

(g) UST system owners and operators must maintain records (in accordance with § 280.34) of each repair until the UST system is permanently closed or undergoes a change-in-service pursuant to § 280.71.

§ 280.34 Reporting and recordkeeping.

Owners and operators of UST systems must cooperate fully with inspections, monitoring and testing conducted by the implementing agency, as well as requests for document submission, testing, and monitoring by the owner or operator pursuant to section 9005 of Subtitle I of the Solid Waste Disposal Act, as amended.

(a) *Reporting.* Owners and operators must submit the following information to the implementing agency:

(1) Notification for all UST systems (§ 280.22), which includes certification of installation for new UST systems (§ 280.20(e)) and notification when any person assumes ownership of an UST system (§ 280.22(b));

(2) Notification prior to UST systems switching to certain regulated substances (§ 280.32(b));

(3) Reports of all releases including suspected releases (§ 280.50), spills and overfills (§ 280.53), and confirmed releases (§ 280.61);

(4) Corrective actions planned or taken including initial abatement measures (§ 280.62), initial site characterization (§ 280.63), free product removal (§ 280.64), investigation of soil and groundwater cleanup (§ 280.65), and corrective action plan (§ 280.66); and

(5) A notification before permanent closure or change-in-service (§ 280.71).

(b) *Recordkeeping.* Owners and operators must maintain the following information:

(1) A corrosion expert's analysis of site corrosion potential if corrosion protection equipment is not used (§ 280.20(a)(4); § 280.20(b)(3)).

(2) Documentation of operation of corrosion protection equipment (§ 280.31(d));

(3) Documentation of compatibility for UST systems (§ 280.32(c));

(4) Documentation of UST system repairs (§ 280.33(g));

(5) Documentation of compliance for spill and overfill prevention equipment and containment sumps used for interstitial monitoring of piping (§ 280.35(c));

(6) Documentation of periodic walkthrough inspections (§ 280.36(b));

(7) Documentation of compliance with release detection requirements (§ 280.45);

(8) Results of the site investigation conducted at permanent closure (§ 280.74); and

(9) Documentation of operator training (§ 280.245).

(c) *Availability and maintenance of records.* Owners and operators must keep the records required either:

(1) At the UST site and immediately available for inspection by the implementing agency; or

(2) At a readily available alternative site and be provided for inspection to the implementing agency upon request.

(3) In the case of permanent closure records required under § 280.74, owners and operators are also provided with the additional alternative of mailing closure records to the implementing agency if they cannot be kept at the site or an alternative site as indicated in paragraphs (c)(1) and (2) of this section.

§ 280.35 Periodic testing of spill prevention equipment and containment sumps used for interstitial monitoring of piping and periodic inspection of overfill prevention equipment.

(a) Owners and operators of UST systems with spill and overfill prevention equipment and containment sumps used for interstitial monitoring of piping must meet these requirements to ensure the equipment is operating properly and will prevent releases to the environment:

(1) Spill prevention equipment (such as a catchment basin, spill bucket, or other spill containment device) and containment sumps used for interstitial monitoring of piping must prevent releases to the environment by meeting one of the following:

(i) The equipment is double walled and the integrity of both walls is periodically monitored at a frequency not less than the frequency of the walkthrough inspections described in § 280.36. Owners and operators must begin meeting paragraph (a)(1)(ii) of this section and conduct a test within 30 days of discontinuing periodic monitoring of this equipment; or

(ii) The spill prevention equipment and containment sumps used for interstitial monitoring of piping are tested at least once every three years to ensure the equipment is liquid tight by using vacuum, pressure, or liquid testing in accordance with one of the following criteria:

(A) Requirements developed by the manufacturer (Note: Owners and operators may use this option only if the manufacturer has developed requirements);

(B) Code of practice developed by a nationally recognized association or independent testing laboratory; or

(C) Requirements determined by the implementing agency to be no less protective of human health and the environment than the requirements listed in paragraphs (a)(1)(ii)(A) and (B) of this section.

(2) Overfill prevention equipment must be inspected at least once every three years. At a minimum, the inspection must ensure that overfill prevention equipment is set to activate at the correct level specified in § 280.20(c) and will activate when regulated substance reaches that level. Inspections must be conducted in accordance with one of the criteria in paragraph (a)(1)(ii)(A) through (C) of this section.

Note to paragraphs (a)(1)(ii) and (a)(2). The following code of practice may be used to comply with paragraphs (a)(1)(ii) and (a)(2) of this section: Petroleum Equipment Institute Publication RP1200, ''Recommended Practices for the Testing and Verification of Spill, Overfill, Leak Detection and Secondary Containment Equipment at UST Facilities''.

(b) Owners and operators must begin meeting these requirements as follows:

(1) For UST systems in use on or before October 13, 2015, the initial spill prevention equipment test, containment sump test and overfill prevention equipment inspection must be conducted not later than October 13, 2018.

(2) For UST systems brought into use after October 13, 2015, these requirements apply at installation.

(c) Owners and operators must maintain records as follows (in accordance with § 280.34) for spill prevention equipment, containment sumps used for interstitial monitoring of piping, and overfill prevention equipment:

(1) All records of testing or inspection must be maintained for three years; and

(2) For spill prevention equipment and containment sumps used for interstitial monitoring of piping not tested every three years, documentation showing that the prevention equipment is double walled and the integrity of both walls is periodically monitored must be maintained for as long as the equipment is periodically monitored.

§ 280.36 Periodic operation and maintenance walkthrough inspections.

(a) To properly operate and maintain UST systems, not later than October 13, 2018 owners and operators must meet one of the following:

(1) Conduct a walkthrough inspection that, at a minimum, checks the following equipment as specified below:

(i) Every 30 days (Exception: spill prevention equipment at UST systems receiving deliveries at intervals greater than every 30 days may be checked prior to each delivery):

(A) Spill prevention equipment—visually check for damage; remove liquid or debris; check for and remove obstructions in the fill pipe; check the fill cap to make sure it is securely on the fill pipe; and, for double walled spill prevention equipment with interstitial monitoring, check for a leak in the interstitial area; and

(B) Release detection equipment—check to make sure the release detection equipment is operating with no alarms or other unusual operating conditions present; and ensure records of release detection testing are reviewed and current; and

(ii) Annually:

(A) Containment sumps—visually check for damage, leaks to the containment area, or releases to the

environment; remove liquid (in contained sumps) or debris; and, for double walled sumps with interstitial monitoring, check for a leak in the interstitial area; and

(B) Hand held release detection equipment—check devices such as tank gauge sticks or groundwater bailers for operability and serviceability;

(2) Conduct operation and maintenance walkthrough inspections according to a standard code of practice developed by a nationally recognized association or independent testing laboratory that checks equipment comparable to paragraph (a)(1) of this section; or

Note to paragraph (a)(2). The following code of practice may be used to comply with paragraph (a)(2) of this section: Petroleum Equipment Institute Recommended Practice RP 900, ''Recommended Practices for the Inspection and Maintenance of UST Systems''.

(3) Conduct operation and maintenance walkthrough inspections developed by the implementing agency that checks equipment comparable to paragraph (a)(1) of this section.

(b) Owners and operators must maintain records (in accordance with § 280.34) of operation and maintenance walkthrough inspections for one year. Records must include a list of each area checked, whether each area checked was acceptable or needed action taken, a description of actions taken to correct an issue, and delivery records if spill prevention equipment is checked less frequently than every 30 days due to infrequent deliveries.

Subpart D—Release Detection

§ 280.40 General requirements for all UST systems.

(a) Owners and operators of UST systems must provide a method, or combination of methods, of release detection that:

(1) Can detect a release from any portion of the tank and the connected underground piping that routinely contains product;

(2) Is installed and calibrated in accordance with the manufacturer's instructions;

(3) Beginning on October 13, 2018, is operated and maintained, and electronic and mechanical components are tested for proper operation, in accordance with one of the following: manufacturer's instructions; a code of practice developed by a nationally recognized association or independent testing laboratory; or requirements determined by the implementing agency to be no less protective of human health and the environment than the two options listed in paragraphs (a)(1) and (2) of this section. A test of the proper operation must be performed at least annually and, at a minimum, as applicable to the facility, cover the following components and criteria:

(i) Automatic tank gauge and other controllers: test alarm; verify system configuration; test battery backup;

(ii) Probes and sensors: inspect for residual buildup; ensure floats move freely; ensure shaft is not damaged; ensure cables are free of kinks and breaks; test alarm operability and communication with controller;

(iii) Automatic line leak detector: test operation to meet criteria in § 280.44(a) by simulating a leak;

(iv) Vacuum pumps and pressure gauges: ensure proper communication with sensors and controller; and

(v) Hand-held electronic sampling equipment associated with groundwater and vapor monitoring: ensure proper operation.

Note to paragraph (a)(3). The following code of practice may be used to comply with paragraph (a)(3) of this section: Petroleum Equipment Institute Publication RP1200, ''Recommended Practices for the Testing and Verification of Spill, Overfill, Leak Detection and Secondary Containment Equipment at UST Facilities''.

(4) Meets the performance requirements in § 280.43, § 280.44, or subpart K of this part, as applicable, with any performance claims and their manner of determination described in writing by the equipment manufacturer or installer. In addition, the methods listed in § 280.43(b), (c), (d), (h), and (i), § 280.44(a) and (b), and subpart K of this part, must be capable of detecting the leak rate or quantity specified for that method in the corresponding section of the rule with a probability of detection of 0.95 and a probability of false alarm of 0.05.

(b) When a release detection method operated in accordance with the performance standards in § 280.43, § 280.44, or subpart K of this part indicates a release may have occurred, owners and operators must notify the implementing agency in accordance with subpart E of this part.

(c) Any UST system that cannot apply a method of release detection that complies with the requirements of this subpart must complete the closure procedures in subpart G of this part. For previously deferred UST systems described in subparts A and K of this part, this requirement applies after the effective dates described in § 280.10(a)(1)(ii) and (iii) and § 280.251(a).

§ 280.41 Requirements for petroleum UST systems.

Owners and operators of petroleum UST systems must provide release detection for tanks and piping as follows:

(a) *Tanks.* Tanks must be monitored for releases as follows:

(1) Tanks installed on or before April 11, 2016 must be monitored for releases at least every 30 days using one of the methods listed in § 280.43(d) through (i) except that:

(i) UST systems that meet the performance standards in § 280.20 or § 280.21, and the monthly inventory control requirements in § 280.43(a) or (b), may use tank tightness testing (conducted in accordance with § 280.43(c)) at least every 5 years until 10 years after the tank was installed; and

(ii) Tanks with capacity of 550 gallons or less and tanks with a capacity of 551 to 1,000 gallons that meet the tank diameter criteria in § 280.43(b) may use manual tank gauging (conducted in accordance with § 280.43(b)).

(2) Tanks installed after April 11, 2016 must be monitored for releases at least every 30 days in accordance with § 280.43(g).

(b) *Piping.* Underground piping that routinely contains regulated substances must be monitored for releases in a manner that meets one of the following requirements:

(1) Piping installed on or before April 11, 2016 must meet one of the following:

(i) *Pressurized piping.* Underground piping that conveys regulated substances under pressure must:

(A) Be equipped with an automatic line leak detector conducted in accordance with § 280.44(a); and

(B) Have an annual line tightness test conducted in accordance with § 280.44(b) or have monthly monitoring conducted in accordance with § 280.44(c).

(ii) *Suction piping.* Underground piping that conveys regulated substances under suction must either have a line tightness test conducted at least every 3 years and in accordance with § 280.44(b), or use a monthly monitoring method conducted in accordance with § 280.44(c). No release detection is required for suction piping that is designed and constructed to meet the following standards:

(A) The below-grade piping operates at less than atmospheric pressure;

(B) The below-grade piping is sloped so that the contents of the pipe will drain back into the storage tank if the suction is released;

(C) Only one check valve is included in each suction line;

(D) The check valve is located directly below and as close as practical to the suction pump; and

(E) A method is provided that allows compliance with paragraphs (b)(1)(ii)(B) through (D) of this section to be readily determined.

(2) Piping installed or replaced after April 11, 2016 must meet one of the following:

(i) Pressurized piping must be monitored for releases at least every 30 days in accordance with § 280.43(g) and be equipped with an automatic line leak detector in accordance with § 280.44(a)

(ii) Suction piping must be monitored for releases at least every 30 days in accordance with § 280.43(g). No release detection is required for suction piping that meets paragraphs (b)(1)(ii)(A) through (E) of this section.

§ 280.42 Requirements for hazardous substance UST systems.

Owners and operators of hazardous substance UST systems must provide containment that meets the following requirements and monitor these systems using § 280.43(g) at least every 30 days:

(a) Secondary containment systems must be designed, constructed, and installed to:

(1) Contain regulated substances leaked from the primary containment until they are detected and removed;

(2) Prevent the release of regulated substances to the environment at any time during the operational life of the UST system; and

(3) Be checked for evidence of a release at least every 30 days.

Note to paragraph (a). The provisions of 40 CFR 265.193, Containment and Detection of Releases, may be used to comply with these requirements for tanks installed on or before October 13, 2015.

(b) Double walled tanks must be designed, constructed, and installed to:

(1) Contain a leak from any portion of the inner tank within the outer wall; and

(2) Detect the failure of the inner wall.

(c) External liners (including vaults) must be designed, constructed, and installed to:

(1) Contain 100 percent of the capacity of the largest tank within its boundary;

(2) Prevent the interference of precipitation or groundwater intrusion with the ability to contain or detect a release of regulated substances; and

(3) Surround the tank completely (*i.e.,* it is capable of preventing lateral as well as vertical migration of regulated substances).

(d) Underground piping must be equipped with secondary containment that satisfies the requirements of this section (*e.g.,* trench liners, double walled pipe). In addition, underground piping that conveys regulated substances under pressure must be equipped with an automatic line leak detector in accordance with § 280.44(a).

(e) For hazardous substance UST systems installed on or before October 13, 2015 other methods of release detection may be used if owners and operators:

(1) Demonstrate to the implementing agency that an alternate method can detect a release of the stored substance as effectively as any of the methods allowed in § 280.43(b) through (i) can detect a release of petroleum;

(2) Provide information to the implementing agency on effective corrective action technologies, health risks, and chemical and physical properties of the stored substance, and the characteristics of the UST site; and,

(3) Obtain approval from the implementing agency to use the alternate release detection method before the installation and operation of the new UST system.

§ 280.43 Methods of release detection for tanks.

Each method of release detection for tanks used to meet the requirements of § 280.41 must be conducted in accordance with the following:

(a) *Inventory control.* Product inventory control (or another test of equivalent performance) must be conducted monthly to detect a release of at least 1.0 percent of flow-through plus 130 gallons on a monthly basis in the following manner:

(1) Inventory volume measurements for regulated substance inputs, withdrawals, and the amount still remaining in the tank are recorded each operating day;

(2) The equipment used is capable of measuring the level of product over the full range of the tank's height to the nearest one-eighth of an inch;

(3) The regulated substance inputs are reconciled with delivery receipts by measurement of the tank inventory volume before and after delivery;

(4) Deliveries are made through a drop tube that extends to within one foot of the tank bottom;

(5) Product dispensing is metered and recorded within the local standards for meter calibration or an accuracy of 6 cubic inches for every 5 gallons of product withdrawn; and

(6) The measurement of any water level in the bottom of the tank is made to the nearest one-eighth of an inch at least once a month.

Note to paragraph (a). Practices described in the American Petroleum Institute Recommended Practice RP 1621, ''Bulk Liquid Stock Control at Retail Outlets'' may be used, where applicable, as guidance in meeting the requirements of this paragraph (a).

(b) *Manual tank gauging.* Manual tank gauging must meet the following requirements:

(1) Tank liquid level measurements are taken at the beginning and ending of a period using the appropriate minimum duration of test value in the table below during which no liquid is added to or removed from the tank;

(2) Level measurements are based on an average of two consecutive stick readings at both the beginning and ending of the period;

(3) The equipment used is capable of measuring the level of product over the full range of the tank's height to the nearest one-eighth of an inch;

(4) A release is suspected and subject to the requirements of subpart E if the variation between beginning and ending measurements exceeds the weekly or monthly standards in the following table:

Nominal tank capacity	Minimum duration of test	Weekly standard (one test)	Monthly standard (four test average)
550 gallons or less	36 hours	10 gallons	5 gallons
551–1,000 gallons (when tank diameter is 64 inches)	44 hours	9 gallons	4 gallons
551–1,000 gallons (when tank diameter is 48 inches)	58 hours	12 gallons	6 gallons
551–1,000 gallons (also requires periodic tank tightness testing)	36 hours	13 gallons	7 gallons
1,001–2,000 gallons (also requires periodic tank tightness testing)	36 hours	26 gallons	13 gallons

(5) Tanks of 550 gallons or less nominal capacity and tanks with a nominal capacity of 551 to 1,000 gallons that meet the tank diameter criteria in the table in paragraph (b)(4) of this section may use this as the sole method of release detection. All other tanks with a nominal capacity of 551 to 2,000 gallons may use the method in place of inventory control in § 280.43(a). Tanks of greater than 2,000 gallons nominal capacity may not use this method to meet the requirements of this subpart.

(c) *Tank tightness testing.* Tank tightness testing (or another test of equivalent performance) must be capable of detecting a 0.1 gallon per hour leak rate from any portion of the tank that routinely contains product while accounting for the effects of thermal expansion or contraction of the product, vapor pockets, tank deformation, evaporation or condensation, and the location of the water table.

(d) *Automatic tank gauging.* Equipment for automatic tank gauging that tests for the loss of product and conducts inventory control must meet the following requirements:

(1) The automatic product level monitor test can detect a 0.2 gallon per hour leak rate from any portion of the tank that routinely contains product;

(2) The automatic tank gauging equipment must meet the inventory control (or other test of equivalent performance) requirements of § 280.43(a); and

(3) The test must be performed with the system operating in one of the following modes:

(i) In-tank static testing conducted at least once every 30 days; or

(ii) Continuous in-tank leak detection operating on an uninterrupted basis or operating within a process that allows the system to gather incremental measurements to determine the leak status of the tank at least once every 30 days.

(e) *Vapor monitoring.* Testing or monitoring for vapors within the soil gas of the excavation zone must meet the following requirements:

(1) The materials used as backfill are sufficiently porous (*e.g.,* gravel, sand, crushed rock) to readily allow diffusion of vapors from releases into the excavation area;

(2) The stored regulated substance, or a tracer compound placed in the tank system, is sufficiently volatile (*e.g.,* gasoline) to result in a vapor level that is detectable by the monitoring devices located in the excavation zone in the event of a release from the tank;

(3) The measurement of vapors by the monitoring device is not rendered inoperative by the groundwater, rainfall, or soil moisture or other known interferences so that a release could go undetected for more than 30 days;

(4) The level of background contamination in the excavation zone will not interfere with the method used to detect releases from the tank;

(5) The vapor monitors are designed and operated to detect any significant increase in concentration above background of the regulated substance stored in the tank system, a component or components of that substance, or a tracer compound placed in the tank system;

(6) In the UST excavation zone, the site is assessed to ensure compliance with the requirements in paragraphs (e)(1) through (4) of this section and to establish the number and positioning of monitoring wells that will detect releases within the excavation zone from any portion of the tank that routinely contains product; and

(7) Monitoring wells are clearly marked and secured to avoid unauthorized access and tampering.

(f) *Groundwater monitoring.* Testing or monitoring for liquids on the groundwater must meet the following requirements:

(1) The regulated substance stored is immiscible in water and has a specific gravity of less than one;

(2) Groundwater is never more than 20 feet from the ground surface and the hydraulic conductivity of the soil(s) between the UST system and the monitoring wells or devices is not less than 0.01 cm/sec (*e.g.,* the soil should consist of gravels, coarse to medium sands, coarse silts or other permeable materials);

(3) The slotted portion of the monitoring well casing must be designed to prevent migration of natural soils or filter pack into the well and to allow entry of regulated substance on the water table into the well under both high and low groundwater conditions;

(4) Monitoring wells shall be sealed from the ground surface to the top of the filter pack;

(5) Monitoring wells or devices intercept the excavation zone or are as close to it as is technically feasible;

(6) The continuous monitoring devices or manual methods used can detect the presence of at least one-eighth of an inch of free product on top of the groundwater in the monitoring wells;

(7) Within and immediately below the UST system excavation zone, the site is assessed to ensure compliance with the requirements in paragraphs (f)(1) through (5) of this section and to establish the number and positioning of monitoring wells or devices that will detect releases from any portion of the tank that routinely contains product; and

(8) Monitoring wells are clearly marked and secured to avoid unauthorized access and tampering.

(g) *Interstitial monitoring.* Interstitial monitoring between the UST system and a secondary barrier immediately around or beneath it may be used, but only if the system is designed, constructed, and installed to detect a leak from any portion of the tank that routinely contains product and also meets one of the following requirements:

(1) For double walled UST systems, the sampling or testing method can detect a leak through the inner wall in any portion of the tank that routinely contains product;

(2) For UST systems with a secondary barrier within the excavation zone, the sampling or testing method used can detect a leak between the UST system and the secondary barrier;

(i) The secondary barrier around or beneath the UST system consists of artificially constructed material that is sufficiently thick and impermeable (at least 10^{-6} cm/sec for the regulated substance stored) to direct a leak to the monitoring point and permit its detection;

(ii) The barrier is compatible with the regulated substance stored so that a leak from the UST system will not cause a deterioration of the barrier allowing a release to pass through undetected;

(iii) For cathodically protected tanks, the secondary barrier must be installed so that it does not interfere with the proper operation of the cathodic protection system;

(iv) The groundwater, soil moisture, or rainfall will not render the testing or sampling method used inoperative so that a release could go undetected for more than 30 days;

(v) The site is assessed to ensure that the secondary barrier is always above the groundwater and not in a 25-year flood plain, unless the barrier and monitoring designs are for use under such conditions; and,

(vi) Monitoring wells are clearly marked and secured to avoid unauthorized access and tampering.

(3) For tanks with an internally fitted liner, an automated device can detect a leak between the inner wall of the tank and the liner, and the liner is compatible with the substance stored.

(h) *Statistical inventory reconciliation.* Release detection methods based on the application of statistical principles to inventory data similar to those described in § 280.43(a) must meet the following requirements:

(1) Report a quantitative result with a calculated leak rate;

(2) Be capable of detecting a leak rate of 0.2 gallon per hour or a release of 150 gallons within 30 days; and

(3) Use a threshold that does not exceed one-half the minimum detectible leak rate.

(i) *Other methods.* Any other type of release detection method, or combination of methods, can be used if:

(1) It can detect a 0.2 gallon per hour leak rate or a release of 150 gallons within a month with a probability of detection of 0.95 and a probability of false alarm of 0.05; or

(2) The implementing agency may approve another method if the owner and operator can demonstrate that the method can detect a release as effectively as any of the methods allowed in paragraphs (c) through (h) of this section. In comparing methods, the implementing agency shall consider the size of release that the method can detect and the frequency and reliability with which it can be detected. If the method is approved, the owner and operator must comply with any conditions imposed by the implementing agency on its use to ensure the protection of human health and the environment.

§ 280.44 Methods of release detection for piping.

Each method of release detection for piping used to meet the requirements of § 280.41 must be conducted in accordance with the following:

(a) *Automatic line leak detectors.* Methods which alert the operator to the presence of a leak by restricting or shutting off the flow of regulated substances through piping or triggering an audible or visual alarm may be used only if they detect leaks of 3 gallons per hour at 10 pounds per square inch line pressure within 1 hour. An annual test of the operation of the leak detector must be conducted in accordance with § 280.40(a)(3).

(b) *Line tightness testing.* A periodic test of piping may be conducted only if it can detect a 0.1 gallon per hour leak rate at one and one-half times the operating pressure.

(c) *Applicable tank methods.* Except as described in § 280.41(a), any of the methods in § 280.43(e) through (i) may be used if they are designed to detect a release from any portion of the underground piping that routinely contains regulated substances.

§ 280.45 Release detection recordkeeping.

All UST system owners and operators must maintain records in accordance with § 280.34 demonstrating compliance with all applicable requirements of this subpart. These records must include the following:

(a) All written performance claims pertaining to any release detection system used, and the manner in which these claims have been justified or tested by the equipment manufacturer or installer, must be maintained for 5 years, or for another reasonable period of time determined by the implementing agency, from the date of installation. Not later than October 13, 2018, records of site assessments required under § 280.43(e)(6) and (f)(7) must be maintained for as long as the methods are used. Records of site assessments developed after October 13, 2015 must be signed by a professional engineer or professional geologist, or equivalent licensed professional with experience in environmental engineering, hydrogeology, or other relevant technical discipline acceptable to the implementing agency;

(b) The results of any sampling, testing, or monitoring must be maintained for at least one year, or for another reasonable period of time determined by the implementing agency, except as follows:

(1) The results of annual operation tests conducted in accordance with § 280.40(a)(3) must be maintained for three years. At a minimum, the results must list each component tested, indicate whether each component tested meets criteria in § 280.40(a)(3) or needs to have action taken, and describe any action taken to correct an issue; and

(2) The results of tank tightness testing conducted in accordance with § 280.43(c) must be retained until the next test is conducted; and

(3) The results of tank tightness testing, line tightness testing, and vapor monitoring using a tracer compound placed in the tank system conducted in accordance with § 280.252(d) must be retained until the next test is conducted; and

(c) Written documentation of all calibration, maintenance, and repair of release detection equipment permanently located on-site must be maintained for at least one year after the servicing work is completed, or for another reasonable time period determined by the implementing agency. Any schedules of required calibration and maintenance provided by the release detection equipment manufacturer must be retained for five years from the date of installation.

Subpart E—Release Reporting, Investigation, and Confirmation

§ 280.50 Reporting of suspected releases.

Owners and operators of UST systems must report to the implementing agency within 24 hours, or another reasonable period specified by the implementing agency, and follow the procedures in § 280.52 for any of the following conditions:

(a) The discovery by owners and operators or others of released regulated substances at the UST site or in the surrounding area (such as the presence of free product or vapors in soils, basements, sewer and utility lines, and nearby surface water).

(b) Unusual operating conditions observed by owners and operators (such as the erratic behavior of product dispensing equipment, the sudden loss of product from the UST system, an unexplained presence of water in the tank, or liquid in the interstitial space of secondarily contained systems), unless:

(1) The system equipment or component is found not to be releasing regulated substances to the environment;

(2) Any defective system equipment or component is immediately repaired or replaced; and

(3) For secondarily contained systems, except as provided for in § 280.43(g)(2)(iv), any liquid in the interstitial space not used as part of the interstitial monitoring method (for example, brine filled) is immediately removed.

(c) Monitoring results, including investigation of an alarm, from a release detection method required under §§ 280.41 and 280.42 that indicate a release may have occurred unless:

(1) The monitoring device is found to be defective, and is immediately repaired, recalibrated or replaced, and additional monitoring does not confirm the initial result;

(2) The leak is contained in the secondary containment and:

(i) Except as provided for in § 280.43(g)(2)(iv), any liquid in the interstitial space not used as part of the interstitial monitoring method (for example, brine filled) is immediately removed; and

(ii) Any defective system equipment or component is immediately repaired or replaced;

(3) In the case of inventory control described in § 280.43(a), a second month of data does not confirm the initial result or the investigation determines no release has occurred; or

(4) The alarm was investigated and determined to be a non-release event

(for example, from a power surge or caused by filling the tank during release detection testing).

§ 280.51 Investigation due to off-site impacts.

When required by the implementing agency, owners and operators of UST systems must follow the procedures in § 280.52 to determine if the UST system is the source of off-site impacts. These impacts include the discovery of regulated substances (such as the presence of free product or vapors in soils, basements, sewer and utility lines, and nearby surface and drinking waters) that has been observed by the implementing agency or brought to its attention by another party.

§ 280.52 Release investigation and confirmation steps.

Unless corrective action is initiated in accordance with subpart F, owners and operators must immediately investigate and confirm all suspected releases of regulated substances requiring reporting under § 280.50 within 7 days, or another reasonable time period specified by the implementing agency, using either the following steps or another procedure approved by the implementing agency:

(a) *System test.* Owners and operators must conduct tests (according to the requirements for tightness testing in §§ 280.43(c) and 280.44(b) or, as appropriate, secondary containment testing described in § 280.33(d)).

(1) The test must determine whether:

(i) A leak exists in that portion of the tank that routinely contains product, or the attached delivery piping; or

(ii) A breach of either wall of the secondary containment has occurred.

(2) If the system test confirms a leak into the interstice or a release, owners and operators must repair, replace, upgrade, or close the UST system. In addition, owners and operators must begin corrective action in accordance with subpart F of this part if the test results for the system, tank, or delivery piping indicate that a release exists.

(3) Further investigation is not required if the test results for the system, tank, and delivery piping do not indicate that a release exists and if environmental contamination is not the basis for suspecting a release.

(4) Owners and operators must conduct a site check as described in paragraph (b) of this section if the test results for the system, tank, and delivery piping do not indicate that a release exists but environmental contamination is the basis for suspecting a release.

(b) *Site check.* Owners and operators must measure for the presence of a release where contamination is most likely to be present at the UST site. In selecting sample types, sample locations, and measurement methods, owners and operators must consider the nature of the stored substance, the type of initial alarm or cause for suspicion, the type of backfill, the depth of groundwater, and other factors appropriate for identifying the presence and source of the release.

(1) If the test results for the excavation zone or the UST site indicate that a release has occurred, owners and operators must begin corrective action in accordance with subpart F of this part;

(2) If the test results for the excavation zone or the UST site do not indicate that a release has occurred, further investigation is not required.

§ 280.53 Reporting and cleanup of spills and overfills.

(a) Owners and operators of UST systems must contain and immediately clean up a spill or overfill and report to the implementing agency within 24 hours, or another reasonable time period specified by the implementing agency, and begin corrective action in accordance with subpart F of this part in the following cases:

(1) Spill or overfill of petroleum that results in a release to the environment that exceeds 25 gallons or another reasonable amount specified by the implementing agency, or that causes a sheen on nearby surface water; and

(2) Spill or overfill of a hazardous substance that results in a release to the environment that equals or exceeds its reportable quantity under CERCLA (40 CFR part 302).

Note to paragraph (a). Pursuant to §§ 302.6 and 355.40 of this chapter, a release of a hazardous substance equal to or in excess of its reportable quantity must also be reported immediately (rather than within 24 hours) to the National Response Center under sections 102 and 103 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 and to appropriate state and local authorities under Title III of the Superfund Amendments and Reauthorization Act of 1986.

(b) Owners and operators of UST systems must contain and immediately clean up a spill or overfill of petroleum that is less than 25 gallons or another reasonable amount specified by the implementing agency, and a spill or overfill of a hazardous substance that is less than the reportable quantity. If cleanup cannot be accomplished within 24 hours, or another reasonable time period established by the implementing agency, owners and operators must immediately notify the implementing agency.

Subpart F—Release Response and Corrective Action for UST Systems Containing Petroleum or Hazardous Substances

§ 280.60 General.

Owners and operators of petroleum or hazardous substance UST systems must, in response to a confirmed release from the UST system, comply with the requirements of this subpart except for USTs excluded under § 280.10(b) and UST systems subject to RCRA Subtitle C corrective action requirements under section 3004(u) of the Resource Conservation and Recovery Act, as amended.

§ 280.61 Initial response.

Upon confirmation of a release in accordance with § 280.52 or after a release from the UST system is identified in any other manner, owners and operators must perform the following initial response actions within 24 hours of a release or within another reasonable period of time determined by the implementing agency:

(a) Report the release to the implementing agency (*e.g.,* by telephone or electronic mail);

(b) Take immediate action to prevent any further release of the regulated substance into the environment; and

(c) Identify and mitigate fire, explosion, and vapor hazards.

§ 280.62 Initial abatement measures and site check.

(a) Unless directed to do otherwise by the implementing agency, owners and operators must perform the following abatement measures:

(1) Remove as much of the regulated substance from the UST system as is necessary to prevent further release to the environment;

(2) Visually inspect any aboveground releases or exposed belowground releases and prevent further migration of the released substance into surrounding soils and groundwater;

(3) Continue to monitor and mitigate any additional fire and safety hazards posed by vapors or free product that have migrated from the UST excavation zone and entered into subsurface structures (such as sewers or basements);

(4) Remedy hazards posed by contaminated soils that are excavated or exposed as a result of release confirmation, site investigation, abatement, or corrective action activities. If these remedies include treatment or disposal of soils, the owner and operator must comply with applicable state and local requirements;

(5) Measure for the presence of a release where contamination is most

likely to be present at the UST site, unless the presence and source of the release have been confirmed in accordance with the site check required by § 280.52(b) or the closure site assessment of § 280.72(a). In selecting sample types, sample locations, and measurement methods, the owner and operator must consider the nature of the stored substance, the type of backfill, depth to groundwater and other factors as appropriate for identifying the presence and source of the release; and

(6) Investigate to determine the possible presence of free product, and begin free product removal as soon as practicable and in accordance with § 280.64.

(b) Within 20 days after release confirmation, or within another reasonable period of time determined by the implementing agency, owners and operators must submit a report to the implementing agency summarizing the initial abatement steps taken under paragraph (a) of this section and any resulting information or data.

§ 280.63 Initial site characterization.

(a) Unless directed to do otherwise by the implementing agency, owners and operators must assemble information about the site and the nature of the release, including information gained while confirming the release or completing the initial abatement measures in §§ 280.60 and 280.61. This information must include, but is not necessarily limited to the following:

(1) Data on the nature and estimated quantity of release;

(2) Data from available sources and/or site investigations concerning the following factors: Surrounding populations, water quality, use and approximate locations of wells potentially affected by the release, subsurface soil conditions, locations of subsurface sewers, climatological conditions, and land use;

(3) Results of the site check required under § 280.62(a)(5); and

(4) Results of the free product investigations required under § 280.62(a)(6), to be used by owners and operators to determine whether free product must be recovered under § 280.64.

(b) Within 45 days of release confirmation or another reasonable period of time determined by the implementing agency, owners and operators must submit the information collected in compliance with paragraph (a) of this section to the implementing agency in a manner that demonstrates its applicability and technical adequacy, or in a format and according to the schedule required by the implementing agency.

§ 280.64 Free product removal.

At sites where investigations under § 280.62(a)(6) indicate the presence of free product, owners and operators must remove free product to the maximum extent practicable as determined by the implementing agency while continuing, as necessary, any actions initiated under §§ 280.61 through 280.63, or preparing for actions required under §§ 280.65 through 280.66. In meeting the requirements of this section, owners and operators must:

(a) Conduct free product removal in a manner that minimizes the spread of contamination into previously uncontaminated zones by using recovery and disposal techniques appropriate to the hydrogeologic conditions at the site, and that properly treats, discharges or disposes of recovery byproducts in compliance with applicable local, state, and federal regulations;

(b) Use abatement of free product migration as a minimum objective for the design of the free product removal system;

(c) Handle any flammable products in a safe and competent manner to prevent fires or explosions; and

(d) Unless directed to do otherwise by the implementing agency, prepare and submit to the implementing agency, within 45 days after confirming a release, a free product removal report that provides at least the following information:

(1) The name of the person(s) responsible for implementing the free product removal measures;

(2) The estimated quantity, type, and thickness of free product observed or measured in wells, boreholes, and excavations;

(3) The type of free product recovery system used;

(4) Whether any discharge will take place on-site or off-site during the recovery operation and where this discharge will be located;

(5) The type of treatment applied to, and the effluent quality expected from, any discharge;

(6) The steps that have been or are being taken to obtain necessary permits for any discharge; and

(7) The disposition of the recovered free product.

§ 280.65 Investigations for soil and groundwater cleanup.

(a) In order to determine the full extent and location of soils contaminated by the release and the presence and concentrations of dissolved product contamination in the groundwater, owners and operators must conduct investigations of the release, the release site, and the surrounding area possibly affected by the release if any of the following conditions exist:

(1) There is evidence that groundwater wells have been affected by the release (*e.g.,* as found during release confirmation or previous corrective action measures);

(2) Free product is found to need recovery in compliance with § 280.64;

(3) There is evidence that contaminated soils may be in contact with groundwater (*e.g.,* as found during conduct of the initial response measures or investigations required under §§ 280.60 through 280.64); and

(4) The implementing agency requests an investigation, based on the potential effects of contaminated soil or groundwater on nearby surface water and groundwater resources.

(b) Owners and operators must submit the information collected under paragraph (a) of this section as soon as practicable or in accordance with a schedule established by the implementing agency.

§ 280.66 Corrective action plan.

(a) At any point after reviewing the information submitted in compliance with §§ 280.61 through 280.63, the implementing agency may require owners and operators to submit additional information or to develop and submit a corrective action plan for responding to contaminated soils and groundwater. If a plan is required, owners and operators must submit the plan according to a schedule and format established by the implementing agency. Alternatively, owners and operators may, after fulfilling the requirements of §§ 280.61 through 280.63, choose to submit a corrective action plan for responding to contaminated soil and groundwater. In either case, owners and operators are responsible for submitting a plan that provides for adequate protection of human health and the environment as determined by the implementing agency, and must modify their plan as necessary to meet this standard.

(b) The implementing agency will approve the corrective action plan only after ensuring that implementation of the plan will adequately protect human health, safety, and the environment. In making this determination, the implementing agency should consider the following factors as appropriate:

(1) The physical and chemical characteristics of the regulated

substance, including its toxicity, persistence, and potential for migration;

(2) The hydrogeologic characteristics of the facility and the surrounding area;

(3) The proximity, quality, and current and future uses of nearby surface water and groundwater;

(4) The potential effects of residual contamination on nearby surface water and groundwater;

(5) An exposure assessment; and

(6) Any information assembled in compliance with this subpart.

(c) Upon approval of the corrective action plan or as directed by the implementing agency, owners and operators must implement the plan, including modifications to the plan made by the implementing agency. They must monitor, evaluate, and report the results of implementing the plan in accordance with a schedule and in a format established by the implementing agency.

(d) Owners and operators may, in the interest of minimizing environmental contamination and promoting more effective cleanup, begin cleanup of soil and groundwater before the corrective action plan is approved provided that they:

(1) Notify the implementing agency of their intention to begin cleanup;

(2) Comply with any conditions imposed by the implementing agency, including halting cleanup or mitigating adverse consequences from cleanup activities; and

(3) Incorporate these self-initiated cleanup measures in the corrective action plan that is submitted to the implementing agency for approval.

§ 280.67 Public participation.

(a) For each confirmed release that requires a corrective action plan, the implementing agency must provide notice to the public by means designed to reach those members of the public directly affected by the release and the planned corrective action. This notice may include, but is not limited to, public notice in local newspapers, block advertisements, public service announcements, publication in a state register, letters to individual households, or personal contacts by field staff.

(b) The implementing agency must ensure that site release information and decisions concerning the corrective action plan are made available to the public for inspection upon request.

(c) Before approving a corrective action plan, the implementing agency may hold a public meeting to consider comments on the proposed corrective action plan if there is sufficient public interest, or for any other reason.

(d) The implementing agency must give public notice that complies with paragraph (a) of this section if implementation of an approved corrective action plan does not achieve the established cleanup levels in the plan and termination of that plan is under consideration by the implementing agency.

Subpart G—Out-of-Service UST Systems and Closure

§ 280.70 Temporary closure.

(a) When an UST system is temporarily closed, owners and operators must continue operation and maintenance of corrosion protection in accordance with § 280.31, and any release detection in accordance with subparts D and K of this part. Subparts E and F of this part must be complied with if a release is suspected or confirmed. However, release detection and release detection operation and maintenance testing and inspections in subparts C and D of this part are not required as long as the UST system is empty. The UST system is empty when all materials have been removed using commonly employed practices so that no more than 2.5 centimeters (one inch) of residue, or 0.3 percent by weight of the total capacity of the UST system, remain in the system. In addition, spill and overfill operation and maintenance testing and inspections in subpart C of this part are not required.

(b) When an UST system is temporarily closed for 3 months or more, owners and operators must also comply with the following requirements:

(1) Leave vent lines open and functioning; and

(2) Cap and secure all other lines, pumps, manways, and ancillary equipment.

(c) When an UST system is temporarily closed for more than 12 months, owners and operators must permanently close the UST system if it does not meet either performance standards in § 280.20 for new UST systems or the upgrading requirements in § 280.21, *except that* the spill and overfill equipment requirements do not have to be met. Owners and operators must permanently close the substandard UST systems at the end of this 12-month period in accordance with §§ 280.71 through 280.74, *unless* the implementing agency provides an extension of the 12-month temporary closure period. Owners and operators must complete a site assessment in accordance with § 280.72 before such an extension can be applied for.

§ 280.71 Permanent closure and changes-in-service.

(a) At least 30 days before beginning either permanent closure or a change-in-service under paragraphs (b) and (c) of this section, or within another reasonable time period determined by the implementing agency, owners and operators must notify the implementing agency of their intent to permanently close or make the change-in-service, *unless* such action is in response to corrective action. The required assessment of the excavation zone under § 280.72 must be performed after notifying the implementing agency but before completion of the permanent closure or a change-in-service.

(b) To permanently close a tank, owners and operators must empty and clean it by removing all liquids and accumulated sludges. All tanks taken out of service permanently must: be removed from the ground, filled with an inert solid material, or closed in place in a manner approved by the implementing agency.

(c) Continued use of an UST system to store a non-regulated substance is considered a change-in-service. Before a change-in-service, owners and operators must empty and clean the tank by removing all liquid and accumulated sludge and conduct a site assessment in accordance with § 280.72.

Note to § 280.71. The following cleaning and closure procedures may be used to comply with this section:

(A) American Petroleum Institute Recommended Practice RP 1604, ''Closure of Underground Petroleum Storage Tanks'';

(B) American Petroleum Institute Standard 2015, ''Safe Entry and Cleaning of Petroleum Storage Tanks, Planning and Managing Tank Entry From Decommissioning Through Recommissioning'';

(C) American Petroleum Institute Recommended Practice 2016, ''Guidelines and Procedures for Entering and Cleaning Petroleum Storage Tanks'';

(D) American Petroleum Institute Recommended Practice RP 1631, ''Interior Lining and Periodic Inspection of Underground Storage Tanks,'' may be used as guidance for compliance with this section;

(E) National Fire Protection Association Standard 326, ''Standard for the Safeguarding of Tanks and Containers for Entry, Cleaning, or Repair''; and

(F) National Institute for Occupational Safety and Health Publication 80–106, ''Criteria for a Recommended Standard . . . Working in Confined Space'' may be used as guidance for conducting safe closure procedures at some hazardous substance tanks.

§ 280.72 Assessing the site at closure or change-in-service.

(a) Before permanent closure or a change-in-service is completed, owners

and operators must measure for the presence of a release where contamination is most likely to be present at the UST site. In selecting sample types, sample locations, and measurement methods, owners and operators must consider the method of closure, the nature of the stored substance, the type of backfill, the depth to groundwater, and other factors appropriate for identifying the presence of a release. The requirements of this section are satisfied if one of the external release detection methods allowed in § 280.43(e) and (f) is operating in accordance with the requirements in § 280.43 at the time of closure, and indicates no release has occurred.

(b) If contaminated soils, contaminated groundwater, or free product as a liquid or vapor is discovered under paragraph (a) of this section, or by any other manner, owners and operators must begin corrective action in accordance with subpart F of this part.

§ 280.73 Applicability to previously closed UST systems.

When directed by the implementing agency, the owner and operator of an UST system permanently closed before December 22, 1988 must assess the excavation zone and close the UST system in accordance with this subpart if releases from the UST may, in the judgment of the implementing agency, pose a current or potential threat to human health and the environment.

§ 280.74 Closure records.

Owners and operators must maintain records in accordance with § 280.34 that are capable of demonstrating compliance with closure requirements under this subpart. The results of the excavation zone assessment required in § 280.72 must be maintained for at least three years after completion of permanent closure or change-in-service in one of the following ways:

(a) By the owners and operators who took the UST system out of service;

(b) By the current owners and operators of the UST system site; or

(c) By mailing these records to the implementing agency if they cannot be maintained at the closed facility.

Subpart H—Financial Responsibility

§ 280.90 Applicability.

(a) This subpart applies to owners and operators of all petroleum underground storage tank (UST) systems except as otherwise provided in this section.

(b) Owners and operators of petroleum UST systems are subject to these requirements in accordance with § 280.91.

(c) State and Federal government entities whose debts and liabilities are the debts and liabilities of a state or the United States are exempt from the requirements of this subpart.

(d) The requirements of this subpart do not apply to owners and operators of any UST system described in § 280.10(b), (c)(1), (c)(3), or (c)(4).

(e) If the owner and operator of a petroleum underground storage tank are separate persons, only one person is required to demonstrate financial responsibility; however, both parties are liable in event of noncompliance.

§ 280.91 Compliance dates.

Owners of petroleum underground storage tanks must comply with the requirements of this subpart. Previously deferred UST systems must comply with the requirements of this subpart according to the schedule in § 280.251(a).

§ 280.92 Definition of terms.

When used in this subpart, the following terms shall have the meanings given below:

Accidental release means any sudden or nonsudden release of petroleum arising from operating an underground storage tank that results in a need for corrective action and/or compensation for bodily injury or property damage neither expected nor intended by the tank owner or operator.

Bodily injury shall have the meaning given to this term by applicable state law; however, this term shall not include those liabilities which, consistent with standard insurance industry practices, are excluded from coverage in liability insurance policies for bodily injury.

Chief Financial Officer, in the case of local government owners and operators, means the individual with the overall authority and responsibility for the collection, disbursement, and use of funds by the local government.

Controlling interest means direct ownership of at least 50 percent of the voting stock of another entity.

Director of the Implementing Agency means the EPA Regional Administrator, or, in the case of a state with a program approved under section 9004, the Director of the designated state or local agency responsible for carrying out an approved UST program.

Financial reporting year means the latest consecutive twelve-month period for which any of the following reports used to support a financial test is prepared:

(1) A 10–K report submitted to the SEC;

(2) An annual report of tangible net worth submitted to Dun and Bradstreet; or

(3) Annual reports submitted to the Energy Information Administration or the Rural Utilities Service.

Note to the definition of *Financial reporting year.* ''Financial reporting year'' may thus comprise a fiscal or a calendar year period.

Legal defense cost is any expense that an owner or operator or provider of financial assurance incurs in defending against claims or actions brought:

(1) By EPA or a state to require corrective action or to recover the costs of corrective action;

(2) By or on behalf of a third party for bodily injury or property damage caused by an accidental release; or

(3) By any person to enforce the terms of a financial assurance mechanism.

Local government shall have the meaning given this term by applicable state law and includes Indian tribes. The term is generally intended to include:

(1) Counties, municipalities, townships, separately chartered and operated special districts (including local government public transit systems and redevelopment authorities), and independent school districts authorized as governmental bodies by state charter or constitution; and

(2) Special districts and independent school districts established by counties, municipalities, townships, and other general purpose governments to provide essential services.

Occurrence means an accident, including continuous or repeated exposure to conditions, which results in a release from an underground storage tank.

Note to the definition of *Occurrence.* This definition is intended to assist in the understanding of these regulations and is not intended either to limit the meaning of ''occurrence'' in a way that conflicts with standard insurance usage or to prevent the use of other standard insurance terms in place of ''occurrence.''

Owner or operator, when the owner or operator are separate parties, refers to the party that is obtaining or has obtained financial assurances.

Petroleum marketing facilities include all facilities at which petroleum is produced or refined and all facilities from which petroleum is sold or transferred to other petroleum marketers or to the public.

Property damage shall have the meaning given this term by applicable state law. This term shall not include those liabilities which, consistent with standard insurance industry practices,

are excluded from coverage in liability insurance policies for property damage. However, such exclusions for property damage shall not include corrective action associated with releases from tanks which are covered by the policy.

Provider of financial assurance means an entity that provides financial assurance to an owner or operator of an underground storage tank through one of the mechanisms listed in §§ 280.95 through 280.107, including a guarantor, insurer, risk retention group, surety, issuer of a letter of credit, issuer of a state-required mechanism, or a state.

Substantial business relationship means the extent of a business relationship necessary under applicable state law to make a guarantee contract issued incident to that relationship valid and enforceable. A guarantee contract is issued ''incident to that relationship'' if it arises from and depends on existing economic transactions between the guarantor and the owner or operator.

Substantial governmental relationship means the extent of a governmental relationship necessary under applicable state law to make an added guarantee contract issued incident to that relationship valid and enforceable. A guarantee contract is issued ''incident to that relationship'' if it arises from a clear commonality of interest in the event of an UST release such as coterminous boundaries, overlapping constituencies, common groundwater aquifer, or other relationship other than monetary compensation that provides a motivation for the guarantor to provide a guarantee.

Tangible net worth means the tangible assets that remain after deducting liabilities; such assets do not include intangibles such as goodwill and rights to patents or royalties. For purposes of this definition, ''assets'' means all existing and all probable future economic benefits obtained or controlled by a particular entity as a result of past transactions.

Termination under § 280.97(b)(1) and (2) means only those changes that could result in a gap in coverage as where the insured has not obtained substitute coverage or has obtained substitute coverage with a different retroactive date than the retroactive date of the original policy.

§ 280.93 Amount and scope of required financial responsibility.

(a) Owners or operators of petroleum underground storage tanks must demonstrate financial responsibility for taking corrective action and for compensating third parties for bodily injury and property damage caused by accidental releases arising from the operation of petroleum underground storage tanks in at least the following per-occurrence amounts:

(1) For owners or operators of petroleum underground storage tanks that are located at petroleum marketing facilities, or that handle an average of more than 10,000 gallons of petroleum per month based on annual throughput for the previous calendar year; $1 million.

(2) For all other owners or operators of petroleum underground storage tanks; $500,000.

(b) Owners or operators of petroleum underground storage tanks must demonstrate financial responsibility for taking corrective action and for compensating third parties for bodily injury and property damage caused by accidental releases arising from the operation of petroleum underground storage tanks in at least the following annual aggregate amounts:

(1) For owners or operators of 1 to 100 petroleum underground storage tanks, $1 million; and

(2) For owners or operators of 101 or more petroleum underground storage tanks, $2 million.

(c) For the purposes of paragraphs (b) and (f) of this section, only, ''a petroleum underground storage tank'' means a single containment unit and does not mean combinations of single containment units.

(d) Except as provided in paragraph (e) of this section, if the owner or operator uses separate mechanisms or separate combinations of mechanisms to demonstrate financial responsibility for:

(1) Taking corrective action;

(2) Compensating third parties for bodily injury and property damage caused by sudden accidental releases; or

(3) Compensating third parties for bodily injury and property damage caused by nonsudden accidental releases, the amount of assurance provided by each mechanism or combination of mechanisms must be in the full amount specified in paragraphs (a) and (b) of this section.

(e) If an owner or operator uses separate mechanisms or separate combinations of mechanisms to demonstrate financial responsibility for different petroleum underground storage tanks, the annual aggregate required shall be based on the number of tanks covered by each such separate mechanism or combination of mechanisms.

(f) Owners or operators shall review the amount of aggregate assurance provided whenever additional petroleum underground storage tanks are acquired or installed. If the number of petroleum underground storage tanks for which assurance must be provided exceeds 100, the owner or operator shall demonstrate financial responsibility in the amount of at least $2 million of annual aggregate assurance by the anniversary of the date on which the mechanism demonstrating financial responsibility became effective. If assurance is being demonstrated by a combination of mechanisms, the owner or operator shall demonstrate financial responsibility in the amount of at least $2 million of annual aggregate assurance by the first-occurring effective date anniversary of any one of the mechanisms combined (other than a financial test or guarantee) to provide assurance.

(g) The amounts of assurance required under this section exclude legal defense costs.

(h) The required per-occurrence and annual aggregate coverage amounts do not in any way limit the liability of the owner or operator.

§ 280.94 Allowable mechanisms and combinations of mechanisms.

(a) Subject to the limitations of paragraphs (b) and (c) of this section:

(1) An owner or operator, including a local government owner or operator, may use any one or combination of the mechanisms listed in §§ 280.95 through 280.103 to demonstrate financial responsibility under this subpart for one or more underground storage tanks; and

(2) A local government owner or operator may use any one or combination of the mechanisms listed in §§ 280.104 through 280.107 to demonstrate financial responsibility under this subpart for one or more underground storage tanks.

(b) An owner or operator may use a guarantee under § 280.96 or surety bond under § 280.98 to establish financial responsibility only if the Attorney(s) General of the state(s) in which the underground storage tanks are located has (have) submitted a written statement to the implementing agency that a guarantee or surety bond executed as described in this section is a legally valid and enforceable obligation in that state.

(c) An owner or operator may use self-insurance in combination with a guarantee only if, for the purpose of meeting the requirements of the financial test under this rule, the financial statements of the owner or operator are not consolidated with the financial statements of the guarantor.

§ 280.95 Financial test of self-insurance.

(a) An owner or operator, and/or guarantor, may satisfy the requirements

of § 280.93 by passing a financial test as specified in this section. To pass the financial test of self-insurance, the owner or operator, and/or guarantor must meet the criteria of paragraph (b) or (c) of this section based on year-end financial statements for the latest completed fiscal year.

(b)(1) The owner or operator, and/or guarantor, must have a tangible net worth of at least ten times:

(i) The total of the applicable aggregate amount required by § 280.93, based on the number of underground storage tanks for which a financial test is used to demonstrate financial responsibility to EPA under this section or to a state implementing agency under a state program approved by EPA under 40 CFR part 281;

(ii) The sum of the corrective action cost estimates, the current closure and post-closure care cost estimates, and amount of liability coverage for which a financial test is used to demonstrate financial responsibility to EPA under 40 CFR 264.101, 264.143, 264.145, 265.143, 265.145, 264.147, and 265.147 or to a state implementing agency under a state program authorized by EPA under 40 CFR part 271; and

(iii) The sum of current plugging and abandonment cost estimates for which a financial test is used to demonstrate financial responsibility to EPA under 40 CFR 144.63 or to a state implementing agency under a state program authorized by EPA under 40 CFR part 145.

(2) The owner or operator, and/or guarantor, must have a tangible net worth of at least $10 million.

(3) The owner or operator, and/or guarantor, must have a letter signed by the chief financial officer worded as specified in paragraph (d) of this section.

(4) The owner or operator, and/or guarantor, must either:

(i) File financial statements annually with the U.S. Securities and Exchange Commission, the Energy Information Administration, or the Rural Utilities Service; or

(ii) Report annually the firm's tangible net worth to Dun and Bradstreet, and Dun and Bradstreet must have assigned the firm a financial strength rating of 4A or 5A.

(5) The firm's year-end financial statements, if independently audited, cannot include an adverse auditor's opinion, a disclaimer of opinion, or a ''going concern'' qualification.

(c)(1) The owner or operator, and/or guarantor must meet the financial test requirements of 40 CFR 264.147(f)(1), substituting the appropriate amounts specified in § 280.93(b)(1) and (2) for the ''amount of liability coverage'' each time specified in that section.

(2) The fiscal year-end financial statements of the owner or operator, and/or guarantor, must be examined by an independent certified public accountant and be accompanied by the accountant's report of the examination.

(3) The firm's year-end financial statements cannot include an adverse auditor's opinion, a disclaimer of opinion, or a ''going concern'' qualification.

(4) The owner or operator, and/or guarantor, must have a letter signed by the chief financial officer, worded as specified in paragraph (d) of this section.

(5) If the financial statements of the owner or operator, and/or guarantor, are not submitted annually to the U.S. Securities and Exchange Commission, the Energy Information Administration or the Rural Utilities Service, the owner or operator, and/or guarantor, must obtain a special report by an independent certified public accountant stating that:

(i) He has compared the data that the letter from the chief financial officer specifies as having been derived from the latest year-end financial statements of the owner or operator, and/or guarantor, with the amounts in such financial statements; and

(ii) In connection with that comparison, no matters came to his attention which caused him to believe that the specified data should be adjusted.

(d) To demonstrate that it meets the financial test under paragraph (b) or (c) of this section, the chief financial officer of the owner or operator, or guarantor, must sign, within 120 days of the close of each financial reporting year, as defined by the twelve-month period for which financial statements used to support the financial test are prepared, a letter worded exactly as follows, except that the instructions in brackets are to be replaced by the relevant information and the brackets deleted:

Letter From Chief Financial Officer

I am the chief financial officer of [insert: name and address of the owner or operator, or guarantor]. This letter is in support of the use of [insert: ''the financial test of self-insurance,'' and/or ''guarantee''] to demonstrate financial responsibility for [insert: ''taking corrective action'' and/or ''compensating third parties for bodily injury and property damage''] caused by [insert: ''sudden accidental releases'' or ''nonsudden accidental releases'' or ''accidental releases''] in the amount of at least [insert: dollar amount] per occurrence and [insert: dollar amount] annual aggregate arising from operating (an) underground storage tank(s).

Underground storage tanks at the following facilities are assured by this financial test or a financial test under an authorized State program by this [insert: ''owner or operator,'' and/or ''guarantor'']: [List for each facility: the name and address of the facility where tanks assured by this financial test are located, and whether tanks are assured by this financial test or a financial test under a State program approved under 40 CFR part 281. If separate mechanisms or combinations of mechanisms are being used to assure any of the tanks at this facility, list each tank assured by this financial test or a financial test under a State program authorized under 40 CFR part 281 by the tank identification number provided in the notification submitted pursuant to 40 CFR 280.22 or the corresponding State requirements.]

A [insert: ''financial test,'' and/or ''guarantee''] is also used by this [insert: ''owner or operator,'' or ''guarantor''] to demonstrate evidence of financial responsibility in the following amounts under other EPA regulations or state programs authorized by EPA under 40 CFR parts 271 and 145:

EPA Regulations	Amount
Closure (§§ 264.143 and 265.143)	$____
Post-Closure Care (§§ 264.145 and 265.145)	$____
Liability Coverage (§§ 264.147 and 265.147)	$____
Corrective Action (§ 264.101(b))	$____
Plugging and Abandonment (§ 144.63)	$____
Closure	$____
Post-Closure Care	$____
Liability Coverage	$____
Corrective Action	$____
Plugging and Abandonment	$____
Total	$____

This [insert: ''owner or operator,'' or ''guarantor''] has not received an adverse opinion, a disclaimer of opinion, or a ''going concern'' qualification from an independent auditor on his financial statements for the latest completed fiscal year.

[Fill in the information for Alternative I if the criteria of paragraph (b) of § 280.95 are being used to demonstrate compliance with the financial test requirements. Fill in the information for Alternative II if the criteria of paragraph (c) of § 280.95 are being used to demonstrate compliance with the financial test requirements.]

Alternative I

1. Amount of annual UST aggregate coverage being assured by a financial test, and/or guarantee ..... $____
2. Amount of corrective action, closure and post-closure care costs, liability coverage, and plugging and abandonment costs covered by a financial test, and/or guarantee ..... $____
3. Sum of lines 1 and 2 ..... $____
4. Total tangible assets ..... $____
5. Total liabilities [if any of the amount reported on line 3 is included in total liabilities, you may deduct that amount from this line and add that amount to line 6] ..... $____
6. Tangible net worth [subtract line 5 from line 4] ..... $____

	Yes No
7. Is line 6 at least $10 million?	__ __
8. Is line 6 at least 10 times line 3?	__ __
9. Have financial statements for the latest fiscal year been filed with the Securities and Exchange Commission?	__ __
10. Have financial statements for the latest fiscal year been filed with the Energy Information Administration?	__ __
11. Have financial statements for the latest fiscal year been filed with the Rural Utilities Service?	__ __
12. Has financial information been provided to Dun and Bradstreet, and has Dun and Bradstreet provided a financial strength rating of 4A or 5A? [Answer ''Yes'' only if both criteria have been met.]	.....

Alternative II

1. Amount of annual UST aggregate coverage being assured by a test, and/or guarantee ..... $____
2. Amount of corrective action, closure and post-closure care costs, liability coverage, and plugging and abandonment costs covered by a financial test, and/or guarantee ..... $____
3. Sum of lines 1 and 2 ..... $____
4. Total tangible assets ..... $____
5. Total liabilities [if any of the amount reported on line 3 is included in total liabilities, you may deduct that amount from this line and add that amount to line 6] ..... $____
6. Tangible net worth [subtract line 5 from line 4] ..... $____
7. Total assets in the U.S. [required only if less than 90 percent of assets are located in the U.S.] ..... $____

	Yes No
8. Is line 6 at least $10 million?	__ __
	__ __
9. Is line 6 at least 6 times line 3?	__ __

Alternative I

10. Are at least 90 percent of assets located in the U.S.? [If ''No,'' complete line 11.]	__ __
11. Is line 7 at least 6 times line 3? [Fill in either lines 12–15 or lines 16–18:]	__ __
	Yes No
12. Current assets	$____
13. Current liabilities	$____
14. Net working capital [subtract line 13 from line 12]	$____
	Yes No
15. Is line 14 at least 6 times line 3?	__ __
16. Current bond rating of most recent bond issue	__ __
17. Name of rating service	__ __
18. Date of maturity of bond	__ __
19. Have financial statements for the latest fiscal year been filed with the SEC, the Energy Information Administration, or the Rural Utilities Service?	__ __

[If ''No,'' please attach a report from an independent certified public accountant certifying that there are no material differences between the data as reported in lines 4–18 above and the financial statements for the latest fiscal year.]

[For both Alternative I and Alternative II complete the certification with this statement.]

I hereby certify that the wording of this letter is identical to the wording specified in 40 CFR 280.95(d) as such regulations were constituted on the date shown immediately below.

[Signature]
[Name]
[Title]
[Date]

(e) If an owner or operator using the test to provide financial assurance finds that he or she no longer meets the requirements of the financial test based on the year-end financial statements, the owner or operator must obtain alternative coverage within 150 days of the end of the year for which financial statements have been prepared.

(f) The Director of the implementing agency may require reports of financial condition at any time from the owner or operator, and/or guarantor. If the Director finds, on the basis of such reports or other information, that the owner or operator, and/or guarantor, no longer meets the financial test requirements of § 280.95(b) or (c) and (d), the owner or operator must obtain alternate coverage within 30 days after notification of such a finding.

(g) If the owner or operator fails to obtain alternate assurance within 150 days of finding that he or she no longer meets the requirements of the financial test based on the year-end financial statements, or within 30 days of notification by the Director of the implementing agency that he or she no longer meets the requirements of the financial test, the owner or operator must notify the Director of such failure within 10 days.

§ 280.96 Guarantee.

(a) An owner or operator may satisfy the requirements of § 280.93 by obtaining a guarantee that conforms to the requirements of this section. The guarantor must be:

(1) A firm that:

(i) Possesses a controlling interest in the owner or operator;

(ii) Possesses a controlling interest in a firm described under paragraph (a)(1)(i) of this section; or,

(iii) Is controlled through stock ownership by a common parent firm that possesses a controlling interest in the owner or operator; or,

(2) A firm engaged in a substantial business relationship with the owner or operator and issuing the guarantee as an act incident to that business relationship.

(b) Within 120 days of the close of each financial reporting year the guarantor must demonstrate that it meets the financial test criteria of § 280.95 based on year-end financial statements for the latest completed financial reporting year by completing the letter from the chief financial officer described in § 280.95(d) and must deliver the letter to the owner or operator. If the guarantor fails to meet the requirements of the financial test at the end of any financial reporting year, within 120 days of the end of that financial reporting year the guarantor shall send by certified mail, before cancellation or nonrenewal of the guarantee, notice to the owner or operator. If the Director of the implementing agency notifies the guarantor that he no longer meets the requirements of the financial test of § 280.95(b) or (c) and (d), the guarantor must notify the owner or operator within 10 days of receiving such notification from the Director. In both cases, the guarantee will terminate no less than 120 days after the date the owner or operator receives the notification, as evidenced by the return receipt. The owner or operator must obtain alternative coverage as specified in § 280.114(e).

(c) The guarantee must be worded as follows, except that instructions in brackets are to be replaced with the relevant information and the brackets deleted:

Guarantee

Guarantee made this [date] by [name of guaranteeing entity], a business entity organized under the laws of the state of [name of state], herein referred to as guarantor, to [the state implementing agency] and to any and all third parties, and obligees, on behalf of [owner or operator] of [business address].

Recitals.

(1) Guarantor meets or exceeds the financial test criteria of 40 CFR 280.95(b) or (c) and (d) and agrees to comply with the requirements for guarantors as specified in 40 CFR 280.96(b).

(2) [Owner or operator] owns or operates the following underground storage tank(s) covered by this guarantee: [List the number of tanks at each facility and the name(s) and address(es) of the facility(ies) where the tanks are located. If more than one instrument is used to assure different tanks at any one facility, for each tank covered by this instrument, list the tank identification number provided in the notification submitted pursuant to 40 CFR 280.22 or the corresponding state requirement, and the name and address of the facility.] This guarantee satisfies 40 CFR part 280, subpart H requirements for assuring funding for [insert: ''taking corrective action'' and/or ''compensating third parties for bodily injury and property damage caused by'' either ''sudden accidental releases'' or ''nonsudden accidental releases'' or ''accidental releases''; if coverage is different for different tanks or locations, indicate the type of coverage applicable to each tank or location] arising from operating the above-identified underground storage tank(s) in the amount of [insert dollar amount] per occurrence and [insert dollar amount] annual aggregate.

(3) [Insert appropriate phrase: ''On behalf of our subsidiary'' (if guarantor is corporate parent of the owner or operator); ''On behalf of our affiliate'' (if guarantor is a related firm of the owner or operator); or ''Incident to our business relationship with'' (if guarantor is providing the guarantee as an incident to a substantial business relationship with owner or operator)] [owner or operator], guarantor guarantees to [implementing agency] and to any and all third parties that:

In the event that [owner or operator] fails to provide alternative coverage within 60 days after receipt of a notice of cancellation of this guarantee and the [Director of the implementing agency] has determined or suspects that a release has occurred at an underground storage tank covered by this guarantee, the guarantor, upon instructions from the [Director], shall fund a standby trust fund in accordance with the provisions of 40 CFR 280.112, in an amount not to exceed the coverage limits specified above.

In the event that the [Director] determines that [owner or operator] has failed to perform corrective action for releases arising out of the operation of the above-identified tank(s) in accordance with 40 CFR part 280, subpart F, the guarantor upon written instructions from the [Director] shall fund a standby trust in accordance with the provisions of 40 CFR 280.112, in an amount not to exceed the coverage limits specified above.

If [owner or operator] fails to satisfy a judgment or award based on a determination of liability for bodily injury or property damage to third parties caused by [''sudden'' and/or ''nonsudden''] accidental releases arising from the operation of the above-identified tank(s), or fails to pay an amount agreed to in settlement of a claim arising from or alleged to arise from such injury or damage, the guarantor, upon written instructions from the [Director], shall fund a standby trust in accordance with the provisions of 40 CFR 280.112 to satisfy such judgment(s), award(s), or settlement agreement(s) up to the limits of coverage specified above.

(4) Guarantor agrees that if, at the end of any fiscal year before cancellation of this guarantee, the guarantor fails to meet the financial test criteria of 40 CFR 280.95(b) or (c) and (d), guarantor shall send within 120 days of such failure, by certified mail, notice to [owner or operator]. The guarantee will terminate 120 days from the date of receipt of the notice by [owner or operator], as evidenced by the return receipt.

(5) Guarantor agrees to notify [owner or operator] by certified mail of a voluntary or involuntary proceeding under Title 11 (Bankruptcy), U.S. Code naming guarantor as debtor, within 10 days after commencement of the proceeding.

(6) Guarantor agrees to remain bound under this guarantee notwithstanding any modification or alteration of any obligation of [owner or operator] pursuant to 40 CFR part 280.

(7) Guarantor agrees to remain bound under this guarantee for so long as [owner or operator] must comply with the applicable financial responsibility requirements of 40 CFR part 280, subpart H for the above-identified tank(s), except that guarantor may cancel this guarantee by sending notice by certified mail to [owner or operator], such cancellation to become effective no earlier than 120 days after receipt of such notice by [owner or operator], as evidenced by the return receipt.

(8) The guarantor's obligation does not apply to any of the following:

(a) Any obligation of [insert owner or operator] under a workers' compensation, disability benefits, or unemployment compensation law or other similar law;

(b) Bodily injury to an employee of [insert owner or operator] arising from, and in the course of, employment by [insert owner or operator];

(c) Bodily injury or property damage arising from the ownership, maintenance, use, or entrustment to others of any aircraft, motor vehicle, or watercraft;

(d) Property damage to any property owned, rented, loaded to, in the care, custody, or control of, or occupied by [insert owner or operator] that is not the direct result of a release from a petroleum underground storage tank;

(e) Bodily damage or property damage for which [insert owner or operator] is obligated to pay damages by reason of the assumption of liability in a contract or agreement other than a contract or agreement entered into to meet the requirements of 40 CFR 280.93.

(9) Guarantor expressly waives notice of acceptance of this guarantee by [the implementing agency], by any or all third parties, or by [owner or operator].

I hereby certify that the wording of this guarantee is identical to the wording specified in 40 CFR 280.96(c) as such regulations were constituted on the effective date shown immediately below.

Effective date:_____

[Name of guarantor]

[Authorized signature for guarantor]

[Name of person signing]

[Title of person signing]

_____

Signature of witness or notary:

(d) An owner or operator who uses a guarantee to satisfy the requirements of § 280.93 must establish a standby trust fund when the guarantee is obtained. Under the terms of the guarantee, all amounts paid by the guarantor under the guarantee will be deposited directly into the standby trust fund in accordance with instructions from the Director of the implementing agency under § 280.112. This standby trust fund must meet the requirements specified in § 280.103.

§ 280.97 Insurance and risk retention group coverage.

(a) An owner or operator may satisfy the requirements of § 280.93 by obtaining liability insurance that conforms to the requirements of this section from a qualified insurer or risk

retention group. Such insurance may be in the form of a separate insurance policy or an endorsement to an existing insurance policy.

(b) Each insurance policy must be amended by an endorsement worded as specified in paragraph (b)(1) of this section, or evidenced by a certificate of insurance worded as specified in paragraph (b)(2) of this section, except that instructions in brackets must be replaced with the relevant information and the brackets deleted:

(1) Endorsement.

Name: [name of each covered location]

Address: [address of each covered location]

Policy Number:

Period of Coverage: [current policy period]

Address of [Insurer or Risk Retention Group]:

Name of Insured:

Address of Insured:

Endorsement:

1. This endorsement certifies that the policy to which the endorsement is attached provides liability insurance covering the following underground storage tanks:

[List the number of tanks at each facility and the name(s) and address(es) of the facility(ies) where the tanks are located. If more than one instrument is used to assure different tanks at any one facility, for each tank covered by this instrument, list the tank identification number provided in the notification submitted pursuant to 40 CFR 280.22, or the corresponding state requirement, and the name and address of the facility.] for [insert: ''taking corrective action'' and/or ''compensating third parties for bodily injury and property damage caused by'' either ''sudden accidental releases'' or ''nonsudden accidental releases'' or ''accidental releases''; in accordance with and subject to the limits of liability, exclusions, conditions, and other terms of the policy; if coverage is different for different tanks or locations, indicate the type of coverage applicable to each tank or location] arising from operating the underground storage tank(s) identified above.

The limits of liability are [insert the dollar amount of the ''each Occurrence'' and ''annual aggregate'' limits of the Insurer's or Group's liability; if the amount of coverage is different for different types of coverage or for different underground storage tanks or locations, indicate the amount of coverage for each type of coverage and/or for each underground storage tank or location], exclusive of legal defense costs, which are subject to a separate limit under the policy. This coverage is provided under [policy number]. The effective date of said policy is [date].

2. The insurance afforded with respect to such occurrences is subject to all of the terms and conditions of the policy; provided, however, that any provisions inconsistent with subsections (a) through (e) of this Paragraph 2 are hereby amended to conform with subsections (a) through (e);

a. Bankruptcy or insolvency of the insured shall not relieve the [''Insurer'' or ''Group''] of its obligations under the policy to which this endorsement is attached.

b. The [''Insurer'' or ''Group''] is liable for the payment of amounts within any deductible applicable to the policy to the provider of corrective action or a damaged third-party, with a right of reimbursement by the insured for any such payment made by the [''Insurer'' or ''Group'']. This provision does not apply with respect to that amount of any deductible for which coverage is demonstrated under another mechanism or combination of mechanisms as specified in 40 CFR 280.95–280.102 and 280.104–280.107.

c. Whenever requested by [a Director of an implementing agency], the [''Insurer'' or ''Group''] agrees to furnish to [the Director] a signed duplicate original of the policy and all endorsements.

d. Cancellation or any other termination of the insurance by the [''Insurer'' or ''Group''], except for non-payment of premium or misrepresentation by the insured, will be effective only upon written notice and only after the expiration of 60 days after a copy of such written notice is received by the insured. Cancellation for non-payment of premium or misrepresentation by the insured will be effective only upon written notice and only after expiration of a minimum of 10 days after a copy of such written notice is received by the insured.

[Insert for claims-made policies:

e. The insurance covers claims otherwise covered by the policy that are reported to the [''Insurer'' or ''Group''] within six months of the effective date of cancellation or non-renewal of the policy except where the new or renewed policy has the same retroactive date or a retroactive date earlier than that of the prior policy, and which arise out of any covered occurrence that commenced after the policy retroactive date, if applicable, and prior to such policy renewal or termination date. Claims reported during such extended reporting period are subject to the terms, conditions, limits, including limits of liability, and exclusions of the policy.]

I hereby certify that the wording of this instrument is identical to the wording in 40 CFR 280.97(b)(1) and that the [''Insurer'' or ''Group''] is [''licensed to transact the business of insurance or eligible to provide insurance as an excess or surplus lines insurer in one or more states'']].

[Signature of authorized representative of Insurer or Risk Retention Group]

[Name of person signing]

[Title of person signing], Authorized Representative of [name of Insurer or Risk Retention Group]

[Address of Representative]

(2) *Certificate of Insurance.*

Name: [name of each covered location]

Address: [address of each covered location]

Policy Number:

Endorsement (if applicable):

Period of Coverage: [current policy period]

Name of [Insurer or Risk Retention Group]:

Address of [Insurer or Risk Retention Group]:

Name of Insured:

Address of Insured:

Certification:

1. [Name of Insurer or Risk Retention Group], [the ''Insurer'' or ''Group''], as identified above, hereby certifies that it

has issued liability insurance covering the following underground storage tank(s):

[List the number of tanks at each facility and the name(s) and address(es) of the facility(ies) where the tanks are located. If more than one instrument is used to assure different tanks at any one facility, for each tank covered by this instrument, list the tank identification number provided in the notification submitted pursuant to 40 CFR 280.22, or the corresponding state requirement, and the name and address of the facility.] for [insert: ''taking corrective action'' and/or ''compensating third parties for bodily injury and property damage caused by'' either ''sudden accidental releases'' or ''nonsudden accidental releases'' or ''accidental releases''; in accordance with and subject to the limits of liability, exclusions, conditions, and other terms of the policy; if coverage is different for different tanks or locations, indicate the type of coverage applicable to each tank or location] arising from operating the underground storage tank(s) identified above.

The limits of liability are [insert the dollar amount of the ''each occurrence'' and ''annual aggregate'' limits of the Insurer's or Group's liability; if the amount of coverage is different for different types of coverage or for different underground storage tanks or locations, indicate the amount of coverage for each type of coverage and/or for each underground storage tank or location], exclusive of legal defense costs, which are subject to a separate limit under the policy. This coverage is provided under [policy number]. The effective date of said policy is [date].

2. The [''Insurer'' or ''Group''] further certifies the following with respect to the insurance described in Paragraph 1:

a. Bankruptcy or insolvency of the insured shall not relieve the [''Insurer'' or ''Group''] of its obligations under the policy to which this certificate applies.

b. The [''Insurer'' or ''Group''] is liable for the payment of amounts within any deductible applicable to the policy to the provider of corrective action or a damaged third-party, with a right of reimbursement by the insured for any such payment made by the [''Insurer'' or ''Group'']. This provision does not apply with respect to that amount of any deductible for which coverage is demonstrated under another mechanism or combination of mechanisms as specified in 40 CFR 280.95–280.102 and 280.104–280.107.

c. Whenever requested by [a Director of an implementing agency], the [''Insurer'' or ''Group''] agrees to furnish to [the Director] a signed duplicate original of the policy and all endorsements.

d. Cancellation or any other termination of the insurance by the [''Insurer'' or ''Group''], except for non-payment of premium or misrepresentation by the insured, will be effective only upon written notice and only after the expiration of 60 days after a copy of such written notice is received by the insured. Cancellation for non-payment of premium or misrepresentation by the insured will be effective only upon written notice and only after expiration of a minimum of 10 days after a copy of such written notice is received by the insured.

[Insert for claims-made policies]:

e. The insurance covers claims otherwise covered by the policy that are reported to the [''Insurer'' or ''Group''] within six months of the effective date of cancellation or non-renewal of the policy except where the new or renewed policy has the same retroactive date or a retroactive date earlier than that of the prior policy, and which arise out of any covered occurrence that commenced after the policy retroactive date, if applicable, and prior to such policy renewal or termination date. Claims reported during such extended reporting period are subject to the terms, conditions, limits, including limits of liability, and exclusions of the policy.]

I hereby certify that the wording of this instrument is identical to the wording in 40 CFR 280.97(b)(2) and that the [''Insurer'' or ''Group''] is [''licensed to transact the business of insurance, or eligible to provide insurance as an excess or surplus lines insurer, in one or more states'']

[Signature of authorized representative of Insurer]

[Type name]

[Title], Authorized Representative of [name of Insurer or Risk Retention Group]

[Address of Representative]

(c) Each insurance policy must be issued by an insurer or a risk retention group that, at a minimum, is licensed to transact the business of insurance or eligible to provide insurance as an excess or surplus lines insurer in one or more states.

§ 280.98 Surety bond.

(a) An owner or operator may satisfy the requirements of § 280.93 by obtaining a surety bond that conforms to the requirements of this section. The surety company issuing the bond must be among those listed as acceptable sureties on federal bonds in the latest Circular 570 of the U.S. Department of the Treasury.

(b) The surety bond must be worded as follows, except that instructions in brackets must be replaced with the relevant information and the brackets deleted:

Performance Bond

Date bond executed:

Period of coverage:

Principal: [legal name and business address of owner or operator]

Type of organization: [insert ''individual,'' ''joint venture,'' ''partnership,'' or ''corporation'']

State of incorporation (if applicable):

Surety(ies): [name(s) and business address(es)]

Scope of Coverage: [List the number of tanks at each facility and the name(s) and address(es) of the facility(ies) where the tanks are located. If more than one instrument is used to assure different tanks at any one facility, for each tank covered by this instrument, list the tank identification number provided in the notification submitted pursuant to 40 CFR 280.22, or the corresponding state requirement, and the name and address of the facility. List the coverage guaranteed by the bond: ''taking corrective action'' and/or ''compensating third parties for bodily injury and property damage caused by'' either ''sudden accidental releases'' or ''nonsudden accidental releases'' or ''accidental releases'' ''arising from operating the underground storage Tank'']

Penal sums of bond:

Per occurrence $

Annual aggregate $

Surety's bond number:

Know All Persons by These Presents, that we, the Principal and Surety(ies), hereto are firmly bound to [the implementing agency], in the above penal sums for the payment of which we bind ourselves, our heirs, executors, administrators, successors, and assigns jointly and severally; provided that, where the Surety(ies) are corporations acting as co-sureties, we, the Sureties, bind ourselves in such sums jointly and severally only for the purpose of allowing a joint action or actions against any or all of us, and for all other purposes each Surety binds itself,

jointly and severally with the Principal, for the payment of such sums only as is set forth opposite the name of such Surety, but if no limit of liability is indicated, the limit of liability shall be the full amount of the penal sums.

Whereas said Principal is required under Subtitle I of the Solid Waste Disposal Act, as amended, to provide financial assurance for [insert: ''taking corrective action'' and/or ''compensating third parties for bodily injury and property damage caused by'' either ''sudden accidental releases'' or ''nonsudden accidental releases'' or ''accidental releases''; if coverage is different for different tanks or locations, indicate the type of coverage applicable to each tank or location] arising from operating the underground storage tanks identified above, and

Whereas said Principal shall establish a standby trust fund as is required when a surety bond is used to provide such financial assurance;

Now, therefore, the conditions of the obligation are such that if the Principal shall faithfully [''take corrective action, in accordance with 40 CFR part 280, subpart F and the Director of the state implementing agency's instructions for,'' and/or ''compensate injured third parties for bodily injury and property damage caused by'' either ''sudden accidental releases'' or ''nonsudden accidental releases'' or ''accidental releases''] arising from operating the tank(s) identified above, or if the Principal shall provide alternate financial assurance, as specified in 40 CFR part 280, subpart H, within 120 days after the date the notice of cancellation is received by the Principal from the Surety(ies), then this obligation shall be null and void; otherwise it is to remain in full force and effect.

Such obligation does not apply to any of the following:

(a) Any obligation of [insert owner or operator] under a workers' compensation, disability benefits, or unemployment compensation law or other similar law;

(b) Bodily injury to an employee of [insert owner or operator] arising from, and in the course of, employment by [insert owner or operator];

(c) Bodily injury or property damage arising from the ownership, maintenance, use, or entrustment to others of any aircraft, motor vehicle, or watercraft;

(d) Property damage to any property owned, rented, loaned to, in the care, custody, or control of, or occupied by [insert owner or operator] that is not the direct result of a release from a petroleum underground storage tank;

(e) Bodily injury or property damage for which [insert owner or operator] is obligated to pay damages by reason of the assumption of liability in a contract or agreement other than a contract or agreement entered into to meet the requirements of 40 CFR 280.93.

The Surety(ies) shall become liable on this bond obligation only when the Principal has failed to fulfill the conditions described above.

Upon notification by [the Director of the implementing agency] that the Principal has failed to [''take corrective action, in accordance with 40 CFR part 280, subpart F and the Director's instructions,'' and/or ''compensate injured third parties''] as guaranteed by this bond, the Surety(ies) shall either perform [''corrective action in accordance with 40 CFR part 280 and the Director's instructions,'' and/or ''third-party liability compensation''] or place funds in an amount up to the annual aggregate penal sum into the standby trust fund as directed by [the Regional Administrator or the Director] under 40 CFR 280.112.

Upon notification by [the Director] that the Principal has failed to provide alternate financial assurance within 60 days after the date the notice of cancellation is received by the Principal from the Surety(ies) and that [the Director] has determined or suspects that a release has occurred, the Surety(ies) shall place funds in an amount not exceeding the annual aggregate penal sum into the standby trust fund as directed by [the Director] under 40 CFR 280.112.

The Surety(ies) hereby waive(s) notification of amendments to applicable laws, statutes, rules, and regulations and agrees that no such amendment shall in any way alleviate its (their) obligation on this bond.

The liability of the Surety(ies) shall not be discharged by any payment or succession of payments hereunder, unless and until such payment or payments shall amount in the annual aggregate to the penal sum shown on the face of the bond, but in no event shall the obligation of the Surety(ies) hereunder exceed the amount of said annual aggregate penal sum.

The Surety(ies) may cancel the bond by sending notice of cancellation by certified mail to the Principal, provided, however, that cancellation shall not occur during the 120 days beginning on the date of receipt of the notice of cancellation by the Principal, as evidenced by the return receipt.

The Principal may terminate this bond by sending written notice to the Surety(ies).

In Witness Thereof, the Principal and Surety(ies) have executed this Bond and have affixed their seals on the date set forth above.

The persons whose signatures appear below hereby certify that they are authorized to execute this surety bond on behalf of the Principal and Surety(ies) and that the wording of this surety bond is identical to the wording specified in 40 CFR 280.98(b) as such regulations were constituted on the date this bond was executed.

Principal

[Signature(s)]
[Names(s)]
[Title(s)]
[Corporate seal]

Corporate Surety(ies)

[Name and address]
[State of Incorporation: _____]
[Liability limit: $ _____]
[Signature(s)]
[Names(s) and title(s)]
[Corporate seal]

[For every co-surety, provide signature(s), corporate seal, and other information in the same manner as for Surety above.]

Bond premium: $ _____

(c) Under the terms of the bond, the surety will become liable on the bond obligation when the owner or operator fails to perform as guaranteed by the bond. In all cases, the surety's liability is limited to the per-occurrence and annual aggregate penal sums.

(d) The owner or operator who uses a surety bond to satisfy the requirements of § 280.93 must establish a standby trust fund when the surety bond is acquired. Under the terms of the bond, all amounts paid by the surety under the bond will be deposited directly into the standby trust fund in accordance with instructions from the Director under § 280.112. This standby trust fund must meet the requirements specified in § 280.103.

§ 280.99 Letter of credit.

(a) An owner or operator may satisfy the requirements of § 280.93 by obtaining an irrevocable standby letter of credit that conforms to the requirements of this section. The issuing institution must be an entity that has the authority to issue letters of credit in each state where used and whose letter-of-credit operations are regulated and examined by a federal or state agency.

(b) The letter of credit must be worded as follows, except that instructions in brackets are to be replaced with the relevant information and the brackets deleted:

Irrevocable Standby Letter of Credit

[Name and address of issuing institution]

[Name and address of Director(s) of state implementing agency(ies)]

Dear Sir or Madam: We hereby establish our Irrevocable Standby Letter of Credit No. ____ in your favor, at the request and for the account of [owner or operator name] of [address] up to the aggregate amount of [in words] U.S. dollars ($[insert dollar amount]), available upon presentation [insert, if more than one Director of a state implementing agency is a beneficiary, ''by any one of you''] of

(1) your sight draft, bearing reference to this letter of credit, No. ____ and

(2) your signed statement reading as follows: ''I certify that the amount of the draft is payable pursuant to regulations issued under authority of Subtitle I of the Solid Waste Disposal Act, as amended.''

This letter of credit may be drawn on to cover [insert: ''taking corrective action'' and/or ''compensating third parties for bodily injury and property damage caused by'' either ''sudden accidental releases'' or ''nonsudden accidental releases'' or ''accidental releases''] arising from operating the underground storage tank(s) identified below in the amount of [in words] $[insert dollar amount] per occurrence and [in words] $[insert dollar amount] annual aggregate:

[List the number of tanks at each facility and the name(s) and address(es) of the facility(ies) where the tanks are located. If more than one instrument is used to assure different tanks at any one facility, for each tank covered by this instrument, list the tank identification number provided in the notification submitted pursuant to 40 CFR 280.22, or the corresponding state requirement, and the name and address of the facility.]

The letter of credit may not be drawn on to cover any of the following:

(a) Any obligation of [insert owner or operator] under a workers' compensation, disability benefits, or unemployment compensation law or other similar law;

(b) Bodily injury to an employee of [insert owner or operator] arising from, and in the course of, employment by [insert owner or operator];

(c) Bodily injury or property damage arising from the ownership, maintenance, use, or entrustment to others of any aircraft, motor vehicle, or watercraft;

(d) Property damage to any property owned, rented, loaned to, in the care, custody, or control of, or occupied by [insert owner or operator] that is not the direct result of a release from a petroleum underground storage tank;

(e) Bodily injury or property damage for which [insert owner or operator] is obligated to pay damages by reason of the assumption of liability in a contract or agreement other than a contract or agreement entered into to meet the requirements of 40 CFR 280.93.

This letter of credit is effective as of [date] and shall expire on [date], but such expiration date shall be automatically extended for a period of [at least the length of the original term] on [expiration date] and on each successive expiration date, unless, at least 120 days before the current expiration date, we notify [owner or operator] by certified mail that we have decided not to extend this letter of credit beyond the current expiration date. In the event that [owner or operator] is so notified, any unused portion of the credit shall be available upon presentation of your sight draft for 120 days after the date of receipt by [owner or operator], as shown on the signed return receipt.

Whenever this letter of credit is drawn on under and in compliance with the terms of this credit, we shall duly honor such draft upon presentation to us, and we shall deposit the amount of the draft directly into the standby trust fund of [owner or operator] in accordance with your instructions.

We certify that the wording of this letter of credit is identical to the wording specified in 40 CFR 280.99(b) as such regulations were constituted on the date shown immediately below.

[Signature(s) and title(s) of official(s) of issuing institution]

[Date]

This credit is subject to [insert ''the most recent edition of the Uniform Customs and Practice for Documentary Credits, published and copyrighted by the International Chamber of Commerce,'' or ''the Uniform Commercial Code'']. (c) An owner or operator who uses a letter of credit to satisfy the requirements of § 280.93 must also establish a standby trust fund when the letter of credit is acquired. Under the terms of the letter of credit, all amounts paid pursuant to a draft by the Director of the implementing agency will be deposited by the issuing institution directly into the standby trust fund in accordance with instructions from the Director under § 280.112. This standby trust fund must meet the requirements specified in § 280.103.

(d) The letter of credit must be irrevocable with a term specified by the issuing institution. The letter of credit must provide that credit be automatically renewed for the same term as the original term, unless, at least 120 days before the current expiration date, the issuing institution notifies the owner or operator by certified mail of its decision not to renew the letter of credit. Under the terms of the letter of credit, the 120 days will begin on the date when the owner or operator receives the notice, as evidenced by the return receipt.

§ 280.100 Use of state-required mechanism.

(a) For underground storage tanks located in a state that does not have an approved program, and where the state requires owners or operators of underground storage tanks to demonstrate financial responsibility for taking corrective action and/or for compensating third parties for bodily injury and property damage, an owner or operator may use a state-required financial mechanism to meet the requirements of § 280.93 if the Regional Administrator determines that the state mechanism is at least equivalent to the financial mechanisms specified in this subpart.

(b) The Regional Administrator will evaluate the equivalency of a state-required mechanism principally in terms of: certainty of the availability of funds for taking corrective action and/or for compensating third parties; the amount of funds that will be made available; and the types of costs covered. The Regional Administrator may also consider other factors as is necessary.

(c) The state, an owner or operator, or any other interested party may submit to the Regional Administrator a written petition requesting that one or more of the state-required mechanisms be considered acceptable for meeting the requirements of § 280.93. The submission must include copies of the appropriate state statutory and regulatory requirements and must show the amount of funds for corrective action and/or for compensating third parties assured by the mechanism(s). The Regional Administrator may require the petitioner to submit additional information as is deemed necessary to make this determination.

(d) Any petition under this section may be submitted on behalf of all of the state's underground storage tank owners and operators.

(e) The Regional Administrator will notify the petitioner of his determination regarding the mechanism's acceptability in lieu of financial mechanisms specified in this

subpart. Pending this determination, the owners and operators using such mechanisms will be deemed to be in compliance with the requirements of § 280.93 for underground storage tanks located in the state for the amounts and types of costs covered by such mechanisms.

§ 280.101 State fund or other state assurance.

(a) An owner or operator may satisfy the requirements of § 280.93 for underground storage tanks located in a state, where EPA is administering the requirements of this subpart, which assures that monies will be available from a state fund or state assurance program to cover costs up to the limits specified in § 280.93 or otherwise assures that such costs will be paid if the Regional Administrator determines that the state's assurance is at least equivalent to the financial mechanisms specified in this subpart.

(b) The Regional Administrator will evaluate the equivalency of a state fund or other state assurance principally in terms of: Certainty of the availability of funds for taking corrective action and/or for compensating third parties; the amount of funds that will be made available; and the types of costs covered. The Regional Administrator may also consider other factors as is necessary.

(c) The state must submit to the Regional Administrator a description of the state fund or other state assurance to be supplied as financial assurance, along with a list of the classes of underground storage tanks to which the funds may be applied. The Regional Administrator may require the state to submit additional information as is deemed necessary to make a determination regarding the acceptability of the state fund or other state assurance. Pending the determination by the Regional Administrator, the owner or operator of a covered class of USTs will be deemed to be in compliance with the requirements of § 280.93 for the amounts and types of costs covered by the state fund or other state assurance.

(d) The Regional Administrator will notify the state of his determination regarding the acceptability of the state's fund or other assurance in lieu of financial mechanisms specified in this subpart. Within 60 days after the Regional Administrator notifies a state that a state fund or other state assurance is acceptable, the state must provide to each owner or operator for which it is assuming financial responsibility a letter or certificate describing the nature of the state's assumption of responsibility. The letter or certificate from the state must include, or have attached to it, the following information: the facility's name and address and the amount of funds for corrective action and/or for compensating third parties that is assured by the state. The owner or operator must maintain this letter or certificate on file as proof of financial responsibility in accordance with § 280.111(b)(8).

§ 280.102 Trust fund.

(a) An owner or operator may satisfy the requirements of § 280.93 by establishing a trust fund that conforms to the requirements of this section. The trustee must be an entity that has the authority to act as a trustee and whose trust operations are regulated and examined by a federal agency or an agency of the state in which the fund is established.

(b) The wording of the trust agreement must be identical to the wording specified in § 280.103(b)(1), and must be accompanied by a formal certification of acknowledgement as specified in § 280.103(b)(2).

(c) The trust fund, when established, must be funded for the full required amount of coverage, or funded for part of the required amount of coverage and used in combination with other mechanism(s) that provide the remaining required coverage.

(d) If the value of the trust fund is greater than the required amount of coverage, the owner or operator may submit a written request to the Director of the implementing agency for release of the excess.

(e) If other financial assurance as specified in this subpart is substituted for all or part of the trust fund, the owner or operator may submit a written request to the Director of the implementing agency for release of the excess.

(f) Within 60 days after receiving a request from the owner or operator for release of funds as specified in paragraph (d) or (e) of this section, the Director of the implementing agency will instruct the trustee to release to the owner or operator such funds as the Director specifies in writing.

§ 280.103 Standby trust fund.

(a) An owner or operator using any one of the mechanisms authorized by §§ 280.96, 280.98, or 280.99 must establish a standby trust fund when the mechanism is acquired. The trustee of the standby trust fund must be an entity that has the authority to act as a trustee and whose trust operations are regulated and examined by a Federal agency or an agency of the state in which the fund is established.

(b)(1) The standby trust agreement, or trust agreement, must be worded as follows, except that instructions in brackets are to be replaced with the relevant information and the brackets deleted:

Trust Agreement

Trust agreement, the ''Agreement,'' entered into as of [date] by and between [name of the owner or operator], a [name of state] [insert ''corporation,'' ''partnership,'' ''association,'' or ''proprietorship''], the ''Grantor,'' and [name of corporate trustee], [insert ''Incorporated in the state of _____ '' or ''a national bank''], the ''Trustee.''

Whereas, the United States Environmental Protection Agency, ''EPA,'' an agency of the United States Government, has established certain regulations applicable to the Grantor, requiring that an owner or operator of an underground storage tank shall provide assurance that funds will be available when needed for corrective action and third-party compensation for bodily injury and property damage caused by sudden and nonsudden accidental releases arising from the operation of the underground storage tank. The attached Schedule A lists the number of tanks at each facility and the name(s) and address(es) of the facility(ies) where the tanks are located that are covered by the [insert ''standby'' where trust agreement is standby trust agreement] trust agreement.

[Whereas, the Grantor has elected to establish [insert either ''a guarantee,'' ''surety bond,'' or ''letter of credit''] to provide all or part of such financial assurance for the underground storage tanks identified herein and is required to establish a standby trust fund able to accept payments from the instrument (This paragraph is only applicable to the standby trust agreement.)];

Whereas, the Grantor, acting through its duly authorized officers, has selected the Trustee to be the trustee under this agreement, and the Trustee is willing to act as trustee;

Now, therefore, the Grantor and the Trustee agree as follows:

Section 1. Definitions

As used in this Agreement:

(a) The term ''Grantor'' means the owner or operator who enters into this Agreement and any successors or assigns of the Grantor.

(b) The term ''Trustee'' means the Trustee who enters into this Agreement and any successor Trustee.

Section 2. Identification of the Financial Assurance Mechanism

This Agreement pertains to the [identify the financial assurance mechanism, either a guarantee, surety bond, or letter of credit, from which the standby trust fund is established to receive payments (This paragraph is only applicable to the standby trust agreement.)].

Section 3. Establishment of Fund

The Grantor and the Trustee hereby establish a trust fund, the ''Fund,'' for the benefit of [implementing agency]. The Grantor and the Trustee intend that no third party have access to the Fund except as herein provided. [The Fund is established initially as a standby to receive payments and shall not consist of any property.] Payments made by the provider of financial assurance pursuant to [the Director of the implementing agency's] instruction are transferred to the Trustee and are referred to as the Fund, together with all earnings and profits thereon, less any payments or distributions made by the Trustee pursuant to this Agreement. The Fund shall be held by the Trustee, IN TRUST, as hereinafter provided. The Trustee shall not be responsible nor shall it undertake any responsibility for the amount or adequacy of, nor any duty to collect from the Grantor as provider of financial assurance, any payments necessary to discharge any liability of the Grantor established by [the state implementing agency]

Section 4. Payment for [''Corrective Action'' and/or ''Third-Party Liability Claims'']

The Trustee shall make payments from the Fund as [the Director of the implementing agency] shall direct, in writing, to provide for the payment of the costs of [insert: ''taking corrective action'' and/or ''compensating third parties for bodily injury and property damage caused by'' either ''sudden accidental releases'' or ''nonsudden accidental Releases'' or ''accidental releases''] arising from operating the tanks covered by the financial assurance mechanism identified in this Agreement.

The Fund may not be drawn upon to cover any of the following:

(a) Any obligation of [insert owner or operator] under a workers' compensation, disability benefits, or unemployment compensation law or other similar law;

(b) Bodily injury to an employee of [insert owner or operator] arising from, and in the course of employment by [insert owner or operator];

(c) Bodily injury or property damage arising from the ownership, maintenance, use, or entrustment to others of any aircraft, motor vehicle, or watercraft;

(d) Property damage to any property owned, rented, loaned to, in the care, custody, or control of, or occupied by [insert owner or operator] that is not the direct result of a release from a petroleum underground storage tank;

(e) Bodily injury or property damage for which [insert owner or operator] is obligated to pay damages by reason of the assumption of liability in a contract or agreement other than a contract or agreement entered into to meet the requirements of 40 CFR 280.93.

The Trustee shall reimburse the Grantor, or other persons as specified by [the Director], from the Fund for corrective action expenditures and/or third-party liability claims in such amounts as [the Director] shall direct in writing. In addition, the Trustee shall refund to the Grantor such amounts as [the Director] specifies in writing. Upon refund, such funds shall no longer constitute part of the Fund as defined herein.

Section 5. Payments Comprising the Fund

Payments made to the Trustee for the Fund shall consist of cash and securities acceptable to the Trustee.

Section 6. Trustee Management

The Trustee shall invest and reinvest the principal and income of the Fund and keep the Fund invested as a single fund, without distinction between principal and income, in accordance with general investment policies and guidelines which the Grantor may communicate in writing to the Trustee from time to time, subject, however, to the provisions of this Section. In investing, reinvesting, exchanging, selling, and managing the Fund, the Trustee shall discharge his duties with respect to the trust fund solely in the interest of the beneficiaries and with the care, skill, prudence, and diligence under the circumstances then prevailing which persons of prudence, acting in a like capacity and familiar with such matters, would use in the conduct of an enterprise of a like character and with like aims; except that:

(i) Securities or other obligations of the Grantor, or any other owner or operator of the tanks, or any of their affiliates as defined in the Investment Company Act of 1940, as amended, 15 U.S.C. 80a–2(a), shall not be acquired or held, unless they are securities or other obligations of the federal or a state government;

(ii) The Trustee is authorized to invest the Fund in time or demand deposits of the Trustee, to the extent insured by an agency of the federal or state government; and

(iii) The Trustee is authorized to hold cash awaiting investment or distribution uninvested for a reasonable time and without liability for the payment of interest thereon.

Section 7. Commingling and Investment

The Trustee is expressly authorized in its discretion:

(a) To transfer from time to time any or all of the assets of the Fund to any common, commingled, or collective trust fund created by the Trustee in which the Fund is eligible to participate, subject to all of the provisions thereof, to be commingled with the assets of other trusts participating therein; and

(b) To purchase shares in any investment company registered under the Investment Company Act of 1940, 15 U.S.C. 80a–1 *et seq.,* including one which may be created, managed, underwritten, or to which investment advice is rendered or the shares of which are sold by the Trustee. The Trustee may vote such shares in its discretion.

Section 8. Express Powers of Trustee

Without in any way limiting the powers and discretions conferred upon the Trustee by the other provisions of this Agreement or by law, the Trustee is expressly authorized and empowered:

(a) To sell, exchange, convey, transfer, or otherwise dispose of any property held by it, by public or private sale. No person dealing with the Trustee shall be bound to see to the application of the purchase money or to inquire into the validity or expediency of any such sale or other disposition;

(b) To make, execute, acknowledge, and deliver any and all documents of transfer and conveyance and any and all other instruments that may be necessary or appropriate to carry out the powers herein granted;

(c) To register any securities held in the Fund in its own name or in the name of a nominee and to hold any security in bearer form or in book entry, or to combine certificates representing such securities with certificates of the same issue held by the Trustee in other fiduciary capacities, or to deposit or arrange for the deposit of such securities in a qualified central depository even though, when so deposited, such securities may be merged and held in bulk in the name of the nominee of such depository with other securities deposited therein by another person, or

to deposit or arrange for the deposit of any securities issued by the United States Government, or any agency or instrumentality thereof, with a Federal Reserve bank, but the books and records of the Trustee shall at all times show that all such securities are part of the Fund;

(d) To deposit any cash in the Fund in interest-bearing accounts maintained or savings certificates issued by the Trustee, in its separate corporate capacity, or in any other banking institution affiliated with the Trustee, to the extent insured by an agency of the federal or state government; and

(e) To compromise or otherwise adjust all claims in favor of or against the Fund.

Section 9. Taxes and Expenses

All taxes of any kind that may be assessed or levied against or in respect of the Fund and all brokerage commissions incurred by the Fund shall be paid from the Fund. All other expenses incurred by the Trustee in connection with the administration of this Trust, including fees for legal services rendered to the Trustee, the compensation of the Trustee to the extent not paid directly by the Grantor, and all other proper charges and disbursements of the Trustee shall be paid from the Fund.

Section 10. Advice of Counsel

The Trustee may from time to time consult with counsel, who may be counsel to the Grantor, with respect to any questions arising as to the construction of this Agreement or any action to be taken hereunder. The Trustee shall be fully protected, to the extent permitted by law, in acting upon the advice of counsel.

Section 11. Trustee Compensation

The Trustee shall be entitled to reasonable compensation for its services as agreed upon in writing from time to time with the Grantor.

Section 12. Successor Trustee

The Trustee may resign or the Grantor may replace the Trustee, but such resignation or replacement shall not be effective until the Grantor has appointed a successor trustee and this successor accepts the appointment. The successor trustee shall have the same powers and duties as those conferred upon the Trustee hereunder. Upon the successor trustee's acceptance of the appointment, the Trustee shall assign, transfer, and pay over to the successor trustee the funds and properties then constituting the Fund. If for any reason the Grantor cannot or does not act in the event of the resignation of the Trustee, the Trustee may apply to a court of competent jurisdiction for the appointment of a successor trustee or for instructions. The successor trustee shall specify the date on which it assumes administration of the trust in writing sent to the Grantor and the present Trustee by certified mail 10 days before such change becomes effective. Any expenses incurred by the Trustee as a result of any of the acts contemplated by this Section shall be paid as provided in Section 9.

Section 13. Instructions to the Trustee

All orders, requests, and instructions by the Grantor to the Trustee shall be in writing, signed by such persons as are designated in the attached Schedule B or such other designees as the Grantor may designate by amendment to Schedule B. The Trustee shall be fully protected in acting without inquiry in accordance with the Grantor's orders, requests, and instructions. All orders, requests, and instructions by [the Director of the implementing agency] to the Trustee shall be in writing, signed by [the Director], and the Trustee shall act and shall be fully protected in acting in accordance with such orders, requests, and instructions. The Trustee shall have the right to assume, in the absence of written notice to the contrary, that no event constituting a change or a termination of the authority of any person to act on behalf of the Grantor or [the director] hereunder has occurred. The Trustee shall have no duty to act in the absence of such orders, requests, and instructions from the Grantor and/or [the Director], except as provided for herein.

Section 14. Amendment of Agreement

This Agreement may be amended by an instrument in writing executed by the Grantor and the Trustee, or by the Trustee and [the Director of the implementing agency] if the Grantor ceases to exist.

Section 15. Irrevocability and Termination

Subject to the right of the parties to amend this Agreement as provided in Section 14, this Trust shall be irrevocable and shall continue until terminated at the written direction of the Grantor and the Trustee, or by the Trustee and [the Director of the implementing agency], if the Grantor ceases to exist. Upon termination of the Trust, all remaining trust property, less final trust administration expenses, shall be delivered to the Grantor.

Section 16. Immunity and Indemnification

The Trustee shall not incur personal liability of any nature in connection with any act or omission, made in good faith, in the administration of this Trust, or in carrying out any directions by the Grantor or [the Director of the implementing agency] issued in accordance with this Agreement. The Trustee shall be indemnified and saved harmless by the Grantor, from and against any personal liability to which the Trustee may be subjected by reason of any act or conduct in its official capacity, including all expenses reasonably incurred in its defense in the event the Grantor fails to provide such defense.

Section 17. Choice of Law

This Agreement shall be administered, construed, and enforced according to the laws of the state of [insert name of state], or the Comptroller of the Currency in the case of National Association banks.

Section 18. Interpretation

As used in this Agreement, words in the singular include the plural and words in the plural include the singular. The descriptive headings for each section of this Agreement shall not affect the interpretation or the legal efficacy of this Agreement.

In Witness whereof the parties have caused this Agreement to be executed by their respective officers duly authorized and their corporate seals (if applicable) to be hereunto affixed and attested as of the date first above written. The parties below certify that the wording of this Agreement is identical to the wording specified in 40 CFR 280.103(b)(1) as such regulations were constituted on the date written above.

[Signature of Grantor]

[Name of the Grantor]

[Title]

Attest:

[Signature of Trustee]
[Name of the Trustee]
[Title]
[Seal]
[Signature of Witness]
[Name of the Witness]
[Title]
[Seal]

(2) The standby trust agreement, or trust agreement must be accompanied by a formal certification of acknowledgement similar to the following. State requirements may differ on the proper content of this acknowledgment.

State of

County of

On this [date], before me personally came [owner or operator] to me known, who, being by me duly sworn, did depose and say that she/he resides at [address], that she/he is [title] of [corporation], the corporation described in and which executed the above instrument; that she/he knows the seal of said corporation; that the seal affixed to such instrument is such corporate seal; that it was so affixed by order of the Board of Directors of said corporation; and that she/he signed her/his name thereto by like order.

[Signature of Notary Public]

[Name of Notary Public]

(c) The Director of the implementing agency will instruct the trustee to refund the balance of the standby trust fund to the provider of financial assurance if the Director determines that no additional corrective action costs or third-party liability claims will occur as a result of a release covered by the financial assurance mechanism for which the standby trust fund was established.

(d) An owner or operator may establish one trust fund as the depository mechanism for all funds assured in compliance with this rule.

§ 280.104 Local government bond rating test.

(a) A general purpose local government owner or operator and/or local government serving as a guarantor may satisfy the requirements of § 280.93 by having a currently outstanding issue or issues of general obligation bonds of $1 million or more, excluding refunded obligations, with a Moody's rating of Aaa, Aa, A, or Baa, or a Standard & Poor's rating of AAA, AA, A, or BBB. Where a local government has multiple outstanding issues, or where a local government's bonds are rated by both Moody's and Standard and Poor's, the lowest rating must be used to determine eligibility. Bonds that are backed by credit enhancement other than municipal bond insurance may not be considered in determining the amount of applicable bonds outstanding.

(b) A local government owner or operator or local government serving as a guarantor that is not a general-purpose local government and does not have the legal authority to issue general obligation bonds may satisfy the requirements of § 280.93 by having a currently outstanding issue or issues of revenue bonds of $1 million or more, excluding refunded issues, and by also having a Moody's rating of Aaa, Aa, A, or Baa, or a Standard & Poor's rating of AAA, AA, A, or BBB as the lowest rating for any rated revenue bond issued by the local government. Where bonds are rated by both Moody's and Standard & Poor's, the lower rating for each bond must be used to determine eligibility. Bonds that are backed by credit enhancement may not be considered in determining the amount of applicable bonds outstanding.

(c) The local government owner or operator and/or guarantor must maintain a copy of its bond rating published within the last 12 months by Moody's or Standard & Poor's.

(d) To demonstrate that it meets the local government bond rating test, the chief financial officer of a general purpose local government owner or operator and/or guarantor must sign a letter worded exactly as follows, except that the instructions in brackets are to be replaced by the relevant information and the brackets deleted:

Letter from Chief Financial Officer

I am the chief financial officer of [insert: name and address of local government owner or operator, or guarantor]. This letter is in support of the use of the bond rating test to demonstrate financial responsibility for [insert: ''taking corrective action'' and/or ''compensating third parties for bodily injury and property damage''] caused by [insert: ''sudden accidental releases'' or ''nonsudden accidental releases'' or ''accidental releases''] in the amount of at least [insert: dollar amount] per occurrence and [insert: dollar amount] annual aggregate arising from operating (an) underground storage tank(s).

Underground storage tanks at the following facilities are assured by this bond rating test: [List for each facility: the name and address of the facility where tanks are assured by the bond rating test].

The details of the issue date, maturity, outstanding amount, bond rating, and bond rating agency of all outstanding bond issues that are being used by [name of local government owner or operator, or guarantor] to demonstrate financial responsibility are as follows:

Issue date	Maturity date	Outstanding amount	Bond rating	Rating agency
			[Moody's or Standard & Poor's]	

The total outstanding obligation of [insert amount], excluding refunded bond issues, exceeds the minimum amount of $1 million. All outstanding general obligation bonds issued by this government that have been rated by Moody's or Standard & Poor's are rated as at least investment grade (Moody's Baa or Standard & Poor's BBB) based on the most recent ratings published within the last 12 months. Neither rating service has provided notification within the last 12 months of downgrading of bond ratings below investment grade or of withdrawal of bond rating other than for repayment of outstanding bond issues.

I hereby certify that the wording of this letter is identical to the wording specified in 40 CFR 280.104(d) as such regulations were constituted on the date shown immediately below.

[Date]

[Signature]

[Name]

[Title]

(e) To demonstrate that it meets the local government bond rating test, the chief financial officer of local government owner or operator and/or guarantor other than a general purpose government must sign a letter worded exactly as follows, except that the instructions in brackets are to be replaced by the relevant information and the brackets deleted:

Letter from Chief Financial Officer

I am the chief financial officer of [insert: name and address of local government owner or operator, or guarantor]. This letter is in support of the use of the bond rating test to demonstrate financial responsibility for [insert: ''taking corrective action'' and/or ''compensating third parties for bodily injury and property damage''] caused by [insert: ''sudden accidental releases'' or ''nonsudden accidental releases'' or ''accidental releases''] in the amount of at least [insert: dollar amount] per occurrence and [insert: dollar amount] annual aggregate arising from operating (an) underground storage tank(s). This local government is not organized to provide general governmental services and does not have the legal authority under state law or constitutional provisions to issue general obligation debt.

Underground storage tanks at the following facilities are assured by this bond rating test: [List for each facility: the name and address of the facility where tanks are assured by the bond rating test].

The details of the issue date, maturity, outstanding amount, bond rating, and bond rating agency of all outstanding revenue bond issues that are being used by [name of local government owner or operator, or guarantor] to demonstrate financial responsibility are as follows:

Issue date	Maturity date	Outstanding amount	Bond rating	Rating agency
			[Moody's or Standard & Poor's]	

The total outstanding obligation of [insert amount], excluding refunded bond issues, exceeds the minimum amount of $1 million. All outstanding revenue bonds issued by this government that have been rated by Moody's or Standard & Poor's are rated as at least investment grade (Moody's Baa or Standard & Poor's BBB) based on the most recent ratings published within the last 12 months. The revenue bonds listed are not backed by third-party credit enhancement or insured by a municipal bond insurance company. Neither rating service has provided notification within the last 12 months of downgrading of bond ratings below investment grade or of withdrawal of bond rating other than for repayment of outstanding bond issues.

I hereby certify that the wording of this letter is identical to the wording specified in 40 CFR 280.104(e) as such regulations were constituted on the date shown immediately below.

[Date]

[Signature]

[Name]

[Title]

(f) The Director of the implementing agency may require reports of financial condition at any time from the local government owner or operator, and/or local government guarantor. If the Director finds, on the basis of such reports or other information, that the local government owner or operator, and/or guarantor, no longer meets the local government bond rating test requirements of § 280.104, the local government owner or operator must obtain alternative coverage within 30 days after notification of such a finding.

(g) If a local government owner or operator using the bond rating test to provide financial assurance finds that it no longer meets the bond rating test requirements, the local government owner or operator must obtain alternative coverage within 150 days of the change in status.

(h) If the local government owner or operator fails to obtain alternate assurance within 150 days of finding that it no longer meets the requirements of the bond rating test or within 30 days of notification by the Director of the implementing agency that it no longer meets the requirements of the bond rating test, the owner or operator must notify the Director of such failure within 10 days.

§ 280.105 Local government financial test.

(a) A local government owner or operator may satisfy the requirements of § 280.93 by passing the financial test specified in this section. To be eligible to use the financial test, the local government owner or operator must have the ability and authority to assess and levy taxes or to freely establish fees and charges. To pass the local government financial test, the owner or operator must meet the criteria of paragraphs (b)(2) and (3) of this section based on year-end financial statements for the latest completed fiscal year.

(b)(1) The local government owner or operator must have the following information available, as shown in the year-end financial statements for the latest completed fiscal year:

(i) *Total revenues.* Consists of the sum of general fund operating and non-operating revenues including net local taxes, licenses and permits, fines and forfeitures, revenues from use of money and property, charges for services, investment earnings, sales (property, publications, etc.), intergovernmental revenues (restricted and unrestricted), and total revenues from all other governmental funds including enterprise, debt service, capital projects, and special revenues, but excluding revenues to funds held in a trust or agency capacity. For purposes of this test, the calculation of total revenues shall exclude all transfers between funds under the direct control of the local government using the financial test (interfund transfers), liquidation of investments, and issuance of debt.

(ii) *Total expenditures.* Consists of the sum of general fund operating and non-operating expenditures including public safety, public utilities, transportation, public works, environmental protection, cultural and recreational, community development, revenue sharing, employee benefits and compensation, office management, planning and zoning, capital projects, interest payments on debt, payments for retirement of debt principal, and total expenditures from all other governmental funds including enterprise, debt service, capital projects, and special revenues. For purposes of this test, the calculation of total expenditures shall exclude all transfers between funds under the direct control of the local government using the financial test (interfund transfers).

(iii) *Local revenues.* Consists of total revenues (as defined in paragraph (b)(1)(i) of this section) minus the sum of all transfers from other governmental entities, including all monies received from Federal, state, or local government sources.

(iv) *Debt service.* Consists of the sum of all interest and principal payments on all long-term credit obligations and all interest-bearing short-term credit obligations. Includes interest and principal payments on general obligation bonds, revenue bonds, notes, mortgages, judgments, and interest bearing warrants. Excludes payments on non-interest-bearing short-term obligations, interfund obligations, amounts owed in a trust or agency capacity, and advances and contingent loans from other governments.

(v) *Total funds.* Consists of the sum of cash and investment securities from all funds, including general, enterprise, debt service, capital projects, and special revenue funds, but excluding employee retirement funds, at the end of the local government's financial reporting year. Includes Federal securities, Federal agency securities, state and local government securities, and other securities such as bonds, notes and mortgages. For purposes of this test, the calculation of total funds shall exclude agency funds, private trust funds, accounts receivable, value of real property, and other non-security assets.

(vi) Population consists of the number of people in the area served by the local government.

(2) The local government's year-end financial statements, if independently audited, cannot include an adverse auditor's opinion or a disclaimer of opinion. The local government cannot have outstanding issues of general obligation or revenue bonds that are rated as less than investment grade.

(3) The local government owner or operator must have a letter signed by the chief financial officer worded as specified in paragraph (c) of this section.

(c) To demonstrate that it meets the financial test under paragraph (b) of this section, the chief financial officer of the local government owner or operator, must sign, within 120 days of the close of each financial reporting year, as defined by the twelve-month period for which financial statements used to support the financial test are prepared, a letter worded exactly as follows, except that the instructions in brackets are to be replaced by the relevant information and the brackets deleted:

Letter From Chief Financial Officer

I am the chief financial officer of [insert: name and address of the owner or operator]. This letter is in support of the use of the local government financial test to demonstrate financial responsibility for [insert: ''taking corrective action'' and/or ''compensating third parties for bodily injury and property damage''] caused by [insert: ''sudden accidental releases'' or ''nonsudden accidental releases'' or ''accidental releases''] in the amount of at least [insert: dollar amount] per occurrence and [insert: dollar amount] annual aggregate arising from operating [an] underground storage tank[s].

Underground storage tanks at the following facilities are assured by this financial test [List for each facility: the name and address of the facility where tanks assured by this financial test are located. If separate mechanisms or combinations of mechanisms are being used to assure any of the tanks at this facility, list each tank assured by this financial test by the tank identification number provided in the notification submitted pursuant to 40 CFR 280.22 or the corresponding state requirements.]

This owner or operator has not received an adverse opinion, or a disclaimer of opinion from an independent auditor on its financial statements for the latest completed fiscal year. Any outstanding issues of general obligation or revenue bonds, if rated, have a Moody's rating of Aaa, Aa, A, or Baa or a Standard and Poor's rating of AAA, AA, A, or BBB; if rated by both firms, the bonds have a Moody's rating of Aaa, Aa, A, or Baa and a Standard and Poor's rating of AAA, AA, A, or BBB.

Worksheet for Municipal Financial Test

Part I: Basic Information

1. Total Revenues

a. Revenues (dollars)

Value of revenues excludes liquidation of investments and issuance of debt. Value includes all general fund operating and non-operating revenues, as well as all revenues from all other governmental funds including enterprise, debt service, capital projects, and special revenues, but excluding revenues to funds held in a trust or agency capacity.

b. Subtract interfund transfers (dollars)

c. Total Revenues (dollars)

2. Total Expenditures

a. Expenditures (dollars)

Value consists of the sum of general fund operating and non-operating expenditures including interest payments on debt, payments for retirement of debt principal, and total expenditures from all other governmental funds including enterprise, debt service, capital projects, and special revenues.

b. Subtract interfund transfers (dollars) _____

c. Total Expenditures (dollars)

3. Local Revenues

a. Total Revenues (from 1c) (dollars)_____

b. Subtract total intergovernmental transfers (dollars)_____

c. Local Revenues (dollars)_____

4. Debt Service

a. Interest and fiscal charges (dollars) _____

b. Add debt retirement (dollars)_____

c. Total Debt Service (dollars)_____

5. Total Funds (Dollars)_____ (Sum of amounts held as cash and investment securities from all funds, excluding amounts held for employee retirement funds, agency funds, and trust funds)

6. Population (Persons)_____

Part II: Application of Test

7. Total Revenues to Population

a. Total Revenues (from 1c)_____

b. Population (from 6)_____

c. Divide 7a by 7b_____

d. Subtract 417_____

e. Divide by 5,212_____

f. Multiply by 4.095_____

8. Total Expenses to Population

a. Total Expenses (from 2c)_____

b. Population (from 6) _____

c. Divide 8a by 8b_____

d. Subtract 524_____

e. Divide by 5,401_____

f. Multiply by 4.095_____

9. Local Revenues to Total Revenues

a. Local Revenues (from 3c)_____

b. Total Revenues (from 1c)_____

c. Divide 9a by 9b_____

d. Subtract .695_____

e. Divide by .205_____

f. Multiply by 2.840_____

10. Debt Service to Population

a. Debt Service (from 4c)_____

b. Population (from 6)_____

c. Divide 10a by 10b_____

d. Subtract 51_____

e. Divide by 1,038_____

f. Multiply by −1.866_____

11. Debt Service to Total Revenues

a. Debt Service (from 4c)_____

b. Total Revenues (from 1c)_____

c. Divide 11a by 11b_____

d. Subtract .068_____

e. Divide by .259_____

f. Multiply by −3.533_____

12. Total Revenues to Total Expenses

a. Total Revenues (from 1c)_____

b. Total Expenses (from 2c)_____

c. Divide 12a by 12b_____

d. Subtract .910_____

e. Divide by .899_____

f. Multiply by 3.458_____

13. Funds Balance to Total Revenues

a. Total Funds (from 5)_____

b. Total Revenues (from 1c)_____

c. Divide 13a by 13b_____

d. Subtract .891_____

e. Divide by 9.156_____

f. Multiply by 3.270_____

14. Funds Balance to Total Expenses

a. Total Funds (from 5)_____

b. Total Expenses (from 2c)_____

c. Divide 14a by 14b_____

d. Subtract .866_____

e. Divide by 6.409_____

f. Multiply by 3.270_____

15. Total Funds to Population_____

a. Total Funds (from 5)_____

b. Population (from 6)_____

c. Divide 15a by 15b_____

d. Subtract 270_____

e. Divide by 4,548_____

f. Multiply by 1.866_____

16. Add 7f + 8f + 9f + 10f + 11f + 12f + 13f + 14f + 15f + 4.937_____

I hereby certify that the financial index shown on line 16 of the worksheet is greater than zero and that

the wording of this letter is identical to the wording specified in 40 CFR 280.105(c) as such regulations were constituted on the date shown immediately below.

[Date]
[Signature]
[Name]
[Title]

(d) If a local government owner or operator using the test to provide financial assurance finds that it no longer meets the requirements of the financial test based on the year-end financial statements, the owner or operator must obtain alternative coverage within 150 days of the end of the year for which financial statements have been prepared.

(e) The Director of the implementing agency may require reports of financial condition at any time from the local government owner or operator. If the Director finds, on the basis of such reports or other information, that the local government owner or operator no longer meets the financial test requirements of § 280.105(b) and (c), the owner or operator must obtain alternate coverage within 30 days after notification of such a finding.

(f) If the local government owner or operator fails to obtain alternate assurance within 150 days of finding that it no longer meets the requirements of the financial test based on the year-end financial statements or within 30 days of notification by the Director of the implementing agency that it no longer meets the requirements of the financial test, the owner or operator must notify the Director of such failure within 10 days.

§ 280.106 Local government guarantee.

(a) A local government owner or operator may satisfy the requirements of § 280.93 by obtaining a guarantee that conforms to the requirements of this section. The guarantor must be either the state in which the local government owner or operator is located or a local government having a ''substantial governmental relationship'' with the owner and operator and issuing the guarantee as an act incident to that relationship. A local government acting as the guarantor must:

(1) Demonstrate that it meets the bond rating test requirement of § 280.104 and deliver a copy of the chief financial officer's letter as contained in § 280.104(d) and (e) to the local government owner or operator; or

(2) Demonstrate that it meets the worksheet test requirements of § 280.105 and deliver a copy of the chief financial officer's letter as contained in § 280.105(c) to the local government owner or operator; or

(3) Demonstrate that it meets the local government fund requirements of § 280.107(a), (b), or (c) and deliver a copy of the chief financial officer's letter as contained in § 280.107 to the local government owner or operator.

(b) If the local government guarantor is unable to demonstrate financial assurance under any of §§ 280.104, 280.105, or 280.107(a), (b), or (c), at the end of the financial reporting year, the guarantor shall send by certified mail, before cancellation or non-renewal of the guarantee, notice to the owner or operator. The guarantee will terminate no less than 120 days after the date the owner or operator receives the notification, as evidenced by the return receipt. The owner or operator must obtain alternative coverage as specified in § 280.114(e).

(c) The guarantee agreement must be worded as specified in paragraph (d) or (e) of this section, depending on which of the following alternative guarantee arrangements is selected:

(1) If, in the default or incapacity of the owner or operator, the guarantor guarantees to fund a standby trust as directed by the Director of the implementing agency, the guarantee shall be worded as specified in paragraph (d) of this section.

(2) If, in the default or incapacity of the owner or operator, the guarantor guarantees to make payments as directed by the Director of the implementing agency for taking corrective action or compensating third parties for bodily injury and property damage, the guarantee shall be worded as specified in paragraph (e) of this section.

(d) If the guarantor is a state, the local government guarantee with standby trust must be worded exactly as follows, except that instructions in brackets are to be replaced with relevant information and the brackets deleted:

Local Government Guarantee With Standby Trust Made by a State

Guarantee made this [date] by [name of state], herein referred to as guarantor, to [the state implementing agency] and to any and all third parties, and obliges, on behalf of [local government owner or operator].

Recitals

(1) Guarantor is a state.

(2) [Local government owner or operator] owns or operates the following underground storage tank(s) covered by this guarantee: [List the number of tanks at each facility and the name(s) and address(es) of the facility(ies) where the tanks are located. If more than one instrument is used to assure different tanks at any one facility, for each tank covered by this instrument, list the tank identification number provided in the notification submitted pursuant to 40 CFR part 280 or the corresponding state requirement, and the name and address of the facility.] This guarantee satisfies 40 CFR part 280, subpart H requirements for assuring funding for [insert: ''taking corrective action'' and/or ''compensating third parties for bodily injury and property damage caused by'' either ''sudden accidental releases'' or ''nonsudden accidental releases'' or ''accidental releases''; if coverage is different for different tanks or locations, indicate the type of coverage applicable to each tank or location] arising from operating the above-identified underground storage tank(s) in the amount of [insert dollar amount] per occurrence and [insert dollar amount] annual aggregate.

(3) Guarantor guarantees to [implementing agency] and to any and all third parties that:

In the event that [local government owner or operator] fails to provide alternative coverage within 60 days after receipt of a notice of cancellation of this guarantee and the [Director of the implementing agency] has determined or suspects that a release has occurred at an underground storage tank covered by this guarantee, the guarantor, upon instructions from the [Director] shall fund a standby trust fund in accordance with the provisions of 40 CFR 280.112, in an amount not to exceed the coverage limits specified above.

In the event that the [Director] determines that [local government owner or operator] has failed to perform corrective action for releases arising out of the operation of the above-identified tank(s) in accordance with 40 CFR part 280, subpart F, the guarantor upon written instructions from the [Director] shall fund a standby trust fund in accordance with the provisions of 40 CFR 280.112, in an amount not to exceed the coverage limits specified above.

If [owner or operator] fails to satisfy a judgment or award based on a determination of liability for bodily injury or property damage to third parties caused by [''sudden'' and/or ''nonsudden''] accidental releases arising from the operation of the above-identified tank(s), or fails to pay an amount agreed to in settlement of a claim arising from or alleged to arise from such injury or damage, the guarantor, upon written instructions from the [Director], shall fund a standby trust in accordance with the provisions

of 40 CFR 280.112 to satisfy such judgment(s), award(s), or settlement agreement(s) up to the limits of coverage specified above.

(4) Guarantor agrees to notify [owner or operator] by certified mail of a voluntary or involuntary proceeding under Title 11 (Bankruptcy), U.S. Code naming guarantor as debtor, within 10 days after commencement of the proceeding.

(5) Guarantor agrees to remain bound under this guarantee notwithstanding any modification or alteration of any obligation of [owner or operator] pursuant to 40 CFR part 280.

(6) Guarantor agrees to remain bound under this guarantee for so long as [local government owner or operator] must comply with the applicable financial responsibility requirements of 40 CFR part 280, subpart H for the above identified tank(s), except that guarantor may cancel this guarantee by sending notice by certified mail to [owner or operator], such cancellation to become effective no earlier than 120 days after receipt of such notice by [owner or operator], as evidenced by the return receipt.

(7) The guarantor's obligation does not apply to any of the following:

(a) Any obligation of [local government owner or operator] under a workers' compensation, disability benefits, or unemployment compensation law or other similar law;

(b) Bodily injury to an employee of [insert: local government owner or operator] arising from, and in the course of, employment by [insert: local government owner or operator];

(c) Bodily injury or property damage arising from the ownership, maintenance, use, or entrustment to others of any aircraft, motor vehicle, or watercraft;

(d) Property damage to any property owned, rented, loaned to, in the care, custody, or control of, or occupied by [insert: local government owner or operator] that is not the direct result of a release from a petroleum underground storage tank;

(e) Bodily damage or property damage for which [insert owner or operator] is obligated to pay damages by reason of the assumption of liability in a contract or agreement other than a contract or agreement entered into to meet the requirements of 40 CFR 280.93.

(8) Guarantor expressly waives notice of acceptance of this guarantee by [the implementing agency], by any or all third parties, or by [local government owner or operator],

I hereby certify that the wording of this guarantee is identical to the wording specified in 40 CFR 280.106(d) as such regulations were constituted on the effective date shown immediately below.

Effective date:

[Name of guarantor]
[Authorized signature for guarantor]
[Name of person signing]
[Title of person signing]
Signature of witness or notary:

If the guarantor is a local government, the local government guarantee with standby trust must be worded exactly as follows, except that instructions in brackets are to be replaced with relevant information and the brackets deleted:

Local Government Guarantee With Standby Trust Made by a Local Government

Guarantee made this [date] by [name of guaranteeing entity], a local government organized under the laws of [name of state], herein referred to as guarantor, to [the state implementing agency] and to any and all third parties, and obliges, on behalf of [local government owner or operator].

Recitals

(1) Guarantor meets or exceeds [select one: the local government bond rating test requirements of 40 CFR 280.104, the local government financial test requirements of 40 CFR 280.105, or the local government fund under 40 CFR 280.107(a), 280.107(b), or 280.107(c)].

(2) [Local government owner or operator] owns or operates the following underground storage tank(s) covered by this guarantee: [List the number of tanks at each facility and the name(s) and address(es) of the facility(ies) where the tanks are located. If more than one instrument is used to assure different tanks at any one facility, for each tank covered by this instrument, list the tank identification number provided in the notification submitted pursuant to 40 CFR part 280 or the corresponding state requirement, and the name and address of the facility.] This guarantee satisfies 40 CFR part 280, subpart H requirements for assuring funding for [insert: ''taking corrective action'' and/or ''compensating third parties for bodily injury and property damage caused by'' either ''sudden accidental Releases'' or ''nonsudden accidental releases'' or ''accidental Releases''; if coverage is different for different tanks or locations, indicate the type of coverage applicable to each tank or location] arising from operating the above-identified underground storage tank(s) in the amount of [insert dollar amount] per occurrence and [insert: dollar amount] annual aggregate.

(3) Incident to our substantial governmental relationship with [local government owner or operator], guarantor guarantees to [implementing agency] and to any and all third parties that:

In the event that [local government owner or operator] fails to provide alternative coverage within 60 days after receipt of a notice of cancellation of this guarantee and the [Director of the implementing agency] has determined or suspects that a release has occurred at an underground storage tank covered by this guarantee, the guarantor, upon instructions from the [Director] shall fund a standby trust fund in accordance with the provisions of 40 CFR 280.112, in an amount not to exceed the coverage limits specified above.

In the event that the [Director] determines that [local government owner or operator] has failed to perform corrective action for releases arising out of the operation of the above-identified tank(s) in accordance with 40 CFR part 280, subpart F, the guarantor upon written instructions from the [Director] shall fund a standby trust fund in accordance with the provisions of 40 CFR 280.112, in an amount not to exceed the coverage limits specified above.

If [owner or operator] fails to satisfy a judgment or award based on a determination of liability for bodily injury or property damage to third parties caused by [''sudden'' and/or ''nonsudden''] accidental releases arising from the operation of the above-identified tank(s), or fails to pay an amount agreed to in settlement of a claim arising from or alleged to arise from such injury or damage, the guarantor, upon written instructions from the [Director], shall fund a standby trust in accordance with the provisions of 40 CFR 280.112 to satisfy such judgment(s), award(s), or settlement agreement(s) up to the limits of coverage specified above.

(4) Guarantor agrees that, if at the end of any fiscal year before cancellation of this guarantee, the guarantor fails to meet or exceed the requirements of the financial responsibility mechanism specified in paragraph (1), guarantor shall send within 120 days of such failure, by certified mail, notice to [local government owner or operator], as evidenced by the return receipt.

(5) Guarantor agrees to notify [owner or operator] by certified mail of a voluntary or involuntary proceeding under Title 11 (Bankruptcy), U.S. Code naming guarantor as debtor, within 10 days after commencement of the proceeding.

(6) Guarantor agrees to remain bound under this guarantee notwithstanding any modification or alteration of any

obligation of [owner or operator] pursuant to 40 CFR part 280.

(7) Guarantor agrees to remain bound under this guarantee for so long as [local government owner or operator] must comply with the applicable financial responsibility requirements of 40 CFR part 280, subpart H for the above identified tank(s), except that guarantor may cancel this guarantee by sending notice by certified mail to [owner or operator], such cancellation to become effective no earlier than 120 days after receipt of such notice by [owner or operator], as evidenced by the return receipt.

(8) The guarantor's obligation does not apply to any of the following:

(a) Any obligation of [local government owner or operator] under a workers' compensation, disability benefits, or unemployment compensation law or other similar law;

(b) Bodily injury to an employee of [insert: local government owner or operator] arising from, and in the course of, employment by [insert: local government owner or operator];

(c) Bodily injury or property damage arising from the ownership, maintenance, use, or entrustment to others of any aircraft, motor vehicle, or watercraft;

(d) Property damage to any property owned, rented, loaned to, in the care, custody, or control of, or occupied by [insert: local government owner or operator] that is not the direct result of a release from a petroleum underground storage tank;

(e) Bodily damage or property damage for which [insert: owner or operator] is obligated to pay damages by reason of the assumption of liability in a contract or agreement other than a contract or agreement entered into to meet the requirements of 40 CFR 280.93.

(9) Guarantor expressly waives notice of acceptance of this guarantee by [the implementing agency], by any or all third parties, or by [local government owner or operator].

I hereby certify that the wording of this guarantee is identical to the wording specified in 40 CFR 280.106(d) as such regulations were constituted on the effective date shown immediately below.

Effective date:

[Name of guarantor]
[Authorized signature for guarantor]
[Name of person signing]
[Title of person signing]
Signature of witness or notary:

(e) If the guarantor is a state, the local government guarantee without standby trust must be worded exactly as follows, except that instructions in brackets are to be replaced with relevant information and the brackets deleted:

Local Government Guarantee Without Standby Trust Made by a State

Guarantee made this [date] by [name of state], herein referred to as guarantor, to [the state implementing agency] and to any and all third parties, and obliges, on behalf of [local government owner or operator].

Recitals

(1) Guarantor is a state.

(2) [Local government owner or operator] owns or operates the following underground storage tank(s) covered by this guarantee: [List the number of tanks at each facility and the name(s) and address(es) of the facility(ies) where the tanks are located. If more than one instrument is used to assure different tanks at any one facility, for each tank covered by this instrument, list the tank identification number provided in the notification submitted pursuant to 40 CFR part 280 or the corresponding state requirement, and the name and address of the facility.] This guarantee satisfies 40 CFR part 280, subpart H requirements for assuring funding for [insert: ''taking corrective action'' and/or ''compensating third parties for bodily injury and property damage caused by'' either ''sudden accidental releases'' or ''nonsudden accidental releases'' or ''accidental releases''; if coverage is different for different tanks or locations, indicate the type of coverage applicable to each tank or location] arising from operating the above-identified underground storage tank(s) in the amount of [insert: dollar amount] per occurrence and [insert: dollar amount] annual aggregate.

(3) Guarantor guarantees to [implementing agency] and to any and all third parties and obliges that:

In the event that [local government owner or operator] fails to provide alternative coverage within 60 days after receipt of a notice of cancellation of this guarantee and the [Director of the implementing agency] has determined or suspects that a release has occurred at an underground storage tank covered by this guarantee, the guarantor, upon written instructions from the [Director] shall make funds available to pay for corrective actions and compensate third parties for bodily injury and property damage in an amount not to exceed the coverage limits specified above.

In the event that the [Director] determines that [local government owner or operator] has failed to perform corrective action for releases arising out of the operation of the above-identified tank(s) in accordance with 40 CFR part 280, subpart F, the guarantor upon written instructions from the [Director] shall make funds available to pay for corrective actions in an amount not to exceed the coverage limits specified above.

If [owner or operator] fails to satisfy a judgment or award based on a determination of liability for bodily injury or property damage to third parties caused by [''sudden'' and/or ''nonsudden''] accidental releases arising from the operation of the above-identified tank(s), or fails to pay an amount agreed to in settlement of a claim arising from or alleged to arise from such injury or damage, the guarantor, upon written instructions from the [Director], shall make funds available to compensate third parties for bodily injury and property damage in an amount not to exceed the coverage limits specified above.

(4) Guarantor agrees to notify [owner or operator] by certified mail of a voluntary or involuntary proceeding under Title 11 (Bankruptcy), U.S. Code naming guarantor as debtor, within 10 days after commencement of the proceeding.

(5) Guarantor agrees to remain bound under this guarantee notwithstanding any modification or alteration of any obligation of [owner or operator] pursuant to 40 CFR part 280.

(6) Guarantor agrees to remain bound under this guarantee for so long as [local government owner or operator] must comply with the applicable financial responsibility requirements of 40 CFR part 280, subpart H for the above identified tank(s), except that guarantor may cancel this guarantee by sending notice by certified mail to [owner or operator], such cancellation to become effective no earlier than 120 days after receipt of such notice by [owner or operator], as evidenced by the return receipt. If notified of a probable release, the guarantor agrees to remain bound to the terms of this guarantee for all charges arising from the release, up to the coverage limits specified above, notwithstanding the cancellation of the guarantee with respect to future releases.

(7) The guarantor's obligation does not apply to any of the following:

(a) Any obligation of [local government owner or operator] under a workers' compensation disability benefits, or unemployment compensation law or other similar law;

(b) Bodily injury to an employee of [insert local government owner or operator] arising from, and in the course of, employment by [insert: local government owner or operator];

(c) Bodily injury or property damage arising from the ownership, maintenance, use, or entrustment to others of any aircraft, motor vehicle, or watercraft;

(d) Property damage to any property owned, rented, loaned to, in the care, custody, or control of, or occupied by [insert: local government owner or operator] that is not the direct result of a release from a petroleum underground storage tank;

(e) Bodily damage or property damage for which [insert: owner or operator] is obligated to pay damages by reason of the assumption of liability in a contract or agreement other than a contract or agreement entered into to meet the requirements of 40 CFR 280.93.

(8) Guarantor expressly waives notice of acceptance of this guarantee by [the implementing agency], by any or all third parties, or by [local government owner or operator].

I hereby certify that the wording of this guarantee is identical to the wording specified in 40 CFR 280.106(e) as such regulations were constituted on the effective date shown immediately below.

Effective date:

[Name of guarantor]
[Authorized signature for guarantor]
[Name of person signing]
[Title of person signing]
Signature of witness or notary:

If the guarantor is a local government, the local government guarantee without standby trust must be worded exactly as follows, except that instructions in brackets are to be replaced with relevant information and the brackets deleted:

Local Government Guarantee Without Standby Trust Made by a Local Government

Guarantee made this [date] by [name of guaranteeing entity], a local government organized under the laws of [name of state], herein referred to as guarantor, to [the state implementing agency] and to any and all third parties, and obliges, on behalf of [local government owner or operator].

Recitals

(1) Guarantor meets or exceeds [select one: the local government bond rating test requirements of 40 CFR 280.104, the local government financial test requirements of 40 CFR 280.105, the local government fund under 40 CFR 280.107(a), 280.107(b), or 280.107(c)].

(2) [Local government owner or operator] owns or operates the following underground storage tank(s) covered by this guarantee: [List the number of tanks at each facility and the name(s) and address(es) of the facility(ies) where the tanks are located. If more than one instrument is used to assure different tanks at any one facility, for each tank covered by this instrument, list the tank identification number provided in the notification submitted pursuant to 40 CFR part 280 or the corresponding state requirement, and the name and address of the facility.] This guarantee satisfies 40 CFR part 280, subpart H requirements for assuring funding for [insert: ''taking corrective action'' and/or ''compensating third parties for bodily injury and property damage caused by'' either ''sudden accidental releases'' or ''nonsudden accidental releases'' or ''accidental releases''; if coverage is different for different tanks or locations, indicate the type of coverage applicable to each tank or location] arising from operating the above-identified underground storage tank(s) in the amount of [insert: dollar amount] per occurrence and [insert: dollar amount] annual aggregate.

(3) Incident to our substantial governmental relationship with [local government owner or operator], guarantor guarantees to [implementing agency] and to any and all third parties and obliges that:

In the event that [local government owner or operator] fails to provide alternative coverage within 60 days after receipt of a notice of cancellation of this guarantee and the [Director of the implementing agency] has determined or suspects that a release has occurred at an underground storage tank covered by this guarantee, the guarantor, upon written instructions from the [Director] shall make funds available to pay for corrective actions and compensate third parties for bodily injury and property damage in an amount not to exceed the coverage limits specified above.

In the event that the [Director] determines that [local government owner or operator] has failed to perform corrective action for releases arising out of the operation of the above-identified tank(s) in accordance with 40 CFR part 280, subpart F, the guarantor upon written instructions from the [Director] shall make funds available to pay for corrective actions in an amount not to exceed the coverage limits specified above.

If [owner or operator] fails to satisfy a judgment or award based on a determination of liability for bodily injury or property damage to third parties caused by [''sudden'' and/or ''nonsudden''] accidental releases arising from the operation of the above-identified tank(s), or fails to pay an amount agreed to in settlement of a claim arising from or alleged to arise from such injury or damage, the guarantor, upon written instructions from the [Director], shall make funds available to compensate third parties for bodily injury and property damage in an amount not to exceed the coverage limits specified above.

(4) Guarantor agrees that if at the end of any fiscal year before cancellation of this guarantee, the guarantor fails to meet or exceed the requirements of the financial responsibility mechanism specified in paragraph (1), guarantor shall send within 120 days of such failure, by certified mail, notice to [local government owner or operator], as evidenced by the return receipt.

(5) Guarantor agrees to notify [owner or operator] by certified mail of a voluntary or involuntary proceeding under Title 11 (Bankruptcy), U.S. Code naming guarantor as debtor, within 10 days after commencement of the proceeding.

(6) Guarantor agrees to remain bound under this guarantee notwithstanding any modification or alteration of any obligation of [owner or operator] pursuant to 40 CFR part 280.

(7) Guarantor agrees to remain bound under this guarantee for so long as [local government owner or operator] must comply with the applicable financial responsibility requirements of 40 CFR part 280, subpart H for the above identified tank(s), except that guarantor may cancel this guarantee by sending notice by certified mail to [owner or operator], such cancellation to become effective no earlier than 120 days after receipt of such notice by [owner or operator], as evidenced by the return receipt. If notified of a probable release, the guarantor agrees to remain bound to the terms of this guarantee for all charges arising from the release, up to the coverage limits specified above, notwithstanding the cancellation of the guarantee with respect to future releases.

(8) The guarantor's obligation does not apply to any of the following:

(a) Any obligation of [local government owner or operator] under a workers' compensation disability benefits, or unemployment compensation law or other similar law;

(b) Bodily injury to an employee of [insert: local government owner or operator] arising from, and in the course of, employment by [insert: local government owner or operator];

(c) Bodily injury or property damage arising from the ownership, maintenance, use, or entrustment to others of any aircraft, motor vehicle, or watercraft;

(d) Property damage to any property owned, rented, loaned to, in the care,

custody, or control of, or occupied by [insert: local government owner or operator] that is not the direct result of a release from a petroleum underground storage tank;

(e) Bodily damage or property damage for which [insert: owner or operator] is obligated to pay damages by reason of the assumption of liability in a contract or agreement other than a contract or agreement entered into to meet the requirements of 40 CFR 280.93.

(9) Guarantor expressly waives notice of acceptance of this guarantee by [the implementing agency], by any or all third parties, or by [local government owner or operator],

I hereby certify that the wording of this guarantee is identical to the wording specified in 40 CFR 280.106(e) as such regulations were constituted on the effective date shown immediately below.

Effective date:

[Name of guarantor]
[Authorized signature for guarantor]
[Name of person signing]
[Title of person signing]
Signature of witness or notary:

§ 280.107 Local government fund.

A local government owner or operator may satisfy the requirements of § 280.93 by establishing a dedicated fund account that conforms to the requirements of this section. Except as specified in paragraph (b) of this section, a dedicated fund may not be commingled with other funds or otherwise used in normal operations. A dedicated fund will be considered eligible if it meets one of the following requirements:

(a) The fund is dedicated by state constitutional provision, or local government statute, charter, ordinance, or order to pay for taking corrective action and for compensating third parties for bodily injury and property damage caused by accidental releases arising from the operation of petroleum underground storage tanks and is funded for the full amount of coverage required under § 280.93, or funded for part of the required amount of coverage and used in combination with other mechanism(s) that provide the remaining coverage; or

(b) The fund is dedicated by state constitutional provision, or local government statute, charter, ordinance, or order as a contingency fund for general emergencies, including taking corrective action and compensating third parties for bodily injury and property damage caused by accidental releases arising from the operation of petroleum underground storage tanks, and is funded for five times the full amount of coverage required under § 280.93, or funded for part of the required amount of coverage and used in combination with other mechanism(s) that provide the remaining coverage. If the fund is funded for less than five times the amount of coverage required under § 280.93, the amount of financial responsibility demonstrated by the fund may not exceed one-fifth the amount in the fund; or

(c) The fund is dedicated by state constitutional provision, or local government statute, charter, ordinance or order to pay for taking corrective action and for compensating third parties for bodily injury and property damage caused by accidental releases arising from the operation of petroleum underground storage tanks. A payment is made to the fund once every year for seven years until the fund is fully-funded. This seven year period is hereafter referred to as the ''pay-in-period.'' The amount of each payment must be determined by this formula:

$$\frac{TF - CF}{Y}$$

Where TF is the total required financial assurance for the owner or operator, CF is the current amount in the fund, and Y is the number of years remaining in the pay-in-period; and,

(1) The local government owner or operator has available bonding authority, approved through voter referendum (if such approval is necessary prior to the issuance of bonds), for an amount equal to the difference between the required amount of coverage and the amount held in the dedicated fund. This bonding authority shall be available for taking corrective action and for compensating third parties for bodily injury and property damage caused by accidental releases arising from the operation of petroleum underground storage tanks; or

(2) The local government owner or operator has a letter signed by the appropriate state attorney general stating that the use of the bonding authority will not increase the local government's debt beyond the legal debt ceilings established by the relevant state laws. The letter must also state that prior voter approval is not necessary before use of the bonding authority.

(d) To demonstrate that it meets the requirements of the local government fund, the chief financial officer of the local government owner or operator and/or guarantor must sign a letter worded exactly as follows, except that the instructions in brackets are to be replaced by the relevant information and the brackets deleted:

Letter from Chief Financial Officer

I am the chief financial officer of [insert: name and address of local government owner or operator, or guarantor]. This letter is in support of the use of the local government fund mechanism to demonstrate financial responsibility for [insert: ''taking corrective action'' and/or ''compensating third parties for bodily injury and property damage''] caused by [insert: ''sudden accidental releases'' or ''nonsudden accidental releases'' or ''accidental releases''] in the amount of at least [insert: dollar amount] per occurrence and [insert: dollar amount] annual aggregate arising from operating (an) underground storage tank(s).

Underground storage tanks at the following facilities are assured by this local government fund mechanism: [List for each facility: The name and address of the facility where tanks are assured by the local government fund].

[Insert: ''The local government fund is funded for the full amount of coverage required under § 280.93, or funded for part of the required amount of coverage and used in combination with other mechanism(s) that provide the remaining coverage.'' or ''The local government fund is funded for five times the full amount of coverage required under § 280.93, or funded for part of the required amount of coverage and used in combination with other mechanisms(s) that provide the remaining coverage,'' or ''A payment is made to the fund once every year for seven years until the fund is fully-funded and [name of local government owner or operator] has available bonding authority, approved through voter referendum, of an amount equal to the difference between the required amount of coverage and the amount held in the dedicated fund'' or ''A payment is made to the fund once every year for seven years until the fund is fully-funded and I have attached a letter signed by the State Attorney General stating that (1) the use of the bonding authority will not increase the local government's debt beyond the legal debt ceilings established by the relevant state laws and (2) that prior voter approval is not necessary before use of the bonding authority'']

The details of the local government fund are as follows:

Amount in Fund (market value of fund at close of last fiscal year):

[If fund balance is incrementally funded as specified in § 280.107(c), insert:

Amount added to fund in the most recently completed fiscal year:

Number of years remaining in the pay-in-period: _____]

A copy of the state constitutional provision, or local government statute, charter, ordinance or order dedicating the fund is attached.

I hereby certify that the wording of this letter is identical to the wording specified in 40 CFR 280.107(d) as such regulations were constituted on the date shown immediately below.

[Date]
[Signature]
[Name]
[Title]

§ 280.108 Substitution of financial assurance mechanisms by owner or operator.

(a) An owner or operator may substitute any alternate financial assurance mechanisms as specified in this subpart, provided that at all times he maintains an effective financial assurance mechanism or combination of mechanisms that satisfies the requirements of § 280.93.

(b) After obtaining alternate financial assurance as specified in this subpart, an owner or operator may cancel a financial assurance mechanism by providing notice to the provider of financial assurance.

§ 280.109 Cancellation or nonrenewal by a provider of financial assurance.

(a) Except as otherwise provided, a provider of financial assurance may cancel or fail to renew an assurance mechanism by sending a notice of termination by certified mail to the owner or operator.

(1) Termination of a local government guarantee, a guarantee, a surety bond, or a letter of credit may not occur until 120 days after the date on which the owner or operator receives the notice of termination, as evidenced by the return receipt.

(2) Termination of insurance or risk retention coverage, except for non-payment or misrepresentation by the insured, or state-funded assurance may not occur until 60 days after the date on which the owner or operator receives the notice of termination, as evidenced by the return receipt. Termination for non-payment of premium or misrepresentation by the insured may not occur until a minimum of 10 days after the date on which the owner or operator receives the notice of termination, as evidenced by the return receipt.

(b) If a provider of financial responsibility cancels or fails to renew for reasons other than incapacity of the provider as specified in § 280.114, the owner or operator must obtain alternate coverage as specified in this section within 60 days after receipt of the notice of termination. If the owner or operator fails to obtain alternate coverage within 60 days after receipt of the notice of termination, the owner or operator must notify the Director of the implementing agency of such failure and submit:

(1) The name and address of the provider of financial assurance;

(2) The effective date of termination; and

(3) The evidence of the financial assistance mechanism subject to the termination maintained in accordance with § 280.111(b).

§ 280.110 Reporting by owner or operator.

(a) An owner or operator must submit the appropriate forms listed in § 280.111(b) documenting current evidence of financial responsibility to the Director of the implementing agency:

(1) Within 30 days after the owner or operator identifies a release from an underground storage tank required to be reported under § 280.53 or § 280.61;

(2) If the owner or operator fails to obtain alternate coverage as required by this subpart, within 30 days after the owner or operator receives notice of:

(i) Commencement of a voluntary or involuntary proceeding under Title 11 (Bankruptcy), U.S. Code, naming a provider of financial assurance as a debtor;

(ii) Suspension or revocation of the authority of a provider of financial assurance to issue a financial assurance mechanism;

(iii) Failure of a guarantor to meet the requirements of the financial test;

(iv) Other incapacity of a provider of financial assurance; or

(3) As required by §§ 280.95(g) and 280.109(b).

(b) An owner or operator must certify compliance with the financial responsibility requirements of this part as specified in the new tank notification form when notifying the appropriate state or local agency of the installation of a new underground storage tank under § 280.22.

(c) The Director of the Implementing Agency may require an owner or operator to submit evidence of financial assurance as described in § 280.111(b) or other information relevant to compliance with this subpart at any time.

§ 280.111 Recordkeeping.

(a) Owners or operators must maintain evidence of all financial assurance mechanisms used to demonstrate financial responsibility under this subpart for an underground storage tank until released from the requirements of this subpart under § 208.113. An owner or operator must maintain such evidence at the underground storage tank site or the owner's or operator's place of work. Records maintained off-site must be made available upon request of the implementing agency.

(b) An owner or operator must maintain the following types of evidence of financial responsibility:

(1) An owner or operator using an assurance mechanism specified in §§ 280.95 through 280.100 or § 280.102 or §§ 280.104 through 280.107 must maintain a copy of the instrument worded as specified.

(2) An owner or operator using a financial test or guarantee, or a local government financial test or a local government guarantee supported by the local government financial test must maintain a copy of the chief financial officer's letter based on year-end financial statements for the most recent completed financial reporting year. Such evidence must be on file no later than 120 days after the close of the financial reporting year.

(3) An owner or operator using a guarantee, surety bond, or letter of credit must maintain a copy of the signed standby trust fund agreement and copies of any amendments to the agreement.

(4) A local government owner or operator using a local government guarantee under § 280.106(d) must maintain a copy of the signed standby trust fund agreement and copies of any amendments to the agreement.

(5) A local government owner or operator using the local government bond rating test under § 280.104 must maintain a copy of its bond rating published within the last twelve months by Moody's or Standard & Poor's.

(6) A local government owner or operator using the local government guarantee under § 280.106, where the guarantor's demonstration of financial responsibility relies on the bond rating test under § 280.104 must maintain a copy of the guarantor's bond rating published within the last twelve months by Moody's or Standard & Poor's.

(7) An owner or operator using an insurance policy or risk retention group coverage must maintain a copy of the signed insurance policy or risk retention group coverage policy, with the endorsement or certificate of insurance and any amendments to the agreements.

(8) An owner or operator covered by a state fund or other state assurance must maintain on file a copy of any

evidence of coverage supplied by or required by the state under § 280.101(d).

(9) An owner or operator using a local government fund under § 280.107 must maintain the following documents:

(i) A copy of the state constitutional provision or local government statute, charter, ordinance, or order dedicating the fund; and

(ii) Year-end financial statements for the most recent completed financial reporting year showing the amount in the fund. If the fund is established under § 280.107(c) using incremental funding backed by bonding authority, the financial statements must show the previous year's balance, the amount of funding during the year, and the closing balance in the fund.

(iii) If the fund is established under § 280.107(c) using incremental funding backed by bonding authority, the owner or operator must also maintain documentation of the required bonding authority, including either the results of a voter referendum (under § 280.107(c)(1)), or attestation by the State Attorney General as specified under § 280.107(c)(2).

(10) A local government owner or operator using the local government guarantee supported by the local government fund must maintain a copy of the guarantor's year-end financial statements for the most recent completed financial reporting year showing the amount of the fund.

(11)(i) An owner or operator using an assurance mechanism specified in §§ 280.95 through 280.107 must maintain an updated copy of a certification of financial responsibility worded as follows, except that instructions in brackets are to be replaced with the relevant information and the brackets deleted:

Certification of Financial Responsibility

[Owner or operator] hereby certifies that it is in compliance with the requirements of subpart H of 40 CFR part 280.

The financial assurance mechanism(s) used to demonstrate financial responsibility under subpart H of 40 CFR part 280 is (are) as follows:

[For each mechanism, list the type of mechanism, name of issuer, mechanism number (if applicable), amount of coverage, effective period of coverage and whether the mechanism covers ''taking corrective action'' and/or ''compensating third parties for bodily injury and property damage caused by'' either ''sudden accidental releases'' or ''nonsudden accidental releases'' or ''accidental releases.'']

[Signature of owner or operator]
[Name of owner or operator]
[Title]
[Date]
[Signature of witness or notary]
[Name of witness or notary]
[Date]

(ii) The owner or operator must update this certification whenever the financial assurance mechanism(s) used to demonstrate financial responsibility change(s).

§ 280.112 Drawing on financial assurance mechanisms.

(a) Except as specified in paragraph (d) of this section, the Director of the implementing agency shall require the guarantor, surety, or institution issuing a letter of credit to place the amount of funds stipulated by the Director, up to the limit of funds provided by the financial assurance mechanism, into the standby trust if:

(1)(i) The owner or operator fails to establish alternate financial assurance within 60 days after receiving notice of cancellation of the guarantee, surety bond, letter of credit, or, as applicable, other financial assurance mechanism; and

(ii) The Director determines or suspects that a release from an underground storage tank covered by the mechanism has occurred and so notifies the owner or operator or the owner or operator has notified the Director pursuant to subparts E or F of a release from an underground storage tank covered by the mechanism; or

(2) The conditions of paragraph (b)(1) or (b)(2)(i) or (ii) of this section are satisfied.

(b) The Director of the implementing agency may draw on a standby trust fund when:

(1) The Director makes a final determination that a release has occurred and immediate or long-term corrective action for the release is needed, and the owner or operator, after appropriate notice and opportunity to comply, has not conducted corrective action as required under subpart F of this part; or

(2) The Director has received either:

(i) Certification from the owner or operator and the third-party liability claimant(s) and from attorneys representing the owner or operator and the third-party liability claimant(s) that a third-party liability claim should be paid. The certification must be worded as follows, except that instructions in brackets are to be replaced with the relevant information and the brackets deleted:

Certification of Valid Claim

The undersigned, as principals and as legal representatives of [insert: owner or operator] and [insert: name and address of third-party claimant], hereby certify that the claim of bodily injury [and/or] property damage caused by an accidental release arising from operating [owner's or operator's] underground storage tank should be paid in the amount of $[_].

[Signatures]
Owner or Operator
Attorney for Owner or Operator
(Notary)
Date
[Signatures]
Claimant(s)
Attorney(s) for Claimant(s)
(Notary)
Date
or

(ii) A valid final court order establishing a judgment against the owner or operator for bodily injury or property damage caused by an accidental release from an underground storage tank covered by financial assurance under this subpart and the Director determines that the owner or operator has not satisfied the judgment.

(c) If the Director of the implementing agency determines that the amount of corrective action costs and third-party liability claims eligible for payment under paragraph (b) of this section may exceed the balance of the standby trust fund and the obligation of the provider of financial assurance, the first priority for payment shall be corrective action costs necessary to protect human health and the environment. The Director shall pay third-party liability claims in the order in which the Director receives certifications under paragraph (b)(2)(i) of this section, and valid court orders under paragraph (b)(2)(ii) of this section.

(d) A governmental entity acting as guarantor under § 280.106(e), the local government guarantee without standby trust, shall make payments as directed by the Director under the circumstances described in § 280.112(a), (b), and (c).

§ 280.113 Release from the requirements.

An owner or operator is no longer required to maintain financial responsibility under this subpart for an underground storage tank after the tank has been permanently closed or undergoes a change-in-service or, if corrective action is required, after corrective action has been completed and the tank has been permanently closed or undergoes a change-in-service as required by subpart G of this part.

§ 280.114 Bankruptcy or other incapacity of owner or operator or provider of financial assurance.

(a) Within 10 days after commencement of a voluntary or

involuntary proceeding under Title 11 (Bankruptcy), U.S. Code, naming an owner or operator as debtor, the owner or operator must notify the Director of the implementing agency by certified mail of such commencement and submit the appropriate forms listed in § 280.111(b) documenting current financial responsibility.

(b) Within 10 days after commencement of a voluntary or involuntary proceeding under Title 11 (Bankruptcy), U.S. Code, naming a guarantor providing financial assurance as debtor, such guarantor must notify the owner or operator by certified mail of such commencement as required under the terms of the guarantee specified in § 280.96.

(c) Within 10 days after commencement of a voluntary or involuntary proceeding under Title 11 (Bankruptcy), U.S. Code, naming a local government owner or operator as debtor, the local government owner or operator must notify the Director of the implementing agency by certified mail of such commencement and submit the appropriate forms listed in § 280.111(b) documenting current financial responsibility.

(d) Within 10 days after commencement of a voluntary or involuntary proceeding under Title 11 (Bankruptcy), U.S. Code, naming a guarantor providing a local government financial assurance as debtor, such guarantor must notify the local government owner or operator by certified mail of such commencement as required under the terms of the guarantee specified in § 280.106.

(e) An owner or operator who obtains financial assurance by a mechanism other than the financial test of self-insurance will be deemed to be without the required financial assurance in the event of a bankruptcy or incapacity of its provider of financial assurance, or a suspension or revocation of the authority of the provider of financial assurance to issue a guarantee, insurance policy, risk retention group coverage policy, surety bond, letter of credit, or state-required mechanism. The owner or operator must obtain alternate financial assurance as specified in this subpart within 30 days after receiving notice of such an event. If the owner or operator does not obtain alternate coverage within 30 days after such notification, he must notify the Director of the implementing agency.

(f) Within 30 days after receipt of notification that a state fund or other state assurance has become incapable of paying for assured corrective action or third-party compensation costs, the owner or operator must obtain alternate financial assurance.

§ 280.115 Replenishment of guarantees, letters of credit, or surety bonds.

(a) If at any time after a standby trust is funded upon the instruction of the Director of the implementing agency with funds drawn from a guarantee, local government guarantee with standby trust, letter of credit, or surety bond, and the amount in the standby trust is reduced below the full amount of coverage required, the owner or operator shall by the anniversary date of the financial mechanism from which the funds were drawn:

(1) Replenish the value of financial assurance to equal the full amount of coverage required; or

(2) Acquire another financial assurance mechanism for the amount by which funds in the standby trust have been reduced.

(b) For purposes of this section, the full amount of coverage required is the amount of coverage to be provided by § 280.93. If a combination of mechanisms was used to provide the assurance funds which were drawn upon, replenishment shall occur by the earliest anniversary date among the mechanisms.

§ 280.116 Suspension of enforcement. [Reserved]

Subpart I—Lender Liability

§ 280.200 Definitions.

(a) UST technical standards, as used in this subpart, refers to the UST preventative and operating requirements under subparts B, C, D, G, J, and K of this part and § 280.50.

(b) *Petroleum production, refining, and marketing.* (1) *Petroleum production* means the production of crude oil or other forms of petroleum (as defined in § 280.12) as well as the production of petroleum products from purchased materials.

(2) *Petroleum refining* means the cracking, distillation, separation, conversion, upgrading, and finishing of refined petroleum or petroleum products.

(3) *Petroleum marketing* means the distribution, transfer, or sale of petroleum or petroleum products for wholesale or retail purposes.

(c) *Indicia of ownership* means evidence of a secured interest, evidence of an interest in a security interest, or evidence of an interest in real or personal property securing a loan or other obligation, including any legal or equitable title or deed to real or personal property acquired through or incident to foreclosure. Evidence of such interests include, but are not limited to, mortgages, deeds of trust, liens, surety bonds and guarantees of obligations, title held pursuant to a lease financing transaction in which the lessor does not select initially the leased property (hereinafter ''lease financing transaction''), and legal or equitable title obtained pursuant to foreclosure. Evidence of such interests also includes assignments, pledges, or other rights to or other forms of encumbrance against property that are held primarily to protect a security interest. A person is not required to hold title or a security interest in order to maintain indicia of ownership.

(d) *A holder* is a person who, upon the effective date of this regulation or in the future, maintains indicia of ownership (as defined in § 280.200(c)) primarily to protect a security interest (as defined in § 280.200(f)(1)) in a petroleum UST or UST system or facility or property on which a petroleum UST or UST system is located. A holder includes the initial holder (such as a loan originator); any subsequent holder (such as a successor-in-interest or subsequent purchaser of the security interest on the secondary market); a guarantor of an obligation, surety, or any other person who holds ownership indicia primarily to protect a security interest; or a receiver or other person who acts on behalf or for the benefit of a holder.

(e) *A borrower, debtor, or obligor* is a person whose UST or UST system or facility or property on which the UST or UST system is located is encumbered by a security interest. These terms may be used interchangeably.

(f) *Primarily to protect a security interest* means that the holder's indicia of ownership are held primarily for the purpose of securing payment or performance of an obligation.

(1) *Security interest* means an interest in a petroleum UST or UST system or in the facility or property on which a petroleum UST or UST system is located, created or established for the purpose of securing a loan or other obligation. Security interests include but are not limited to mortgages, deeds of trusts, liens, and title pursuant to lease financing transactions. Security interests may also arise from transactions such as sale and leasebacks, conditional sales, installment sales, trust receipt transactions, certain assignments, factoring agreements, accounts receivable financing arrangements, and consignments, if the transaction creates or establishes an interest in an UST or UST system or in the facility or property on which the UST or UST system is located, for the

purpose of securing a loan or other obligation.

(2) *Primarily to protect a security interest,* as used in this subpart, does not include indicia of ownership held primarily for investment purposes, nor ownership indicia held primarily for purposes other than as protection for a security interest. A holder may have other, secondary reasons for maintaining indicia of ownership, but the primary reason why any ownership indicia are held must be as protection for a security interest.

(g) *Operation* means, for purposes of this subpart, the use, storage, filling, or dispensing of petroleum contained in an UST or UST system.

§ 280.210 Participation in management.

The term ''participating in the management of an UST or UST system'' means that, subsequent to the effective date of this subpart, December 6, 1995, the holder is engaging in decisionmaking control of, or activities related to, operation of the UST or UST system, as defined herein.

(a) *Actions that are participation in management.* (1) Participation in the management of an UST or UST system means, for purposes of this subpart, actual participation by the holder in the management or control of decisionmaking related to the operation of an UST or UST system. Participation in management does not include the mere capacity or ability to influence or the unexercised right to control UST or UST system operations. A holder is participating in the management of the UST or UST system only if the holder either:

(i) Exercises decisionmaking control over the operational (as opposed to financial or administrative) aspects of the UST or UST system, such that the holder has undertaken responsibility for all or substantially all of the management of the UST or UST system; or

(ii) Exercises control at a level comparable to that of a manager of the borrower's enterprise, such that the holder has assumed or manifested responsibility for the overall management of the enterprise encompassing the day-to-day decisionmaking of the enterprise with respect to all, or substantially all, of the operational (as opposed to financial or administrative) aspects of the enterprise.

(2) Operational aspects of the enterprise relate to the use, storage, filling, or dispensing of petroleum contained in an UST or UST system, and include functions such as that of a facility or plant manager, operations manager, chief operating officer, or chief executive officer. Financial or administrative aspects include functions such as that of a credit manager, accounts payable/receivable manager, personnel manager, controller, chief financial officer, or similar functions. Operational aspects of the enterprise do not include the financial or administrative aspects of the enterprise, or actions associated with environmental compliance, or actions undertaken voluntarily to protect the environment in accordance with applicable requirements in this part or applicable state requirements in those states that have been delegated authority by EPA to administer the UST program pursuant to 42 U.S.C. 6991c and 40 CFR part 281.

(b) *Actions that are not participation in management pre-foreclosure.* (1) *Actions at the inception of the loan or other transaction.* No act or omission prior to the time that indicia of ownership are held primarily to protect a security interest constitutes evidence of participation in management within the meaning of this subpart. A prospective holder who undertakes or requires an environmental investigation (which could include a site assessment, inspection, and/or audit) of the UST or UST system or facility or property on which the UST or UST system is located (in which indicia of ownership are to be held), or requires a prospective borrower to clean up contamination from the UST or UST system or to comply or come into compliance (whether prior or subsequent to the time that indicia of ownership are held primarily to protect a security interest) with any applicable law or regulation, is not by such action considered to be participating in the management of the UST or UST system or facility or property on which the UST or UST system is located.

(2) *Loan policing and work out.* Actions that are consistent with holding ownership indicia primarily to protect a security interest do not constitute participation in management for purposes of this subpart. The authority for the holder to take such actions may, but need not, be contained in contractual or other documents specifying requirements for financial, environmental, and other warranties, covenants, conditions, representations or promises from the borrower. Loan policing and work out activities cover and include all such activities up to foreclosure, exclusive of any activities that constitute participation in management.

(i) *Policing the security interest or loan.* (A) A holder who engages in policing activities prior to foreclosure will remain within the exemption provided that the holder does not together with other actions participate in the management of the UST or UST system as provided in § 280.210(a). Such policing actions include, but are not limited to, requiring the borrower to clean up contamination from the UST or UST system during the term of the security interest; requiring the borrower to comply or come into compliance with applicable federal, state, and local environmental and other laws, rules, and regulations during the term of the security interest; securing or exercising authority to monitor or inspect the UST or UST system or facility or property on which the UST or UST system is located (including on-site inspections) in which indicia of ownership are maintained, or the borrower's business or financial condition during the term of the security interest; or taking other actions to adequately police the loan or security interest (such as requiring a borrower to comply with any warranties, covenants, conditions, representations, or promises from the borrower).

(B) Policing activities also include undertaking by the holder of UST environmental compliance actions and voluntary environmental actions taken in compliance with this part, provided that the holder does not otherwise participate in the management or daily operation of the UST or UST system as provided in § 280.210(a) and § 280.230. Such allowable actions include, but are not limited to, release detection and release reporting, release response and corrective action, temporary or permanent closure of an UST or UST system, UST upgrading or replacement, and maintenance of corrosion protection. A holder who undertakes these actions must do so in compliance with the applicable requirements in this part or applicable state requirements in those states that have been delegated authority by EPA to administer the UST program pursuant to 42 U.S.C. 6991c and 40 CFR part 281. A holder may directly oversee these environmental compliance actions and voluntary environmental actions, and directly hire contractors to perform the work, and is not by such action considered to be participating in the management of the UST or UST system.

(ii) *Loan work out.* A holder who engages in work out activities prior to foreclosure will remain within the exemption provided that the holder does not together with other actions participate in the management of the UST or UST system as provided in § 280.210(a). For purposes of this rule, ''work out'' refers to those actions by which a holder, at any time prior to

foreclosure, seeks to prevent, cure, or mitigate a default by the borrower or obligor; or to preserve, or prevent the diminution of, the value of the security. Work out activities include, but are not limited to, restructuring or renegotiating the terms of the security interest; requiring payment of additional rent or interest; exercising forbearance; requiring or exercising rights pursuant to an assignment of accounts or other amounts owing to an obligor; requiring or exercising rights pursuant to an escrow agreement pertaining to amounts owing to an obligor; providing specific or general financial or other advice, suggestions, counseling, or guidance; and exercising any right or remedy the holder is entitled to by law or under any warranties, covenants, conditions, representations, or promises from the borrower.

(c) Foreclosure on an UST or UST system or facility or property on which an UST or UST system is located, and participation in management activities post-foreclosure.

(1) *Foreclosure.* (i) Indicia of ownership that are held primarily to protect a security interest include legal or equitable title or deed to real or personal property acquired through or incident to foreclosure. For purposes of this subpart, the term ''foreclosure'' means that legal, marketable or equitable title or deed has been issued, approved, and recorded, and that the holder has obtained access to the UST, UST system, UST facility, and property on which the UST or UST system is located, provided that the holder acted diligently to acquire marketable title or deed and to gain access to the UST, UST system, UST facility, and property on which the UST or UST system is located. The indicia of ownership held after foreclosure continue to be maintained primarily as protection for a security interest provided that the holder undertakes to sell, re-lease an UST or UST system or facility or property on which the UST or UST system is located, held pursuant to a lease financing transaction (whether by a new lease financing transaction or substitution of the lessee), or otherwise divest itself of the UST or UST system or facility or property on which the UST or UST system is located, in a reasonably expeditious manner, using whatever commercially reasonable means are relevant or appropriate with respect to the UST or UST system or facility or property on which the UST or UST system is located, taking all facts and circumstances into consideration, and provided that the holder does not participate in management (as defined in § 280.210(a)) prior to or after foreclosure.

(ii) For purposes of establishing that a holder is seeking to sell, re-lease pursuant to a lease financing transaction (whether by a new lease financing transaction or substitution of the lessee), or divest in a reasonably expeditious manner an UST or UST system or facility or property on which the UST or UST system is located, the holder may use whatever commercially reasonable means as are relevant or appropriate with respect to the UST or UST system or facility or property on which the UST or UST system is located, or may employ the means specified in § 280.210(c)(2). A holder that outbids, rejects, or fails to act upon a written *bona fide,* firm offer of fair consideration for the UST or UST system or facility or property on which the UST or UST system is located, as provided in § 280.210(c)(2), is not considered to hold indicia of ownership primarily to protect a security interest.

(2) Holding foreclosed property for disposition and liquidation. A holder, who does not participate in management prior to or after foreclosure, may sell, re-lease, pursuant to a lease financing transaction (whether by a new lease financing transaction or substitution of the lessee), an UST or UST system or facility or property on which the UST or UST system is located, liquidate, wind up operations, and take measures, prior to sale or other disposition, to preserve, protect, or prepare the secured UST or UST system or facility or property on which the UST or UST system is located. A holder may also arrange for an existing or new operator to continue or initiate operation of the UST or UST system. The holder may conduct these activities without voiding the security interest exemption, subject to the requirements of this subpart.

(i) A holder establishes that the ownership indicia maintained after foreclosure continue to be held primarily to protect a security interest by, within 12 months following foreclosure, listing the UST or UST system or the facility or property on which the UST or UST system is located, with a broker, dealer, or agent who deals with the type of property in question, or by advertising the UST or UST system or facility or property on which the UST or UST system is located, as being for sale or disposition on at least a monthly basis in either a real estate publication or a trade or other publication suitable for the UST or UST system or facility or property on which the UST or UST system is located, or a newspaper of general circulation (defined as one with a circulation over 10,000, or one suitable under any applicable federal, state, or local rules of court for publication required by court order or rules of civil procedure) covering the location of the UST or UST system or facility or property on which the UST or UST system is located. For purposes of this provision, the 12-month period begins to run from December 6, 1995 or from the date that the marketable title or deed has been issued, approved and recorded, and the holder has obtained access to the UST, UST system, UST facility and property on which the UST or UST system is located, whichever is later, provided that the holder acted diligently to acquire marketable title or deed and to obtain access to the UST, UST system, UST facility and property on which the UST or UST system is located. If the holder fails to act diligently to acquire marketable title or deed or to gain access to the UST or UST system, the 12-month period begins to run from December 6, 1995 or from the date on which the holder first acquires either title to or possession of the secured UST or UST system, or facility or property on which the UST or UST system is located, whichever is later.

(ii) A holder that outbids, rejects, or fails to act upon an offer of fair consideration for the UST or UST system or the facility or property on which the UST or UST system is located, establishes by such outbidding, rejection, or failure to act, that the ownership indicia in the secured UST or UST system or facility or property on which the UST or UST system is located are not held primarily to protect the security interest, unless the holder is required, in order to avoid liability under federal or state law, to make a higher bid, to obtain a higher offer, or to seek or obtain an offer in a different manner.

(A) Fair consideration, in the case of a holder maintaining indicia of ownership primarily to protect a senior security interest in the UST or UST system or facility or property on which the UST or UST system is located, is the value of the security interest as defined in this section. The value of the security interest includes all debt and costs incurred by the security interest holder, and is calculated as an amount equal to or in excess of the sum of the outstanding principal (or comparable amount in the case of a lease that constitutes a security interest) owed to the holder immediately preceding the acquisition of full title (or possession in the case of a lease financing transaction) pursuant to foreclosure, plus any unpaid interest, rent, or penalties

(whether arising before or after foreclosure). The value of the security interest also includes all reasonable and necessary costs, fees, or other charges incurred by the holder incident to work out, foreclosure, retention, preserving, protecting, and preparing, prior to sale, the UST or UST system or facility or property on which the UST or UST system is located, re-lease, pursuant to a lease financing transaction (whether by a new lease financing transaction or substitution of the lessee), of an UST or UST system or facility or property on which the UST or UST system is located, or other disposition. The value of the security interest also includes environmental investigation costs (which could include a site assessment, inspection, and/or audit of the UST or UST system or facility or property on which the UST or UST system is located), and corrective action costs incurred under §§ 280.51 through 280.67 or any other costs incurred as a result of reasonable efforts to comply with any other applicable federal, state or local law or regulation; less any amounts received by the holder in connection with any partial disposition of the property and any amounts paid by the borrower (if not already applied to the borrower's obligations) subsequent to the acquisition of full title (or possession in the case of a lease financing transaction) pursuant to foreclosure. In the case of a holder maintaining indicia of ownership primarily to protect a junior security interest, fair consideration is the value of all outstanding higher priority security interests plus the value of the security interest held by the junior holder, each calculated as set forth in this paragraph (c).

(B) Outbids, rejects, or fails to act upon an offer of fair consideration means that the holder outbids, rejects, or fails to act upon within 90 days of receipt, a written, *bona fide,* firm offer of fair consideration for the UST or UST system or facility or property on which the UST or UST system is located received at any time after six months following foreclosure, as defined in § 280.210(c). A ''written, *bona fide,* firm offer'' means a legally enforceable, commercially reasonable, cash offer solely for the foreclosed UST or UST system or facility or property on which the UST or UST system is located, including all material terms of the transaction, from a ready, willing, and able purchaser who demonstrates to the holder's satisfaction the ability to perform. For purposes of this provision, the six-month period begins to run from December 6, 1995 or from the date that marketable title or deed has been issued, approved and recorded to the holder, and the holder has obtained access to the UST, UST system, UST facility and property on which the UST or UST system is located, whichever is later, provided that the holder was acting diligently to acquire marketable title or deed and to obtain access to the UST or UST system, UST facility and property on which the UST or UST system is located. If the holder fails to act diligently to acquire marketable title or deed or to gain access to the UST or UST system, the six-month period begins to run from December 6, 1995 or from the date on which the holder first acquires either title to or possession of the secured UST or UST system, or facility or property on which the UST or UST system is located, whichever is later.

(3) Actions that are not participation in management post-foreclosure. A holder is not considered to be participating in the management of an UST or UST system or facility or property on which the UST or UST system is located when undertaking actions under this part, provided that the holder does not otherwise participate in the management or daily operation of the UST or UST system as provided in § 280.210(a) and § 280.230. Such allowable actions include, but are not limited to, release detection and release reporting, release response and corrective action, temporary or permanent closure of an UST or UST system, UST upgrading or replacement, and maintenance of corrosion protection. A holder who undertakes these actions must do so in compliance with the applicable requirements in this part or applicable state requirements in those states that have been delegated authority by EPA to administer the UST program pursuant to 42 U.S.C. 6991c and 40 CFR part 281. A holder may directly oversee these environmental compliance actions and voluntary environmental actions, and directly hire contractors to perform the work, and is not by such action considered to be participating in the management of the UST or UST system.

§ 280.220 Ownership of an underground storage tank or underground storage tank system or facility or property on which an underground storage tank or underground storage tank system is located.

Ownership of an UST or UST system or facility or property on which an UST or UST system is located. A holder is not an ''owner'' of a petroleum UST or UST system or facility or property on which a petroleum UST or UST system is located for purposes of compliance with the UST technical standards as defined in § 280.200(a), the UST corrective action requirements under §§ 280.51 through 280.67, and the UST financial responsibility requirements under §§ 280.90 through 280.111, provided the person:

(a) Does not participate in the management of the UST or UST system as defined in § 280.210; and

(b) Does not engage in petroleum production, refining, and marketing as defined in § 280.200(b).

§ 280.230 Operating an underground storage tank or underground storage tank system.

(a) *Operating an UST or UST system prior to foreclosure.* A holder, prior to foreclosure, as defined in § 280.210(c), is not an ''operator'' of a petroleum UST or UST system for purposes of compliance with the UST technical standards as defined in § 280.200(a), the UST corrective action requirements under §§ 280.51 through 280.67, and the UST financial responsibility requirements under §§ 280.90 through 280.111, provided that, after December 6, 1995, the holder is not in control of or does not have responsibility for the daily operation of the UST or UST system.

(b) *Operating an UST or UST system after foreclosure.* The following provisions apply to a holder who, through foreclosure, as defined in § 280.210(c), acquires a petroleum UST or UST system or facility or property on which a petroleum UST or UST system is located.

(1) A holder is not an ''operator'' of a petroleum UST or UST system for purposes of compliance with this part if there is an operator, other than the holder, who is in control of or has responsibility for the daily operation of the UST or UST system, and who can be held responsible for compliance with applicable requirements of this part or applicable state requirements in those states that have been delegated authority by EPA to administer the UST program pursuant to 42 U.S.C. 6991c and 40 CFR part 281.

(2) If another operator does not exist, as provided for under paragraph (b)(1) of this section, a holder is not an ''operator'' of the UST or UST system, for purposes of compliance with the UST technical standards as defined in § 280.200(a), the UST corrective action requirements under §§ 280.51 through 280.67, and the UST financial responsibility requirements under §§ 280.90 through 280.111, provided that the holder:

(i) Empties all of its known USTs and UST systems within 60 calendar days

after foreclosure or within 60 calendar days after December 6, 1995, whichever is later, or another reasonable time period specified by the implementing agency, so that no more than 2.5 centimeters (one inch) of residue, or 0.3 percent by weight of the total capacity of the UST system, remains in the system; leaves vent lines open and functioning; and caps and secures all other lines, pumps, manways, and ancillary equipment; and

(ii) Empties those USTs and UST systems that are discovered after foreclosure within 60 calendar days after discovery or within 60 calendar days after December 6, 1995, whichever is later, or another reasonable time period specified by the implementing agency, so that no more than 2.5 centimeters (one inch) of residue, or 0.3 percent by weight of the total capacity of the UST system, remains in the system; leaves vent lines open and functioning; and caps and secures all other lines, pumps, manways, and ancillary equipment.

(3) If another operator does not exist, as provided for under paragraph (b)(1) of this section, in addition to satisfying the conditions under paragraph (b)(2) of this section, the holder must either:

(i) Permanently close the UST or UST system in accordance with §§ 280.71 through 280.74, except § 280.72(b); or

(ii) Temporarily close the UST or UST system in accordance with the following applicable provisions of § 280.70:

(A) Continue operation and maintenance of corrosion protection in accordance with § 280.31;

(B) Report suspected releases to the implementing agency; and

(C) Conduct a site assessment in accordance with § 280.72(a) if the UST system is temporarily closed for more than 12 months and the UST system does not meet either the performance standards in § 280.20 for new UST systems or the upgrading requirements in § 280.21, except that the spill and overfill equipment requirements do not have to be met. The holder must report any suspected releases to the implementing agency. For purposes of this provision, the 12-month period begins to run from December 6, 1995 or from the date on which the UST system is emptied and secured under paragraph (b)(2) of this section, whichever is later.

(4) The UST system can remain in temporary closure until a subsequent purchaser has acquired marketable title to the UST or UST system or facility or property on which the UST or UST system is located. Once a subsequent purchaser acquires marketable title to the UST or UST system or facility or property on which the UST or UST system is located, the purchaser must decide whether to operate or close the UST or UST system in accordance with applicable requirements in this part or applicable state requirements in those states that have been delegated authority by EPA to administer the UST program pursuant to 42 U.S.C. 6991c and 40 CFR part 281.

Subpart J—Operator Training

§ 280.240 General requirement for all UST systems.

Not later than October 13, 2018, all owners and operators of UST systems must ensure they have designated Class A, Class B, and Class C operators who meet the requirements of this subpart.

§ 280.241 Designation of Class A, B, and C operators.

UST system owners and operators must designate:

(a) At least one Class A and one Class B operator for each UST or group of USTs at a facility; and

(b) Each individual who meets the definition of Class C operator at the UST facility as a Class C operator.

§ 280.242 Requirements for operator training.

UST system owners and operators must ensure Class A, Class B, and Class C operators meet the requirements of this section. Any individual designated for more than one operator class must successfully complete the required training program or comparable examination according to the operator class in which the individual is designated.

(a) *Class A operators.* Each designated Class A operator must either be trained in accordance with paragraphs (a)(1) and (2) of this section or pass a comparable examination in accordance with paragraph (e) of this section.

(1) At a minimum, the training program for the Class A operator must provide general knowledge of the requirements in this paragraph (a). At a minimum, the training must teach the Class A operators, as applicable, about the purpose, methods, and function of:

(i) Spill and overfill prevention;

(ii) Release detection;

(iii) Corrosion protection;

(iv) Emergency response;

(v) Product and equipment compatibility and demonstration;

(vi) Financial responsibility;

(vii) Notification and storage tank registration;

(viii) Temporary and permanent closure;

(ix) Related reporting, recordkeeping, testing, and inspections;

(x) Environmental and regulatory consequences of releases; and

(xi) Training requirements for Class B and Class C operators.

(2) At a minimum, the training program must evaluate Class A operators to determine these individuals have the knowledge and skills to make informed decisions regarding compliance and determine whether appropriate individuals are fulfilling the operation, maintenance, and recordkeeping requirements for UST systems in accordance with paragraph (a)(1) of this section.

(b) *Class B operators.* Each designated Class B operator must either receive training in accordance with paragraphs (b)(1) and (2) of this section or pass a comparable examination, in accordance with paragraph (e) of this section.

(1) At a minimum, the training program for the Class B operator must cover either: general requirements that encompass all regulatory requirements and typical equipment used at UST facilities; or site-specific requirements which address only the regulatory requirements and equipment specific to the facility. At a minimum, the training program for Class B operators must teach the Class B operator, as applicable, about the purpose, methods, and function of:

(i) Operation and maintenance;

(ii) Spill and overfill prevention;

(iii) Release detection and related reporting;

(iv) Corrosion protection;

(v) Emergency response;

(vi) Product and equipment compatibility and demonstration;

(vii) Reporting, recordkeeping, testing, and inspections;

(viii) Environmental and regulatory consequences of releases; and

(ix) Training requirements for Class C operators.

(2) At a minimum, the training program must evaluate Class B operators to determine these individuals have the knowledge and skills to implement applicable UST regulatory requirements in the field on the components of typical UST systems or, as applicable, site-specific equipment used at an UST facility in accordance with paragraph (b)(1) of this section.

(c) *Class C operators.* Each designated Class C operator must either: be trained by a Class A or Class B operator in accordance with paragraphs (c)(1) and (2) of this section; complete a training program in accordance with paragraphs (c)(1) and (2) of this section; or pass a comparable examination, in accordance with paragraph (e) of this section.

(1) At a minimum, the training program for the Class C operator must teach the Class C operators to take appropriate actions (including notifying

appropriate authorities) in response to emergencies or alarms caused by spills or releases resulting from the operation of the UST system.

(2) At a minimum, the training program must evaluate Class C operators to determine these individuals have the knowledge and skills to take appropriate action (including notifying appropriate authorities) in response to emergencies or alarms caused by spills or releases from an underground storage tank system.

(d) *Training program.* Any training program must meet the minimum requirements of this section and include an evaluation through testing, a practical demonstration, or another approach acceptable to the implementing agency.

(e) *Comparable examination.* A comparable examination must, at a minimum, test the knowledge of the Class A, Class B, or Class C operators in accordance with the requirements of paragraphs (a), (b), or (c) of this section, as applicable.

§ 280.243 Timing of operator training.

(a) An owner and operator must ensure that designated Class A, Class B, and Class C operators meet the requirements in § 280.242 not later than October 13, 2018.

(b) Class A and Class B operators designated after October 13, 2018 must meet requirements in § 280.242 within 30 days of assuming duties.

(c) Class C operators designated after October 13, 2018 must be trained before assuming duties of a Class C operator.

§ 280.244 Retraining.

Class A and Class B operators of UST systems determined by the implementing agency to be out of compliance must complete a training program or comparable examination in accordance with requirements in § 280.242. The training program or comparable examination must be developed or administered by an independent organization, the implementing agency, or a recognized authority. At a minimum, the training must cover the area(s) determined to be out of compliance. UST system owners and operators must ensure Class A and Class B operators are retrained pursuant to this section no later than 30 days from the date the implementing agency determines the facility is out of compliance except in one of the following situations:

(a) Class A and Class B operators take annual refresher training. Refresher training for Class A and Class B operators must cover all applicable requirements in § 280.242, or

(b) The implementing agency, at its discretion, waives this retraining requirement for either the Class A or Class B operator or both.

§ 280.245 Documentation.

Owners and operators of underground storage tank systems must maintain a list of designated Class A, Class B, and Class C operators and maintain records verifying that training and retraining, as applicable, have been completed, in accordance with § 280.34 as follows:

(a) The list must:

(1) Identify all Class A, Class B, and Class C operators currently designated for the facility; and

(2) Include names, class of operator trained, date assumed duties, date each completed initial training, and any retraining.

(b) Records verifying completion of training or retraining must be a paper or electronic record for Class A, Class B, and Class C operators. The records, at a minimum, must identify name of trainee, date trained, operator training class completed, and list the name of the trainer or examiner and the training company name, address, and telephone number. Owners and operators must maintain these records for as long as Class A, Class B, and Class C operators are designated. The following requirements also apply to the following types of training:

(1) Records from classroom or field training programs (including Class C operator training provided by the Class A or Class B operator) or a comparable examination must, at a minimum, be signed by the trainer or examiner;

(2) Records from computer based training must, at a minimum, indicate the name of the training program and web address, if Internet based; and

(3) Records of retraining must include those areas on which the Class A or Class B operator has been retrained.

Subpart K—UST Systems with Field-Constructed Tanks and Airport Hydrant Fuel Distribution Systems

§ 280.250 Definitions.

For purposes of this subpart, the following definitions apply:

Airport hydrant fuel distribution system (also called airport hydrant system) means an UST system which fuels aircraft and operates under high pressure with large diameter piping that typically terminates into one or more hydrants (fill stands). The airport hydrant system begins where fuel enters one or more tanks from an external source such as a pipeline, barge, rail car, or other motor fuel carrier.

Field-constructed tank means a tank constructed in the field. For example, a tank constructed of concrete that is poured in the field, or a steel or fiberglass tank primarily fabricated in the field is considered field-constructed.

§ 280.251 General requirements.

(a) *Implementation of requirements.* Owners and operators must comply with the requirements of this part for UST systems with field-constructed tanks and airport hydrant systems as follows:

(1) For UST systems installed on or before October 13, 2015 the requirements are effective according to the following schedule:

Requirement	Effective date
Upgrading UST systems; general operating requirements; and operator training	October 13, 2018.
Release detection	October 13, 2018.
Release reporting, response, and investigation; closure; financial responsibility and notification (except as provided in paragraph (b) of this section).	October 13, 2015.

(2) For UST systems installed after October 13, 2015, the requirements apply at installation.

(b) Not later than October 13, 2018, all owners of previously deferred UST systems must submit a one-time notice of tank system existence to the implementing agency, using the form in appendix I of this part or a state form in accordance with § 280.22(c). Owners and operators of UST systems in use as of October 13, 2015 must demonstrate financial responsibility at the time of submission of the notification form.

(c) Except as provided in § 280.252, owners and operators must comply with the requirements of subparts A through H and J of this part.

(d) In addition to the codes of practice listed in § 280.20, owners and operators may use military construction criteria, such as Unified Facilities Criteria (UFC) 3–460–01, *Petroleum Fuel Facilities,* when designing, constructing, and

installing airport hydrant systems and UST systems with field-constructed tanks.

§ 280.252 Additions, exceptions, and alternatives for UST systems with field-constructed tanks and airport hydrant systems.

(a) *Exception to piping secondary containment requirements.* Owners and operators may use single walled piping when installing or replacing piping associated with UST systems with field-constructed tanks greater than 50,000 gallons and piping associated with airport hydrant systems. Piping associated with UST systems with field-constructed tanks less than or equal to 50,000 gallons not part of an airport hydrant system must meet the secondary containment requirement when installed or replaced.

(b) *Upgrade requirements.* Not later than October 13, 2018, airport hydrant systems and UST systems with field-constructed tanks where installation commenced on or before October 13, 2015 must meet the following requirements or be permanently closed pursuant to subpart G of this part.

(1) *Corrosion protection.* UST system components in contact with the ground that routinely contain regulated substances must meet one of the following:

(i) Except as provided in paragraph (a) of this section, the new UST system performance standards for tanks at § 280.20(a) and for piping at § 280.20(b); or

(ii) Be constructed of metal and cathodically protected according to a code of practice developed by a nationally recognized association or independent testing laboratory and meets the following:

(A) Cathodic protection must meet the requirements of § 280.20(a)(2)(ii), (iii), and (iv) for tanks, and § 280.20(b)(2)(ii), (iii), and (iv) for piping.

(B) Tanks greater than 10 years old without cathodic protection must be assessed to ensure the tank is structurally sound and free of corrosion holes prior to adding cathodic protection. The assessment must be by internal inspection or another method determined by the implementing agency to adequately assess the tank for structural soundness and corrosion holes.

Note to paragraph (b). The following codes of practice may be used to comply with this paragraph (b):

(A) NACE International Standard Practice SP 0285, ''External Control of Underground Storage Tank Systems by Cathodic Protection'';

(B) NACE International Standard Practice SP 0169, ''Control of External Corrosion on Underground or Submerged Metallic Piping Systems'';

(C) National Leak Prevention Association Standard 631, Chapter C, ''Internal Inspection of Steel Tanks for Retrofit of Cathodic Protection''; or

(D) American Society for Testing and Materials Standard G158, ''Standard Guide for Three Methods of Assessing Buried Steel Tanks''.

(2) *Spill and overfill prevention equipment.* To prevent spilling and overfilling associated with product transfer to the UST system, all UST systems with field-constructed tanks and airport hydrant systems must comply with new UST system spill and overfill prevention equipment requirements specified in § 280.20(c).

(c) *Walkthrough inspections.* In addition to the walkthrough inspection requirements in § 280.36, owners and operators must inspect the following additional areas for airport hydrant systems at least once every 30 days if confined space entry according to the Occupational Safety and Health Administration (see 29 CFR part 1910) is not required or at least annually if confined space entry is required and keep documentation of the inspection according to § 280.36(b).

(1) Hydrant pits—visually check for any damage; remove any liquid or debris; and check for any leaks, and

(2) Hydrant piping vaults—check for any hydrant piping leaks.

(d) *Release detection.* Owners and operators of UST systems with field-constructed tanks and airport hydrant systems must begin meeting the release detection requirements described in this subpart not later than October 13, 2018.

(1) *Methods of release detection for field-constructed tanks.* Owners and operators of field-constructed tanks with a capacity less than or equal to 50,000 gallons must meet the release detection requirements in subpart D of this part. Owners and operators of field-constructed tanks with a capacity greater than 50,000 gallons must meet either the requirements in subpart D (except § 280.43(e) and (f) must be combined with inventory control as stated below) or use one or a combination of the following alternative methods of release detection:

(i) Conduct an annual tank tightness test that can detect a 0.5 gallon per hour leak rate;

(ii) Use an automatic tank gauging system to perform release detection at least every 30 days that can detect a leak rate less than or equal to one gallon per hour. This method must be combined with a tank tightness test that can detect a 0.2 gallon per hour leak rate performed at least every three years;

(iii) Use an automatic tank gauging system to perform release detection at least every 30 days that can detect a leak rate less than or equal to two gallons per hour. This method must be combined with a tank tightness test that can detect a 0.2 gallon per hour leak rate performed at least every two years;

(iv) Perform vapor monitoring (conducted in accordance with § 280.43(e) for a tracer compound placed in the tank system) capable of detecting a 0.1 gallon per hour leak rate at least every two years;

(v) Perform inventory control (conducted in accordance with Department of Defense Directive 4140.25; ATA Airport Fuel Facility Operations and Maintenance Guidance Manual; or equivalent procedures) at least every 30 days that can detect a leak equal to or less than 0.5 percent of flow-through; and

(A) Perform a tank tightness test that can detect a 0.5 gallon per hour leak rate at least every two years; or

(B) Perform vapor monitoring or groundwater monitoring (conducted in accordance with § 280.43(e) or (f), respectively, for the stored regulated substance) at least every 30 days; or

(vi) Another method approved by the implementing agency if the owner and operator can demonstrate that the method can detect a release as effectively as any of the methods allowed in paragraphs (d)(1)(i) through (v) of this section. In comparing methods, the implementing agency shall consider the size of release that the method can detect and the frequency and reliability of detection.

(2) *Methods of release detection for piping.* Owners and operators of underground piping associated with field-constructed tanks less than or equal to 50,000 gallons must meet the release detection requirements in subpart D of this part. Owners and operators of underground piping associated with airport hydrant systems and field-constructed tanks greater than 50,000 gallons must follow either the requirements in subpart D (except § 280.43(e) and (f) must be combined with inventory control as stated below) or use one or a combination of the following alternative methods of release detection:

(i)(A) Perform a semiannual or annual line tightness test at or above the piping operating pressure in accordance with the table below.

MAXIMUM LEAK DETECTION RATE PER TEST SECTION VOLUME

Test section volume (gallons)	Semiannual test—leak detection rate not to exceed (gallons per hour)	Annual test—leak detection rate not to exceed (gallons per hour)
<50,000	1.0	0.5
≥50,000 to <75,000	1.5	0.75
≥75,000 to <100,000	2.0	1.0
≥100,000	3.0	1.5

(B) Piping segment volumes ≥100,000 gallons not capable of meeting the maximum 3.0 gallon per hour leak rate for the semiannual test may be tested at a leak rate up to 6.0 gallons per hour according to the following schedule:

PHASE IN FOR PIPING SEGMENTS ≥100,000 GALLONS IN VOLUME

First test	Not later than October 13, 2018 (may use up to 6.0 gph leak rate).
Second test	Between October 13, 2018 and October 13, 2021 (may use up to 6.0 gph leak rate).
Third test	Between October 13, 2021 and October 13, 2022 (must use 3.0 gph for leak rate).
Subsequent tests	After October 13, 2022, begin using semiannual or annual line testing according to the Maximum Leak Detection Rate Per Test Section Volume table above.

(ii) Perform vapor monitoring (conducted in accordance with § 280.43(e) for a tracer compound placed in the tank system) capable of detecting a 0.1 gallon per hour leak rate at least every two years;

(iii) Perform inventory control (conducted in accordance with Department of Defense Directive 4140.25; ATA Airport Fuel Facility Operations and Maintenance Guidance Manual; or equivalent procedures) at least every 30 days that can detect a leak equal to or less than 0.5 percent of flow-through; and

(A) Perform a line tightness test (conducted in accordance with paragraph (d)(2)(i) of this section using the leak rates for the semiannual test) at least every two years; or

(B) Perform vapor monitoring or groundwater monitoring (conducted in accordance with § 280.43(e) or (f), respectively, for the stored regulated substance) at least every 30 days; or

(iv) Another method approved by the implementing agency if the owner and operator can demonstrate that the method can detect a release as effectively as any of the methods allowed in paragraphs (d)(2)(i) through (iii) of this section. In comparing methods, the implementing agency shall consider the size of release that the method can detect and the frequency and reliability of detection.

(3) *Recordkeeping for release detection.* Owners and operators must maintain release detection records according to the recordkeeping requirements in § 280.45.

(e) *Applicability of closure requirements to previously closed UST systems.* When directed by the implementing agency, the owner and operator of an UST system with field-constructed tanks or airport hydrant system permanently closed before October 13, 2015 must assess the excavation zone and close the UST system in accordance with subpart G of this part if releases from the UST may, in the judgment of the implementing agency, pose a current or potential threat to human health and the environment.

Appendix I to Part 280—Notification for Underground Storage Tanks (Forms)

EPA

United States
Environmental Protection Agency
Washington, DC 20460

OMB Control No. 2050-0068
Approval expires XX/XX/XX

Notification for Underground Storage Tanks

Implementing Agency Name And Address:

IMPLEMENTING AGENCY USE ONLY

ID NUMBER:

DATE RECEIVED:

DATE ENTERED INTO COMPUTER:

DATA ENTRY CLERK INITIALS:

OWNER WAS CONTACTED TO CLARIFY RESPONSES, COMMENTS:

TYPE OF NOTIFICATION

☐ A. NEW FACILITY OR ONE-TIME NOTIFICATION (previously deferred system) ☐ B. AMENDED ☐ C. CLOSURE OR CHANGE-IN-SERVICE

_____ Number of tanks at facility

_____ Number of continuation sheets attached

INSTRUCTIONS AND GENERAL INFORMATION

Please **type or print in ink**. Also, be sure you have signatures in ink for sections VIII and XI. Complete a notification form for each location containing underground storage tanks. If more than 5 tanks are owned at this location, you may photocopy pages 3 through 6 and use them for additional tanks.

The primary purpose of this notification form is to provide information about the installation, existence, changes to, and closure of underground storage tank systems (USTs) that store or have stored petroleum or hazardous substances. The information you provide will be based on reasonably available records, or in the absence of such records, your knowledge or recollection.

Federal law requires UST owners to use this notification form for all USTs storing regulated substances that are brought into use after May 8, 1986, or USTs in the ground as of May 8, 1986 that have stored regulated substances at any time since January 1, 1974. The information requested is required by Section 9002 of the Solid Waste Disposal Act (SWDA), as amended.

Who Must Notify? 40 CFR part 280, as amended, requires owners of USTs that store regulated substances (unless exempted) to notify implementing agencies of the existence of their USTs. Owner is defined as:

- In the case of an UST in use on November 8, 1984, or brought into use after that date, any person who owns an UST used for storage, use, or dispensing of regulated substances; or
- In the case of an UST in use before November 8, 1984, but no longer in use on that date, any person who owned the UST immediately before its discontinuation.

Also, owners of previously deferred UST systems with field-constructed tanks and airport hydrant fuel distribution systems in the ground as of October 13, 2015 must submit a one-time notification of existence by October 13, 2018. Owners of UST systems with field-constructed tanks and airport hydrant fuel distribution systems brought into use after October 13, 2015 are considered new facilities and must follow the same notification requirements as all other UST owners.

What USTs Are Included? An UST system is defined as any one or combination of tanks that is used to contain an accumulation of regulated substances, and whose volume (including connected underground piping) is 10 percent or more beneath the ground. Regulated USTs store petroleum or hazardous substances (see **What Substances Are Covered** below). This includes UST systems with field-constructed tanks and airport hydrant fuel distribution systems.

What Tanks Are Excluded From Notification (see § 280.10 and § 280.12)?

- Tanks removed from the ground before May 8, 1986;
- Farm or residential tanks of 1,100 gallons or less capacity storing motor fuel for noncommercial purposes;
- Tanks storing heating oil for use on the premises where stored;
- Septic tanks;
- Certain pipeline facilities regulated under chapters 601 and 603 of Title 49;
- Surface impoundments, pits, ponds, or lagoons;
- Storm water or wastewater collection systems;
- Flow-through process tanks;
- Liquid traps or associated gathering lines directly related to oil or gas production and gathering operations;
- Tanks on or above the floor of underground areas, such as basements or tunnels;
- Tanks with a capacity of 110 gallons or less;
- Wastewater treatment tank systems;
- UST systems containing radioactive material that are regulated under the Atomic Energy Act of 1954;
- UST systems that are part of an emergency generator system at nuclear power generation facilities regulated by the Nuclear Regulatory Commission under 10 CFR part 50.

What Substances Are Covered? The notification requirements apply to USTs containing petroleum or certain hazardous substances. Petroleum includes gasoline, used oil, diesel fuel, crude oil or any fraction thereof which is liquid at standard conditions of temperature and pressure (60 degrees Fahrenheit and 14.7 pounds per square inch absolute). Hazardous substances are those found in Section 101 (14) of the Comprehensive Environmental Response, Compensation and Liability Act of 1980, with the exception of those substances regulated as hazardous waste under Subtitle C of the Resource Conservation and Recovery Act.

When And Who To Notify? Owners who bring USTs into use after May 8, 1986 must submit this notification form to the implementing agency within 30 days of bringing the UST into use. If the implementing agency requires notification of any amendments to the facility, send information to the implementing agency immediately.

Penalties: Any owner who knowingly fails to notify or submits false information shall be subject to a civil penalty not to exceed $16,000 for each tank for which notification is not given or for which false information is given.

I. OWNERSHIP OF USTs

Owner Name (Corporation, Individual, Public Agency, Or Other Entity)

Street Address

County

City | State | Zip Code

Phone Number (Include Area Code)

II. LOCATION OF USTs

If required by implementing agency, give the geographic location of USTs either in decimal degrees, or degrees, minutes, and seconds. Example: Latitude: 36.123480 (or 36° 7' 24.4"), Longitude: -106.549876 (or -106° 32' 59.6")

Latitude _____ **Longitude** _____

Facility Name Or Company Site Identifier, As Applicable

☐ If address is the same as in Section I, check the box and proceed to section III.
If address is different, enter address below:

Street Address

County

City | State | Zip Code

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United States
Environmental Protection Agency
Washington, DC 20460

OMB Control No. 2050-0068
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Notification For Underground Storage Tanks

III. TYPE OF OWNER

- ☐ Federal Government
- ☐ State Government
- ☐ Commercial
- ☐ Tribal Government
- ☐ Local Government
- ☐ Private

IV. INDIAN COUNTRY

USTs are located on land within an Indian reservation or on trust lands outside reservation boundaries ☐

Federally recognized tribe where USTs are located:

V. TYPE OF FACILITY

- ☐ Auto Dealership
- ☐ Commercial Airport Or Airline
- ☐ Contractor
- ☐ Farm
- ☐ Federal – Non-military
- ☐ Federal – Military
- ☐ Gas Station
- ☐ Industrial
- ☐ Petroleum Distributor
- ☐ Railroad
- ☐ Residential
- ☐ Trucking Or Transport
- ☐ Utilities
- ☐ Other (Explain) _____

VI. CONTACT PERSON IN CHARGE OF TANKS

Name:	Job Title:	Address:	Phone Number (Include Area Code):

VII. FINANCIAL RESPONSIBILITY

☐ I have met the financial responsibility requirements (in accordance with 40 CFR part 280 Subpart H) by using the following mechanisms:

(check all that apply)

- ☐ Bond Rating Test
- ☐ Commercial Insurance
- ☐ Guarantee
- ☐ Letter Of Credit
- ☐ Local Government Financial Test
- ☐ Risk Retention Group
- ☐ Self-insurance (Financial Test)
- ☐ State Fund
- ☐ Surety Bond
- ☐ Trust Fund
- ☐ Other Method (describe here) _____

☐ I do not have to meet financial responsibility requirements because 40 CFR part 280 Subpart H is not applicable to me (e.g., if you are a state or federal owner).

VIII. CERTIFICATION (Read and sign after completing ALL SECTIONS of this notification form)

I certify under penalty of law that I have personally examined and am familiar with the information submitted in Sections I through XI of this notification form and all attached documents, and that based on my inquiry of those individuals immediately responsible for obtaining the information, I believe that the submitted information is true, accurate, and complete.

Name and official title of owner or owner's authorized representative (Print)	Signature	Date Signed

Paperwork Reduction Act Notice
The public reporting and recordkeeping burden for this collection of information is estimated to average 30 minutes per response. Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the Director, Collection Strategies Division, U.S. Environmental Protection Agency (2822T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed form to this address.

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Notification For Underground Storage Tanks

IX. DESCRIPTION OF UNDERGROUND STORAGE TANKS (Complete for all tanks and piping at this location)

Tank Identification Number	Tank No.	Tank No.	Tank No.	Tank No.	Tank No.
1. Status Of Tank (check only one)					
Currently In Use	☐	☐	☐	☐	☐
Temporarily Closed	☐	☐	☐	☐	☐
Permanently Closed	☐	☐	☐	☐	☐
2. Date Of Installation (month/year)					
3. Estimated Total Capacity (gallons)					
4. Tank Attributes (check all that apply)					
Asphalt Coated Or Bare Steel	☐	☐	☐	☐	☐
Cathodically Protected Steel (impressed current)	☐	☐	☐	☐	☐
Cathodically Protected Steel (sacrificial anodes)	☐	☐	☐	☐	☐
Coated and Cathodically Protected Steel (impressed current)	☐	☐	☐	☐	☐
Coated and Cathodically Protected Steel (sacrificial anodes)	☐	☐	☐	☐	☐
Composite (steel clad with noncorrodible material)	☐	☐	☐	☐	☐
Concrete	☐	☐	☐	☐	☐
Fiberglass Reinforced Plastic	☐	☐	☐	☐	☐
Noncorrodible Tank Jacket	☐	☐	☐	☐	☐
Lined Interior	☐	☐	☐	☐	☐
Excavation Liner	☐	☐	☐	☐	☐
Double Walled	☐	☐	☐	☐	☐
Manifolded	☐	☐	☐	☐	☐
Compartmentalized	☐	☐	☐	☐	☐
Field-constructed	☐	☐	☐	☐	☐
Unknown	☐	☐	☐	☐	☐
Other, Specify Here	_____	_____	_____	_____	_____
Check Box If Tank Has Ever Been Repaired	☐	☐	☐	☐	☐
5. Overfill Protection Installed (check all that apply)					
Automatic Shutoff	☐	☐	☐	☐	☐
Flow Restrictor	☐	☐	☐	☐	☐
High-level Alarm	☐	☐	☐	☐	☐
Other, Specify Here	_____	_____	_____	_____	_____
6. Spill Prevention Installed	☐	☐	☐	☐	☐
Double Walled	☐	☐	☐	☐	☐

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Notification For Underground Storage Tanks

Tank Identification Number	Tank No.	Tank No.	Tank No.	Tank No.	Tank No.
7. Piping Attributes (check all that apply)					
Bare Steel	☐	☐	☐	☐	☐
Galvanized Steel	☐	☐	☐	☐	☐
Fiberglass Reinforced Plastic	☐	☐	☐	☐	☐
Flexible Plastic	☐	☐	☐	☐	☐
Copper	☐	☐	☐	☐	☐
Cathodically Protected (impressed current)	☐	☐	☐	☐	☐
Cathodically Protected (sacrificial anodes)	☐	☐	☐	☐	☐
Double Walled	☐	☐	☐	☐	☐
Secondary Containment	☐	☐	☐	☐	☐
Airport Hydrant Piping	☐	☐	☐	☐	☐
Unknown	☐	☐	☐	☐	☐
Other, Specify Here	_____	_____	_____	_____	_____
8. Piping Delivery Type (check all that apply)					
Safe Suction (no valve at tank)	☐	☐	☐	☐	☐
U.S. Suction (valve at tank)	☐	☐	☐	☐	☐
Pressure	☐	☐	☐	☐	☐
Gravity Feed	☐	☐	☐	☐	☐
9. Substance Currently Stored (or last stored in the case of closed tanks) (check all that apply)					
Gasoline (containing ≤ 10% ethanol)	☐	☐	☐	☐	☐
Diesel	☐	☐	☐	☐	☐
Biodiesel	☐	☐	☐	☐	☐
Kerosene	☐	☐	☐	☐	☐
Heating Oil	☐	☐	☐	☐	☐
Used Oil	☐	☐	☐	☐	☐
Gasoline Containing >10% Ethanol (specify amount of ethanol)	_____	_____	_____	_____	_____
Diesel Containing >20% Biodiesel (specify amount of biodiesel)	_____	_____	_____	_____	_____
Other, specify here	_____	_____	_____	_____	_____
Hazardous Substance	☐	☐	☐	☐	☐
CERCLA Name Or CAS Number	_____	_____	_____	_____	_____
Mixture Of Substances	☐	☐	☐	☐	☐
Please Specify Substances Here	_____	_____	_____	_____	_____

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Previous editions may be used while supplies last.

EPA	United States **Environmental Protection Agency** Washington, DC 20460	OMB Control No. 2050-0068 Approval expires XX/XX/XX

Notification For Underground Storage Tanks

Tank Identification Number	Tank No.		Tank No.		Tank No.		Tank No.		Tank No.	
10. Release Detection (check all that apply)	TANK	PIPE	TANK	PIPE	TANK	PIPE	TANK	PIPE	TANK	PIPE
Manual Tank Gauging	☐		☐		☐		☐		☐	
Tank Tightness Testing	☐		☐		☐		☐		☐	
Inventory Control	☐		☐		☐		☐		☐	
Automatic Tank Gauging	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Vapor Monitoring	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Groundwater Monitoring	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Interstitial Monitoring (required for new or replaced tanks or piping)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Statistical Inventory Reconciliation	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Automatic Line Leak Detectors		☐		☐		☐		☐		☐
Line Tightness Testing		☐		☐		☐		☐		☐
No Release Detection Required (such as some types of suction piping)	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Other Method Allowed By Implementing Agency	☐	☐	☐	☐	☐	☐	☐	☐	☐	☐
Other, Specify Here	_____		_____		_____		_____		_____	

X. CLOSURE OR CHANGE IN SERVICE

1. Closure Or Change In Service					
Estimated Date The UST Was Last Used For Storing Regulated Substances (month/day/year)	_____	_____	_____	_____	_____
Check Box If This Is A Change In Service (i.e., Change of storage to a non-regulated substance)	☐	☐	☐	☐	☐
2. Tank Closure					
Estimated Date Tank Closed (month/day/year)	_____	_____	_____	_____	_____
(check all that apply below)					
Tank Removed From Ground	☐	☐	☐	☐	☐
Tank Closed In Ground	☐	☐	☐	☐	☐
Tank Filled With Inert Material	☐	☐	☐	☐	☐
Describe The Inert Fill Material Here	_____	_____	_____	_____	_____
3. Site Assessment					
Check Box If The Site Assessment Was Completed	☐	☐	☐	☐	☐
Check Box If Evidence Of A Release Was Detected	☐	☐	☐	☐	☐
Other, Specify Here	_____	_____	_____	_____	_____

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EPA	United States **Environmental Protection Agency** Washington, DC 20460	OMB Control No. 2050-0068 Approval expires XX/XX/XX

Notification For Underground Storage Tanks

Tank Identification Number	Tank No.	Tank No.	Tank No.	Tank No.	Tank No.
XI. CERTIFICATION OF INSTALLATION (Complete For UST Systems Installed After December 22, 1988 And For Airport Hydrant Distribution Systems And Field-Constructed USTs Installed After October 13, 2015)					
Installer Of Tank And Piping (check all that apply)					
Installer Certified By Tank And Piping Manufacturers	☐	☐	☐	☐	☐
Installer Certified Or Licensed By The Implementing Agency	☐	☐	☐	☐	☐
Installation Inspected By A Registered Engineer	☐	☐	☐	☐	☐
Installation Inspected And Approved By Implementing Agency	☐	☐	☐	☐	☐
Manufacturer's Installation Checklists Have Been Completed	☐	☐	☐	☐	☐
Another Method Allowed By Implementing Agency	☐	☐	☐	☐	☐
Specify Other Method Here	_____	_____	_____	_____	_____

Signature Of UST Installer Certifying Proper Installation Of UST System

_____	_____	_____
Name	Signature	Date
_____	_____	
Position	Company	

EPA Form 7530-1 (Rev. 6-2015) Electronic and paper versions acceptable.
Previous editions may be used while supplies last.

Appendix II to Part 280—Notification of Ownership for Underground Storage Tanks (Form)

EPA	United States Environmental Protection Agency Washington, DC 20460	OMB Control No. 2050-0068 Approval expires XX/XX/XX

Notification of Ownership Change for Underground Storage Tanks

Implementing Agency Name And Address:	IMPLEMENTING AGENCY USE ONLY
	ID NUMBER:
	DATE RECEIVED:
	DATE ENTERED INTO COMPUTER:
	DATA ENTRY CLERK INITIALS:
	OWNER WAS CONTACTED TO CLARIFY RESPONSES, COMMENTS:

INSTRUCTIONS AND GENERAL INFORMATION

Please type or print in ink. Also, be sure you have signatures in ink.

The primary purpose of this notification form is to inform implementing agencies of ownership changes for underground storage tank (UST) systems that store or have stored petroleum or hazardous substances.

Federal regulation requires UST owners to notify the implementing agency of any ownership change for USTs storing regulated substances after October 13, 2015.

Who Must Notify? 40 CFR part 280, as amended, requires owners of USTs that store regulated substances (unless exempted) to notify implementing agencies of any ownership changes. Owner is defined as:

- In the case of an UST in use on November 8, 1984, or brought into use after that date, any person who owns an UST used for storage, use, or dispensing of regulated substances; or
- In the case of an UST in use before November 8, 1984, but no longer in use on that date, any person who owned the UST immediately before its discontinuation.

What USTs Are Included? An UST system is defined as any one or combination of tanks that is used to contain an accumulation of regulated substances, and whose volume (including connected underground piping) is 10 percent or more beneath the ground. Regulated USTs store petroleum or hazardous substances (see What Substances Are Covered to the right). This includes UST systems with field-constructed tanks and airport hydrant fuel distribution systems.

When And Who To Notify? Any owner or operator who assumes ownership of a regulated UST system must submit this notification form to the implementing agency within 30 days of assuming such ownership.

What Tanks Are Excluded From Notification (see § 280.10 and § 280.12)?

- Tanks removed from the ground before May 8, 1986;
- Farm or residential tanks of 1,100 gallons or less capacity storing motor fuel for noncommercial purposes;
- Tanks storing heating oil for use on the premises where stored;
- Septic tanks;
- Certain pipeline facilities regulated under chapters 601 and 603 of Title 49;
- Surface impoundments, pits, ponds, or lagoons;
- Storm water or wastewater collection systems;
- Flow-through process tanks;
- Liquid traps or associated gathering lines directly related to oil or gas production and gathering operations;
- Tanks on or above the floor of underground areas, such as basements or tunnels;
- Tanks with a capacity of 110 gallons or less;
- Wastewater treatment tank systems;
- UST systems containing radioactive material that are regulated under the Atomic Energy Act of 1954;
- UST systems that are part of an emergency generator system at nuclear power generation facilities regulated by the Nuclear Regulatory Commission under 10 CFR part 50.

What Substances Are Covered? The notification requirements apply to USTs containing petroleum or certain hazardous substances. Petroleum includes gasoline, used oil, diesel fuel, crude oil or any fraction thereof which is liquid at standard conditions of temperature and pressure (60 degrees Fahrenheit and 14.7 pounds per square inch absolute). Hazardous substances are those found in Section 101 (14) of the Comprehensive Environmental Response, Compensation and Liability Act of 1980, with the exception of those substances regulated as hazardous waste under Subtitle C of the Resource Conservation and Recovery Act.

Penalties: Any owner who knowingly fails to notify or submits false information shall be subject to a civil penalty not to exceed $16,000 for each tank for which notification is not given or for which false information is given.

OWNERSHIP OF USTs Corporation, Individual, Public Agency, Or Other Entity		FACILITY NAME AND LOCATION OF USTs
Current Owner Name	Previous Owner Name	Facility Name ☐ Check here if name changed after ownership
Current Owner Address	Previous Owner Address	☐ Check this box if the physical address of the USTs is the same as the current owner address. If address is different, enter address below: If required by implementing agency, give the geographic location of USTs either in decimal degrees, or degrees, minutes, and seconds. Example: Latitude: 36.12348 (or 36° 7' 24.4"), Longitude: -106.549876 (or -106° 32' 59.6") Latitude _____ Longitude _____
Current Owner Phone	Previous Owner Phone	Date Of Ownership Change

Signature Of Current Owner: _____ Date: _____

Paperwork Reduction Act Notice

The public reporting and recordkeeping burden for this collection of information is estimated to average 30 minutes per response. Send comments on the Agency's need for this information, the accuracy of the provided burden estimates, and any suggested methods for minimizing respondent burden, including through the use of automated collection techniques to the Director, Collection Strategies Division, U.S. Environmental Protection Agency (2822T), 1200 Pennsylvania Ave., NW, Washington, D.C. 20460. Include the OMB control number in any correspondence. Do not send the completed form to this address.

EPA Form 6200-10 Electronic and paper versions acceptable.

Appendix III to Part 280—Statement for Shipping Tickets and Invoices

Note. A federal law (the Solid Waste Disposal Act, as amended), requires owners of certain underground storage tanks to notify implementing agencies of the existence of their tanks. Notifications must be made within 30 days of bringing the tank into use. Consult EPA's regulation at 40 CFR 280.22 to determine if you are affected by this law.

■ 2. Revise part 281 to read as follows:

PART 281—APPROVAL OF STATE UNDERGROUND STORAGE TANK PROGRAMS

Subpart A—Purpose, General Requirements and Scope

Sec.
281.10 Purpose.
281.11 General requirements.
281.12 Scope and definitions.

Subpart B—Components of a Program Application

281.20 Program application.
281.21 Description of state program.
281.22 Procedures for adequate enforcement.
281.23 Memorandum of agreement.
281.24 Attorney General's statement.

Subpart C—Criteria for No Less Stringent

281.30 New UST system design, construction, installation, and notification.
281.31 Upgrading existing UST systems.
281.32 General operating requirements.
281.33 Release detection.
281.34 Release reporting, investigation, and confirmation.
281.35 Release response and corrective action.
281.36 Out-of-service UST systems and closure.
281.37 Financial responsibility for UST systems containing petroleum.
281.38 Lender liability.
281.39 Operator training.

Subpart D—Adequate Enforcement of Compliance

281.40 Requirements for compliance program and authority.
281.41 Requirements for enforcement authority.
281.42 Requirements for public participation.
281.43 Sharing of information.

Subpart E—Approval Procedures

281.50 Approval procedures for state programs.
281.51 Revision of approved state programs.

Subpart F—Withdrawal of Approval of State Programs

281.60 Criteria for withdrawal of approval of state programs.
281.61 Procedures for withdrawal of approval of state programs.

Authority: 42 U.S.C. 6912, 6991(c), 6991(d), 6991(e), 6991(i), 6991(k).

Subpart A—Purpose, General Requirements and Scope

§ 281.10 Purpose.

(a) This part specifies the requirements that state programs must meet for approval by the Administrator under section 9004 of the Solid Waste Disposal Act, and the procedures EPA will follow in approving, revising and withdrawing approval of state programs.

(b) State submissions for program approval must be in accordance with the procedures set out in this part.

(c) A state may apply for approval under this part at any time after the promulgation of release detection, prevention, and corrective action regulations under § 9003 of the Solid Waste Disposal Act.

(d) Any state program approved by the Administrator under this part shall at all times be conducted in accordance with the requirements of this part.

§ 281.11 General requirements.

(a) *State program elements.* The following substantive elements of a state program must be addressed in a state application for approval:

(1) Requirements for all existing and new underground storage tanks:

(i) New UST systems (design, construction, installation, and notification);

(ii) Upgrading of existing UST systems;

(iii) General operating requirements;

(iv) Release detection;

(v) Release reporting, investigation, and confirmation;

(vi) Out-of-service USTs and closure;

(vii) Release response and corrective action;

(viii) Financial responsibility for UST systems containing petroleum; and

(ix) Operator training.

(2) Provisions for adequate enforcement of compliance with the above program elements.

(b) *Final approval.* The state must demonstrate that its requirements under each state program element for existing and new UST systems are no less stringent than the corresponding federal requirements as set forth in subpart C of this part. The state must also demonstrate that it has a program that provides adequate enforcement of compliance with these requirements.

(c) States with programs approved under this part are authorized to administer the state program in lieu of the federal program and will have primary enforcement responsibility with respect to the requirements of the approved program. EPA retains authority to take enforcement action in approved states as necessary and will notify the designated lead state agency of any such intended action.

§ 281.12 Scope and definitions.

(a) *Scope.* (1) The Administrator may approve either partial or complete state programs. A ''partial'' state program regulates either solely UST systems containing petroleum or solely UST systems containing hazardous substances. If a ''partial'' state program is approved, EPA will administer the remaining part of the program. A ''complete'' state program regulates both petroleum and hazardous substance tanks.

(2) EPA will administer the UST program in Indian country, except where Congress has clearly expressed an intention to grant a state authority to regulate petroleum and hazardous substance USTs in Indian country. In either case, this decision will not impair a state's ability to obtain program approval for petroleum or hazardous substances in non-Indian country in accordance with this part.

(3) Nothing in this subpart precludes a state from:

(i) Adopting or enforcing requirements that are more stringent or more extensive than those required under this part; or

(ii) Operating a program with a greater scope of coverage than that required under this part. Where an approved state program has a greater scope of coverage than required by federal law, the additional coverage is not part of the federally-approved program.

(b) *Definitions.* (1) The definitions in 40 CFR part 280 apply to this entire part except as described below.

(i) States may use the definitions associated with tank and piping secondary containment as defined in section 9003 of the Solid Waste Disposal Act.

(ii) States may use the definitions associated with operator training as described in § 9010 of the Solid Waste Disposal Act.

(2) For the purposes of this part the term ''final approval'' means the approval received by a state program that meets the requirements in § 281.11(b).

Subpart B—Components of a Program Application

§ 281.20 Program application.

Any state that seeks to administer a program under this part must submit an application containing the following parts:

(a) A transmittal letter from the Governor of the state requesting program approval;

(b) A description in accordance with § 281.21 of the state program and operating procedures;

(c) A demonstration of the state's procedures to ensure adequate enforcement;

(d) A Memorandum of Agreement outlining roles and responsibilities of EPA and the implementing agency;

(e) An Attorney General's statement in accordance with § 281.25 certifying to applicable state authorities; and

(f) Copies of all applicable state statutes and regulations.

§ 281.21 Description of state program.

A state seeking to administer a program under this part must submit a description of the program it proposes to administer under state law in lieu of the federal program. The description of a state's existing or planned program must include:

(a) The scope of the state program:

(1) Whether the state program regulates UST systems containing petroleum or hazardous substances, or both;

(2) Whether the state program is more stringent or broader in scope than the federal program, and in what ways; and

(3) Whether the state has any existing authority in Indian country or has existing agreements with Indian tribes relevant to the regulation of underground storage tanks.

(b) The organization and structure of the state and local agencies with responsibility for administering the program. The jurisdiction and responsibilities of all state and local implementing agencies must be delineated, appropriate procedures for coordination set forth, and one state agency designated as a ''lead agency'' to facilitate communications between EPA and the state.

(c) Staff resources to carry out and enforce the required state program elements, both existing and planned, including the number of employees, agency where employees are located, general duties of the employees, and current limits or restrictions on hiring or utilization of staff.

(d) An existing state funding mechanism to meet the estimated costs of administering and enforcing the required state program elements, and any restrictions or limitations upon this funding.

§ 281.22 Procedures for adequate enforcement.

A state must submit a description of its compliance monitoring and enforcement procedures, including related state administrative or judicial review procedures.

§ 281.23 Memorandum of agreement.

EPA and the approved state will negotiate a Memorandum of Agreement (MOA) containing proposed areas of coordination and shared responsibilities between the state and EPA and separate EPA and state roles and responsibilities in areas including, but not limited to: Implementation of partial state programs; enforcement; compliance monitoring; EPA oversight; and sharing and reporting of information. At the time of approval, the MOA must be signed by the Regional Administrator and the appropriate official of the state lead agency.

§ 281.24 Attorney General's statement.

(a) A state must submit a written demonstration from the Attorney General that the laws and regulations of the state provide adequate authority to carry out the program described under § 281.21 and to meet other requirements of this part. This statement may be signed by independent legal counsel for the state rather than the Attorney General, provided that such counsel has full authority to independently represent the state Agency in court on all matters pertaining to the state program. This statement must include citations to the specific statutes, administrative regulations, and where appropriate, judicial decisions that demonstrate adequate authority to regulate and enforce requirements for UST systems. State statutes and regulations cited by the state Attorney General must be fully effective when the program is approved.

(b) If a state currently has authority over underground storage tank activities in Indian country, the statement must contain an appropriate analysis of the state's authority.

Subpart C—Criteria for No Less Stringent

§ 281.30 New UST system design, construction, installation, and notification.

In order to be considered no less stringent than the corresponding federal requirements for new UST system design, construction, installation, and notification, the state must have requirements that ensure all new underground storage tanks, and the attached piping in contact with the ground and used to convey the regulated substance stored in the tank, conform to the following:

(a) Be designed, constructed, and installed in a manner that will prevent releases for their operating life due to manufacturing defects, structural failure, or corrosion. Unless the state requires manufacturer and installer financial responsibility and installer certification in accordance with section 9003(i)(2) of the Solid Waste Disposal Act, then the state must meet the following:

(1) New or replaced tanks and piping must use interstitial monitoring within secondary containment in accordance with section 9003(i)(1) of the Solid Waste Disposal Act except as follows:

(i) Underground piping associated with: Airport hydrant systems or field-constructed tanks greater than 50,000 gallons or

(ii) Underground suction piping that meets § 281.33(d)(2)(ii).

(2) New motor fuel dispenser systems installed and connected to an UST system must be equipped with under-dispenser containment in accordance with section 9003(i)(1) of the Solid Waste Disposal Act.

Note to paragraph (a). Codes of practice developed by nationally recognized organizations and national independent testing laboratories may be used to demonstrate that the state program requirements are no less stringent in this area.

(b) Be provided with equipment to prevent spills and tank overfills when new tanks are installed or existing tanks are upgraded, unless the tank does not receive more than 25 gallons at one time. Flow restrictors used in vent lines are not allowable forms of overfill prevention when overfill prevention is installed or replaced.

(c) All UST system owners and operators must notify the implementing agency of the existence of any new UST system and notify the implementing agency within a reasonable timeframe when assuming ownership of an UST system using a process designated by the implementing agency.

§ 281.31 Upgrading existing UST systems.

In order to be considered no less stringent than the corresponding federal upgrading requirements, the state must have requirements that ensure existing UST systems meet the requirements of § 281.30; are upgraded to prevent releases for their operating life due to corrosion, spills, or overfills; or are permanently closed with the following exceptions:

(a) Upgrade requirements for previously deferred UST systems. Previously deferred airport hydrant fuel distribution systems and UST systems with field-constructed tanks must within three years of the effective date of its state requirements meet the requirements of § 281.30 or be permanently closed. This provision would not apply, however, to states that did not defer these UST systems and

already had, prior to the effective date of this provision, existing requirements with specified compliance periods for these types of UST systems.

(b) Upgrade requirements for other UST systems. States may allow UST systems to be upgraded if the state determines that the upgrade is appropriate to prevent releases for the operating life of the UST system due to corrosion and spills or overfills.

§ 281.32 General operating requirements.

In order to be considered no less stringent than the corresponding federal general operating requirements, the state must have requirements that ensure all new and existing UST systems conform to the following:

(a) Prevent spills and overfills by ensuring that the space in the tank is sufficient to receive the volume to be transferred and that the transfer operation is monitored constantly;

(b) Where equipped with cathodic protection, be operated and maintained by a person with sufficient training and experience in preventing corrosion, and in a manner that ensures that no releases occur during the operating life of the UST system;

Note to paragraph (b). Codes of practice developed by nationally recognized organizations and national independent testing laboratories may be used to demonstrate the state program requirements are no less stringent.

(c) Be made of or lined with materials that are compatible with the substance stored; in order to ensure compatibility, the state requirements must also include provisions for demonstrating compatibility with new and innovative regulated substances or other regulated substances identified by the implementing agency or include other provisions determined by the implementing agency to be no less protective of human health and the environment than the provisions for demonstrating compatibility;

(d) At the time of upgrade or repair, be structurally sound and upgraded or repaired in a manner that will prevent releases due to structural failure or corrosion during their operating lives;

(e) Have spill and overfill prevention equipment periodically tested or inspected in a manner and frequency that ensures its functionality for the operating life of the equipment and have the integrity of containment sumps used for interstitial monitoring of piping periodically tested in a manner and frequency that prevents releases during the operating life of the UST system;

(f) Have operation and maintenance walkthrough inspections periodically conducted in a manner and frequency that ensures proper operation and maintenance for the operating life of the UST system; and

(g) Have records of monitoring, testing, repairs, and inspections. These records must be made readily available when requested by the implementing agency.

§ 281.33 Release detection.

In order to be considered no less stringent than the corresponding federal requirements for release detection, the state must have requirements that at a minimum ensure all UST systems are provided with release detection that conforms to the following:

(a) *General methods.* Release detection requirements for owners and operators must consist of a method, or combination of methods, that is:

(1) Capable of detecting a release of the regulated substance from any portion of the UST system that routinely contains regulated substances—as effectively as any of the methods allowed under this part—for as long as the UST system is in operation. In comparing methods, the implementing agency shall consider the size of release that the method can detect and the speed and reliability with which the release can be detected.

(2) Designed, installed, calibrated, operated and maintained so that releases will be detected in accordance with the capabilities of the method;

(3) Operated and maintained, and electronic and mechanical components and other equipment are tested or inspected periodically, in a manner and frequency that ensures proper operation to detect releases for the operating life of the release detection equipment.

(b) *Phase-in of requirements.* Release detection requirements must, at a minimum, be applied at all UST systems immediately, except for UST systems previously deferred under § 280.10(a)(1). Release detection requirements must, at a minimum, be scheduled to be applied to those previously deferred UST systems as follows:

(1) Immediately when a new previously deferred UST system is installed; and

(2) For any previously deferred UST system within three years of the effective date of its state requirements. This provision would not apply, however, to states that did not defer these UST systems and already had, prior to the effective date of this provision, existing release detection requirements with specified compliance periods for these types of UST systems.

(c) *Requirements for petroleum tanks.* All petroleum tanks must meet the following requirements:

(1) All petroleum tanks must be sampled, tested, or checked for releases at least monthly, except that tanks installed before October 13, 2015 or upgraded tanks (that is, tanks and piping protected from releases due to corrosion and equipped with both spill and overfill prevention devices) may temporarily use monthly inventory control (or its equivalent) in combination with tightness testing (or its equivalent) conducted every five years for the first 10 years after the tank is installed; and

(2) New or replaced petroleum tanks must use interstitial monitoring within secondary containment in accordance with section 9003(i)(1) of the Solid Waste Disposal Act except when the state requires manufacturer and installer financial responsibility and installer certification in accordance with section 9003(i)(2) of the Solid Waste Disposal Act.

(d) *Requirements for petroleum piping.* All underground piping attached to the tank that routinely conveys petroleum must conform to the following:

(1) If the petroleum is conveyed under greater than atmospheric pressure:

(i) The piping must be equipped with release detection that detects a release within an hour by restricting or shutting off flow or sounding an alarm; and

(ii) The piping must have monthly monitoring applied or annual tightness tests conducted.

(2) If suction lines are used:

(i) Tightness tests must be conducted at least once every three years, unless a monthly method of detection is applied to this piping; or

(ii) The piping is designed to allow the contents of the pipe to drain back into the storage tank if the suction is released and is also designed to allow an inspector to immediately determine the integrity of the piping system.

(3) Except as provided for in § 281.30(a)(1) new or replaced petroleum piping must use interstitial monitoring within secondary containment in accordance with section 9003(i)(1) of the Solid Waste Disposal Act except when the state requires evidence of financial responsibility and certification in accordance with section 9003(i)(2) of the Solid Waste Disposal Act.

(e) *Requirements for hazardous substance UST systems.* All new hazardous substance UST systems must use interstitial monitoring within secondary containment of the tanks and the attached underground piping that

conveys the regulated substance stored in the tank. For hazardous substance UST systems installed prior to October 13, 2015, owners and operators can use another form of release detection if the owner and operator can demonstrate to the state (or the state otherwise determines) that another method will detect a release of the regulated substance as effectively as other methods allowed under the state program for petroleum UST systems and that effective corrective action technology is available for the hazardous substance being stored that can be used to protect human health and the environment.

§ 281.34 Release reporting, investigation, and confirmation.

In order to be considered no less stringent than the corresponding federal requirements for release reporting, investigation, and confirmation, the state must have requirements that ensure all owners and operators conform with the following:

(a) Promptly investigate all suspected releases, including:

(1) When unusual operating conditions, release detection signals and environmental conditions at the site suggest a release of regulated substances may have occurred or the interstitial space may have been compromised; and

(2) When required by the implementing agency to determine the source of a release having an impact in the surrounding area; and

(b) Promptly report all confirmed underground releases and any spills and overfills that are not contained and cleaned up.

(c) Ensure that all owners and operators contain and clean up unreported spills and overfills in a manner that will protect human health and the environment.

§ 281.35 Release response and corrective action.

In order to be considered no less stringent than the corresponding federal requirements for release response and corrective action, the state must have requirements that ensure:

(a) All releases from UST systems are promptly assessed and further releases are stopped;

(b) Actions are taken to identify, contain and mitigate any immediate health and safety threats that are posed by a release (such activities include investigation and initiation of free product removal, if present);

(c) All releases from UST systems are investigated to determine if there are impacts on soil and groundwater, and any nearby surface waters. The extent of soil and groundwater contamination must be delineated when a potential threat to human health and the environment exists.

(d) All releases from UST systems are cleaned up through soil and groundwater remediation and any other steps are taken, as necessary to protect human health and the environment;

(e) Adequate information is made available to the state to demonstrate that corrective actions are taken in accordance with the requirements of paragraphs (a) through (d) of this section. This information must be submitted in a timely manner that demonstrates its technical adequacy to protect human health and the environment; and

(f) In accordance with § 280.67, the state must notify the affected public of all confirmed releases requiring a plan for soil and groundwater remediation, and upon request provide or make available information to inform the interested public of the nature of the release and the corrective measures planned or taken.

§ 281.36 Out-of-service UST systems and closure.

In order to be considered no less stringent than the corresponding federal requirements for temporarily closed UST systems and permanent closure, the state must have requirements that ensure UST systems conform with the following:

(a) *Removal from service.* All new and existing UST systems temporarily closed must:

(1) Continue to comply with general operating requirements, release reporting and investigation, and release response and corrective action;

(2) Continue to comply with release detection requirements if regulated substances are stored in the tank;

(3) Be closed off to outside access; and

(4) Be permanently closed if the UST system has not been protected from corrosion and has not been used in one year, unless the state approves an extension after the owner and operator conducts a site assessment.

(b) *Permanent closure of UST systems.* All tanks and piping must be cleaned and permanently closed in a manner that eliminates the potential for safety hazards and any future releases. The owner or operator must notify the state of permanent UST system closures. The site must also be assessed to determine if there are any present or were past releases, and if so, release response and corrective action requirements must be complied with.

(c) All UST systems taken out of service before the effective date of the federal regulations must permanently close in accordance with paragraph (b) of this section when directed by the implementing agency.

§ 281.37 Financial responsibility for UST systems containing petroleum.

(a) In order to be considered no less stringent than the federal requirements for financial responsibility for UST systems containing petroleum, the state requirements for financial responsibility for petroleum UST systems must ensure that:

(1) Owners and operators have $1 million per occurrence for corrective action and third-party claims in a timely manner to protect human health and the environment;

(2) Owners and operators not engaged in petroleum production, refining, and marketing and who handle a throughput of 10,000 gallons of petroleum per month or less have $500,000 per occurrence for corrective action and third-party claims in a timely manner to protect human health and the environment;

(3) Owners and operators of 1 to 100 petroleum USTs must have an annual aggregate of $1 million; and

(4) Owners and operators of 101 or more petroleum USTs must have an annual aggregate of $2 million.

(b) States may allow the use of a wide variety of financial assurance mechanisms to meet this requirement. Each financial mechanism must meet the following criteria in order to be no less stringent than the federal requirements. The mechanism must: Be valid and enforceable; be issued by a provider that is qualified or licensed in the state; not permit cancellation without allowing the state to draw funds; ensure that funds will only and directly be used for corrective action and third party liability costs; and require that the provider notify the owner or operator of any circumstances that would impair or suspend coverage.

(c) States must require owners and operators to maintain records that demonstrate compliance with the state financial responsibility requirements, and these records must be made readily available when requested by the implementing agency.

§ 281.38 Lender liability.

(a) A state program that contains a security interest exemption will be considered to be no less stringent than, and as broad in scope as, the federal program provided that the state's exemption:

(1) Mirrors the security interest exemption provided for in 40 CFR part 280, subpart I; or

(2) Achieves the same effect as provided by the following key criteria:

(i) A holder, meaning a person who maintains indicia of ownership primarily to protect a security interest in a petroleum UST or UST system or facility or property on which a petroleum UST or UST system is located, who does not participate in the management of the UST or UST system as defined under § 280.10 of this chapter, and who does not engage in petroleum production, refining, and marketing as defined under § 280.200(b) of this chapter is not:

(A) An ''owner'' of a petroleum UST or UST system or facility or property on which a petroleum UST or UST system is located for purposes of compliance with the requirements of 40 CFR part 280; or

(B) An ''operator'' of a petroleum UST or UST system for purposes of compliance with the requirements of 40 CFR part 280, provided the holder is not in control of or does not have responsibility for the daily operation of the UST or UST system.

(ii) [Reserved]

(b) [Reserved]

§ 281.39 Operator training.

In order to be considered no less stringent than the corresponding federal requirements for operator training, the state must have an operator training program that meets the minimum requirements of section 9010 of the Solid Waste Disposal Act.

Subpart D—Adequate Enforcement of Compliance

§ 281.40 Requirements for compliance monitoring program and authority.

(a) Any authorized representative of the state engaged in compliance inspections, monitoring, or testing must have authority to obtain by request any information from an owner or operator with respect to the UST system(s) that is necessary to determine compliance with the UST regulations.

(b) Any authorized representative of the state must have authority to require an owner or operator to conduct monitoring or testing.

(c) Authorized representatives must have the authority to enter any site or premises subject to UST regulations or in which records relevant to the operation of the UST system(s) are kept, and to copy these records, obtain samples of regulated substances, and inspect or conduct the monitoring or testing of UST system(s).

(d) State programs must have procedures for receipt, evaluation, retention, and investigation of records and reports required of owners or operators and must provide for enforcement of failure to submit these records and reports.

(e)(1) State programs must have inspection procedures to determine, independent of information supplied by regulated persons, compliance with program requirements, and must provide for enforcement of failure to comply with the program requirements. States must maintain a program for systematic inspections of facilities subject to UST regulations in a manner designed to determine compliance or non-compliance, to verify accuracy of information submitted by owners or operators of regulated USTs, and to verify adequacy of methods used by owners or operators in developing that information.

(2) When inspections are conducted, samples taken, or other information gathered, these procedures must be conducted in a manner (for example, using proper ''chain of custody'' procedures) that will produce evidence admissible in an enforcement proceeding, or in court.

(f) Public effort in reporting violations must be encouraged and states must make available information on reporting procedures. State programs must maintain a program for investigating information obtained from the public about suspected violations of UST program requirements.

(g) The state must maintain the data collected through inspections and evaluation of records in such a manner that the implementing agency can monitor over time the compliance status of the regulated community. Any compilation, index, or inventory of such facilities and activities shall be made available to EPA upon request.

§ 281.41 Requirements for enforcement authority.

(a) Any state administering a program must have the authority to implement the following remedies for violations of state program requirements:

(1) To restrain immediately and effectively any person by order or by suit in state court from engaging in any unauthorized activity that is endangering or causing damage to public health or the environment;

(2) To sue in courts of competent jurisdiction to enjoin any threatened or continuing violation of any program requirement;

(3) To assess or sue to recover in court civil penalties as follows:

(i) Civil penalties for failure to notify or for submitting false information pursuant to tank notification requirements must be capable of being assessed up to $5,000 or more per violation.

(ii) Civil penalties for failure to comply with any state requirements or standards for existing or new tank systems must be capable of being assessed for each instance of violation, up to $5,000 or more for each tank for each day of violation. If the violation is continuous, civil penalties shall be capable of being assessed up to $5,000 or more for each day of violation.

(4) To prohibit the delivery, deposit, or acceptance of a regulated substance into an underground storage tank identified by the implementing agency to be ineligible for such delivery, deposit, or acceptance in accordance with section 9012 of the Solid Waste Disposal Act.

(b) The burden of proof and degree of knowledge or intent required under state law for establishing violations under paragraph (a)(3) of this section, must be no greater than the burden of proof or degree of knowledge or intent that EPA must provide when it brings an action under Subtitle I of the Solid Waste Disposal Act.

(c) A civil penalty assessed, sought, or agreed upon by the implementing agency(ies) under paragraph (a)(3) of this section must be appropriate to the violation.

§ 281.42 Requirements for public participation.

Any state administering a program must provide for public participation in the state enforcement process by providing any one of the following three options:

(a) Authority that allows intervention analogous to Federal Rule 24(a)(2) from Title IV of the Federal Rules of Civil Procedure, and assurance by the state that it will not oppose intervention under the state analogue to Rule 24(a)(2) on the ground that the applicant's interest is adequately represented by the state.

(b) Authority that allows intervention of right in any civil action to obtain the remedies specified in § 281.41 by any citizen having an interest that is or may be adversely affected; or

(c) Assurance by the appropriate state agency that:

(1) It will provide notice and opportunity for public comment on all proposed settlements of civil enforcement actions (except where immediate action is necessary to adequately protect human health and the environment);

(2) It will investigate and provide responses to citizen complaints about violations; and

(3) It will not oppose citizen intervention when permissive intervention is allowed by statute, rule, or regulation.

§ 281.43 Sharing of information.

(a) States with approved programs must furnish EPA, upon request, any information in state files obtained or used in the administration of the state program. This information includes:

(1) Any information submitted to the state under a claim of confidentiality. The state must submit that claim to EPA when providing such information. Any information obtained from a state and subject to a claim of confidentiality will be treated in accordance with federal regulations in 40 CFR part 2; and

(2) Any information that is submitted to the state without a claim of confidentiality. EPA may make this information available to the public without further notice.

(b) EPA must furnish to states with approved programs, upon request, any information in EPA files that the state needs to administer its approved state program. Such information includes:

(1) Any information that is submitted to EPA without a claim of confidentiality; and

(2) Any information submitted to EPA under a claim of confidentiality, subject to the conditions in 40 CFR part 2.

Subpart E—Approval Procedures

§ 281.50 Approval procedures for state programs.

(a) The following procedures are required for all applications, regardless of whether the application is for a partial or complete program, as defined in § 281.12.

(b) Before submitting an application to EPA for approval of a state program, the state must provide an opportunity for public notice and comment in the development of its underground storage tank program.

(c) When EPA receives a state program application, EPA will examine the application and notify the state whether its application is complete, in accordance with the application components required in § 281.20. The 180-day statutory review period begins only after EPA has determined that a complete application has been received.

(d) The state and EPA may by mutual agreement extend the review period.

(e) After receipt of a complete program application, the Administrator will tentatively determine approval or disapproval of the state program. EPA shall issue public notice of the tentative determination in the **Federal Register** and other mechanisms to attract state-wide attention. Notice of the tentative determination must also:

(1) Afford the public 30 days after the notice to comment on the state's application and the Administrator's tentative determination; and

(2) Include a general statement of the areas of concern, if the Administrator indicates the state program may not be approved; and

(3) Note the availability for inspection by the public of the state program application; and

(4) Indicate that a public hearing will be held by EPA no earlier than 30 days after notice of the tentative determination unless insufficient public interest is expressed, at which time the Regional Administrator may cancel the public hearing.

(f) Within 180 days of receipt of a complete state program application, the Administrator must make a final determination whether to approve the state program after review of all public comments. EPA will give notice of its determination in the **Federal Register** and codify the approved state program. The notice must include a statement of the reasons for this determination and a response to significant comments received.

§ 281.51 Revision of approved state programs.

(a) Either EPA or the approved state may initiate program revision. Program revision may be necessary when the controlling federal or state statutory or regulatory authority is changed or when responsibility for the state program is shifted to a new agency or agencies. The state must inform EPA of any proposed modifications to its basic statutory or regulatory authority or change in division of responsibility among state agencies. EPA will determine in each case whether a revision of the approved program is required. Approved state programs must submit a revised application within three years of any changes to this part that requires a program revision.

(b) Whenever the Administrator has reason to believe that circumstances have changed with respect to an approved state program or the federal program, the Administrator may request, and the state must provide, a revised application as prescribed by EPA.

(c) The Administrator will approve or disapprove program revisions based on the requirements of this part and Subtitle I of the Solid Waste Disposal Act pursuant to the procedures under this section, or under § 281.50 if EPA has reason to believe the proposed revision will receive significant negative comment from the public.

(1) The Administrator must issue public notice of planned approval or disapproval of a state program revision in the **Federal Register** and other mechanisms to attract state-wide attention. The public notice must summarize the state program revision, indicate whether EPA intends to approve or disapprove the revision, and provide for an opportunity to comment for a period of 30 days.

(2) The Administrator's decision on the proposed revision becomes effective 60 days after the date of publication in the **Federal Register** in accordance with paragraph (c)(1) of this section, unless significant negative comment opposing the proposed revision is received during the comment period. If significant negative comment is received, EPA must notify the state and within 60 days after the date of publication, publish in the **Federal Register** either:

(i) A withdrawal of the immediate final decision, which will then be treated as a tentative decision in accordance with the applicable procedures of § 281.50(e) and (f); or

(ii) A notice that contains a response to significant negative comments and affirms either that the immediate final decision takes effect or reverses the decision.

(d) Revised state programs that receive approval must be codified in the **Federal Register**.

Subpart F—Withdrawal of Approval of State Programs

§ 281.60 Criteria for withdrawal of approval of state programs.

The Administrator may withdraw program approval when the Agency determines that a state no longer has adequate regulatory or statutory authority or is not administering and enforcing an approved program in accordance with this part. The state must have adequate capability to administer and enforce the state program. In evaluating whether such capability exists, the Agency will consider whether the state is implementing an adequate enforcement program by evaluating the quality of compliance monitoring and enforcement actions.

§ 281.61 Procedures for withdrawal of approval of state programs.

(a) The following procedures apply when a state with an approved program voluntarily transfers to EPA those program responsibilities required by federal law.

(1) The state must give EPA notice of the proposed transfer, and submit, at

least 90 days before the transfer, a plan for the orderly transfer of all relevant program information necessary for EPA to administer the program.

(2) Within 30 days of receiving the state's transfer plan, EPA must evaluate the plan and identify any additional information needed by the federal government for program administration.

(3) At least 30 days before the transfer is to occur, EPA must publish notice of the transfer in the **Federal Register** and other mechanisms to attract state-wide attention.

(b) The following procedures apply when the Administrator considers withdrawing approval.

(1) When EPA begins proceedings to determine whether to withdraw approval of a state program (either on its own initiative or in response to a petition from an interested person), withdrawal proceedings will be conducted in accordance with procedures set out in 40 CFR 271.23(b) and (c), except for § 271.23(b)(8)(iii) to the extent that it deviates from requirements under § 281.60.

(2) If the state fails to take appropriate action within a reasonable time, not to exceed 120 days after notice from the Administrator that the state is not administering and enforcing its program in accordance with the requirements of this part, EPA will withdraw approval of the state's program.

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Part III

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, 414, *et al.*

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, 414, 425, 495

[CMS–1631–P]

RIN 0938–AS40

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This major proposed rule addresses changes to the physician fee schedule, and other Medicare Part B payment policies to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute.

DATES: Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on September 8, 2015.

ADDRESSES: In commenting, please refer to file code CMS–1631–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 *www.regulations.gov*. Follow the instructions for ''submitting a comment.''

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–1631–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–1631–P, Mail Stop C4–26–05, 7500 Security Boulevard, Baltimore, MD 21244–1850.

4. *By hand or courier*. If you prefer, you may deliver (by hand or courier) your written comments before the close of the comment period to either of the following addresses:

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, please call telephone number (410) 786–7195 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

FOR FURTHER INFORMATION CONTACT:

Donta Henson, (410) 786–1947 for any physician payment issues not identified below.

Gail Addis, (410) 786–4522, for issues related to the refinement panel.

Chava Sheffield, (410) 786–2298, for issues related to practice expense methodology, impacts, conversion factors, target, and phase-in provisions.

Jessica Bruton, (410) 786–5991, for issues related to potentially misvalued code lists.

Geri Mondowney, (410) 786–4584, for issues related to geographic practice cost indices and malpractice RVUs.

Ken Marsalek, (410) 786–4502, for issues related to telehealth services.

Ann Marshall, (410) 786–3059, for issues related to advance care planning, and for primary care and care management services.

Michael Soracoe, (410) 786–6312, for issues related to the valuation and coding of the global surgical packages.

Roberta Epps, (410) 786–4503, for issues related to PAMA section 218(a) policy.

Regina Walker-Wren, (410) 786–9160, for issues related to the ''incident to'' proposals.

Lindsey Baldwin, (410) 786–1694, for issues related to valuation of moderate sedation and colonoscopy services and portable x-ray transportation fees.

Emily Yoder, (410) 786–1804, for issues related to valuation of radiation treatment services.

Amy Gruber, (410) 786–1542, for issues related to ambulance payment policy.

Corinne Axelrod, (410) 786–5620, for issues related to rural health clinics or federally qualified health centers and payment to grandfathered tribal FQHCs.

Simone Dennis, (410) 786–8409, for issues related to rural health clinics HCPCS reporting.

Edmund Kasaitis (410) 786–0477, for issues related to Part B drugs, biologicals, and biosimilars.

Alesia Hovatter, (410) 786–6861, for issues related to Physician Compare.

Christine Estella, (410) 786–0485, for issues related to the physician quality reporting system and the merit-based incentive payment system.

Alexandra Mugge (410) 786–4457, for issues related to EHR Incentive Program.

Sarah Arceo, (410) 786–2356) or Patrice Holtz, (410–786–5663) for issues related to EHR Incentive Program-CPC initiative and meaningful use aligned reporting.

Christiane LaBonte, (410) 786–7237, for issues related to comprehensive primary care initiative.

Rabia Khan, (410) 786–9328 or Terri Postma, (410) 786–4169, for issues related to Medicare Shared Savings Program.

Kimberly Spalding Bush, (410) 786–3232, or Sabrina Ahmed (410) 786–7499, for issues related to value-based Payment Modifier and Physician Feedback Program.

Frederick Grabau, (410) 786–0206, for issues related to changes to opt-out regulations.

Lisa Ohrin Wilson (410) 786–8852, for issues related to physician self-referral updates.

SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: *http://www.regulations.gov*. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid

Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1–800–743–3951.

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Acronyms

In addition, because of the many organizations and terms to which we refer by acronym in this proposed rule, we are listing these acronyms and their corresponding terms in alphabetical order below:

AAA Abdominal aortic aneurysms
ACO Accountable care organization
AMA American Medical Association
ASC Ambulatory surgical center
ATA American Telehealth Association
ATRA American Taxpayer Relief Act (Pub. L. 112–240)
BBA Balanced Budget Act of 1997 (Pub. L. 105–33)
BBRA [Medicare, Medicaid and State Child Health Insurance Program] Balanced Budget Refinement Act of 1999 (Pub. L. 106–113)
CAD Coronary artery disease
CAH Critical access hospital
CBSA Core-Based Statistical Area
CCM Chronic care management
CEHRT Certified EHR technology
CF Conversion factor
CG–CAHPS Clinician and Group Consumer Assessment of Healthcare Providers and Systems
CLFS Clinical Laboratory Fee Schedule
CNM Certified nurse-midwife
CP Clinical psychologist
CPC Comprehensive Primary Care
CPEP Clinical Practice Expert Panel
CPT [Physicians] Current Procedural Terminology (*CPT codes, descriptions and other data only are copyright 2014 American Medical Association. All rights reserved.*)
CQM Clinical quality measure
CSW Clinical social worker
CT Computed tomography
CY Calendar year
DFAR Defense Federal Acquisition Regulations
DHS Designated health services
DM Diabetes mellitus
DSMT Diabetes self-management training
eCQM Electronic clinical quality measures
EHR Electronic health record
E/M Evaluation and management
EP Eligible professional
eRx Electronic prescribing
ESRD End-stage renal disease
FAR Federal Acquisition Regulations
FFS Fee-for-service
FQHC Federally qualified health center
FR Federal Register
GAF Geographic adjustment factor
GAO Government Accountability Office
GPCI Geographic practice cost index
GPO Group purchasing organization
GPRO Group practice reporting option
GTR Genetic Testing Registry
HCPCS Healthcare Common Procedure Coding System
HHS [Department of] Health and Human Services
HOPD Hospital outpatient department
HPSA Health professional shortage area
IDTF Independent diagnostic testing facility
IPPS Inpatient Prospective Payment System
IQR Inpatient Quality Reporting
ISO Insurance service office
IWPUT Intensity of work per unit of time
LCD Local coverage determination
MA Medicare Advantage
MAC Medicare Administrative Contractor
MAP Measure Applications Partnership
MAPCP Multi-payer Advanced Primary Care Practice
MAV Measure application validity [process]
MCP Monthly capitation payment
MedPAC Medicare Payment Advisory Commission
MEI Medicare Economic Index
MFP Multi-Factor Productivity
MIPPA Medicare Improvements for Patients and Providers Act (Pub. L. 110–275)
MMA Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108–173, enacted on December 8, 2003)
MP Malpractice
MPPR Multiple procedure payment reduction
MRA Magnetic resonance angiography
MRI Magnetic resonance imaging
MSA Metropolitan Statistical Areas
MSPB Medicare Spending per Beneficiary
MSSP Medicare Shared Savings Program
MU Meaningful use
NCD National coverage determination
NCQDIS National Coalition of Quality Diagnostic Imaging Services
NP Nurse practitioner
NPI National Provider Identifier
NPP Nonphysician practitioner
NQS National Quality Strategy
OACT CMS's Office of the Actuary
OBRA '89 Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239)
OBRA '90 Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508)
OES Occupational Employment Statistics
OMB Office of Management and Budget
OPPS Outpatient prospective payment system
OT Occupational therapy
PA Physician assistant
PAMA Protecting Access to Medicare Act of 2014 (Pub. L. 113–93)
PC Professional component
PCIP Primary Care Incentive Payment
PE Practice expense
PE/HR Practice expense per hour
PEAC Practice Expense Advisory Committee
PECOS Provider Enrollment, Chain, and Ownership System
PFS Physician Fee Schedule
PLI Professional Liability Insurance
PMA Premarket approval
PQRS Physician Quality Reporting System
PPIS Physician Practice Expense Information Survey
PT Physical therapy
PY Performance year
QCDR Qualified clinical data registry
QRUR Quality and Resources Use Report
RBRVS Resource-based relative value scale

RFA Regulatory Flexibility Act
RHC Rural health clinic
RIA Regulatory impact analysis
RUC American Medical Association/ Specialty Society Relative (Value) Update Committee
RUCA Rural Urban Commuting Area
RVU Relative value unit
SBA Small Business Administration
SGR Sustainable growth rate
SIM State Innovation Model
SLP Speech-language pathology
SMS Socioeconomic Monitoring System
SNF Skilled nursing facility
TAP Technical Advisory Panel
TC Technical component
TIN Tax identification number
UAF Update adjustment factor
UPIN Unique Physician Identification Number
USPSTF United States Preventive Services Task Force
VBP Value-based purchasing
VM Value-Based Payment Modifier

Addenda Available Only Through the Internet on the CMS Web Site

The PFS Addenda along with other supporting documents and tables referenced in this proposed rule are available through the Internet on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. Click on the link on the left side of the screen titled, ''PFS Federal Regulations Notices'' for a chronological list of PFS **Federal Register** and other related documents. For the CY 2016 PFS proposed rule, refer to item CMS–1631–P. Readers who experience any problems accessing any of the Addenda or other documents referenced in this rule and posted on the CMS Web site identified above should contact Donta Henson at (410) 786–1947.

CPT (Current Procedural Terminology) Copyright Notice

Throughout this proposed rule, we use CPT codes and descriptions to refer to a variety of services. We note that CPT codes and descriptions are copyright 2015 American Medical Association. All Rights Reserved. CPT is a registered trademark of the American Medical Association (AMA). Applicable Federal Acquisition Regulations (FAR) and Defense Federal Acquisition Regulations (DFAR) apply.

I. Executive Summary and Background

A. Executive Summary

1. Purpose

This major proposed rule proposes to revise payment polices under the Medicare Physician Fee Schedule (PFS) and make other policy changes related to Medicare Part B payment. These proposed changes would be applicable to services furnished in CY 2016.

2. Summary of the Major Provisions

The Social Security Act (the Act) requires us to establish payments under the PFS based on national uniform relative value units (RVUs) that account for the relative resources used in furnishing a service. The Act requires that RVUs be established for three categories of resources: Work, practice expense (PE); and malpractice (MP) expense; and, that we establish by regulation each year's payment amounts for all physicians' services paid under the PFS, incorporating geographic adjustments to reflect the variations in the costs of furnishing services in different geographic areas. In this major proposed rule, we establish RVUs for CY 2016 for the PFS, and other Medicare Part B payment policies, to ensure that our payment systems are updated to reflect changes in medical practice and the relative value of services, as well as changes in the statute. In addition, this proposed rule includes discussions and proposals regarding:

- Potentially Misvalued PFS Codes.
- Telehealth Services.
- Advance Care Planning Services.
- Establishing Values for New, Revised, and Misvalued Codes.
- Target for Relative Value Adjustments for Misvalued Services.
- Phase-in of Significant RVU Reductions.
- ''Incident to'' policy.
- Portable X-Ray Transportation Fee.
- Updating the Ambulance Fee Schedule regulations.
- Changes in Geographic Area Delineations for Ambulance Payment.
- Chronic Care Management Services for RHCs and FQHCs.
- HCPCS Coding for RHCs.
- Payment to Grandfathered Tribal FQHCs that were Provider-Based Clinics on or before April 7, 2000.
- Payment for Biosimilars under Medicare Part B.
- Physician Compare Web site.
- Physician Quality Reporting System.
- Medicare Shared Savings Program.
- Electronic Health Record (EHR) Incentive Program.
- Value-Based Payment Modifier and the Physician Feedback Program.

3. Summary of Costs and Benefits

The Act requires that annual adjustments to PFS RVUs may not cause annual estimated expenditures to differ by more than $20 million from what they would have been had the adjustments not been made. If adjustments to RVUs would cause expenditures to change by more than $20 million, we must make adjustments to preserve budget neutrality. These adjustments can affect the distribution of Medicare expenditures across specialties. In addition, several proposed changes would affect the specialty distribution of Medicare expenditures. When considering the combined impact of work, PE, and MP RVU changes, the projected payment impacts are small for most specialties; however, the impact would be larger for a few specialties.

We have determined that this major proposed rule is economically significant. For a detailed discussion of the economic impacts, see section VII. of this proposed rule.

B. Background

Since January 1, 1992, Medicare has paid for physicians' services under section 1848 of the Act, ''Payment for Physicians' Services.'' The system relies on national relative values that are established for work, PE, and MP, which are adjusted for geographic cost variations. These values are multiplied by a conversion factor (CF) to convert the RVUs into payment rates. The concepts and methodology underlying the PFS were enacted as part of the Omnibus Budget Reconciliation Act of 1989 (Pub. L. 101–239, enacted on December 19, 1989) (OBRA '89), and the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508, enacted on November 5, 1990) (OBRA '90). The final rule published on November 25, 1991 (56 FR 59502) set forth the first fee schedule used for payment for physicians' services.

We note that throughout this major proposed rule, unless otherwise noted, the term ''practitioner'' is used to describe both physicians and nonphysician practitioners (NPPs) who are permitted to bill Medicare under the PFS for services furnished to Medicare beneficiaries.

1. Development of the Relative Values

a. Work RVUs

The work RVUs established for the initial fee schedule, which was implemented on January 1, 1992, were developed with extensive input from the physician community. A research team at the Harvard School of Public Health developed the original work RVUs for most codes under a cooperative agreement with the Department of Health and Human Services (HHS). In constructing the code-specific vignettes used in determining the original physician work

RVUs, Harvard worked with panels of experts, both inside and outside the federal government, and obtained input from numerous physician specialty groups.

As specified in section 1848(c)(1)(A) of the Act, the work component of physicians' services means the portion of the resources used in furnishing the service that reflects physician time and intensity. We establish work RVUs for new, revised and potentially misvalued codes based on our review of information that generally includes, but is not limited to, recommendations received from the American Medical Association/Specialty Society Relative Value Update Committee (RUC), the Health Care Professionals Advisory Committee (HCPAC), the Medicare Payment Advisory Commission (MedPAC), and other public commenters; medical literature and comparative databases; as well as a comparison of the work for other codes within the Medicare PFS, and consultation with other physicians and health care professionals within CMS and the federal government. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters, and the rationale for their recommendations.

b. Practice Expense RVUs

Initially, only the work RVUs were resource-based, and the PE and MP RVUs were based on average allowable charges. Section 121 of the Social Security Act Amendments of 1994 (Pub. L. 103–432, enacted on October 31, 1994), amended section 1848(c)(2)(C)(ii) of the Act and required us to develop resource-based PE RVUs for each physicians' service beginning in 1998. We were required to consider general categories of expenses (such as office rent and wages of personnel, but excluding malpractice expenses) comprising PEs. The PE RVUs continue to represent the portion of these resources involved in furnishing PFS services.

Originally, the resource-based method was to be used beginning in 1998, but section 4505(a) of the Balanced Budget Act of 1997 (Pub. L. 105–33, enacted on August 5, 1997) (BBA) delayed implementation of the resource-based PE RVU system until January 1, 1999. In addition, section 4505(b) of the BBA provided for a 4-year transition period from the charge-based PE RVUs to the resource-based PE RVUs.

We established the resource-based PE RVUs for each physicians' service in a final rule, published on November 2, 1998 (63 FR 58814), effective for services furnished in CY 1999. Based on the requirement to transition to a resource-based system for PE over a 4-year period, payment rates were not fully based upon resource-based PE RVUs until CY 2002. This resource-based system was based on two significant sources of actual PE data: the Clinical Practice Expert Panel (CPEP) data and the AMA's Socioeconomic Monitoring System (SMS) data. (These data sources are described in greater detail in the CY 2012 final rule with comment period (76 FR 73033).)

Separate PE RVUs are established for services furnished in facility settings, such as a hospital outpatient department (HOPD) or an ambulatory surgical center (ASC), and in nonfacility settings, such as a physician's office. The nonfacility RVUs reflect all of the direct and indirect PEs involved in furnishing a service described by a particular HCPCS code. The difference, if any, in these PE RVUs generally results in a higher payment in the nonfacility setting because in the facility settings some costs are borne by the facility. Medicare's payment to the facility (such as the outpatient prospective payment system (OPPS) payment to the HOPD) would reflect costs typically incurred by the facility. Thus, payment associated with those facility resources is not made under the PFS.

Section 212 of the Balanced Budget Refinement Act of 1999 (Pub. L. 106–113, enacted on November 29, 1999) (BBRA) directed the Secretary of Health and Human Services (the Secretary) to establish a process under which we accept and use, to the maximum extent practicable and consistent with sound data practices, data collected or developed by entities and organizations to supplement the data we normally collect in determining the PE component. On May 3, 2000, we published the interim final rule (65 FR 25664) that set forth the criteria for the submission of these supplemental PE survey data. The criteria were modified in response to comments received, and published in the **Federal Register** (65 FR 65376) as part of a November 1, 2000 final rule. The PFS final rules published in 2001 and 2003, respectively, (66 FR 55246 and 68 FR 63196) extended the period during which we would accept these supplemental data through March 1, 2005.

In the CY 2007 PFS final rule with comment period (71 FR 69624), we revised the methodology for calculating direct PE RVUs from the top-down to the bottom-up methodology beginning in CY 2007. We adopted a 4-year transition to the new PE RVUs. This transition was completed for CY 2010. In the CY 2010 PFS final rule with comment period, we updated the practice expense per hour (PE/HR) data that are used in the calculation of PE RVUs for most specialties (74 FR 61749). In CY 2010, we began a 4-year transition to the new PE RVUs using the updated PE/HR data, which was completed for CY 2013.

c. Malpractice RVUs

Section 4505(f) of the BBA amended section 1848(c) of the Act to require that we implement resource-based MP RVUs for services furnished on or after CY 2000. The resource-based MP RVUs were implemented in the PFS final rule with comment period published November 2, 1999 (64 FR 59380). The MP RVUs are based on commercial and physician-owned insurers' malpractice insurance premium data from all the states, the District of Columbia, and Puerto Rico. For more information on MP RVUs, see section II.C. of this proposed rule.

d. Refinements to the RVUs

Section 1848(c)(2)(B)(i) of the Act requires that we review RVUs no less often than every 5 years. Prior to CY 2013, we conducted periodic reviews of work RVUs and PE RVUs independently. We completed five-year reviews of work RVUs that were effective for calendar years 1997, 2002, 2007, and 2012.

Although refinements to the direct PE inputs initially relied heavily on input from the RUC Practice Expense Advisory Committee (PEAC), the shifts to the bottom-up PE methodology in CY 2007 and to the use of the updated PE/HR data in CY 2010 have resulted in significant refinements to the PE RVUs in recent years.

In the CY 2012 PFS final rule with comment period (76 FR 73057), we finalized a proposal to consolidate reviews of work and PE RVUs under section 1848(c)(2)(B) of the Act and reviews of potentially misvalued codes under section 1848(c)(2)(K) of the Act into one annual process.

In addition to the five-year reviews, beginning for CY 2009, CMS, and the RUC have identified and reviewed a number of potentially misvalued codes on an annual basis based on various identification screens. This annual review of work and PE RVUs for potentially misvalued codes was supplemented by the amendments to section 1848 of the Act, as enacted by section 3134 of the Affordable Care Act, which requires the agency to periodically identify, review and adjust values for potentially misvalued codes.

e. Application of Budget Neutrality to Adjustments of RVUs

As described in section VI.C. of this proposed rule, in accordance with section 1848(c)(2)(B)(ii)(II) of the Act, if revisions to the RVUs caused expenditures for the year to change by more than $20 million, we make adjustments to ensure that expenditures did not increase or decrease by more than $20 million.

2. Calculation of Payments Based on RVUs

To calculate the payment for each service, the components of the fee schedule (work, PE, and MP RVUs) are adjusted by geographic practice cost indices (GPCIs) to reflect the variations in the costs of furnishing the services. The GPCIs reflect the relative costs of work, PE, and MP in an area compared to the national average costs for each component. (See section II.D. of this proposed rule for more information about GPCIs.)

RVUs are converted to dollar amounts through the application of a CF, which is calculated based on a statutory formula by CMS's Office of the Actuary (OACT). The formula for calculating the Medicare fee schedule payment amount for a given service and fee schedule area can be expressed as:

Payment = [(RVU work x GPCI work) + (RVU PE x GPCI PE) + (RVU MP x GPCI MP)] x CF.

3. Separate Fee Schedule Methodology for Anesthesia Services

Section 1848(b)(2)(B) of the Act specifies that the fee schedule amounts for anesthesia services are to be based on a uniform relative value guide, with appropriate adjustment of an anesthesia conversion factor, in a manner to assure that fee schedule amounts for anesthesia services are consistent with those for other services of comparable value. Therefore, there is a separate fee schedule methodology for anesthesia services. Specifically, we establish a separate conversion factor for anesthesia services and we utilize the uniform relative value guide, or base units, as well as time units, to calculate the fee schedule amounts for anesthesia services. Since anesthesia services are not valued using RVUs, a separate methodology for locality adjustments is also necessary. This involves an adjustment to the national anesthesia CF for each payment locality.

4. Most Recent Changes to the Fee Schedule

Section 220(d) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93, enacted on April 1, 2014) added a new subparagraph (O) to section 1848(c)(2) of the Act to establish an annual target for reductions in PFS expenditures resulting from adjustments to relative values of misvalued codes. If the estimated net reduction in expenditures for a year is equal to or greater than the target for that year, the provision specifies that reduced expenditures attributable to such adjustments shall be redistributed in a budget-neutral manner within the PFS. The provision also specifies that the amount by which such reduced expenditures exceed the target for a given year shall be treated as a reduction in expenditures for the subsequent year for purposes of determining whether the target for the subsequent year has been met. The provision also specifies that an amount equal to the difference between the target and the estimated net reduction, called the target recapture amount shall not be taken into account when applying the budget neutrality requirements specified in section 1848(c)(2)(B)(ii)(II) of the Act. The PAMA originally applied the target to CYs 2017 through 2020 and set the target amount to 0.5 percent of the estimated amount of expenditures under the PFS for each of those 4 years.

More recently, section 202 of the Achieving a Better Life Experience Act of 2014 (ABLE) (Division B of Pub. L. 113–295, enacted December 19, 2014) accelerated the application of the target, amending section 1848(c)(2)(O) of the Act to specify that targets would apply for CYs 2016, 2017, and 2018 and set a 1 percent target for CY 2016 and 0.5 percent for CYs 2017 and 2018. The implementation of the target legislation is discussed in section II.F. of this proposed rule.

Section 1848(c)(7) of the Act, as added by section 220(e) of the PAMA, specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs shall be phased-in over a 2-year period. Although section 220(e) of the PAMA required the phase-in of RVU reductions of 20 percent or more to begin for 2017, section 202 of the ABLE Act now requires the phase-in to begin in CY 2016. The implementation of the phase-in legislation is discussed in section II.G. of this proposed rule.

Section 218(a) of the PAMA adds a new section 1834(p) to the statute. Section 1834(p) requires reductions in payment for the technical component (TC) (and the TC of the global fee) of the PFS service and in the hospital OPPS payment (5 percent in 2016, and 15 percent in 2017 and subsequent years) for computed tomography (CT) services (identified as of January 1, 2014 by HCPCS codes 70450–70498, 71250–71275, 72125–72133, 72191–72194, 73200–73206, 73700–73706, 74150–74178, 74261–74263, and 75571–75574, and succeeding codes) furnished using equipment that does not meet each of the attributes of the National Electrical Manufacturers Association (NEMA) Standard XR–29–2013, entitled ''Standard Attributes on CT Equipment Related to Dose Optimization and Management.'' The implementation of section 218(a) of the PAMA is discussed in section II.H. of this proposed rule.

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10, enacted on April 16, 2015) makes several changes to the statute, including but not limited to:

(1) Repealing the sustainable growth rate (SGR) update methodology for physicians' services.

(2) Revising the PFS update for 2015 and subsequent years.

(3) Establishing a Merit-based Incentive Payment System (MIPS) under which eligible professionals (initially including physicians, physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists) receive annual payment increases or decreases based on their performance in a prior period. These and other MACRA provisions are discussions in various sections of this proposed rule. Please refer to the table of contents for the location of the various MACRA provision discussions.

II. Provisions of the Proposed Rule for PFS

A. Determination of Practice Expense (PE) Relative Value Units (RVUs)

1. Overview

Practice expense (PE) is the portion of the resources used in furnishing a service that reflects the general categories of physician and practitioner expenses, such as office rent and personnel wages, but excluding malpractice expenses, as specified in section 1848(c)(1)(B) of the Act. As required by section 1848(c)(2)(C)(ii) of the Act, we use a resource-based system for determining PE RVUs for each physicians' service. We develop PE RVUs by considering the direct and indirect practice resources involved in furnishing each service. Direct expense categories include clinical labor, medical supplies, and medical

equipment. Indirect expenses include administrative labor, office expense, and all other expenses. The sections that follow provide more detailed information about the methodology for translating the resources involved in furnishing each service into service-specific PE RVUs. We refer readers to the CY 2010 PFS final rule with comment period (74 FR 61743 through 61748) for a more detailed explanation of the PE methodology.

2. Practice Expense Methodology

a. Direct Practice Expense

We determine the direct PE for a specific service by adding the costs of the direct resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing that service. The costs of the resources are calculated using the refined direct PE inputs assigned to each CPT code in our PE database, which are generally based on our review of recommendations received from the RUC and those provided in response to public comment periods. For a detailed explanation of the direct PE methodology, including examples, we refer readers to the Five-Year Review of Work Relative Value Units under the PFS and Proposed Changes to the Practice Expense Methodology proposed notice (71 FR 37242) and the CY 2007 PFS final rule with comment period (71 FR 69629).

b. Indirect Practice Expense per Hour Data

We use survey data on indirect PEs incurred per hour worked in developing the indirect portion of the PE RVUs. Prior to CY 2010, we primarily used the practice expense per hour (PE/HR) by specialty that was obtained from the AMA's Socioeconomic Monitoring Surveys (SMS). The AMA administered a new survey in CY 2007 and CY 2008, the Physician Practice Expense Information Survey (PPIS). The PPIS is a multispecialty, nationally representative, PE survey of both physicians and nonphysician practitioners (NPPs) paid under the PFS using a survey instrument and methods highly consistent with those used for the SMS and the supplemental surveys. The PPIS gathered information from 3,656 respondents across 51 physician specialty and health care professional groups. We believe the PPIS is the most comprehensive source of PE survey information available. We used the PPIS data to update the PE/HR data for the CY 2010 PFS for almost all of the Medicare-recognized specialties that participated in the survey.

When we began using the PPIS data in CY 2010, we did not change the PE RVU methodology itself or the manner in which the PE/HR data are used in that methodology. We only updated the PE/HR data based on the new survey. Furthermore, as we explained in the CY 2010 PFS final rule with comment period (74 FR 61751), because of the magnitude of payment reductions for some specialties resulting from the use of the PPIS data, we transitioned its use over a 4-year period from the previous PE RVUs to the PE RVUs developed using the new PPIS data. As provided in the CY 2010 PFS final rule with comment period (74 FR 61751), the transition to the PPIS data was complete for CY 2013. Therefore, PE RVUs from CY 2013 forward are developed based entirely on the PPIS data, except as noted in this section.

Section 1848(c)(2)(H)(i) of the Act requires us to use the medical oncology supplemental survey data submitted in 2003 for oncology drug administration services. Therefore, the PE/HR for medical oncology, hematology, and hematology/oncology reflects the continued use of these supplemental survey data.

Supplemental survey data on independent labs from the College of American Pathologists were implemented for payments beginning in CY 2005. Supplemental survey data from the National Coalition of Quality Diagnostic Imaging Services (NCQDIS), representing independent diagnostic testing facilities (IDTFs), were blended with supplementary survey data from the American College of Radiology (ACR) and implemented for payments beginning in CY 2007. Neither IDTFs, nor independent labs, participated in the PPIS. Therefore, we continue to use the PE/HR that was developed from their supplemental survey data.

Consistent with our past practice, the previous indirect PE/HR values from the supplemental surveys for these specialties were updated to CY 2006 using the MEI to put them on a comparable basis with the PPIS data.

We also do not use the PPIS data for reproductive endocrinology and spine surgery since these specialties currently are not separately recognized by Medicare, nor do we have a method to blend the PPIS data with Medicare-recognized specialty data.

Previously, we established PE/HR values for various specialties without SMS or supplemental survey data by crosswalking them to other similar specialties to estimate a proxy PE/HR. For specialties that were part of the PPIS for which we previously used a crosswalked PE/HR, we instead used the PPIS-based PE/HR. We continue previous crosswalks for specialties that did not participate in the PPIS. However, beginning in CY 2010 we changed the PE/HR crosswalk for portable x-ray suppliers from radiology to IDTF, a more appropriate crosswalk because these specialties are more similar to each other for work time.

For registered dietician services, the resource-based PE RVUs have been calculated in accordance with the final policy that crosswalks the specialty to the ''All Physicians'' PE/HR data, as adopted in the CY 2010 PFS final rule with comment period (74 FR 61752) and discussed in more detail in the CY 2011 PFS final rule with comment period (75 FR 73183).

For CY 2016, we have incorporated the available utilization data for interventional cardiology, which became a recognized Medicare specialty during 2014. We are proposing to use a proxy PE/HR value for interventional cardiology, as there are no PPIS data for this specialty, by crosswalking the PE/HR for from Cardiology, since the specialties furnish similar services in the Medicare claims data. The proposed change is reflected in the ''PE/HR'' file available on the CMS Web site under the supporting data files for the CY 2016 PFS proposed rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html.*

c. Allocation of PE to Services

To establish PE RVUs for specific services, it is necessary to establish the direct and indirect PE associated with each service.

(1) Direct Costs

The relative relationship between the direct cost portions of the PE RVUs for any two services is determined by the relative relationship between the sum of the direct cost resources (that is, the clinical staff, medical supplies, and medical equipment) typically involved with furnishing each of the services. The costs of these resources are calculated from the refined direct PE inputs in our PE database. For example, if one service has a direct cost sum of $400 from our PE database and another service has a direct cost sum of $200, the direct portion of the PE RVUs of the first service would be twice as much as the direct portion of the PE RVUs for the second service.

(2) Indirect Costs

Section II.A.2.b. of this proposed rule describes the current data sources for specialty-specific indirect costs used in our PE calculations. We allocated the

indirect costs to the code level on the basis of the direct costs specifically associated with a code and the greater of either the clinical labor costs or the work RVUs. We also incorporated the survey data described earlier in the PE/HR discussion. The general approach to developing the indirect portion of the PE RVUs is as follows:

- For a given service, we use the direct portion of the PE RVUs calculated as previously described and the average percentage that direct costs represent of total costs (based on survey data) across the specialties that furnish the service to determine an initial indirect allocator. In other words, the initial indirect allocator is calculated so that the direct costs equal the average percentage of direct costs of those specialties furnishing the service. For example, if the direct portion of the PE RVUs for a given service is 2.00 and direct costs, on average, represented 25 percent of total costs for the specialties that furnished the service, the initial indirect allocator would be calculated so that it equals 75 percent of the total PE RVUs. Thus, in this example, the initial indirect allocator would equal 6.00, resulting in a total PE RVUs of 8.00 (2.00 is 25 percent of 8.00 and 6.00 is 75 percent of 8.00).
- Next, we add the greater of the work RVUs or clinical labor portion of the direct portion of the PE RVUs to this initial indirect allocator. In our example, if this service had work RVUs of 4.00 and the clinical labor portion of the direct PE RVUs was 1.50, we would add 4.00 (since the 4.00 work RVUs are greater than the 1.50 clinical labor portion) to the initial indirect allocator of 6.00 to get an indirect allocator of 10.00. In the absence of any further use of the survey data, the relative relationship between the indirect cost portions of the PE RVUs for any two services would be determined by the relative relationship between these indirect cost allocators. For example, if one service had an indirect cost allocator of 10.00 and another service had an indirect cost allocator of 5.00, the indirect portion of the PE RVUs of the first service would be twice as great as the indirect portion of the PE RVUs for the second service.
- Next, we incorporate the specialty-specific indirect PE/HR data into the calculation. In our example, if, based on the survey data, the average indirect cost of the specialties furnishing the first service with an allocator of 10.00 was half of the average indirect cost of the specialties furnishing the second service with an indirect allocator of 5.00, the indirect portion of the PE RVUs of the first service would be equal to that of the second service.

(4) Facility and Nonfacility Costs

For procedures that can be furnished in a physician's office, as well as in a hospital or other facility setting, we establish two PE RVUs: facility and nonfacility. The methodology for calculating PE RVUs is the same for both the facility and nonfacility RVUs, but is applied independently to yield two separate PE RVUs. Because in calculating the PE RVUs for services furnished in a facility, we do not include resources that would generally not be provided by physicians when furnishing the service in a facility, the facility PE RVUs are generally lower than the nonfacility PE RVUs. Medicare makes a separate payment to the facility for its costs of furnishing a service.

(5) Services With Technical Components (TCs) and Professional Components (PCs)

Diagnostic services are generally comprised of two components: A professional component (PC); and a technical component (TC). The PC and TC may be furnished independently or by different providers, or they may be furnished together as a ''global'' service. When services have separately billable PC and TC components, the payment for the global service equals the sum of the payment for the TC and PC. To achieve this we use a weighted average of the ratio of indirect to direct costs across all the specialties that furnish the global service, TCs, and PCs; that is, we apply the same weighted average indirect percentage factor to allocate indirect expenses to the global service, PCs, and TCs for a service. (The direct PE RVUs for the TC and PC sum to the global.)

(6) PE RVU Methodology

For a more detailed description of the PE RVU methodology, we refer readers to the CY 2010 PFS final rule with comment period (74 FR 61745 through 61746).

(a) Setup File

First, we create a setup file for the PE methodology. The setup file contains the direct cost inputs, the utilization for each procedure code at the specialty and facility/nonfacility place of service level, and the specialty-specific PE/HR data calculated from the surveys.

(b) Calculate the Direct Cost PE RVUs

Sum the costs of each direct input.

Step 1: Sum the direct costs of the inputs for each service. Apply a scaling adjustment to the direct inputs.

Step 2: Calculate the aggregate pool of direct PE costs for the current year. Under our current methodology, we first multiply the current year's conversion factor by the product of the current year's PE RVUs and utilization for each service to arrive at the aggregate pool of total PE costs (Step 2a). We then calculate the average direct percentage of the current pool of PE RVUs (using a weighted average of the survey data for the specialties that furnish each service (Step 2b).) We then multiply the result of 2a by the result of 2b to arrive at the aggregate pool of direct PE costs for the current year. For CY 2016, we are proposing a technical improvement to step 2a of this calculation. In place of the step 2a calculation described above, we propose to set the aggregate pool of PE costs equal to the product of the ratio of the current aggregate PE RVUs to current aggregate work RVUs and the proposed aggregate work RVUs. Historically, in allowing the current PE RVUs to determine the size of the base PE pool in the PE methodology, we have assumed that the relationship of PE RVUs to work RVUs is constant from year to year. Since this is not ordinarily the case, by not considering the proposed aggregate work RVUs in determining the size of the base PE pool, we have introduced some minor instability from year to year in the relative shares of work, PE, and MP RVUs. While this proposed modification would result in greater stability in the relationship among the work and PE RVU components in the aggregate, we do not anticipate it will affect the distribution of PE RVUs across specialties. The PE RVUs in addendum B of this proposed rule with comment period reflect this proposed refinement to the PE methodology.

Step 3: Calculate the aggregate pool of direct PE costs for use in ratesetting. This is the product of the aggregate direct costs for all services from Step 1 and the utilization data for that service.

Step 4: Using the results of Step 2 and Step 3, calculate a direct PE scaling adjustment to ensure that the aggregate pool of direct PE costs calculated in Step 3 does not vary from the aggregate pool of direct PE costs for the current year. Apply the scaling factor to the direct costs for each service (as calculated in Step 1).

Step 5: Convert the results of Step 4 to an RVU scale for each service. To do this, divide the results of Step 4 by the CF. Note that the actual value of the CF used in this calculation does not influence the final direct cost PE RVUs, as long as the same CF is used in Step 2 and Step 5. Different CFs will result in different direct PE scaling factors, but

this has no effect on the final direct cost PE RVUs since changes in the CFs and changes in the associated direct scaling factors offset one another.

(c) Create the Indirect Cost PE RVUs

Create indirect allocators.

Step 6: Based on the survey data, calculate direct and indirect PE percentages for each physician specialty.

Step 7: Calculate direct and indirect PE percentages at the service level by taking a weighted average of the results of Step 6 for the specialties that furnish the service. Note that for services with TCs and PCs, the direct and indirect percentages for a given service do not vary by the PC, TC, and global service.

Historically, we have used the specialties that furnish the service in the most recent full year of Medicare claims data (crosswalked to the current year set of codes) to determine which specialties furnish individual procedures. For example, for CY 2015 ratesetting, we used the mix of specialties that furnished the services in the CY 2013 claims data to determine the specialty mix assigned to each code. While we believe that there are clear advantages to using the most recent available data in making these determinations, we have also found that using a single year of data contributes to greater year-to-year instability in PE RVUs for individual codes and often creates extreme, annual fluctuations for low-volume services, as well as delayed fluctuations for some services described by new codes once claims data for those codes becomes available.

We believe that using an average of the three most recent years of available data may increase stability of PE RVUs and mitigate code-level fluctuations for both the full range of PFS codes, and for new and low-volume codes in particular. Therefore, we are proposing to refine this step of the PE methodology to use an average of the 3 most recent years of available Medicare claims data to determine the specialty mix assigned to each code. The PE RVUs in Addendum B of the CMS Web site reflect this proposed refinement to the PE methodology.

Step 8: Calculate the service level allocators for the indirect PEs based on the percentages calculated in Step 7. The indirect PEs are allocated based on the three components: The direct PE RVUs; the clinical PE RVUs; and the work RVUs. For most services the indirect allocator is: Indirect PE percentage * (direct PE RVUs/direct percentage) + work RVUs.

There are two situations where this formula is modified:

- If the service is a global service (that is, a service with global, professional, and technical components), then the indirect PE allocator is: Indirect percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs + work RVUs.
- If the clinical labor PE RVUs exceed the work RVUs (and the service is not a global service), then the indirect allocator is: Indirect PE percentage (direct PE RVUs/direct percentage) + clinical labor PE RVUs.

(*Note:* For global services, the indirect PE allocator is based on both the work RVUs and the clinical labor PE RVUs. We do this to recognize that, for the PC service, indirect PEs will be allocated using the work RVUs, and for the TC service, indirect PEs will be allocated using the direct PE RVUs and the clinical labor PE RVUs. This also allows the global component RVUs to equal the sum of the PC and TC RVUs.)

For presentation purposes in the examples in Table 1, the formulas were divided into two parts for each service.

- The first part does not vary by service and is the indirect percentage (direct PE RVUs/direct percentage).
- The second part is either the work RVU, clinical labor PE RVU, or both depending on whether the service is a global service and whether the clinical PE RVUs exceed the work RVUs (as described earlier in this step).

Apply a scaling adjustment to the indirect allocators.

Step 9: Calculate the current aggregate pool of indirect PE RVUs by multiplying the result of step 2a (as calculated with the proposed change) by the average indirect PE percentage from the survey data.

Step 10: Calculate an aggregate pool of indirect PE RVUs for all PFS services by adding the product of the indirect PE allocators for a service from Step 8 and the utilization data for that service.

Step 11: Using the results of Step 9 and Step 10, calculate an indirect PE adjustment so that the aggregate indirect allocation does not exceed the available aggregate indirect PE RVUs and apply it to indirect allocators calculated in Step 8.

Calculate the indirect practice cost index.

Step 12: Using the results of Step 11, calculate aggregate pools of specialty-specific adjusted indirect PE allocators for all PFS services for a specialty by adding the product of the adjusted indirect PE allocator for each service and the utilization data for that service.

Step 13: Using the specialty-specific indirect PE/HR data, calculate specialty-specific aggregate pools of indirect PE for all PFS services for that specialty by adding the product of the indirect PE/HR for the specialty, the work time for the service, and the specialty's utilization for the service across all services furnished by the specialty.

Step 14: Using the results of Step 12 and Step 13, calculate the specialty-specific indirect PE scaling factors.

Step 15: Using the results of Step 14, calculate an indirect practice cost index at the specialty level by dividing each specialty-specific indirect scaling factor by the average indirect scaling factor for the entire PFS.

Step 16: Calculate the indirect practice cost index at the service level to ensure the capture of all indirect costs. Calculate a weighted average of the practice cost index values for the specialties that furnish the service. (Note: For services with TCs and PCs, we calculate the indirect practice cost index across the global service, PCs, and TCs. Under this method, the indirect practice cost index for a given service (for example, echocardiogram) does not vary by the PC, TC, and global service.)

Step 17: Apply the service level indirect practice cost index calculated in Step 16 to the service level adjusted indirect allocators calculated in Step 11 to get the indirect PE RVUs.

(d) Calculate the Final PE RVUs

Step 18: Add the direct PE RVUs from Step 6 to the indirect PE RVUs from Step 17 and apply the final PE budget neutrality (BN) adjustment. The final PE BN adjustment is calculated by comparing the results of Step 18 to the proposed aggregate work RVUs scaled by the ratio of current aggregate PE and work RVUs, consistent with the proposed changes in Steps 2 and 9. This final BN adjustment is required to redistribute RVUs from step 18 to all PE RVUs in the PFS, and because certain specialties are excluded from the PE RVU calculation for ratesetting purposes, but we note that all specialties are included for purposes of calculating the final BN adjustment. (See ''Specialties excluded from ratesetting calculation'' later in this section.)

(e) Setup File Information

- Specialties excluded from ratesetting calculation: For the purposes of calculating the PE RVUs, we exclude certain specialties, such as certain nonphysician practitioners paid at a percentage of the PFS and low-volume specialties, from the calculation. These specialties are included for the purposes of calculating the BN adjustment. They are displayed in Table 1.

TABLE 1—SPECIALTIES EXCLUDED FROM RATESETTING CALCULATION

Specialty code	Specialty description
49	Ambulatory surgical center.
50	Nurse practitioner.
51	Medical supply company with certified orthotist.
52	Medical supply company with certified prosthetist.
53	Medical supply company with certified prosthetist-orthotist.
54	Medical supply company not included in 51, 52, or 53.
55	Individual certified orthotist.
56	Individual certified prosthetist.
57	Individual certified prosthetist-orthotist.
58	Medical supply company with registered pharmacist.
59	Ambulance service supplier, e.g., private ambulance companies, funeral homes, etc.
60	Public health or welfare agencies.
61	Voluntary health or charitable agencies.
73	Mass immunization roster biller.
74	Radiation therapy centers.
87	All other suppliers (e.g., drug and department stores).
88	Unknown supplier/provider specialty.
89	Certified clinical nurse specialist.
96	Optician.
97	Physician assistant.
A0	Hospital.
A1	SNF.
A2	Intermediate care nursing facility.
A3	Nursing facility, other.
A4	HHA.
A5	Pharmacy.
A6	Medical supply company with respiratory therapist.
A7	Department store.
B2	Pedorthic personnel.
B3	Medical supply company with pedorthic personnel.

• Crosswalk certain low volume physician specialties: Crosswalk the utilization of certain specialties with relatively low PFS utilization to the associated specialties.

• Physical therapy utilization: Crosswalk the utilization associated with all physical therapy services to the specialty of physical therapy.

• Identify professional and technical services not identified under the usual TC and 26 modifiers: Flag the services that are PC and TC services but do not use TC and 26 modifiers (for example, electrocardiograms). This flag associates the PC and TC with the associated global code for use in creating the indirect PE RVUs. For example, the professional service, CPT code 93010 (Electrocardiogram, routine ECG with at least 12 leads; interpretation and report only), is associated with the global service, CPT code 93000 (Electrocardiogram, routine ECG with at least 12 leads; with interpretation and report).

• Payment modifiers: Payment modifiers are accounted for in the creation of the file consistent with current payment policy as implemented in claims processing. For example, services billed with the assistant at surgery modifier are paid 16 percent of the PFS amount for that service; therefore, the utilization file is modified to only account for 16 percent of any service that contains the assistant at surgery modifier. Similarly, for those services to which volume adjustments are made to account for the payment modifiers, time adjustments are applied as well. For time adjustments to surgical services, the intraoperative portion in the work time file is used; where it is not present, the intraoperative percentage from the payment files used by contractors to process Medicare claims is used instead. Where neither is available, we use the payment adjustment ratio to adjust the time accordingly. Table 2 details the manner in which the modifiers are applied.

TABLE 2—APPLICATION OF PAYMENT MODIFIERS TO UTILIZATION FILES

Modifier	Description	Volume adjustment	Time adjustment
80,81,82	Assistant at Surgery	16%	Intraoperative portion.
AS	Assistant at Surgery—Physician Assistant	14% (85% * 16%)	Intraoperative portion.
50 or LT and RT	Bilateral Surgery	150%	150% of work time.
51	Multiple Procedure	50%	Intraoperative portion.
52	Reduced Services	50%	50%.
53	Discontinued Procedure	50%	50%.
54	Intraoperative Care only	Preoperative + Intraoperative Percentages on the payment files used by Medicare contractors to process Medicare claims.	Preoperative + Intraoperative portion.
55	Postoperative Care only	Postoperative Percentage on the payment files used by Medicare contractors to process Medicare claims.	Postoperative portion.
62	Co-surgeons	62.5%	50%.

TABLE 2—APPLICATION OF PAYMENT MODIFIERS TO UTILIZATION FILES—Continued

Modifier	Description	Volume adjustment	Time adjustment
66	Team Surgeons	33%	33%.

We also make adjustments to volume and time that correspond to other payment rules, including special multiple procedure endoscopy rules and multiple procedure payment reductions (MPPRs). We note that section 1848(c)(2)(B)(v) of the Act exempts certain reduced payments for multiple imaging procedures and multiple therapy services from the BN calculation under section 1848(c)(2)(B)(ii)(II) of the Act. These MPPRs are not included in the development of the RVUs.

For anesthesia services, we do not apply adjustments to volume since we use the average allowed charge when simulating RVUs; therefore, the RVUs as calculated already reflect the payments as adjusted by modifiers, and no volume adjustments are necessary. However, a time adjustment of 33 percent is made only for medical direction of two to four cases since that is the only situation where a single practitioner is involved with multiple beneficiaries concurrently, so that counting each service without regard to the overlap with other services would overstate the amount of time spent by the practitioner furnishing these services.

- Work RVUs: The setup file contains the work RVUs from this proposed rule with comment period.

(7) Equipment Cost Per Minute

The equipment cost per minute is calculated as:

*(1/(minutes per year * usage)) * price * ((interest rate/(1-(1/((1 + interest rate)− life of equipment)))) + maintenance)*

Where:

minutes per year = maximum minutes per year if usage were continuous (that is, usage = 1); generally 150,000 minutes.
usage = variable, see discussion below.
price = price of the particular piece of equipment.
life of equipment = useful life of the particular piece of equipment.
maintenance = factor for maintenance; 0.05.
interest rate = variable, see discussion below.

Usage: We currently use an equipment utilization rate assumption of 50 percent for most equipment, with the exception of expensive diagnostic imaging equipment, for which we use a 90 percent assumption as required by section 1848(b)(4)(C) of the Act. We also direct the reader to section II.5.b of this proposed rule for a discussion of our proposed change in the utilization rate assumption for the linear accelerator used in furnishing radiation treatment services.

Maintenance: This factor for maintenance was proposed and finalized during rulemaking for CY 1998 PFS (62 FR 33164). Several stakeholders have suggested that this maintenance factor assumption should be variable, similar to other assumptions in the equipment cost per minute calculation. In CY 2015 rulemaking, we solicited comments regarding the availability of reliable data on maintenance costs that vary for particular equipment items. We received several comments about variable maintenance costs, and in reviewing the information offered in those comments, it is clear that the relationship between maintenance costs and the price of equipment is not necessarily uniform across equipment. However, based on our review of comments, we have been unable to identify a systematic way of varying the maintenance cost assumption relative to the price or useful life of equipment. Therefore, in order to accommodate a variable, as opposed to a standard, maintenance rate within the equipment cost per minute calculation, we believe we would have to gather and maintain valid data on the maintenance costs for each equipment item in the direct PE input database, much like we do for price and useful life.

Given our longstanding difficulties in acquiring accurate pricing information for equipment items, we are seeking comment on whether adding another item-specific financial variable for equipment costs will be likely to increase the accuracy of PE RVUs across the PFS. We note that most of the information for maintenance costs we have received is for capital equipment, and for the most part, this information has been limited to single invoices. Like the invoices for the equipment items themselves, we do not believe that very small numbers of voluntarily submitted invoices are likely to reflect typical costs for all of the same reasons we have discussed in previous rulemaking. We note that some commenters submitted high-level summary data from informal surveys but we currently have no means to validate that data. Therefore, we continue to seek a source of publicly available data on actual maintenance costs for medical equipment to improve the accuracy of the equipment costs used in developing PE RVUs.

Interest Rate: In the CY 2013 final rule with comment period (77 FR 68902), we updated the interest rates used in developing an equipment cost per minute calculation. The interest rate was based on the Small Business Administration (SBA) maximum interest rates for different categories of loan size (equipment cost) and maturity (useful life). The interest rates are listed in Table 3. (See 77 FR 68902 for a thorough discussion of this issue.)

TABLE 3—SBA MAXIMUM INTEREST RATES

Price	Useful life	Interest rate (%)
<$25K	<7 Years	7.50
$25K to $50K	<7 Years	6.50
>$50K	<7 Years	5.50
<$25K	7+ Years	8.00
$25K to $50K	7+ Years	7.00
>$50K	7+ Years	6.00

TABLE 4—CALCULATION OF PE RVUS UNDER METHODOLOGY FOR SELECTED CODES

	Step	Source	Formula	99213 Office visit, est non-facility	33533 CABG, arterial, single facility	71020 chest x-ray nonfacility	71020–TC chest x-ray, nonfacility	71020–26 chest x-ray, nonfacility	93000 ECG, complete, non-facility	93005 ECG, tracing non-facility	93010 ECG, report non-facility
(1) Labor cost (Lab)	Step 1	AMA		13.32	77.52	5.74	5.74	0	5.1	5.1	0
(2) Supply cost (Sup)	Step 1	AMA		2.98	7.34	0.53	0.53	0	1.19	1.19	0
(3) Equipment cost (Eqp)	Step 1	AMA		0.17	0.58	7.08	7.08	0	0.09	0.09	0
(4) Direct cost (Dir)	Step 1		=(1)+(2)+(3)	16.48	85.45	13.36	13.36	0	6.38	6.38	0
(5) Direct adjustment (Dir. Adj.)	Steps 2–4	See footnote*		0.6003	0.6003	0.6003	0.6003	0.6003	0.6003	0.6003	0.6003
(6) Adjusted Labor	Steps 2–4	=Labor * Dir Adj.	=(1)*(5)	8	46.53	3.45	3.45	0	3.06	3.06	0
(7) Adjusted Supplies	Steps 2–4	=Eqp * Dir Adj.	=(2)*(5)	1.79	4.41	0.32	0.32	0	0.72	0.72	0
(8) Adjusted Equipment	Steps 2–4	=Sup * Dir Adj.	=(3)*(5)	0.10	0.35	4.25	4.25	0	0.05	0.05	0
(9) Adjusted Direct	Steps 2–4		=(6)+(7)+(8)	9.89	51.29	8.02	8.02	0	3.83	3.83	0
(10) Conversion Factor (CF)	Step 5	PFS		35.9335	35.9335	35.9335	35.9335	35.9335	35.9335	35.9335	35.9335
(11) Adj. labor cost converted	Step 5	=(Lab * Dir Adj)/CF.	=(6)/(10)	0.22	1.3	0.1	0.1	0	0.09	0.09	0
(12) Adj. supply cost converted	Step 5	=(Sup * Dir Adj)/CF.	=(7)/(10)	0.05	0.12	0.01	0.01	0	0.02	0.02	0
(13) Adj. equipment cost converted.	Step 5	=(Eqp * Dir Adj)/CF.	=(8)/(10)	0	0.01	0.12	0.12	0	0	0	0
(14) Adj. direct cost converted	Step 5		=(11)+(12)+(13)	0.28	1.43	0.22	0.22	0	0.11	0.11	0
(15) Work RVU	Setup File	PFS		0.97	33.75	0.22	0	0.22	0.17	0	0.17
(16) Dir_pct	Steps 6,7	Surveys		0.25	0.17	0.29	0.29	0.29	0.29	0.29	0.29
(17) Ind_pct	Steps 6,7	Surveys		0.75	0.83	0.71	0.71	0.71	0.71	0.71	0.71
(18) Ind. Alloc. Formula (1st part).	Step 8	See Step 8		(14)/(16)*(17)	(14)/(16)*(17)	(14)/(16)*(17)	(14)/(16)*(17)	(14)/(16)*(17)	(14)/(16)*(17)	(14)/(16)*(17)	(14)/(16)*(17)
(19) Ind. Alloc.(1st part)	Step 8		See 18	0.83	6.75	0.54	0.54	0	0.26	0.26	0
(20) Ind. Alloc. Formula (2nd part).	Step 8	See Step 8		(15)	(15)	(15+11)	(11)	(15)	(15+11)	(11)	(15)
(21) Ind. Alloc.(2nd part)	Step 8		See 20	0.97	33.75	0.32	0.1	0.22	0.26	0.09	0.17
(22) Indirect Allocator (1st + 2nd).	Step 8		=(19)+(21)	1.8	40.50	0.86	0.64	0.22	0.52	0.35	0.17
(23) Indirect Adjustment (Ind. Adj.).	Steps 9–11	See Footnote**.		0.3811	0.3811	0.3811	0.3811	0.3811	0.3811	0.3811	0.3811
(24) Adjusted Indirect Allocator	Steps 9–11	=Ind Alloc * Ind Adj.		0.69	15.43	0.33	0.24	0.08	0.2	0.13	0.06
(25) Ind. Practice Cost Index (IPCI).	Steps 12–16.			1.07	0.76	0.98	0.98	0.98	0.9	0.9	0.9
(26) Adjusted Indirect	Step 17	= Adj.Ind Alloc * PCI.	=(24)*(25)	0.73	11.68	0.32	0.24	0.08	0.18	0.12	0.06
(27) Final PE RVU	Step 18	=(Adj Dir + Adj Ind) * Other Adj.	=((14)+(26)) * Other Adj).	1.01	13.15	0.54	0.46	0.08	0.28	0.23	0.06

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Notes: PE RVUs above (row 27), may not match Addendum B due to rounding.

The use of any particular conversion factor (CF) in the table to illustrate the PE Calculation has no effect on the resulting RVUs.

*The direct adj = [current pe rvus * CF * avg dir pct]/[sum direct inputs] = [step2]/[step3]; **The indirect adj =[current pe rvus * avg ind pct]/[sum of ind allocators]=[step9]/[step10]

c. Changes to Direct PE Inputs for Specific Services

In this section, we discuss other CY 2016 proposals related to particular PE inputs. The proposed direct PE inputs are included in the proposed CY 2016 direct PE input database, which is available on the CMS Web site under downloads for the CY 2016 PFS proposed rule with comment period at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

(1) PE Inputs for Digital Imaging Services

Prior to CY 2015 rulemaking, the RUC provided a recommendation regarding the PE inputs for digital imaging services. Specifically, the RUC recommended that we remove supply and equipment items associated with film technology from a list of codes since these items are no longer typical resource inputs. The RUC also recommended that the Picture Archiving and Communication System (PACS) equipment be included for these imaging services since these items are now typically used in furnishing imaging services. However, since we did not receive any invoices for the PACS system, we were unable to determine the appropriate pricing to use for the inputs. For CY 2015, we proposed, and finalized our proposal, to remove the film supply and equipment items, and to create a new equipment item as a proxy for the PACS workstation as a direct expense. We used the current price associated with ED021 (computer, desktop, w-monitor) to price the new item, ED050 (PACS Workstation Proxy), pending receipt of invoices to facilitate pricing specific to the PACS workstation.

Subsequent to establishing payment rates for CY 2015, we received information from several stakeholders regarding pricing for items related to the digital acquisition and storage of images. Some of these stakeholders submitted information that included prices for items clearly categorized as indirect costs within the established PE methodology and equivalent to the storage mechanisms for film. Additionally, some of the invoices we received included other products (like training and maintenance costs) in addition to the equipment items, and there was no distinction on these invoices between the prices for the equipment items themselves and the related services. However, we did receive invoices from one stakeholder that facilitated a proposed price update for the PACS workstation. Therefore, we are proposing to update the price for the PACS workstation to $5,557 from the current price of $2,501 since the latter price was based on the proxy item and the former based on submitted invoices. The PE RVUs in Addendum B on the CMS Web site reflect the updated price.

In addition to the workstation used by the clinical staff acquiring the images and furnishing the technical component of the services, a stakeholder also submitted more detailed information regarding a workstation used by the practitioner interpreting the image in furnishing the professional component of many of these services. As we stated in the CY 2015 final rule with comment period (79 FR 67563), we generally believe that workstations used by these practitioners are more accurately considered indirect costs associated with the professional component of the service. However, we understand that the professional workstations for interpretation of digital images are similar in principle to some of the previous film inputs incorporated into the global and technical components of the codes. Given that many of these services are reported globally in the nonfacility setting, we believe it may be appropriate to include these costs as direct inputs for the associated HCPCS codes. Based on our established methodology, these costs would be incorporated into the PE RVUs of the global and technical component of the HCPCS code. We are seeking comment on whether including the professional workstation as a direct PE input for these codes would be appropriate, given that the resulting PE RVUs would be assigned to the global and technical components of the codes.

Another stakeholder expressed concern about the changes in direct PE inputs for CPT code 76377, (3D radiographic procedure with computerized image post-processing), that were proposed and finalized in CY 2015 rulemaking as part of the film to digital change. Based on a recommendation from the RUC, we removed the input called ''computer workstation, 3D reconstruction CT–MR'' from the direct PE input database and assigned the associated minutes to the proxy for the PACS workstation. We are seeking comment from stakeholders, including the RUC, about whether or not the PACS workstation used in in imaging codes is the same workstation that is used in the postprocessing described by CPT code 76377, or if more specific workstation should be incorporated in the direct PE input database . . .

(2) Standardization of Clinical Labor Tasks

As we noted in PFS rulemaking for CY 2015, we continue to work on revisions to the direct PE input database to provide the number of clinical labor minutes assigned for each task for every code in the database instead of only including the number of clinical labor minutes for the pre-service, service, and post-service periods for each code. In addition to increasing the transparency of the information used to set PE RVUs, this improvement would allow us to compare clinical labor times for activities associated with services across the PFS, which we believe is important to maintaining the relativity of the direct PE inputs. This information will facilitate the identification of the usual numbers of minutes for clinical labor tasks and the identification of exceptions to the usual values. It will also allow for greater transparency and consistency in the assignment of equipment minutes based on clinical labor times. Finally, we believe that the information can be useful in maintaining standard times for particular clinical labor tasks that can be applied consistently to many codes as they are valued over several years, similar in principle to the use of physician pre-service time packages. We believe such standards will provide greater consistency among codes that share the same clinical labor tasks and could improve relativity of values among codes. For example, as medical practice and technologies change over time, changes in the standards could be updated at once for all codes with the applicable clinical labor tasks, instead of waiting for individual codes to be reviewed.

While this work is not yet complete, we anticipate completing it in the near future. In the following paragraphs, we address a series of issues related to clinical labor tasks, particularly relevant to services currently being reviewed under the misvalued code initiative

(a) Clinical Labor Tasks Associated With Digital Imaging

In PFS rulemaking for CY 2015, we noted that the RUC recommendation regarding inputs for digital imaging services indicated that, as each code is reviewed under the misvalued code initiative, the clinical labor tasks associated with digital technology (instead of film) would need to be addressed. When we reviewed that recommendation, we did not have the capability of assigning standard clinical labor times for the hundreds of individual codes since the direct PE

input database did not previously allow for comprehensive adjustments for clinical labor times based on particular clinical labor tasks. Therefore, consistent with the recommendation, we proposed to remove film-based supply and equipment items but maintain clinical labor minutes that were assigned based on film technology.

As noted in the paragraphs above, we continue to improve the direct PE input database by specifying the minutes for each code associated with each clinical labor task. Once completed, this work would allow adjustments to be made to minutes assigned to particular clinical labor tasks related to digital technology, consistent with the changes that were made to individual supply and equipment items. In the meantime, we believe it would be appropriate to establish standard times for clinical labor tasks associated with all digital imaging for purposes of reviewing individual services at present, and for possible broad-based standardization once the changes to the database facilitate our ability to adjust time for existing services. Therefore, we are seeking comment on the appropriate standard minutes for the clinical labor tasks associated with services that use digital technology, which are listed in Table 5. We note that the application of any standardized times we adopt for clinical labor tasks to codes that are not being reviewed in this proposed rule would be considered for possible inclusion in future notice and comment rulemaking.

TABLE 5—CLINICAL LABOR TASKS ASSOCIATED WITH DIGITAL TECHNOLOGY

Clinical labor task	Typical minutes
Availability of prior images confirmed	2
Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist	2
Technologist QC's * images in PACS, checking for all images, reformats, and dose page	2
Review examination with interpreting MD	2
Exam documents scanned into PACS. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue	1

* This clinical labor task is listed as it appears on the ''PE worksheets.'' QC refers to quality control, which we understand to mean the verification of the image using the PACS workstation.

(b) Pathology Clinical Labor Tasks

As with the clinical labor tasks associated with digital imaging, many of the specialized clinical labor tasks associated with pathology services do not have consistent times across those codes. In reviewing the recommendations for pathology services, we have not identified information that suggests that the inconsistencies reflect the judgment that the same tasks take significantly more or less time depending on the individual service for which they are performed, especially given the specificity with which they are described.

We have therefore developed proposed standard times that we have used in proposing direct PE inputs. These times are based on our review and assessment of the current times included for these clinical labor tasks in the direct PE input database. We have listed these proposed standard times in Table 6. For services reviewed for CY 2016, in cases where the RUC-recommended times differed from these standards, we have refined the time for those tasks to align with the values in Table 6. We seek comment on whether these standard times accurately reflect the typical time it takes to perform these clinical labor tasks when furnishing pathology services.

TABLE 6—STANDARD TIMES FOR CLINICAL LABOR TASKS ASSOCIATED WITH PATHOLOGY SERVICES

Clinical Labor Task	Standard clinical labor time
Accession specimen/prepare for examination	4
Assemble and deliver slides with paperwork to pathologists	0.5
Assemble other light microscopy slides, open nerve biopsy slides, and clinical history, and present to pathologist to prepare clinical pathologic interpretation	0.5
Assist pathologist with gross specimen examination	3
Clean room/equipment following procedure (including any equipment maintenance that must be done after the procedure)	1
Dispose of remaining specimens, spent chemicals/other consumables, and hazardous waste	1
Enter patient data, computational prep for antibody testing, generate and apply bar codes to slides, and enter data for automated slide stainer	1
Instrument start-up, quality control functions, calibration, centrifugation, maintaining specimen tracking, logs and labeling	13
Load specimen into flow cytometer, run specimen, monitor data acquisition and data modeling, and unload flow cytometer	7
Preparation: labeling of blocks and containers and document location and processor used	0.5
Prepare automated stainer with solutions and load microscopic slides	4
Prepare specimen containers/preload fixative/label containers/distribute requisition form(s) to physician	0.5
Prepare, pack and transport specimens and records for in-house storage and external storage (where applicable)	1
Print out histograms, assemble materials with paperwork to pathologists. Review histograms and gating with pathologist.	2
Receive phone call from referring laboratory/facility with scheduled procedure to arrange special delivery of specimen procurement kit, including muscle biopsy clamp as needed. Review with sender instructions for preservation of specimen integrity and return arrangements. Contact courier and arrange delivery to referring laboratory/facility	5
Register the patient in the information system, including all demographic and billing information.	4
Stain air dried slides with modified Wright stain. Review slides for malignancy/high cellularity (cross contamination)	3

(c) Clinical Labor Task: ''Complete Botox Log''

In the process of improving the level of detail in the direct PE input database by including the minutes assigned for each clinical labor task, we noticed that there are several codes with minutes assigned for the clinical labor task called ''complete botox log.'' We do not believe the completion of such a log is a direct resource cost of furnishing a medically reasonable and necessary physician's service for a Medicare beneficiary. Therefore, we are proposing to eliminate the minutes assigned for the task ''complete botox log'' from the direct PE input database. The PE RVUs displayed in Addendum B on the CMS Web site were calculated with the modified inputs displayed in the CY 2016 direct PE input database.

(3) Clinical Labor Input Inconsistencies

Subsequent to the publication of the CY 2015 PFS final rule with comment period, stakeholders alerted us to several clerical inconsistencies in the clinical labor nonfacility intraservice time for several vertebroplasty codes with interim final values for CY 2015, based on our understanding of RUC recommended values. We are proposing to correct these inconsistencies in the CY 2016 proposed direct PE input database to reflect the RUC recommended values, without refinement, as stated in the CY 2015 PFS final rule with comment period. The CY 2015 interim final direct PE inputs for these codes are displayed on the CMS Web site under downloads for the CY 2015 PFS final rule with comment period at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.* For CY 2016, we are proposing the following adjustments. For CPT codes 22510 (percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; cervicothoracic) and 22511 (percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; lumbosacral), a value of 45 minutes for labor code L041B (''Radiologic Technologist'') were are proposing to assign for the ''assist physician'' task and a value of 5 minutes for labor code L037D (''RN/LPN/MTA'') for the ''Check dressings & wound/home care instructions/coordinate office visits/prescriptions'' task. For CPT code 22514 (percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; lumbar), we are proposing to adjust the nonfacility intraservice time to 50 minutes for L041B, 50 minutes for L051A (''RN''), 38 minutes for a second L041B, and 12 minutes for L037D. The PE RVUs displayed in Addendum B on the CMS Web site were calculated with the inputs displayed in the CY 2016 direct PE input database.

(4) Freezer

We identified several pathology codes for which equipment minutes are assigned to the item EP110 ''Freezer.'' Minutes are only allocated to particular equipment items when those items cannot be used in conjunction with furnishing services to another patient at the same time. We do not believe that minutes should be allocated to items such as freezers since the storage of any particular specimen or item in a freezer for any given period of time would be unlikely to make the freezer unavailable for storing other specimens or items. Instead, we propose to classify the freezer as an indirect cost because we believe that would be most consistent with the principles underlying the PE methodology since freezers can be used for many specimens at once. The PE RVUs displayed in Addendum B on the CMS Web site were calculated with the modified inputs displayed in the CY 2016 direct PE input database.

(5) Updates to Price for Existing Direct Inputs

In the CY 2011 PFS final rule with comment period (75 FR 73205), we finalized a process to act on public requests to update equipment and supply price and equipment useful life inputs through annual rulemaking beginning with the CY 2012 PFS proposed rule. During 2014, we received a request to update the price of supply item ''antigen, mite'' (SH006) from $4.10 per test to $59. In reviewing the request, it is evident that the requested price update does not apply to the SH006 item but instead represents a different item than the one currently included as an input in CPT code 86490 (skin test, coccidioidomycosis). Therefore, rather than changing the price for SH006 that is included in several codes, we are proposing to create a new supply code for Spherusol, valued at $590 per 1 ml vial and $59 per test, and to include this new item as a supply for 86490 instead of the current input, SH006. We also received a request to update the price for EQ340 (Patient Worn Telemetry System) used only in CPT code 93229 (External mobile cardiovascular telemetry with electrocardiographic recording, concurrent computerized real time data analysis and greater than 24 hours of accessible ECG data storage (retrievable with query) with ECG triggered and patient selected events transmitted to a remote attended surveillance center for up to 30 days; technical support for connection and patient instructions for use, attended surveillance, analysis and transmission of daily and emergent data reports as prescribed by a physician or other qualified health care.) The requestor noted that we had previously proposed and finalized a policy to remove wireless communication and delivery costs related to the equipment item that had previously been included in the direct PE input database as supply items. The requestor asked that we alter the price of the equipment from $21,575 to $23,537 to account for the equipment costs specific to the patient-worn telemetry system.

We have considered this request in the context of the unique nature of this particular equipment item. This equipment item is unique in several ways, including that it is used continuously 24 hours per day and 7 days per week for an individual patient over several weeks. It is also unique in that the equipment is primarily used outside of a healthcare setting. Within our current methodology, we currently account for these unique properties by calculating the per minute costs with different assumptions than those used for most other equipment by increasing the number of hours the equipment is available for use. Therefore, we also believe it would be appropriate to incorporate other unique aspects of the operating costs of this item in our calculation of the equipment cost per minute. We believe the requestor's suggestion to do so by increasing the price of the equipment is practicable and appropriate. Therefore, we are proposing to change the price for EQ340 (Patient Worn Telemetry System) to $23,537. The PE RVUs displayed in Addendum B on the CMS Web site were calculated with the modified inputs displayed in the CY 2016 direct PE input database.

For CY 2015, we received a request to update the price for supply item ''kit, HER–2/neu DNA Probe'' (SL196) from $105 to $144.50. Accordingly, we proposed to update the price to $144.50. In the CY 2015 final rule with comment period, we indicated that we obtained new information suggesting that further study of the price of this item was necessary before proceeding to update

the input price. We obtained pricing information readily available on the Internet that indicated a price of $94 for this item for a particular hospital. Subsequent to the CY 2015 final rule with comment period, stakeholders requested that we use the updated price of $144.50. One stakeholder suggested that the price of $94 likely reflected discounts for volume purchases not received by the typical laboratory. We are seeking comment on how to consider the higher-priced invoice, which is 53 percent higher than the price listed, relative to the price currently in the direct PE database. Specifically, we are seeking information on the price of the disposable supply in the typical case of the service furnished to a Medicare beneficiary, including, based on data, whether the typical Medicare case is furnished by an entity likely to receive a volume discount.

(6) Typical Supply and Equipment Inputs for Pathology Services

In reviewing public comments in response to the CY 2015 PFS final rule with comment period, we re-examined issues around the typical number of pathology tests furnished at once. In the CY 2013 final rule with comment period (77 FR 69074), we noted that the number of blocks assumed for a particular code significantly impacts the assumed clinical labor, supplies, and equipment for that service. We indicated that we had concerns that the assumed number of blocks was inaccurate, and that we sought corroborating, independent evidence that the number of blocks assumed in the current direct PE input recommendations is typical. We note that, given the high volume of many pathology services, these assumptions have a significant impact on the PE RVUs for all other PFS services. We refer readers to section II.I.5.d where we detail our concerns about the lack of information regarding typical batch size and typical block size for many pathology services and solicit stakeholder input on approaches to obtaining accurate information that can facilitate our establishing payment rates that best reflect the relative resources involved in furnishing the typical service, for both pathology services in particular and more broadly for services across the PFS.

d. Developing Nonfacility Rates

We note that not all PFS services are priced in the nonfacility setting, but as medical practice changes, we routinely develop nonfacility prices for particular services when they can be furnished outside of a facility setting. We note that the valuation of a service under the PFS in particular settings does not address whether those services are medically reasonable and necessary in the case of individual patients, including being furnished in a setting appropriate to the patient's medical needs and condition.

(1) Request for Information on Nonfacility Cataract Surgery

Cataract surgery generally has been performed in an ambulatory surgery center (ASC) or a hospital outpatient department (HOPD). Therefore, CMS has not assigned nonfacility PE RVUs under the PFS for cataract surgery. According to Medicare claims data, there are a relatively small number of these services furnished in nonfacility settings. Except in unusual circumstances, anesthesia for cataract surgery is either local or topical/intracameral. Advancements in technology have significantly reduced operating time and improved both the safety of the procedure and patient outcomes. We believe that it is now possible for cataract surgery to be furnished in an in-office surgical suite, especially for routine cases. Cataract surgery patients require a sterile surgical suite with certain equipment and supplies that we believe could be a part of a nonfacility-based setting that is properly constructed and maintained for appropriate infection prevention and control.

We believe that there are potential advantages for all parties to furnishing appropriate cataract surgery cases in the nonfacility setting. Cataract surgery has been for many years the highest volume surgical procedure performed on Medicare beneficiaries. For beneficiaries, cataract surgery in the office setting might provide the additional convenience of receiving the preoperative, operative, and post-operative care in one location. It might also reduce delays associated with registration, processing, and discharge protocols associated with some facilities. Similarly, it might provide surgeons with greater flexibility in scheduling patients at an appropriate site of service depending on the individual patient's needs. For example, routine cases in patients with no comorbidities could be performed in the nonfacility surgical suite, while more complicated cases (for example, pseudoexfoliation) could be scheduled in the ASC or HOPD. In addition, furnishing cataract surgery in the nonfacility setting could result in lower Medicare expenditures for cataract surgery if the nonfacility payment rate were lower than the sum of the PFS facility payment rate and the payment to either the ASC or HOPD.

We are seeking comments from ophthalmologists and other stakeholders on office-based surgical suite cataract surgery. In addition, we are soliciting comments from the RUC and other stakeholders on the direct practice expense inputs involved in furnishing cataract surgery in the nonfacility setting in conjunction with our consideration of information regarding the possibility of developing nonfacility PE RVUs for cataract surgery. We understand that cataract surgery generally requires some standard equipment and supplies (for example; phacoemulsification machine, surgical pack, intraocular lenses (IOL), etc.) that would be incorporated as direct PE inputs in calculating nonfacility PE RVUs.

(2) Direct PE Inputs for Functional Endoscopic Sinus Surgery Services

A stakeholder indicated that due to changes in technology and technique, several codes that describe endoscopic sinus surgeries can now be furnished in the nonfacility setting. According to Medicare claims data, there are a relatively small number of these services furnished in nonfacility settings. These CPT codes are 31254 (Nasal/sinus endoscopy, surgical; with ethmoidectomy, partial (anterior)), 31255 (Nasal/sinus endoscopy, surgical; with ethmoidectomy, total (anterior and posterior)), 31256 (Nasal/sinus endoscopy, surgical, with maxillary antrostomy;), 31267 (Nasal/sinus endoscopy, surgical, with maxillary antrostomy; with removal of tissue from maxillary sinus), 31276 (Nasal/sinus endoscopy, surgical with frontal sinus exploration, with or without removal of tissue from frontal sinus), 31287 (Nasal/sinus endoscopy, surgical, with sphenoidotomy;), and 31288 (Nasal/sinus endoscopy, surgical, with sphenoidotomy; with removal of tissue from the sphenoid sinus). We are seeking input from stakeholders, including the RUC, about the appropriate direct PE inputs for these services.

B. Determination of Malpractice Relative Value Units (RVUs)

1. Overview

Section 1848(c) of the Act requires that each service paid under the PFS be comprised of three components: work, PE, and malpractice (MP) expense. As required by section 1848(c)(2)(C)(iii) of the Act, beginning in CY 2000, MP RVUs are resource based. Malpractice RVUs for new codes after 1991 were

extrapolated from similar existing codes or as a percentage of the corresponding work RVU. Section 1848(c)(2)(B)(i) of the Act also requires that we review, and if necessary adjust, RVUs no less often than every 5 years. In the CY 2015 PFS final rule with comment period, we implemented the third review and update of MP RVUs. For a discussion of the third review and update of MP RVUs see the CY 2015 proposed rule (79 FR 40349 through 40355) and final rule with comment period (79 FR 67591 through 67596).

As explained in the CY 2011 PFS final rule with comment period (75 FR 73208), MP RVUs for new and revised codes effective before the next five-year review of MP RVUs (for example, effective CY 2016 through CY 2019, assuming that the next review of MP RVUs occurs for CY 2020) are determined either by a direct crosswalk from a similar source code or by a modified crosswalk to account for differences in work RVUs between the new/revised code and the source code. For the modified crosswalk approach, we adjust (or ''scale'') the MP RVU for the new/revised code to reflect the difference in work RVU between the source code and the new/revised work value (or, if greater, the clinical labor portion of the fully implemented PE RVU) for the new code. For example, if the proposed work RVU for a revised code is 10 percent higher than the work RVU for its source code, the MP RVU for the revised code would be increased by 10 percent over the source code MP RVU. Under this approach the same risk factor is applied for the new/revised code and source code, but the work RVU for the new/revised code is used to adjust the MP RVUs for risk.

For CY 2016, we propose to continue our current approach for determining MP RVUs for new/revised codes. For the new and revised codes for which we include proposed work values and PE inputs in the proposed rule, we will also publish the proposed MP crosswalks used to determine their MP RVUs in the proposed rule. The MP crosswalks for those new and revised codes will be subject to public comment and finalized in the CY 2016 PFS final rule. The MP crosswalks for new and revised codes with interim final values established in the CY 2016 final rule will be implemented for CY 2016 and subject to public comment. They will then be finalized in the CY 2017 PFS final rule with comment period.

2. Proposed Annual Update of MP RVUs

In the CY 2012 PFS final rule with comment period (76 FR 73057), we finalized a process to consolidate the five-year reviews of physician work and PE RVUs with our annual review of potentially misvalued codes. We discussed the exclusion of MP RVUs from this process at the time, and we stated that, since it is not feasible to obtain updated specialty level MP insurance premium data on an annual basis, we believe the comprehensive review of MP RVUs should continue to occur at 5-year intervals. In the CY 2015 PFS proposed rule (79 FR 40349 through 40355), we stated that there are two main aspects to the update of MP RVUs: (1) Recalculation of specialty risk factors based upon updated premium data; and (2) recalculation of service level RVUs based upon the mix of practitioners providing the service. In the CY 2015 PFS final rule with comment period (79 FR 67596), in response to several stakeholders' comments, we stated that we would address potential changes regarding the frequency of MP RVU updates in a future proposed rule. For CY 2016, we are proposing to begin conducting annual MP RVU updates to reflect changes in the mix of practitioners providing services, and to adjust MP RVUs for risk. Under this approach, the specialty-specific risk factors would continue to be updated every five years using updated premium data, but would remain unchanged between the 5-year reviews. However, in an effort to ensure that MP RVUs are as current as possible, our proposal would involve recalibrating all MP RVUs on an annual basis to reflect the specialty mix based on updated Medicare claims data. Since under this proposal, we would be recalculating the MP RVUs annually, we are also proposing to maintain the relative pool of MP RVUs from year to year; this will preserve the relative weight of MP RVUs to work and PE RVUs. We are proposing to calculate the current pool of MP RVUs by using a process parallel to the one we use in calculating the pool of PE RVUs. (We direct the reader to section II.2.b.(6) for detailed description of that process, including a proposed technical revision for 2016.) To determine the specialty mix assigned to each code, we are also proposing to use the same process used in the PE methodology, described in section II.2.b.(6) of this proposed rule. We note that for CY 2016, we are proposing to modify the specialty mix assignment methodology to use an average of the 3 most recent years of available data instead of a single year of data as is our current policy. We anticipate that this change will increase the stability of PE and MP RVUs and mitigate code-level fluctuations for all services paid under the PFS, and for new and low-volume codes in particular. We are also proposing to no longer apply the dominant specialty for low volume services, because the primary rationale for the policy has been mitigated by this proposed change in methodology. However, we are not proposing to adjust the code-specific overrides established in prior rulemaking for codes where the claims data are inconsistent with a specialty that could be reasonably expected to furnish the service. We believe that these proposed changes will serve to balance the advantages of using annually updated information with the need for year-to-year stability in values. We seek comment on both aspects of the proposal: updating the specialty mix for MP RVUs annually (while continuing to update specialty-specific risk factors every 5 years using updated premium data); and using the same process to determine the specialty mix assigned to each code as is used in the PE methodology, including the proposed modification to use the most recent 3 years of claims data. We also seek comment on whether this approach will be helpful in addressing some of the concerns regarding the calculation of MP RVUs for services with low volume in the Medicare population, including the possibility of limiting our use of code-specific overrides of the claims data.

We are also proposing an additional refinement in our process for assigning MP RVUs to individual codes. Historically, we have used a floor of 0.01 MP RVUs for all nationally-priced PFS codes. This means that even when the code-level calculation for the MP RVU falls below 0.005, we have rounded to 0.01. In general, we believe this approach accounts for the minimum MP costs associated with each service furnished to a Medicare beneficiary. However, in examining the calculation of MP RVUs, we do not believe that this floor should apply to add-on codes. Since add-on codes must be reported with another code, there is already an MP floor of 0.01 that applies to the base code, and therefore, to each individual service. By applying the floor to add-on codes, the current methodology practically creates a 0.02 floor for any service reported with one add-on code, and 0.03 for those with 2 add-on codes, etc. Therefore, we are proposing to maintain the 0.01 MP RVU floor for all nationally-priced PFS services that are described by base codes, but not for add-on codes. We will continue to calculate, display, and make payments that include MP RVUs for

add-on codes that are calculated to 0.01 or greater, including those that round to 0.01. We are only proposing to allow the MP RVUs for add-on codes to round to 0.00 where the calculated MP RVU is less than 0.005.

We will continue to study the appropriate frequency for collecting and updating premium data and will address any further proposed changes in future rulemaking.

3. MP RVU Update for Anesthesia Services

In the CY 2015 PFS proposed rule (79 FR 40354 through 40355), we did not include an adjustment under the anesthesia fee schedule to reflect updated MP premium information, and stated that we intended to propose an anesthesia adjustment for MP in the CY 2016 PFS proposed rule. We also solicited comments regarding how to best reflect updated MP premium amounts under the anesthesiology fee schedule.

As we previously explained, anesthesia services under the PFS are paid based upon a separate fee schedule, so routine updates must be calculated in a different way than those for services for which payment is calculated based upon work, PE, and MP RVUs. To apply budget neutrality and relativity updates to the anesthesiology fee schedule, we typically develop proxy RVUs for individual anesthesia services that are derived from the total portion of PFS payments made through the anesthesia fee schedule. We then update the proxy RVUs as we would the RVUs for other PFS services and adjust the anesthesia fee schedule conversion factor based on the differences between the original proxy RVUs and those adjusted for relativity and budget neutrality.

We believe that taking the same approach to update the anesthesia fee schedule based on new MP premium data is appropriate. However, because work RVUs are integral to the MP RVU methodology and anesthesia services do not have work RVUs, we decided to seek potential alternatives prior to implementing our approach in conjunction with the proposed CY 2015 MP RVUs based on updated premium data. One commenter supported the delay in proposing to update the MP for anesthesia at the same time as updating the rest of the PFS, and another commenter suggested using mean anesthesia MP premiums per provider over a 4 or 5 year period prorated by Medicare utilization to yield the MP expense for anesthesia services; no commenters offered alternatives to calculating updated MP for anesthesia services. The latter suggestion might apply more broadly to the MP methodology for the PFS and does not address the methodology as much as the data source.

We continue to believe that payment rates for anesthesia should reflect MP resource costs relative to the rest of the PFS, including updates to reflect changes over time. Therefore, for CY 2016, in order to appropriately update the MP resource costs for anesthesia, we are proposing to make adjustments to the anesthesia conversion factor to reflect the updated premium information collected for the five year review. To determine the appropriate adjustment, we calculated imputed work RVUs and MP RVUs for the anesthesiology fee schedule services using the work, PE, and MP shares of the anesthesia fee schedule. Again, this is consistent with our longstanding approach to making annual adjustments to the PE and work RVU portions of the anesthesiology fee schedule. To reflect differences in the complexity and risk among the anesthesia fee schedule services, we multiplied the service-specific risk factor for each anesthesia fee schedule service by the CY 2016 imputed proxy work RVUs and used the product as the updated raw proxy MP RVUs for each anesthesia service for CY 2016. We then applied the same scaling adjustments to these raw proxy MP RVUs that we apply to the remainder of the PFS MP RVUs. Finally, we calculated the aggregate difference between the 2015 proxy MP RVUs and the proxy MP RVUs calculated for CY 2016. We then adjusted the portion of the anesthesia conversion factor attributable to MP proportionately; we refer the reader to section VI.C. of this proposed rule for the Anesthesia Fee Schedule Conversion Factors for CY 2016. We are inviting public comments regarding this proposal.

4. MP RVU Methodology Refinements

In the CY 2015 PFS final rule with comment period (79 FR 67591 through 67596), we finalized updated MP RVUs that were calculated based on updated MP premium data obtained from state insurance rate filings. The methodology used in calculating the finalized CY 2015 review and update of resource-based MP RVUs largely paralleled the process used in the CY 2010 update. We posted our contractor's report, ''Final Report on the CY 2015 Update of Malpractice RVUs'' on the CMS Web site. It is also located under the supporting documents section of the CY 2015 PFS final rule with comment period located at *http://www.cms.gov/PhysicianFeeSched/*. A more detailed explanation of the 2015 MP RVU update can be found in the CY 2015 PFS proposed rule (79 FR 40349 through 40355).

In the CY 2015 PFS proposed rule, we outlined the steps for calculating MP RVUs. In the process of calculating MP RVUs for purposes of this proposed rule, we have identified a necessary refinement to way we have calculated Step 1, which involves computing a preliminary national average premium for each specialty, to align the calculations within the methodology to the calculations described within the aforementioned contractor's report. Specifically, in the calculation of the national premium for each specialty (refer to equations 2.3, 2.4, 2.5 in the aforementioned contractor's report), we calculate a weighted sum of premiums across areas and divide it by a weighted sum of MP GPCIs across areas. The calculation currently takes the ratio of sums, rather than the weighted average of the local premiums to the MP GPCI in that area. Instead, we are proposing to update the calculation to use a price-adjusted premium (that is, the premium divided by the GPCI) in each area, and then taking a weighted average of those adjusted premiums. The CY 2016 PFS proposed rule MP RVUs were calculated in this manner.

Additionally, in the calculation of the national average premium for each specialty as discussed above, our current methodology used the total RVUs in each area as the weight in the numerator (that is, for premiums), and total MP RVUs as the weights in the denominator (that is, for the MP GPCIs). After further consideration, we believe that the use of these RVU weights is problematic. Use of weights that are central to the process at hand presents potential circularity since both weights incorporate MP RVUs as part of the computation to calculate MP RVUs. The use of different weights for the numerator and denominator introduces potential inconsistency. Instead, we believe that it would be better to use a different measure that is independent of MP RVUs and better represents the reason for weighting. Specifically, we are proposing to use area population as a share of total U.S. population as the weight. The premium data are for all MP premium costs, not just those associated with Medicare patients, so we believe that the distribution of the population does a better job of capturing the role of each area's premium in the ''national'' premium for each specialty than our previous Medicare-specific measure. Use of population weights also avoids the potential problems of circularity and inconsistency.

The CY 2016 PFS proposed MP RVUs, as displayed in Addendum B of this proposed rule, reflect MP RVUs calculated following our established methodology, with the inclusion of the proposals and refinements described above.

C. Potentially Misvalued Services Under the Physician Fee Schedule

1. Background

Section 1848(c)(2)(B) of the Act directs the Secretary to conduct a periodic review, not less often than every 5 years, of the RVUs established under the PFS. Section 1848(c)(2)(K) of the Act requires the Secretary to periodically identify potentially misvalued services using certain criteria and to review and make appropriate adjustments to the relative values for those services. Section 1848(c)(2)(L) to the Act also requires the Secretary to develop a process to validate the RVUs of certain potentially misvalued codes under the PFS, using the same criteria used to identify potentially misvalued codes, and to make appropriate adjustments.

As discussed in section I.B. of this proposed rule, each year we develop appropriate adjustments to the RVUs taking into account recommendations provided by the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC), the Medicare Payment Advisory Commission (MedPAC), and others. For many years, the RUC has provided us with recommendations on the appropriate relative values for new, revised, and potentially misvalued PFS services. We review these recommendations on a code-by-code basis and consider these recommendations in conjunction with analyses of other data, such as claims data, to inform the decision-making process to establish relative values for these codes. We may also consider analyses of work time, work RVUs, or direct practice expense (PE) inputs using other data sources, such as Department of Veteran Affairs (VA), National Surgical Quality Improvement Program (NSQIP), the Society for Thoracic Surgeons (STS), and the Physician Quality Reporting System (PQRS) databases. In addition to considering the most recently available data, we also assess the results of physician surveys and specialty recommendations submitted to us by the RUC. We also consider information provided by other stakeholders. We conduct a review to assess the appropriate RVUs in the context of contemporary medical practice. We note that section 1848(c)(2)(A)(ii) of the Act authorizes the use of extrapolation and other techniques to determine the RVUs for physicians' services for which specific data are not available, in addition to requiring us to take into account the results of consultations with organizations representing physicians who furnish the services. In accordance with section 1848(c) of the Act, we determine and make appropriate adjustments to the RVUs. We discuss these methodologies as applied to particular codes in section I.B. of this proposed rule.

Section 1848(c)(2)(K)(ii) of the Act augments our efforts by directing the Secretary to specifically examine, as determined appropriate, potentially misvalued services in the following categories:

- Codes that have experienced the fastest growth.
- Codes that have experienced substantial changes in practice expenses.
- Codes that describe new technologies or services within an appropriate time period (such as 3 years) after the relative values are initially established for such codes.
- Codes which are multiple codes that are frequently billed in conjunction with furnishing a single service.
- Codes with low relative values, particularly those that are often billed multiple times for a single treatment.
- Codes that have not been subject to review since implementation of the fee schedule.
- Codes that account for the majority of spending under the PFS.
- Codes for services that have experienced a substantial change in the hospital length of stay or procedure time.
- Codes for which there may be a change in the typical site of service since the code was last valued.
- Codes for which there is a significant difference in payment for the same service between different sites of service.
- Codes for which there may be anomalies in relative values within a family of codes.
- Codes for services where there may be efficiencies when a service is furnished at the same time as other services.
- Codes with high intra-service work per unit of time.
- Codes with high practice expense relative value units.
- Codes with high cost supplies.
- Codes as determined appropriate by the Secretary.

Section 1848(c)(2)(K)(iii) of the Act also specifies that the Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services. In addition, the Secretary may conduct surveys, other data collection activities, studies, or other analyses, as the Secretary determines to be appropriate, to facilitate the review and appropriate adjustment of potentially misvalued services. This section also authorizes the use of analytic contractors to identify and analyze potentially misvalued codes, conduct surveys or collect data, and make recommendations on the review and appropriate adjustment of potentially misvalued services. Additionally, this section provides that the Secretary may coordinate the review and adjustment of any RVU with the periodic review described in section 1848(c)(2)(B) of the Act. Section 1848(c)(2)(K)(iii)(V) of the Act specifies that the Secretary may make appropriate coding revisions (including using existing processes for consideration of coding changes) that may include consolidation of individual services into bundled codes for payment under the PFS.

2. Progress in Identifying and Reviewing Potentially Misvalued Codes

To fulfill our statutory mandate, we have identified and reviewed numerous potentially misvalued codes as specified in section 1848(c)(2)(K)(ii) of the Act, and we plan to continue our work examining potentially misvalued codes in these areas over the upcoming years. As part of our current process, we identify potentially misvalued codes for review, and request recommendations from the RUC and other public commenters on revised work RVUs and direct PE inputs for those codes. The RUC, through its own processes, also identifies potentially misvalued codes for review. Through our public nomination process for potentially misvalued codes established in the CY 2012 PFS final rule with comment period, other individuals and stakeholder groups submit nominations for review of potentially misvalued codes as well.

Since CY 2009, as a part of the annual potentially misvalued code review and Five-Year Review process, we have reviewed over 1,560 potentially misvalued codes to refine work RVUs and direct PE inputs. We have assigned appropriate work RVUs and direct PE inputs for these services as a result of these reviews. A more detailed discussion of the extensive prior reviews of potentially misvalued codes is included in the CY 2012 PFS final rule with comment period (76 FR 73052

through 73055). In the CY 2012 final rule with comment period, we finalized our policy to consolidate the review of physician work and PE at the same time (76 FR 73055 through 73958), and established a process for the annual public nomination of potentially misvalued services.

In the CY 2013 final rule with comment period, we built upon the work we began in CY 2009 to review potentially misvalued codes that have not been reviewed since the implementation of the PFS (so-called ''Harvard-valued codes''). In CY 2009, we requested recommendations from the RUC to aid in our review of Harvard-valued codes that had not yet been reviewed, focusing first on high-volume, low intensity codes (73 FR 38589). In the Fourth Five-Year Review, we requested recommendations from the RUC to aid in our review of Harvard-valued codes with annual utilization of greater than 30,000 (76 FR 32410). In the CY 2013 final rule with comment period, we identified as potentially misvalued Harvard-valued services with annual allowed charges that total at least $10,000,000. In addition to the Harvard-valued codes, in the CY 2013 final rule with comment period we finalized for review a list of potentially misvalued codes that have stand-alone PE (codes with physician work and no listed work time, and codes with no physician work and listed work time).

In the CY 2014 final rule with comment period, we finalized for review a list of potentially misvalued services. We included on the list for review ultrasound guidance codes that had longer procedure times than the typical procedure with which the code is billed to Medicare. We also finalized our proposal to replace missing post-operative hospital E/M visit information and work time for approximately 100 global surgery codes. In CY 2014, we also considered a proposal to limit Medicare PFS payments for services furnished in a non-facility setting when the PFS payment would exceed the combined Medicare payment made to the practitioner under the PFS and facility payment made to either the ASC or hospital outpatient. Based upon extensive public comment we did not finalize this proposal.

In the CY 2015 final rule with comment period, we finalized a list of potentially misvalued services. The potentially misvalued codes list included the publicly nominated CPT code 41530; two neurostimulator implantation codes, CPT 64553 and 64555; four epidural injection codes, CPT 62310, 62311, 62318 and 62319; three breast mammography codes, CPT 77055, 77056 and 77057; an abdominal aortic aneurysm ultrasound screening code, HCPCS G0389; a prostate biopsy code, G0416; and an obesity behavioral group counseling code, HCPCS G0473. We also finalized our ''high expenditure services across specialty'' screen as a tool to identify potentially misvalued codes though we did not finalize the particular list of codes identified in that rule as potentially misvalued. In CY 2015, we also considered and finalized a proposal addressing the valuation and coding of global surgical packages, which would revalue and transition 10 and 90-day global codes to 0-day codes. We also sought comment on approaches to revalue services that included moderate sedation as an inherent part of furnishing the procedure.

3. Validating RVUs of Potentially Misvalued Codes

Section 1848(c)(2)(L) of the Act requires the Secretary to establish a formal process to validate RVUs under the PFS. The Act specifies that the validation process may include validation of work elements (such as time, mental effort and professional judgment, technical skill and physical effort, and stress due to risk) involved with furnishing a service and may include validation of the pre-, post-, and intra-service components of work. The Secretary is directed, as part of the validation, to validate a sampling of the work RVUs of codes identified through any of the 16 categories of potentially misvalued codes specified in section 1848(c)(2)(K)(ii) of the Act. Furthermore, the Secretary may conduct the validation using methods similar to those used to review potentially misvalued codes, including conducting surveys, other data collection activities, studies, or other analyses as the Secretary determines to be appropriate to facilitate the validation of RVUs of services.

In the CY 2011 PFS proposed rule (75 FR 40068) and CY 2012 PFS proposed rule (76 FR 42790), we solicited public comments on possible approaches, methodologies, and data sources that we should consider for a validation process. A summary of the comments along with our responses is included in the CY 2011 PFS final rule with comment period (75 FR 73217) and the CY 2012 PFS final rule with comment period (73054 through 73055).

We contracted with two outside entities to develop validation models for RVUs. Given the central role of time in establishing work RVUs and the concerns that have been raised about the current time values used in rate setting, we contracted with the Urban Institute to collect time data from several practices for services selected by the contractor in consultation with CMS. Urban Institute has used a variety of approaches to develop objective time estimates, depending on the type of service. Objective time estimates will be compared to the current time values used in the fee schedule. The project team will then convene groups of physicians from a range of specialties to review the new time data and the potential implications for work and the ratio of work to time. Urban Institute has prepared an interim report, ''Development of a Model for the Valuation of Work Relative Value Units,'' which discusses the challenges encountered in collecting objective time data and offers some thoughts on how these can be overcome. This interim report is posted on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/Downloads/RVUs-Validation-UrbanInterimReport.pdf.* A final report will be available once the project is complete.

The second contract is with the RAND Corporation, which is using available data to build a validation model to predict work RVUs and the individual components of work RVUs, time and intensity. The model design was informed by the statistical methodologies and approach used to develop the initial work RVUs and to identify potentially misvalued procedures under current CMS and RUC processes. RAND consulted with a technical expert panel on model design issues and the test results. The RAND report is available on the CMS Web site under downloads for the CY 2015 PFS Final Rule with Comment Period at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices-Items/CMS–1612–FC.html.*

4. CY 2016 Identification of Potentially Misvalued Services for Review

a. Public Nomination of Potentially Misvalued Codes

In the CY 2012 PFS final rule with comment period, we finalized a process for the public to nominate potentially misvalued codes (76 FR 73058). The public and stakeholders may nominate potentially misvalued codes for review by submitting the code with supporting documentation during the 60-day public comment period following the release of the annual PFS final rule with comment period. Supporting documentation for codes nominated for the annual review of potentially misvalued codes may

include, but are not limited to, the following:

- Documentation in the peer reviewed medical literature or other reliable data that there have been changes in physician work due to one or more of the following: technique; knowledge and technology; patient population; site-of-service; length of hospital stay; and work time.
- An anomalous relationship between the code being proposed for review and other codes.
- Evidence that technology has changed physician work, that is, diffusion of technology.
- Analysis of other data on time and effort measures, such as operating room logs or national and other representative databases.
- Evidence that incorrect assumptions were made in the previous valuation of the service, such as a misleading vignette, survey, or flawed crosswalk assumptions in a previous evaluation.
- Prices for certain high cost supplies or other direct PE inputs that are used to determine PE RVUs are inaccurate and do not reflect current information.
- Analyses of work time, work RVU, or direct PE inputs using other data sources (for example, Department of Veteran Affairs (VA) National Surgical Quality Improvement Program (NSQIP), the Society for Thoracic Surgeons (STS) National Database, and the Physician Quality Reporting System (PQRS) databases).
- National surveys of work time and intensity from professional and management societies and organizations, such as hospital associations.

After we receive the nominated codes during the 60-day comment period following the release of the annual PFS final rule with comment period, we evaluate the supporting documentation and assess whether the nominated codes appear to be potentially misvalued codes appropriate for review under the annual process. In the following year's PFS proposed rule, we publish the list of nominated codes and indicate whether we are proposing each nominated code as a potentially misvalued code.

During the comment period on the CY 2015 proposed rule and final rule with comment period, we received nominations and supporting documentation for three codes to be considered as potentially misvalued codes. We evaluated the supporting documentation for each nominated code to ascertain whether the submitted information demonstrated that the code should be proposed as potentially misvalued.

CPT Code 36516 (Therapeutic apheresis; with extracorporeal selective adsorption or selective filtration and plasma reinfusion) was nominated for review as potentially misvalued. The nominator stated that CPT code 36516 is misvalued because of incorrect direct and indirect PE inputs and an incorrect work RVU. Specifically, the nominator stated that the direct supply costs failed to include an $18 disposable bag and the $37 cost for biohazard waste disposal of the post-treatment bag, and the labor costs associated with nursing being inaccurate. The nominator also stated that the overhead expenses associated with this service were unrealistic and that the current work RVU undervalues a physician's time and expertise. We are proposing this code as a potentially misvalued code. We note that we established a policy in CY 2011 to consider biohazard bags as an indirect expense, and not as a direct PE input (75 FR 73192).

CPT Codes 52441 (Cystourethroscopy with insertion of permanent adjustable transprostatic implant; single implant) and 52442 (Cystourethroscopy with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant) were nominated for review as potentially misvalued. The nominator stated that the costs of the direct practice expense inputs were inaccurate, including the cost of the implant. We are proposing these codes as potentially misvalued codes.

b. Electronic Analysis of Implanted Neurostimulator (CPT Codes 95970–95982)

All of the inputs for CPT codes 95971 (Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming), 95972 (Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, up to one hour) and 95973 (Electronic analysis of implanted neurostimulator pulse generator system (eg, rate, pulse amplitude, pulse duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex spinal cord, or peripheral (ie, peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, each additional 30 minutes after first hour (List separately in addition to code for primary procedure)) were reviewed and valued in the CY 2015 final rule with comment period (79 FR 67670). Due to significant time changes in the base codes, we believe the entire family detailed in Table 7 should be considered as potentially misvalued and reviewed in a manner consistent with our review of CPT codes 95971, 95972 and 95973.

TABLE 7—PROPOSED POTENTIALLY MISVALUED CODES IDENTIFIED IN THE ELECTRONIC ANALYSIS OF IMPLANTED NEUROSTIMULATOR FAMILY

HCPCS	Short descriptor
95970	Analyze neurostim no prog.
95974	Cranial neurostim complex.
95975	Cranial neurostim complex.
95978	Analyze neurostim brain/1h.
95979	Analyz neurostim brain addon.
95980	Io anal gast n-stim init.
95981	Io anal gast n-stim subsq.
95982	Io ga n-stim subsq w/reprog.

c. Review of High Expenditure Services across Specialties with Medicare Allowed Charges of $10,000,000 or More

In the CY 2015 PFS rule, we proposed and finalized the high expenditure screen as a tool to identify potentially misvalued codes in the statutory category of ''codes that account for the majority of spending under the PFS.'' We also identified codes through this screen and proposed them as potentially misvalued in the CY 2015 PFS proposed rule (79 FR 40337–40338). However, given the resources required for the revaluation of codes with 10- and 90-day global periods, we did not finalize those codes as potentially misvalued codes in the CY 2015 PFS final rule with comment period. We stated that we would re-run the high expenditure screen at a future date, and subsequently propose the specific set of

codes that meet the high expenditure criteria as potentially misvalued codes (79 FR 67578).

We believe that our current resources will not necessitate further delay in proceeding with the high expenditure screen for CY 2016. We have re-run the screen with the same criteria finalized in last year's rule. However, in developing this year's proposed list, we excluded all codes with 10- and 90-day global periods since we believe these codes should be reviewed as part of the global surgery revaluation. We are proposing the 118 codes listed in Table 8 as potentially misvalued codes, identified using the high expenditure screen under the statutory category, ''codes that account for the majority of spending under the PFS.''

To develop this list, we followed the same approach taken last year except we excluded 10 and 90- day global periods. Specifically, we identified the top 20 codes by specialty (using the specialties used in Table 45) in terms of allowed charges. As we did last year, we excluded codes that we have reviewed since CY 2010, those with fewer than $10 million in allowed charges, and those that describe anesthesia or E/M services. We excluded E/M services from the list of proposed potentially misvalued codes for the same reasons that we excluded them in a similar review in CY 2012. These reasons were explained in the CY 2012 final rule with comment period (76 FR 73062 through 73065).

TABLE 8—PROPOSED POTENTIALLY MISVALUED CODES IDENTIFIED THROUGH HIGH EXPENDITURE BY SPECIALTY SCREEN

HCPCS	Short descriptor
10022	Fna w/image
11100	Biopsy skin lesion
11101	Biopsy skin add-on
11730	Removal of nail plate
20550	Inj tendon sheath/ligament
20552	Inj trigger point 1/2 muscl
20553	Inject trigger points 3/>
22614	Spine fusion extra segment
22840	Insert spine fixation device
22842	Insert spine fixation device
22845	Insert spine fixation device
27370	Injection for knee x-ray
29580	Application of paste boot
31500	Insert emergency airway
31575	Diagnostic laryngoscopy
31579	Diagnostic laryngoscopy
31600	Incision of windpipe
33518	Cabg artery-vein two
36215	Place catheter in artery
36556	Insert non-tunnel cv cath
36569	Insert picc cath
36620	Insertion catheter artery
38221	Bone marrow biopsy
51700	Irrigation of bladder

TABLE 8—PROPOSED POTENTIALLY MISVALUED CODES IDENTIFIED THROUGH HIGH EXPENDITURE BY SPECIALTY SCREEN—Continued

HCPCS	Short descriptor
51702	Insert temp bladder cath
51720	Treatment of bladder lesion
51728	Cystometrogram w/vp
51729	Cystometrogram w/vp&up
51784	Anal/urinary muscle study
51797	Intraabdominal pressure test
51798	Us urine capacity measure
52000	Cystoscopy
55700	Biopsy of prostate
58558	Hysteroscopy biopsy
67820	Revise eyelashes
70491	Ct soft tissue neck w/dye
70543	Mri orbt/fac/nck w/o &w/dye
70544	Mr angiography head w/o dye
70549	Mr angiograph neck w/o&w/dye
71010	Chest x-ray 1 view frontal
71020	Chest x-ray 2vw frontal&latl
71260	Ct thorax w/dye
71270	Ct thorax w/o & w/dye
72195	Mri pelvis w/o dye
72197	Mri pelvis w/o & w/dye
73110	X-ray exam of wrist
73130	X-ray exam of hand
73718	Mri lower extremity w/o dye
73720	Mri lwr extremity w/o&w/dye
74000	X-ray exam of abdomen
74022	X-ray exam series abdomen
74181	Mri abdomen w/o dye
74183	Mri abdomen w/o & w/dye
75635	Ct angio abdominal arteries
75710	Artery x-rays arm/leg
75978	Repair venous blockage
76512	Ophth us b w/non-quant a
76519	Echo exam of eye
76536	Us exam of head and neck
77059	Mri both breasts
77263	Radiation therapy planning
77334	Radiation treatment aid(s)
77470	Special radiation treatment
78306	Bone imaging whole body
78452	Ht muscle image spect mult
88185	Flowcytometry/tc add-on
88189	Flowcytometry/read 16 & >
88321	Microslide consultation
88360	Tumor immunohistochem/manual
88361	Tumor immunohistochem/comput
91110	Gi tract capsule endoscopy
92002	Eye exam new patient
92136	Ophthalmic biometry
92240	Icg angiography
92250	Eye exam with photos
92275	Electroretinography
92557	Comprehensive hearing test
92567	Tympanometry
93280	Pm device progr eval dual
93288	Pm device eval in person
93293	Pm phone r-strip device eval
93294	Pm device interrogate remote
93295	Dev interrog remote 1/2/mlt
93296	Pm/icd remote tech serv
93306	Tte w/doppler complete
93350	Stress tte only
93351	Stress tte complete
93503	Insert/place heart catheter
93613	Electrophys map 3d add-on
93965	Extremity study
94010	Breathing capacity test
94620	Pulmonary stress test/simple

TABLE 8—PROPOSED POTENTIALLY MISVALUED CODES IDENTIFIED THROUGH HIGH EXPENDITURE BY SPECIALTY SCREEN—Continued

HCPCS	Short descriptor
95004	Percut allergy skin tests
95165	Antigen therapy services
95957	Eeg digital analysis
96101	Psycho testing by psych/phys
96116	Neurobehavioral status exam
96118	Neuropsych tst by psych/phys
96360	Hydration iv infusion init
96372	Ther/proph/diag inj sc/im
96374	Ther/proph/diag inj iv push
96375	Tx/pro/dx inj new drug addon
96401	Chemo anti-neopl sq/im
96402	Chemo hormon antineopl sq/im
96409	Chemo iv push sngl drug
96411	Chemo iv push addl drug
96567	Photodynamic tx skin
96910	Photochemotherapy with uv-b
97032	Electrical stimulation
97035	Ultrasound therapy
97110	Therapeutic exercises
97112	Neuromuscular reeducation
97113	Aquatic therapy/exercises
97116	Gait training therapy
97140	Manual therapy 1/regions
97530	Therapeutic activities
97535	Self care mngment training
G0283	Elec stim other than wound

5. Valuing Services That Include Moderate Sedation as an Inherent Part of Furnishing the Procedure

The CPT manual includes more than 400 diagnostic and therapeutic procedures, listed in Appendix G, for which CPT has determined that moderate sedation is an inherent part of furnishing the procedure. Therefore, only the procedure code is reported when furnishing the service, and in developing RVUs for these services, we include the resource costs associated with moderate sedation in the valuation of these diagnostic and therapeutic procedures. To the extent that moderate sedation is inherent in the diagnostic or therapeutic service, we believe that the inclusion of moderate sedation in the valuation of the procedure is accurate. In the CY 2015 PFS proposed rule (79 FR 40349), we noted that it appeared that practice patterns for endoscopic procedures were changing, with anesthesia increasingly being separately reported for these procedures. Due to the changing nature of medical practice, we noted that we were considering establishing a uniform approach to valuation for all Appendix G services. We continue to seek an approach that is based on using the best available objective information about the provision of moderate sedation broadly, rather than merely addressing this issue on a code-by-code basis using RUC survey data when individual procedures

are revalued. We sought public comment on approaches to address the appropriate valuation of these services given that moderate sedation is no longer inherent for many of these services. To the extent that Appendix G procedure values are adjusted to no longer include moderate sedation, we requested suggestions as to how moderate sedation should be reported and valued, and how to remove from existing valuations the RVUs and inputs related to moderate sedation.

To establish an approach to valuation for all Appendix G services based on the best data about the provision of moderate sedation, we need to determine the extent of the misvaluation for each code. We know that there are standard packages for the direct PE inputs associated with moderate sedation, and we began to develop approaches to estimate how much of the work is attributable to moderate sedation. However, we believe that we should seek input from the medical community prior to proposing changes in values for these services, given the different methodologies used to develop work RVUs for the hundreds of services in Appendix G. Therefore, we are seeking recommendations from the RUC and other interested stakeholders for appropriate valuation of the work associated with moderate sedation before formally proposing an approach that allows Medicare to adjust payments based on the resource costs associated with the moderate sedation or anesthesia services that are being furnished.

The anesthesia procedure codes 00740 (Anesthesia for procedure on gastrointestinal tract using an endoscope) and 00810 (Anesthesia for procedure on lower intestine using an endoscope) are used for anesthesia furnished in conjunction with lower GI procedures. In reviewing Medicare claims data, we noted that a separate anesthesia service is now reported more than 50 percent of the time that several types of colonoscopy procedures are reported. Given the significant change in the relative frequency with which anesthesia codes are reported with colonoscopy services, we believe the relative values of the anesthesia services should be re-examined. Therefore, we are proposing to identify CPT codes 00740 and 00810 as potentially misvalued. We welcome comments on both of these issues.

6. Improving the Valuation and Coding of the Global Package

a. Proposed Transition of 10-Day and 90-Day Global Packages Into 0-Day Global Packages

In the CY 2015 PFS final rule (79 FR 67582 through 67591) we finalized a policy to transition all 10-day and 90-day global codes to 0-day global codes to improve the accuracy of valuation and payment for the various components of global surgical packages, including pre- and post-operative visits and performance of the surgical procedure. Although we have marginally addressed some of the concerns noted with global packages in previous rulemaking, we believe there is still an unmet need to address some of the fundamental issues with the 10- and 90-day post-operative global packages. We believe it is critical that the RVUs used to develop PFS payment rates reflect the most accurate resource costs associated with PFS services. We believe that valuing global codes that package services together without objective, auditable data on the resource costs associated with the components of the services contained in the packages may significantly skew relativity and create unwarranted payment disparities within PFS fee-for-service payment. We also believe that the resource based valuation of individual physicians' services will continue to serve as a critical foundation for Medicare payment to physicians. Therefore, we believe it is critical that the RVUs under the PFS be based as closely and accurately as possible on the actual resources involved in furnishing the typical occurrence of specific services.

We stated our belief that transforming all 10- and 90-day global codes to 0-day global codes would:

- Increase the accuracy of PFS payment by setting payment rates for individual services based more closely upon the typical resources used in furnishing the procedures;
- Avoid potentially duplicative or unwarranted payments when a beneficiary receives post-operative care from a different practitioner during the global period;
- Eliminate disparities between the payment for E/M services in global periods and those furnished individually;
- Maintain the same-day packaging of pre- and post-operative physicians' services in the 0-day global; and
- Facilitate availability of more accurate data for new payment models and quality research.

b. Impact of the Medicare Access and CHIP Reauthorization Act of 2015

The Medicare Access and CHIP Reauthorization Act (MACRA) was enacted into law on April 16, 2015. Section 523 of the MACRA addresses payment for global surgical packages. Section 523(a) adds a new paragraph at section 1848(c)(8) of the Act. Section 1848(c)(8)(A)(i) of the Act prohibits the Secretary from implementing the policy established in the CY 2015 PFS final rule with comment period that would have transitioned all 10-day and 90-day global surgery packages to 0-day global periods. Section 1848(c)(8)(A)(ii) of the Act provides that nothing in the previous clause shall be construed to prevent the Secretary from revaluing misvalued codes for specific surgical services or assigning values to new or revised codes for surgical services.

Section 1848(c)(8)(B)(i) of the Act requires CMS to develop through rulemaking a process to gather information needed to value surgical services from a representative sample of physicians, and requires that the data collection shall begin no later than January 1, 2017. The collected information must include the number and level of medical visits furnished during the global period and other items and services related to the surgery, as appropriate. This information must be reported on claims at the end of the global period or in another manner specified by the Secretary. Section 1848(c)(8)(B)(ii) of the Act requires that, every 4 years, we must reassess the value of this collected information, and allows us to discontinue the collection if the Secretary determines that we have adequate information from other sources in order to accurately value global surgical services. Section 1848(c)(8)(B)(iii) of the Act specifies that the Inspector General will audit a sample of the collected information to verify its accuracy. Section 1848(c)(8)(C) of the Act requires that, beginning in CY 2019, we must use the information collected as appropriate, along with other available data, to improve the accuracy of valuation of surgical services under the PFS. Section 523(b) of the MACRA adds a new paragraph at section 1848(c)(9) of the Act which authorizes the Secretary, through rulemaking, to delay up to 5 percent of the PFS payment for services for which a physician is required to report information under section 1848(c)(8)(B)(i) of the Act until the required information is reported.

Since section 1848(c)(8)(B)(i) of the Act, as added by section 523(a) of the MACRA, requires us to use rulemaking

to develop and implement the process to gather information needed to value surgical services no later than January 1, 2017, we are seeking input from stakeholders on various aspects of this task. We are soliciting comments from the public regarding the kinds of auditable, objective data (including the number and type of visits and other services furnished by the practitioner reporting the procedure code during the current post-operative periods) needed to increase the accuracy of the values for surgical services. We are also seeking comment on the most efficient means of acquiring these data as accurately and efficiently as possible. For example, we seek information on the extent to which individual practitioners or practices may currently maintain their own data on services, including those furnished during the post-operative period, and how we might collect and objectively evaluate those data for use in increasing the accuracy of the values beginning in CY 2019. We will use the information from the public comments to help develop a proposed approach for the collection of this information in future rulemaking.

Section 1848(c)(8)(C) of the Act mandates that we use the collected data to improve the accuracy of valuation of surgery services beginning in 2019. We described in previous rulemaking (79 FR 67582 through 67591) the limitations and difficulties involved in the appropriate valuation of the global packages, especially when the values of the component services are not clear. We are seeking public comment on potential methods of valuing the individual components of the global surgical package, including the procedure itself, and the pre- and post-operative care, including the follow-up care during post-operative days. We are particularly interested in stakeholder input regarding the overall accuracy of the values and descriptions of the component services within the global packages. For example, we seek information from stakeholders on whether (both qualitatively and quantitatively) postoperative visits differ from other E/M services. We are also interested in stakeholder input on what other items and services related to the surgery, aside from postoperative visits, are furnished to beneficiaries during post-operative care. We believe that stakeholder input regarding these questions will help determine what data should be collected, as well as how to improve the accuracy of the valuations. We welcome the full range of public feedback from stakeholders to assist us in this process.

We intend to provide further opportunities for public feedback prior to developing a proposal for CY 2017 to collect this required data. We also seek comments regarding stakeholder interest in the potential for an open door forum, town hall meetings with the public, or other avenues for direct communication regarding implementation of these provisions of the Act.

D. Refinement Panel

1. Background

As discussed in the CY 1993 PFS final rule with comment period (57 FR 55938), we adopted a refinement panel process to assist us in reviewing the public comments on CPT codes with interim final work RVUs for a year and in developing final work values for the subsequent year. We decided the panel would be composed of a multispecialty group of physicians who would review and discuss the work involved in each procedure under review, and then each panel member would individually rate the work of the procedure. We believed establishing the panel with a multispecialty group would balance the interests of the specialty societies who commented on the work RVUs with the budgetary and redistributive effects that could occur if we accepted extensive increases in work RVUs across a broad range of services.

Following enactment of section 1848(c)(2)(K) of the Act, which required the Secretary periodically to identify and review potentially misvalued codes and make appropriate adjustments to the RVUs, we reassessed the refinement panel process. As detailed in the CY 2011 PFS final rule with comment period (75 FR 73306), we continued using the established refinement panel process with some modifications.

For CY 2015, in light of the changes we made to the process for valuing new, revised and potentially misvalued codes (79 FR 67606), we reassessed the role that the refinement panel process plays in the code valuation process. We noted that the current refinement panel process is tied to the review of interim final values. It provides an opportunity for stakeholders to provide new clinical information that was not available at the time of the RUC valuation that might affect work RVU values that are adopted in the interim final value process. For CY 2015 interim final rates, we stated in the CY 2015 PFS final rule with comment period that we will use the refinement panel process as usual for these codes (79 FR 67609).

2. CY 2016 Refinement Panel Proposal

Beginning in CY 2016, we are proposing to permanently eliminate the refinement panel and instead publish the proposed rates for all interim final codes in the PFS proposed rule for the subsequent year. For example, we will publish the proposed rates for all CY 2016 interim final codes in the CY 2017 PFS proposed rule. With the change in the process for valuing codes adopted in the CY 2015 final rule with comment period (79 FR 67606), proposed values for most codes that are being valued for CY 2016 will be published in the CY 2016 PFS proposed rule. As explained in the CY 2015 final rule with comment period, only a small number of codes being valued for CY 2016 will be published as interim final in the 2016 PFS final rule with comment period and be subject to comment. We will evaluate the comments we receive on these code values, and both respond to these comments and propose values for these codes for CY 2017 in the CY 2017 PFS proposed rule. Therefore, stakeholders will have two opportunities to comment and to provide any new clinical information that was not available at the time of the RUC valuation that might affect work RVU values that are adopted on an interim final basis. We believe that this proposed process, which includes two opportunities for public notice and comment, offers stakeholders a better mechanism and ample opportunity for providing any additional data for our consideration, and discussing any concerns with our interim final values, than the current refinement process. It also provides greater transparency because comments on our rules are made available to the public at *www.regulations.gov*. We welcome comments on this proposed change to eliminate the use of refinement panels in our process for establishing final values for interim final codes.

E. Improving Payment Accuracy for Primary Care and Care Management Services

We are committed to supporting primary care, and we have increasingly recognized care management as one of the critical components of primary care that contributes to better health for individuals and reduced expenditure growth (77 FR 68978). Accordingly, we have prioritized the development and implementation of a series of initiatives designed to improve the accuracy of payment for, and encourage long-term investment in, care management services.

In addition to the Medicare Shared Savings Program, various demonstration initiatives including the Pioneer Accountable Care Organization (ACO), the patient-centered medical home model in the Multi-payer Advanced Primary Care Practice (MAPCP), the Federally Qualified Health Center (FQHC) Advanced Primary Care Practice demonstration, the Comprehensive Primary Care (CPC) initiative, among others (see the CY 2015 PFS final rule (79 FR 67715) for a discussion of these), we also have continued to explore potential refinements to the PFS that would appropriately value care management within Medicare's statutory structure for fee-for-service physician payment and quality reporting. The payment for some non-face-to-face care management services is bundled into the payment for face-to-face evaluation and management (E/M) visits. However, because the current E/M office/outpatient visit CPT codes were designed with an overall orientation toward episodic treatment, we have recognized that these E/M codes may not reflect all the services and resources involved with furnishing certain kinds of care, particularly comprehensive, coordinated care management for certain categories of beneficiaries.

Over several years, we have developed proposals and sought stakeholder input regarding potential PFS refinements to improve the accuracy of payment for care management services. For example, in the CY 2013 PFS final rule with comment period, we adopted a policy to pay separately for transitional care management (TCM) involving the transition of a beneficiary from care furnished by a treating physician during an inpatient stay to care furnished by the beneficiary's primary physician in the community (77 FR 68978 through 68993). In the CY 2014 PFS final rule with comment period, we finalized a policy, beginning in CY 2015 (78 FR 74414), to pay separately for chronic care management (CCM) services furnished to Medicare beneficiaries with two or more chronic conditions. We believe that these new separately billable codes more accurately describe, recognize, and make payment for non-face-to-face care management services furnished by practitioners and clinical staff to particular patient populations.

We view ongoing refinements to payment for care management services as part of a broader strategy to incorporate input and information gathered from research, initiatives, and demonstrations conducted by CMS and other public and private stakeholders, the work of all parties involved in the potentially misvalued code initiative, and, more generally, from the public at large. Based on input and information gathered from these sources, we are considering several potential refinements that would continue our efforts to improve the accuracy of PFS payments. In this section, we discuss these potential refinements.

1. Improved Payment for the Professional Work of Care Management Services

Although both the TCM and CCM services describe certain aspects of professional work, some stakeholders have suggested that neither of these new sets of codes nor the inputs used in their valuations explicitly account for all of the services and resources associated with the more extensive cognitive work that primary care physicians and other practitioners perform in planning and thinking critically about the individual chronic care needs of particular subsets of Medicare beneficiaries. Stakeholders assert that the time and intensity of the cognitive efforts are in addition to the work typically required to supervise and manage the clinical staff associated with the current TCM and CCM codes. Similarly, we continue to receive requests from a few stakeholders for CMS to lead efforts to revise the current CPT E/M codes or construct a new set of E/M codes. The goal of such efforts would be to better describe and value the physician work (time and intensity) specific to primary care and other cognitive specialties in the context of complex care of patients relative to the time and intensity of the procedure-oriented care physicians and practitioners, who use the same codes to report E/M services. Some of these stakeholders have suggested that in current medical practice, many physicians, in addition to the time spent treating acute illnesses, spend substantial time working toward optimal outcomes for patients with chronic conditions and patients they treat episodically, which can involve additional work not reflected in the codes that describe E/M services since that work is not typical across the wide range of practitioners that report the same codes. According to these groups, this work involves medication reconciliation, the assessment and integration of numerous data points, effective coordination of care among multiple other clinicians, collaboration with team members, continuous development and modification of care plans, patient or caregiver education, and the communication of test results.

We agree with stakeholders that it is important for Medicare to use codes that accurately describe the services furnished to Medicare beneficiaries and to accurately reflect the relative resources involved with furnishing those services. Therefore, we are interested in receiving public comments on ways to recognize the different resources (particularly in cognitive work) involved in delivering broad-based, ongoing treatment, beyond those resources already incorporated in the codes that describe the broader range of E/M services. The resource costs of this work may include the time and intensity related to the management of both long-term and, in some cases, episodic conditions. In order to appropriately recognize the different resource costs for this additional cognitive work within the structure of PFS resource-based payments, we are particularly interested in codes that could be used in addition to, not instead of, the current E/M codes.

In principle, these codes could be similar to the hundreds of existing add-on codes that describe additional resource costs, such as additional blocks or slides in pathology services, additional units of repair in dermatologic procedures, or additional complexity in psychotherapy services. For example, these codes might allow for the reporting of the additional time and intensity of the cognitive work often undertaken by primary care and other cognitive specialties in conjunction with an evaluation and management service, much like add-on codes for certain procedures or diagnostic test describe the additional resources sometimes involved in furnishing those services. Similar to the CCM code, the codes might describe the increased resources used over a longer period of time than during one patient visit. For example, the add-on codes could describe the professional time in excess of 30 minutes and/or a certain set of furnished services, per one calendar month for a single patient to coordinate care, provide patient or caregiver education, reconcile and manage medications, assess and integrate data, or develop and modify care plans. Such activity may be particularly relevant for the care of patients with multiple or complicated chronic or acute conditions and should contribute to optimal patient outcomes, including more coordinated, safer care.

Like CCM, we would require that the patient have an established relationship with the billing professional; and additionally, the use of an add-on code would require the extended professional resources to be reported with another

separately payable service. However, in contrast to the CCM code, the new codes might be reported based on the resources involved in professional work, instead of the resource costs in terms of clinical staff time. The codes might also apply broadly to patients in a number of different circumstances, and would not necessarily make reporting the code(s) contingent on particular business models or technologies for medical practices. We are interested in stakeholder comments on the kinds of services that involve the type of cognitive work described above and whether or not the creation of particular codes might improve the accuracy of the relative values used for such services on the PFS. Finally, we are interested in receiving information from stakeholders on the overlap between the kinds of cognitive resource costs discussed above and those already accounted for through the currently payable codes that describe CCM and other care management services.

We strongly encourage stakeholders to comment on this topic in order to assist us in developing potential proposals to address these issues through rulemaking in CY 2016 for implementation in CY 2017. We anticipate using this approach, which would parallel our multi-year approach for implementing CCM and TCM services, in order to facilitate broader input from stakeholders regarding details of implementing such codes, including their structure and description, valuation, and any requirements for reporting.

2. Establishing Separate Payment for Collaborative Care

We believe that the care and management for Medicare beneficiaries with multiple chronic conditions, a particularly complicated disease or acute condition, or common behavioral health conditions often requires extensive discussion, information-sharing and planning between a primary care physician and a specialist (for example, with a neurologist for a patient with Alzheimer's disease plus other chronic diseases). We note that for CY 2014, CPT created four codes that describe interprofessional telephone/internet consultative services (CPT codes 99446–99449). Because Medicare pays for telephone consultations with or about a beneficiary as a part of other services furnished to the beneficiary, we currently do not make separate payment for these services. We note that such interprofessional consultative services are distinct from the face-to-face visits previously reported to Medicare using the consultation codes, and we refer the reader to the CY 2010 PFS final rule for information regarding Medicare payment policies for those services (74 FR 61767).

However, in considering how to improve the accuracy of our payments for care coordination particularly for patients requiring more extensive care, we are seeking comment on how Medicare might accurately account for the resource costs of a more robust interprofessional consultation within the current structure of PFS payment. For example, we would be interested in stakeholders' perspectives regarding whether there are conditions under which it might be appropriate to make separate payment for services like those described by these CPT codes. We are interested in stakeholder input regarding the parameters of, and resources involved in these collaborations between a specialist and primary care practitioner, especially in the context of the structure and valuation of current E/M services. In particular, we are interested in comments about how these collaborations could be distinguished from the kind of services included in other E/M services, how these services could be described if stakeholders believe the current CPT codes are not adequate, and how these services should be valued on the PFS. We are also interested in comments on whether we should tie those interprofessional consultations to a beneficiary encounter and on developing appropriate beneficiary protections to ensure that beneficiaries are fully aware of the involvement of the specialist in the beneficiary's care and the associated benefits of the collaboration between the primary care physician and the specialist physician prior to being billed for such services.

Additionally, we are seeking comment on whether this kind of care might benefit from inclusion in a CMMI model that would allow Medicare to test its effectiveness with a waiver of beneficiary financial liability and/or variation of payment amounts for the consulting and the primary care practitioners. Without such protections, beneficiaries could be responsible for coinsurance for services of physicians whose role in the beneficiary's care is not necessarily understood by the beneficiary. Finally, we also are seeking comment on key technology supports needed to support collaboration between specialist and primary care practitioners in support of high quality care management services, on whether we should consider including technology requirements as part of any proposed services, and on how such requirements could be implemented in a way that minimizes burden on providers. We strongly encourage stakeholders to comment on this topic in order to assist us in developing potential proposals to address these issues through rulemaking in CY 2016 for implementation in CY 2017. We anticipate using this approach, which would parallel our multi-year approach for implementing CCM and TCM services, in order to facilitate broader input from stakeholders regarding details of implementing such codes, including their structure and description, valuation, and any requirements for reporting.

a. Collaborative Care Models for Beneficiaries With Common Behavioral Health Conditions

In recent years, many randomized controlled trials have established an evidence base for an approach to caring for patients with common behavioral health conditions called ''Collaborative Care.'' Collaborative care typically is provided by a primary care team, consisting of a primary care provider and a care manager, who works in collaboration with a psychiatric consultant, such as a psychiatrist. Care is directed by the primary care team and includes structured care management with regular assessments of clinical status using validated tools and modification of treatment as appropriate. The psychiatric consultant provides regular consultations to the primary care team to review the clinical status and care of patients and to make recommendations. Several resources have been published that describe collaborative care models in greater detail and assess their impact, including pieces from the University of Washington (*http://aims.uw.edu/*), the Institute for Clinical and Economic Review (*http://ctaf.org/reports/integration-behavioral-health-primary-care*), and the Cochrane Collaboration (*http://www.cochrane.org/CD006525/DEPRESSN_collaborative-care-for-people-with-depression-and-anxiety*).

Because this particular kind of collaborative care model has been tested and documented in medical literature, we are particularly interested in seeking comment on how coding under the PFS might facilitate appropriate valuation of the services furnished under such a collaborative care model. As these kinds of collaborative models of care become more prevalent, we will evaluate potential refinements to the PFS to account for the provision of services through such a model. We are seeking information to assist us in considering refinements to coding and payment to

address this model in particular. We also would assess application of the collaborative care model for other diagnoses and treatment modalities. For example, we seek comments on how a code similar to the CCM code applicable to multiple diagnoses and treatment plans could be used to describe collaborative care services, as well as other interprofessional services and could be appropriately valued and reported within the resource-based relative value PFS system, and how the resources involved in furnishing such services could be incorporated into the current set of PFS codes without overlap. We also request input on whether requirements similar to those used for CCM services should apply to a new collaborative care code, and whether such a code could be reported in conjunction with CCM or other E/M services. For example, we might consider whether the code should describe a minimum amount of time spent by the psychiatric consultant for a particular patient per one calendar month and be complemented by either the CCM or other care management code to support the care management and primary care elements of the collaborative care model. As with our discussion on interprofessional consultation in this section of the proposed rule, because the patient may not have direct contact with the psychiatric consultant, we seek comment on whether and, if so, how written consent for the non-face-to-face services should be required prior to practitioners reporting any new interprofessional consultation code or the care management code.

We are also seeking comment on appropriate care delivery requirements for billing, the appropriateness of CCM technology requirements or other technology requirements for these services, necessary qualifications for psychiatric consultants, and whether or not there are particular conditions for which payment would be more appropriate than others; as well as how these services may interact with quality reporting, the resource inputs we might use to value the services under the PFS (specifically, work RVUs, time, and direct PE inputs), and whether or not separate codes should be developed for the psychiatric consultant and the care management components of the service.

We are also seeking comment on whether this kind of care model should be implemented through a CMMI demonstration that would allow Medicare to test its effectiveness with a waiver of beneficiary financial liability and/or variation of payment methodology and amounts for the psychiatric consultant and the primary care physician. Again, we strongly encourage stakeholders to comment on this topic in order to assist us in developing potential proposals to address these issues through rulemaking in CY 2016 for implementation in CY 2017.

3. CCM and TCM Services

a. Reducing Administrative Burden for CCM and TCM Services

In CY 2013, we implemented separate payment for TCM services, and in CY 2015, we implemented separate payment for CCM services. Both have many service elements and billing requirements that the physician or nonphysician practitioner must satisfy in order to fully furnish these services and to report these codes (77 FR 68989, 79 FR 67728). These elements and requirements are relatively extensive and generally exceed those for other E/M and similar services. Since the implementation of these services, some practitioners have stated that the service elements and billing requirements are too burdensome, and suggested that they interfere with their ability to provide these care management services to their patients who could benefit from them. In light of this feedback from the physician and practitioner community, we are soliciting comments on steps that we could take to further improve beneficiary access to TCM and CCM services. Our aims in implementing separate payment for these services are that Medicare practitioners are paid appropriately for the services they furnish, and that beneficiaries receive comprehensive care management that benefits their long term health outcomes. However, we understand that excessive requirements on practitioners could possibly undermine the overall goals of the payment policies. We are interested in stakeholder input in how we can best balance access to these services and practitioner burdens such that Medicare beneficiaries may obtain the full benefit of these services.

b. Payment for CPT Codes Related to CCM Services

As we stated in the CY 2015 PFS final rule (79 FR 67719), we believe that Medicare beneficiaries with two or more chronic conditions as defined under the CCM code can benefit from the care management services described by that code, and we want to make this service available to all such beneficiaries. As with most services paid under the PFS, we recognize that furnishing CCM services to some beneficiaries will require more resources and some less; but we value and make payment based upon the typical service. Because CY 2015 is the first year for which we are making separate payment for CCM services, we are seeking information regarding the circumstances under which this service is furnished. This information includes the clinical status of the beneficiaries receiving the service and the resources involved in furnishing the service, such as the number of documented non-face-to-face minutes furnished by clinical staff in the months the code is reported. We would be interested in examining such information in order to identify the range of minutes furnished over those months as well as the distribution of the number of minutes within the total volume of services. We are also seeking objective data regarding the resource costs associated with furnishing the services described by this code. As we review that information, in addition to our own claims data, we will consider any changes in payment and coding that may be warranted in the coming years, including the possibility of establishing separate payment amounts and making Medicare payment for the related CPT codes, such as the complex care coordination codes, CPT codes 99487 and 99489.

F. Target for Relative Value Adjustments for Misvalued Services

Section 220(d) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93, enacted on April 1, 2014) added a new subparagraph at section 1848(c)(2) of the Act to establish an annual target for reductions in PFS expenditures resulting from adjustments to relative values of misvalued codes. Under section 1848(c)(2)(O)(ii) of the Act, if the estimated net reduction in expenditures for a year is equal to or greater than the target for the year, reduced expenditures attributable to such adjustments shall be redistributed in a budget-neutral manner within the PFS in accordance with the existing budget neutrality requirement under section 1848(c)(2)(B)(ii)(II) of the Act. The provision also specifies that the amount by which such reduced expenditures exceeds the target for a given year shall be treated as a net reduction in expenditures for the succeeding year, for purposes of determining whether the target has been met for that subsequent year. Section 1848(c)(2)(O)(iv) of the Act defines a target recapture amount as the amount by which the target for the year exceeds the estimated net reduction in expenditures under the PFS resulting from adjustments to RVUs for misvalued codes. Section 1848(c)(2)(O)(iii) of the

Act specifies that, if the estimated net reduction in PFS expenditures for the year is less than the target for the year, an amount equal to the target recapture amount shall not be taken into account when applying the budget neutrality requirements specified in section 1848(c)(2)(B)(ii)(II) of the Act. Section 220(d) of the PAMA applied to calendar years (CYs) 2017 through 2020 and set the target under section 1848(c)(2)(O)(v) of the Act at 0.5 percent of the estimated amount of expenditures under the PFS for each of those 4 years.

Section 202 of the Achieving a Better Life Experience Act of 2014 (ABLE) (Division B of Pub. L. 113–295, enacted December 19, 2014)) amended section 1848(c)(2)(O) of the Act to accelerate the application of the PFS expenditure reduction target to CYs 2016, 2017, and 2018, and to set a 1 percent target for CY 2016 and 0.5 percent for CYs 2017 and 2018. As a result of these provisions, if the estimated net reduction for a given year is less than the target for that year, payments under the fee schedule will be reduced.

In this section, we are proposing a methodology to implement this statutory provision in a manner consistent with the broader statutory construct of the PFS. In developing this proposed methodology, we have identified several aspects of our approach for which we are specifically seeking comment. We have organized this discussion by identifying and explaining these aspects in particular but we are seeking comment on all aspects of our proposal.

1. Distinguishing ''Misvalued Code'' Adjustments From Other RVU Adjustments

The potentially misvalued code initiative has resulted in changes in PFS payments in several ways. First, potentially misvalued codes have been identified, reviewed, and revalued through notice and comment rulemaking. However, in many cases, the identification of particular codes as potentially misvalued has led to the review and revaluation of related codes, and frequently, to revisions to the underlying coding for large sets of related services. Similarly, the review of individual codes has initiated reviews and proposals to make broader adjustments to values for codes across the PFS, such as when the review of a series of imaging codes prompted a RUC recommendation and CMS proposal to update the direct PE inputs for imaging services to assume digital instead of film costs. This change, originating through the misvalued code initiative, resulted in a significant reduction in RVUs for a large set of PFS services, even though the majority of affected codes were not initially identified through potentially misvalued code screens. Finally, due to both the relativity inherent in the PFS ratesetting process and the budget neutrality requirements specified in section 1848(c)(2)(B)(ii)(II) of the Act, adjustments to the RVUs for individual services necessarily result in the shifting of RVUs to broad sets of other services across the PFS.

To implement the PFS expenditure reduction target provisions under section 1848(c)(2)(O) of the Act, we must identify a subset of the adjustments in RVUs for a year to reflect an estimated ''net reduction'' in expenditures. Therefore, we dismissed the possibility of including all changes in RVUs for a year in calculating the estimated net reduction in PFS expenditures, even though we believe that the redistributions in RVUs to other services are an important aspect of the potentially misvalued code initiative. Conversely, we similarly considered the possibility of limiting the calculation of the estimated net reduction in expenditures to reflect RVU adjustments made to the codes formally identified as ''potentially misvalued.'' We do not believe that calculation would reflect the significant changes in payments that have directly resulted from the review and revaluation of misvalued codes under section 1848(c)(2) of the Act. We further considered whether to include only those codes that underwent a comprehensive review (work and PE). As we previously have stated (76 FR 73057), we believe that a comprehensive review of the work and PE for each code leads to the more accurate assignment of RVUs and appropriate payments under the PFS than do fragmentary adjustments for only one component. However, if we calculated the net reduction in expenditures using revisions to RVUs only from comprehensive reviews, the calculation would not include changes in PE RVUs that result from proposals like the film-to-digital change for imaging services, which not only originated from the review of potentially misvalued codes, but substantially improved the accuracy of PFS payments faster and more efficiently than could have been done through the multiple-year process required to complete a comprehensive review of all imaging codes.

After considering these options, we believe that the best approach is to define the reduction in expenditures as a result of adjustments to RVUs for misvalued codes to include the estimated pool of all services with revised input values. This would limit the pool of RVU adjustments used to calculate the net reduction in expenditures to those for the services for which individual, comprehensive review or broader proposed adjustments have resulted in changes to service-level inputs of work RVUs, direct PE inputs, or MP RVUs, as well as services directly affected by changes to coding for related services. For example, coding changes in certain codes can sometimes necessitate revaluations for related codes that have not been reviewed as misvalued codes, because the coding changes have also affected the scope of the related services. This definition would incorporate all reduced expenditures from revaluations for services that are deliberately addressed as potentially misvalued codes, as well as those for services with broad-based adjustments like film-to-digital and services that are redefined through coding changes as a result of the review of misvalued codes.

Because the annual target is calculated by measuring changes from one year to the next, we also considered how to account for changes in values that are best measured over 3 years, instead of 2 years. Under our current process, the overall change in valuation for many misvalued codes is measured across values for 3 years: The original value in the first year, the interim final value in the second year, and the finalized value in the third year. As we describe in section II.I.2. of this proposed rule, our misvalued code process has been to establish interim final RVUs for the potentially misvalued, new, and revised codes in the final rule with comment period for a year. Then, during the 60-day period following the publication of the final rule with comment period, we accept public comment about those valuations. For the final rule with comment period for the subsequent year, we consider and respond to public comments received on the interim final values, and make any appropriate adjustments to values based on those comments. However, the straightforward calculation of the target would only compare changes between 2 years and not among 3 years, so the contribution of a particular change towards the target for any single year would be measured against only the preceding year without regard to the overall change that takes place over 3 years.

For recent years, interim final values for misvalued codes (year 2) have generally reflected reductions relative to original values (year 1), and for most codes, the interim final values (year 2) are maintained and finalized (year 3). However, when values for particular

codes have changed between the interim final (year 2) and final values (year 3) based on public comment, the general tendency has been that codes increase in the final value (year 3) relative to the interim final value (year 2), even in cases where the final value (year 3) represents a decrease from the original value (year 1). Therefore, for these codes, the year 2 changes compared to year 1 would risk over-representing the overall reduction, while the year 3 to year 2 changes would represent an increase in value. If there were similar targets in every PFS year, and a similar number of misvalued code changes made on an interim final basis, the incongruence in measuring what is really a 3-year change in 2-year increments might not be particularly problematic since each year's calculation would presumably include a similar number of codes measured between years 1 and 2 and years 2 and 3.

However, including changes that take place over 3 years is particularly problematic for calculating the target for CY 2016 for two reasons. First, CY 2015 was the final full year of establishing interim final values for all new, revised, and potentially misvalued codes. Starting with this proposed rule, we are proposing and finalizing values for a significant portion of misvalued codes during one calendar year. Therefore, CY 2015 will include a disproportionate number of services that would be measured between years 2 and 3 relative to the services measured between 1 and 2 years. Second, because there was no target for CY 2015, any reductions that occurred on an interim final basis for CY 2015 were not counted toward achievement of a target. If we were to include any upward adjustments made to these codes based on public comment as ''misvalued code'' changes for CY 2016, we would effectively be counting the service-level increases for 2016 (year 3) relative to 2015 (year 2) against achievement of the target without any consideration to the service-level changes relative to 2014 (year 1), even in cases where the overall change in valuation was negative.

Therefore, we are proposing to exclude code-level input changes for CY 2015 interim final values from the calculation of the CY 2016 misvalued code target since the misvalued change occurred over multiple years, including years not applicable to the misvalued code target provision.

We note that the impact of interim final values in the calculation of targets for future years will be diminished as we transition to proposing values for almost all new, revised, and potentially misvalued codes in the proposed rule. We anticipate a smaller number of interim final values for CY 2016 relative to CY 2015. For calculation of the CY 2018 target, we anticipate almost no impact based on misvalued code adjustments that occur over multiple years.

The list of codes with proposed changes for CY 2016 included under this proposed definition of ''adjustments to RVUs for misvalued codes'' is available on the CMS Web site under downloads for the CY 2016 PFS proposed rule with comment period at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

2. Calculating ''Net Reduction''

Once the RVU changes attributable to misvalued codes are identified, estimated net reductions would be calculated summing the decreases and offsetting any applicable increases in valuation within the changes defined as misvalued, as described above. Because the provision only explicitly addresses reductions, and we recognize many stakeholders will want to maximize the overall magnitude of the measured reductions in order to prevent an overall reduction to the PFS conversion factor, we considered the possibility of ignoring the applicable increases in valuation in the calculation of net reduction. However, we believe that the requirement to calculate ''net'' reductions implies that we are to take into consideration both decreases and increases. Additionally, we believe this approach may be the only practical one due to the presence of new and deleted codes on an annual basis.

For example, a service that is described by a single code in a given year, like intensity-modulated radiation therapy (IMRT) treatment delivery, could be addressed as a misvalued service in a subsequent year through a coding revision that splits the service into two codes, ''simple'' and ''complex.'' If we counted only the reductions in RVUs, we would count only the change in value between the single code and the new code that describes the ''simple'' treatment delivery code. In this scenario, the change in value from the single code to the new ''complex'' treatment delivery code would be ignored, so that even if there were an increase in the payment for IMRT treatment delivery service(s) overall, the mere change in coding would contribute inappropriately to a ''net reduction in expenditures.'' Therefore, we are proposing to net the increases and decreases in values for services, including those for which there are coding revisions, in calculating the estimated net reduction in expenditures as a result of adjustments to RVUs for misvalued codes.

3. Measuring the Adjustments

The most straightforward method to estimating the net reduction in expenditures due to adjustments to RVUs for misvalued codes is to compare the total RVUs of the relevant set of codes (by volume) in the current year to the update year, and divide that by the total RVUs for all codes (by volume) for the current year. This approach is intuitive and relatively easy to replicate.

However, this method is imprecise for several reasons. First, and most significantly, the code-level PE RVUs in the update year include either increases due to the redistribution of RVUs from other services or reductions due to increases in PE for other services. Second, because relativity for work RVUs is maintained through annual adjustments to the CF, the precise value of a work RVU in any given year is adjusted based on the total number of work RVUs in that year. Finally, relativity for the MP RVUs is maintained by both redistribution of MP RVUs and adjustments to the CF, when necessary (under our proposed methodology this is true annually; based on our established methodology the redistribution of the MP RVUs only takes place once every 5 years and the CF is adjusted otherwise). Therefore, to make a more precise assessment of the net reduction in expenditures that are the result of adjustments to the RVUs for misvalued codes, we would need to compare, for the included codes, the update year's total work RVUs (by volume), direct PE RVUs (by volume), indirect PE RVUs (by volume), and MP RVUs (by volume) to the same RVUs in the current year, prior to the application of any scaling factors or adjustments. This would make for a direct comparison between years.

However, this approach would mean that the calculation of the net reduction in expenditures would occur within various steps of the PFS ratesetting methodology. While we believe that this approach would be transparent and external stakeholders could replicate this method, it may be difficult and time-consuming for stakeholders to do so. We also noted that when we modeled the interaction of the phase-in legislation and the calculation of the target using this approach during the development of this proposal, there were methodological challenges in making these calculations. When we simulated the two approaches using

information from prior PFS years, we found that both approaches generally resulted in similar estimated net reductions. After considering these options, we are proposing to use the approach of comparing the total RVUs (by volume) for the relevant set of codes in the current year to the update year, and divide that result by the total RVUs (by volume) for the current year. We seek comment on whether comparing the update year's work RVUs, direct PE RVUs, indirect PE RVUs, and MP RVUs for the relevant set of codes (by volume) prior to the application of any scaling factors or adjustments to those of the current year would be a preferable methodology for determining the estimated net reduction.

4. Estimating the Target for CY 2016

CY 2016 represents a transition year in our new process of proposing values for new, revised and misvalued codes in the proposed rule, rather than establishing them as interim final in the final rule with comment period. For CY 2016, we will propose values for which we had the RUC's recommendations by our deadline of February 10th, and will establish interim final values for any codes received after the February 10th deadline but in time for us to value for the final rule. For CY 2016, there will still be a significant number of codes valued not in the proposed rule but in the final rule with comment period. In future years (with the exception of entirely new services), all codes, even those for which we do not receive RUC recommendations in time for the proposed rule, will be in the proposed rule for the subsequent year and not in the final rule with comment period. Therefore, for CY 2016, unlike for the targets for CY 2017 and CY 2018, because we will not be able to calculate a realistic estimate of the target amount at the time the proposed rule is published, we will not incorporate the impact of the target into the calculation of the proposed PFS payment rates. However, because we would apply any required budget neutrality adjustment related to this provision to the conversion factor, the proposed RVUs for individual services in this proposed rule would be the same, regardless of the estimate of the target. We also refer readers to the regulatory impact analysis section of this proposed rule for an interim estimate of the estimated net reduction in expenditures relative to the 1 percent target for CY 2016, based solely on the proposed changes in this rule.

G. Phase-in of Significant RVU Reductions

Section 1848(c)(7) of the Act, as added by section 220(e) of the PAMA, also specifies that for services that are not new or revised codes, if the total RVUs for a service for a year would otherwise be decreased by an estimated 20 percent or more as compared to the total RVUs for the previous year, the applicable adjustments in work, PE, and MP RVUs shall be phased-in over a 2-year period. Although section 220(e) of the PAMA required the phase-in to begin for 2017, section 202 of the ABLE Act amended section 1848(c)(7) of the Act to require that the phase-in begin for CY 2016.

In this section, we are proposing a methodology to implement this statutory provision. In developing this proposed methodology, we have identified several aspects of our approach for which we are specifically seeking comment, given the challenges inherent in implementing this provision in a manner consistent with the broader statutory construct of the PFS. We have organized this discussion by identifying and explaining these aspects in particular but we are seeking comment on all aspects of our proposal.

1. Identifying Services that are Not New or Revised Codes

As described in this proposed rule, the statute specifies that services described by new or revised codes are not subject to the phase-in of RVUs. We believe this exclusion recognizes the reality that there is no practical way to phase-in over 2 years changes to RVUs that occur as a result of a coding change for a particular service because there is no relevant reference code or value on which to base the transition. To determine which services are described by new or revised codes for purposes of the phase-in provision, we are proposing to apply the phase-in to all services that are described by the same, unrevised code in both the current and update year, and to exclude codes that describe different services in the current and update year. This approach would exclude services described by new codes or existing codes for which the descriptors were altered substantially for the update year to change the services that are reported using the code. We would also exclude as new and revised codes those codes that describe a different set of services in the update year when compared to the current year by virtue of changes in other, related codes, or codes that are part of a family with significant coding revisions. For example, significant coding revisions within a family of codes can change the relationships among codes to the extent that it changes the way that all services in the group are reported, even if some individual codes retain the same number or, in some cases, the same descriptor. Excluding codes from the phase-in when there are significant revisions to the code family would also help to maintain the appropriate rank order among codes in the family, avoiding years for which RVU changes for some codes in a family are in transition while others were fully implemented. This proposed application of the phase-in would also be consistent with previous RVU transitions, especially for PE RVUs, for which we only applied transition values to those codes that described the same service in both the current and the update years. We would also exclude from the phase-in as new and revised codes those codes with changes to the global period, since the code in the current year would not describe the same units of service as the code in the update year.

2. Estimating the 20 Percent Threshold

Because the phase-in of RVUs falls within the budget neutrality requirements specified in section 1848(c)(2)(B)(ii)(II) of the Act, we are proposing to estimate total RVUs for a service prior to the budget-neutrality redistributions that result from implementing phase-in values. We recognize that the result of this approach could mean that some codes may not qualify for the phase-in despite a reduction in RVUs that is ultimately slightly greater than 20 percent due to budget neutrality adjustments that are made after identifying the codes that meet the threshold in order to reflect the phase-in values for other codes. We believe the only alternative to this approach is not practicable, since it would be circular, resulting in cyclical iteration.

3. RVUs in the First Year of the Phase-In

Section 1848(c)(7) of the Act states that the applicable adjustments in work, PE, and MP RVUs shall be phased-in over a 2-year period when the RVU reduction for a code is estimated to be equal to or greater than 20 percent. We believe that there are two reasonable ways to determine the portion of the reduction to be phase-in for the first year. Most recent RVU transitions have distributed the values evenly across several years. For example, for a 2-year transition we would estimate the fully implemented value and set a rate

approximately 50 percent between the value for the current year and the value for the update year. We believe that this is the most intuitive approach to the phase-in and is likely the expectation for many stakeholders. However, we believe that the 50 percent phase-in in the first year has a significant drawback. For instance, since the statute establishes a 20 percent threshold as the trigger for phasing in the change in RVUs, under the 50 percent phase-in approach, a service that is estimated to be reduced by a total of 19 percent for an update year would be reduced by a full 19 percent in that update year, while a service that is estimated to be reduced by 20 percent in an update year would only be reduced 10 percent in that update year.

The logical alternative approach is to consider a 19 percent reduction as the maximum 1-year reduction for any service not described by a new or revised code. This approach would be to reduce the service by the maximum allowed amount (that is, 19 percent) in the first year, and then phase in the remainder of the reduction in the second year. Under this approach, the code that is reduced by 19 percent in a year and the code that would otherwise have been reduced by 20 percent would both be reduced by 19 percent in the first year, and the latter code would see an additional 1 percent reduction in the second year of the phase-in. For most services, this would likely mean that the majority of the reduction would take place in the first year of the phase-in. However, for services with the most drastic reductions (greater than 40 percent), the majority of the reduction would take place in the second year of the phase-in.

After considering both of these options, we are proposing to consider the 19 percent reduction as the maximum 1-year reduction and to phase-in any remaining reduction greater than 19 percent in the second year of the phase-in. We believe that this approach is more equitable for codes with significant reductions but that are less than 20 percent. We are seeking comment on this proposal.

4. Applicable Adjustments to RVUs

The phase-in provision instructs that the applicable adjustments in work, PE, and MP RVUs be phased-in over 2 years for any service that would otherwise be decreased by an estimated amount equal to or greater than 20 percent as compared to the total RVUs for the previous year. However, for several thousand services, we develop separate RVUs for facility and nonfacility sites of service. For nearly one thousand other services, we develop separate RVUs for the professional and technical components of the service and sum those RVUs to allow for global billing. Therefore, for individual practitioners furnishing particular services to Medicare beneficiaries, the relevant changes in RVUs for a particular code are based on the total RVUs for a code for a particular setting (facility/nonfacility) or for a particular component (professional/technical). We believe the most straightforward and fair approach to addressing both the site of service differential and the codes with professional and technical components is to consider the RVUs for the different sites of service and components independently for purposes of identifying when and how the phase-in applies. We are proposing, therefore, to estimate whether a particular code meets the 20 percent threshold for change in total RVUs by taking into account the total RVUs that apply to a particular setting or to a particular component. This would mean that if the change in total facility RVUs for a code met the threshold, then that change would be phased-in over 2 years, even if the change for the total nonfacility RVUs for the same code would not be phased-in over 2 years. Similarly, if the change in the total RVUs for the technical component of a service meets the 20 percent threshold, then that change would be phased-in over 2 years, even if the change for the professional component did not meet the threshold. (Because the global is the sum of the professional and technical components, the portion of the global attributable to the technical component would then be phased-in, while the portion attributable to the professional component would not be.)

However, we note that we create the site of service differential exclusively by developing independent PE RVUs for each service in the nonfacility and facility settings. That is, for these codes, we use the same work RVUs and MP RVUs in both settings and vary only the PE RVUs to implement the difference in resources depending on the setting. Similarly, we use the work RVUs assigned to the professional component codes as the work RVUs for the service when billed globally. Like the codes with the site of service differential, the PE RVUs for each component are developed independently. The resulting PE RVUs are then summed for use as the PE RVUs for the code, billed globally. Since variation of PE RVUs is the only constant across all individual codes, codes with site of service differentials, and codes with professional and technical components, we are proposing to apply all adjustments for the phase-in to the PE RVUs.

We considered alternatives to this approach. For example, for codes with a site of service differential, we considered applying a phase-in for codes in both settings (and all components) whenever the total RVUs in either setting reached the 20 percent threshold. However, there are cases where the total RVUs for a code in one setting (or one component) may reach the 20 percent reduction threshold, while the total RVUs for the other setting (or other component) are increasing. In those cases, applying phase-in values for work or MP RVUs would mean applying an additional increase in total RVUs for particular services. We also considered basing the phase-in of the RVUs for the component codes billed globally and for the codes with site of service differentials developing an overall, blended set of overall PE RVUs using a weighted average of site of service volume in the Medicare claims data. We would then compare the global or blended value in the prior year versus the global or blended value in the current year and apply the phase-in to the value for the current year before re-allocating the new value to the respective RVUs in each setting. We did not pursue this approach for several reasons. First, the resulting phase-in amounts would not relate logically to the values paid to any individual practitioner, except those who bill the PC/TC codes globally. Second, the approach would be so administratively complicated that it would likely be difficult to replicate or predict.

Therefore, we have concluded that applying the adjustments to the PE RVUs for individual codes in order to effect the appropriate phase-in amount is the most straightforward and fair approach to mitigate the impact of significant reductions of total RVUs for services furnished by individual practitioners. The list of codes subject to the phase-in, and the RVUs that result from this proposed methodology, is available on the CMS Web site under downloads for the CY 2016 PFS proposed rule with comment period at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

H. Changes for Computed Tomography (CT) Under the Protecting Access to Medicare Act of 2014 (PAMA) (CY 2016 only)

1. Section 218(a) of the Protecting Access to Medicare Act of 2014 (PAMA)

Section 218(a) of PAMA is entitled ''Quality Incentives To Promote Patient Safety and Public Health in Computed Tomography Diagnostic Imaging.'' It amends the statute by reducing payment for the technical component (TC) (and the TC of the global fee) of the PFS service and the hospital outpatient prospective payment system (OPPS) payment (5 percent in 2016 and 15 percent in 2017 and subsequent years) for computed tomography (CT) services identified by CPT codes 70450–70498, 71250–71275, 72125–72133, 72191–72194, 73200–73206, 73700–73706, 74150–74178, 74261–74263, and 75571–75574 furnished using equipment that does not meet each of the attributes of the National Electrical Manufacturers Association (NEMA) Standard XR–29–2013, entitled ''Standard Attributes on CT Equipment Related to Dose Optimization and Management.''

The statutory provision requires that information be provided and attested to by a supplier and a hospital outpatient department that indicates whether an applicable CT service was furnished that was not consistent with the NEMA CT equipment standard, and that such information may be included on a claim and may be a modifier. The statutory provision also provides that such information shall be verified, as appropriate, as part of the periodic accreditation of suppliers under section 1834(e) of the Act and hospitals under section 1865(a) of the Act. Any reduced expenditures resulting from this provision are not budget neutral. To implement this provision, we will create modifier ''CT'' (Computed tomography services furnished using equipment that does not meet each of the attributes of the National Electrical Manufacturers Association (NEMA) XR–29–2013 standard). Beginning in 2016, claims for CT scans described by above-listed CPT codes (and any successor codes) that are furnished on non-NEMA Standard XR–29–2013-compliant CT scans must include modifier ''CT'' and that modifier will result in the applicable payment reduction for the service.

I. Valuation of Specific Codes

1. Background

Establishing valuations for newly created and revised CPT codes is a routine part of maintaining the PFS. Since inception of the PFS, it has also been a priority to revalue services regularly to assure that the payment rates reflect the changing trends in the practice of medicine and current prices for inputs used in the PE calculations. Initially, this was accomplished primarily through the five-year review process, which resulted in revised work RVUs for CY 1997, CY 2002, CY 2007, and CY 2012, and revised PE RVUs in CY 2001, CY 2006, and CY 2011. Under the five-year review process, revisions in RVUs were proposed in a proposed rule and finalized in a final rule. In addition to the five-year reviews, in each year beginning with CY 2009, CMS and the RUC have identified a number of potentially misvalued codes using various identification screens, as discussed in section II.C. of this proposed rule. Each year, when we received RUC recommendations, our process has been to establish interim final RVUs for the potentially misvalued codes, new codes, and any other codes for which there were coding changes in the final rule with comment period for a year. Then, during the 60-day period following the publication of the final rule with comment period, we accept public comment about those valuations. For services furnished during the calendar year following the publication of interim final rates, we pay for services based upon the interim final values established in the final rule with comment period. In the final rule with comment period for the subsequent year, we consider and respond to public comments received on the interim final values, and make any appropriate adjustments to values based on those comments. We then typically finalize the values for the codes.

2. Process for Valuing New, Revised, and Potentially Misvalued Codes

In the CY 2015 PFS final rule with comment period, we finalized a new process for establishing values for new, revised and potentially misvalued codes. Under the new process, we include proposed values for these services in the proposed rule, rather than establishing them as interim final in the final rule with comment period. CY 2016 represents a transition year for this new process. For CY 2016, we are proposing new values in the proposed rule for the codes for which we received complete RUC recommendations by February 10, 2015. For recommendations regarding any new or revised codes received after the February 10, 2015 deadline, including updated recommendations for codes included in this proposed rule, we will establish interim final values in the final rule with comment period, consistent with previous practice. We note that we will consider all comments received in response to proposed values for codes in this rule, including alternative recommendations to those used in developing the proposed rule. In other words, if the RUC or other interested stakeholders submit public comments that include new recommendations for codes for which we propose values as part of this proposed rule, we would consider those recommendations in developing final values for the codes in the CY 2016 PFS final rule with comment.

Beginning with valuations for CY 2017, the new process will be applicable to all codes. That is, beginning with rulemaking for CY 2017, we will propose values for the vast majority of new, revised, and potentially misvalued codes and consider public comments before establishing final values for the codes; use G-codes as necessary to facilitate continued payment for certain services for which we do not receive recommendations in time to propose values; and adopt interim final values in the case of wholly new services for which there are no predecessor codes or values and for which we do not receive recommendations in time to propose values.

For CY 2016, we received RUC recommendations prior to February 10, 2015 for many new, revised and potentially misvalued codes and have included proposed values for these codes in this proposed rule. However, the RUC recommendations included CPT tracking codes instead of the actual 2016 CPT codes that will first be made available to the public subsequent to the publication of this proposed rule. Because CPT procedure codes are 5 alpha-numeric characters but CPT tracking codes typically have 6 or 7 alpha-numeric characters and CMS systems only utilize 5-character HCPCS codes, we have developed and used alternative 5-character placeholder codes for this proposed rule. For the convenience of stakeholders and commenters with access to the CPT tracking codes, we have displayed a crosswalk from the 5-character placeholder codes to the CPT tracking codes on our Web site under downloads for the CY 2016 PFS proposed rule at *http://www.cms.gov/PhysicianFeeSched/downloads/*. The final CPT codes will be included in the CY 2016 final rule with comment period.

3. Methodology for Establishing Work RVUs

We conducted a review of each code identified in this section and reviewed the current work RVU (if any), RUC-

recommended work RVUs, intensity, time to furnish the preservice, intraservice, and postservice activities, as well as other components of the service that contribute to the value. Our review of recommended work RVUs and time generally includes, but is not limited to, a review of information provided by the RUC, HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the Medicare PFS, consultation with other physicians and health care professionals within CMS and the federal government, as well as Medicare claims data. We also assessed the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. In the CY 2011 PFS final rule with comment period (75 FR 73328 through 73329), we discussed a variety of methodologies and approaches used to develop work RVUs, including survey data, building blocks, crosswalk to key reference or similar codes, and magnitude estimation. More information on these issues is available in that rule. When referring to a survey, unless otherwise noted, we mean the surveys conducted by specialty societies as part of the formal RUC process. The building block methodology is used to construct, or deconstruct, the work RVU for a CPT code based on component pieces of the code. Components used in the building block approach may include preservice, intraservice, or postservice time and post-procedure visits. When referring to a bundled CPT code, the building block components could be the CPT codes that make up the bundled code and the inputs associated with those codes. Magnitude estimation refers to a methodology for valuing physician work that determines the appropriate work RVU for a service by gauging the total amount of physician work for that service relative to the physician work for similar service across the PFS without explicitly valuing the components of that work.

The PFS incorporates cross-specialty and cross-organ system relativity. Valuing services requires an assessment of relative value and takes into account the clinical intensity and time required to furnish a service. In selecting which methodological approach will best determine the appropriate value for a service, we consider the current and recommended work and time values, as well as the intensity of the service, all relative to other services.

Several years ago, to aid in the development of preservice time recommendations for new and revised CPT codes, the RUC created standardized preservice time packages. The packages include preservice evaluation time, preservice positioning time, and preservice scrub, dress and wait time. Currently there are six preservice time packages for services typically furnished in the facility setting, reflecting the different combinations of straightforward or difficult procedure, straightforward or difficult patient, and without or with sedation/anesthesia. Currently, there are three preservice time packages for services typically furnished in the nonfacility setting, reflecting procedures without and with sedation/anesthesia care.

We have developed several standard building block methodologies to value services appropriately when they have common billing patterns. In cases where a service is typically furnished to a beneficiary on the same day as an evaluation and management (E/M) service, we believe that there is overlap between the two services in some of the activities furnished during the preservice evaluation and postservice time. We believe that at least one-third of the work time in both the preservice evaluation and postservice period is duplicative of work furnished during the E/M visit. Accordingly, in cases where we believe that the RUC has not adequately accounted for the overlapping activities in the recommended work RVU and/or times, we adjust the work RVU and/or times to account for the overlap. The work RVU for a service is the product of the time involved in furnishing the service times the intensity of the work. Preservice evaluation time and postservice time both have a long-established intensity of work per unit of time (IWPUT) of 0.0224, which means that 1 minute of preservice evaluation or postservice time equates to 0.0224 of a work RVU. Therefore, in many cases when we remove 2 minutes of preservice time and 2 minutes of postservice time from a procedure to account for the overlap with the same day E/M service, we also remove a work RVU of 0.09 (4 minutes $\times$ 0.0224 IWPUT) if we do not believe the overlap in time has already been accounted for in the work RVU. The RUC has recognized this valuation policy and, in many cases, addresses the overlap in time and work when a service is typically provided on the same day as an E/M service.

Table 11 contains a list of proposed work RVUs for all codes with RUC recommendations received by February 10, 2015. Proposed work RVUs that vary from those recommended by the RUC or for which we do not have RUC recommendations are addressed in the portions of this section that are dedicated to particular codes.

The work RVUs and other payment information for all CY 2016 payable codes are available in Addendum B, including codes for which we have proposed changes in this proposed rule subject to public comment. Addendum B is available on the CMS Web site under downloads for the CY 2016 PFS proposed rule at *http://www.cms.gov/PhysicianFeeSched/downloads/*. The proposed time values for all CY 2016 codes are listed in a file called ''CY 2016 PFS Work Time,'' available on the CMS Web site under downloads for the CY 2016 PFS proposed rule at *http://www.cms.gov/PhysicianFeeSched/downloads/*.

4. Methodology for Establishing the Direct PE Inputs Used to Develop PE RVUs

a. Background

On an annual basis, the RUC provides CMS with recommendations regarding PE inputs for new, revised, and potentially misvalued codes. We review the RUC-recommended direct PE inputs on a code-by-code basis. Like our review of recommended work RVUs, our review of recommended direct PE inputs generally includes, but is not limited to, a review of information provided by the RUC, HCPAC, and other public commenters, medical literature, and comparative databases, as well as a comparison with other codes within the Medicare PFS, consultation with other physicians and health care professionals within CMS and the federal government, as well as Medicare claims data. We also assess the methodology and data used to develop the recommendations submitted to us by the RUC and other public commenters and the rationale for the recommendations. When we determine that the RUC recommendations appropriately estimate the direct PE inputs (clinical labor, disposable supplies, and medical equipment) required for the typical service, consistent with the principles of relativity, and reflect our payment policies, we use those direct PE inputs to value a service. If not, we refine the recommended PE inputs to better reflect our estimate of the PE resources required for the service. We also confirm whether CPT codes should have facility and/or nonfacility direct PE inputs and refine the inputs accordingly.

Our review and refinement of RUC-recommended direct PE input includes many refinements that are common

across codes as well as refinements that are specific to particular services. Table 13 details our refinements of the RUC's direct PE recommendations at the code-specific level. In this proposed rule, we address several refinements that are common across codes, and refinements to particular codes are addressed in the portions of this section that are dedicated to particular codes. We note that for each refinement, we indicate the impact on direct costs for that service. We point out that, on average, in any case where the impact on the direct cost for a particular refinement is $0.32 or less, the refinement has no impact on the final PE RVUs. This calculation considers both the impact on the direct portion of the PE RVU as well as the impact on the indirect allocator for the average service. We also note that nearly half of the refinements listed in Table 13 result in changes under the $0.32 threshold and are unlikely to result in a change to the final RVUs.

We also note that the proposed direct PE inputs for CY 2016 are displayed in the proposed CY 2016 direct PE input database, available on the CMS Web site under the downloads for the CY 2016 proposed rule at *www.cms.gov/PhysicianFeeSched/*. The inputs displayed there have also been used in developing the CY 2016 PE RVUs as displayed in Addendum B of this proposed rule.

b. Common Refinements

(1) Changes in Work Time

Some direct PE inputs are directly affected by revisions in work time. Specifically, changes in the intraservice portions of the work time and changes in the number or level of postoperative visits associated with the global periods result in corresponding changes to direct PE inputs. Although the direct PE input recommendations generally correspond to the work time values associated with services, we believe that in some cases inadvertent discrepancies between work time values and direct PE inputs should be refined in the establishment of proposed direct PE inputs. In other cases, CMS refinement of recommended proposed work times prompts necessary adjustments in the direct PE inputs.

(2) Equipment Time

Prior to CY 2010, the RUC did not generally provide CMS with recommendations regarding equipment time inputs. In CY 2010, in the interest of ensuring the greatest possible degree of accuracy in allocating equipment minutes, we requested that the RUC provide equipment times along with the other direct PE recommendations, and we provided the RUC with general guidelines regarding appropriate equipment time inputs. We continue to appreciate the RUC's willingness to provide us with these additional inputs as part of its PE recommendations.

In general, the equipment time inputs correspond to the service period portion of the clinical labor times. We have clarified this principle, indicating that we consider equipment time as the time within the intraservice period when a clinician is using the piece of equipment plus any additional time that the piece of equipment is not available for use for another patient due to its use during the designated procedure. For those services for which we allocate cleaning time to portable equipment items, because the portable equipment does not need to be cleaned in the room where the service is furnished, we do not include that cleaning time for the remaining equipment items as those items and the room are both available for use for other patients during that time. In addition, when a piece of equipment is typically used during follow-up post-operative visits included in the global period for a service, the equipment time would also reflect that use.

We believe that certain highly technical pieces of equipment and equipment rooms are less likely to be used during all of the pre-service or post-service tasks performed by clinical labor staff on the day of the procedure (the clinical labor service period) and are typically available for other patients even when one member of clinical staff may be occupied with a pre-service or post-service task related to the procedure. We also note that we believe these same assumptions would apply to inexpensive equipment items that are used in conjunction with and located in a room with non-portable highly technical equipment items. Some stakeholders have objected to this rationale for our refinement of equipment minutes on this basis. We refer readers to our extensive discussion in response to those objections in the CY 2012 PFS final rule with comment period (76 FR 73182) and the CY 2015 PFS final rule with comment period (79 FR 67639).

(3) Standard Tasks and Minutes for Clinical Labor Tasks

In general, the preservice, intraservice period, and postservice clinical labor minutes associated with clinical labor inputs in the direct PE input database reflect the sum of particular tasks described in the information that accompanies the RUC-recommended direct PE inputs, commonly called the ''PE worksheets.'' For most of these described tasks, there are a standardized number of minutes, depending on the type of procedure, its typical setting, its global period, and the other procedures with which it is typically reported. The RUC sometimes recommends a number of minutes either greater than or less than the time typically allotted for certain tasks. In those cases, CMS staff reviews the deviations from the standards and any rationale provided for the deviations. When we do not accept the RUC-recommended exceptions, we refine the proposed direct PE inputs to match the standard times for those tasks. In addition, in cases when a service is typically billed with an E/M service, we remove the pre-service clinical labor tasks to avoid duplicative inputs and to reflect the resource costs of furnishing the typical service.

In general, clinical labor tasks fall into one of the categories on the PE worksheets. In cases where tasks cannot be attributed to an existing category, the tasks are labeled ''other clinical activity.'' We believe that continual addition of new and distinct clinical labor tasks each time a code is reviewed under the misvalued code initiative is likely to degrade relativity between newly reviewed services and those with already existing inputs. To mitigate the potential negative impact of these additions, our staff reviews these tasks to determine whether they are fully distinct from existing clinical labor tasks, typically included for other clinically similar services under the PFS, and thoroughly explained in the recommendation. For those tasks that do not meet these criteria, we do not accept these newly recommended clinical labor tasks; two examples of such tasks encountered during our review of the recommendations include ''Enter data into laboratory information system, multiparameter analyses and field data entry, complete quality assurance documentation'' and ''Consult with pathologist regarding representation needed, block selection and appropriate technique.''

In conducting our review of the RUC recommendations for CY 2016, we noted that several of the recommended times for clinical labor tasks associated with pathology services differed across codes, both within the CY 2016 recommendations and in comparison to codes currently in the direct PE database. We refer readers to Table 6 in section II.A.3. of this proposed rule where we outline our proposed standard times for clinical labor tasks associated with pathology services.

(4) Recommended Items That Are Not Direct PE Inputs

In some cases, the PE worksheets included with the RUC recommendations include items that are not clinical labor, disposable supplies, or medical equipment that cannot be allocated to individual services or patients. Two examples of such items are ''emergency service container/safety kit'' and ''service contract.'' We have addressed these kinds of recommendations in previous rulemaking (78 FR 74242), and we do not use these recommended items as direct PE inputs in the calculation of PE RVUs.

(5) Moderate Sedation Inputs

In the CY 2012 PFS final rule (76 FR 73043 through 73049), we finalized a standard package of direct PE inputs for services where moderate sedation is considered inherent in the procedure. In the CY 2015 final rule with comment period, we finalized a refinement to the standard package to include a stretcher for the same length of time as the other equipment items in the standard package. We are proposing to refine the RUC's direct PE recommendations to conform to these policies. This includes the removal of a power table where it was included during the intraservice period, as the stretcher takes the place of the table. These refinements are reflected in the final CY 2016 PFS direct PE input database and detailed in Table 13.

(6) New Supply and Equipment Items

The RUC generally recommends the use of supply and equipment items that already exist in the direct PE input database for new, revised, and potentially misvalued codes. Some recommendations include supply or equipment items that are not currently in the direct PE input database. In these cases, the RUC has historically recommended a new item be created and has facilitated our pricing of that item by working with the specialty societies to provide copies of sales invoices to us. We received invoices for several new supply and equipment items for CY 2016. We have accepted the majority of these items and added them to the direct PE input database. Tables 9 and 10 detail the invoices received for new and existing items in the direct PE database. As discussed in section II.A. of this proposed rule, we encourage stakeholders to review the prices associated with these new and existing items to determine whether these prices appear to be accurate. Where prices appear inaccurate, we encourage stakeholders to provide invoices or other information to improve the accuracy of pricing for these items in the direct PE database. We remind stakeholders that due to the relativity inherent in the development of RVUs, reductions in existing prices for any items in the direct PE database increase the pool of direct PE RVUs available to all other PFS services. Tables 9 and 10 also include the number of invoices received as well as the number of nonfacility allowed services for procedures that use these equipment items. We provide the nonfacility allowed services so that stakeholders will note the impact the particular price might have on PE relativity, as well as to identify items that are used frequently, since we believe that stakeholders are more likely to have better pricing information for items used more frequently. We are concerned that a single invoice may not be reflective of typical costs and encourage stakeholders to provide additional invoices so that we might identify and use accurate prices in the development of PE RVUs.

In some cases, we do not accept the price listed on the invoice that accompanies the recommendation because we identify publicly available alternative prices or information that suggests a different price is more accurate. In these cases, we include this in the discussion of these codes. In other cases, we cannot adequately price a newly recommended item due to inadequate information. Sometimes, no supporting information regarding the price of the item has been included in the recommendation. In other cases, the supporting information does not demonstrate that the item has been purchased at the listed price (for example, vendor price quotes instead of paid invoices). In cases where the information provided on the item allows us to identify clinically appropriate proxy items, we might use existing items as proxies for the newly recommended items. In other cases, we have included the item in the direct PE input database without any associated price. Although including the item without an associated price means that the item does not contribute to the calculation of the proposed PE RVU for particular services, it facilitates our ability to incorporate a price once we obtain information and are able to do so.

(7) Service Period Clinical Labor Time in the Facility Setting

Several of the PE worksheets included in the RUC recommendations contained clinical labor minutes assigned to the service period in the facility setting. Our proposed inputs do not include these minutes because the cost of clinical labor during the service period for a procedure in the facility setting is not considered a resource cost to the practitioner since Medicare makes separate payment to the facility for these costs.

(8) Duplicative Inputs

Several of the PE worksheets included in the RUC recommendations contained time for the equipment item ''xenon light source'' (EQ167). Because there appear to be two special light sources already present (the fiberoptic headlight and the endoscope itself) in the services for which this equipment item was recommended, we are not proposing to include the time for this equipment item from these services, and are seeking comment on whether there is a rationale for including this additional light source as a direct PE input for these procedures.

5. Methodology for Establishing Malpractice RVUs

As discussed in section II.B. of this proposed rule, our malpractice methodology uses a crosswalk to establish risk factors for new services until utilization data becomes available. Table 15 lists the CY 2016 HCPCS codes and their respective source codes used to set the proposed CY 2016 MP RVUs. The MP RVUs for these services are reflected in Addendum B on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

TABLE 9—INVOICES RECEIVED FOR NEW DIRECT PE INPUTS

CPT/HCPCS Codes	Item name	CMS Code	Average price	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
31626	Gold Fiducial Marker	SB053	135	1	6

TABLE 9—INVOICES RECEIVED FOR NEW DIRECT PE INPUTS—Continued

CPT/HCPCS Codes	Item name	CMS Code	Average price	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
3160A, 3160B, 3160C	endoscope, ultrasound radial probe	ES045	0	0	212
3725A	IVUS catheter	SD304	1025	3	795
3725A	IVUS Catheter Sterile Cover	SD305	120	3	795
3725A, 3725B	IVUS system	ES047	134,025	3	2,948
44385, 44386, 45330, 45331, 45332, 45333, 45334, 45335, 45338, 45340, 45346.	Video Sigmoidoscope	ES043	215,00	1	18,058
44401, 45346, 45388	catheter, RF ablation, endoscopic	SC103	1,780	1	3,543
44401, 45346	radiofrequency generator, endoscopy	EQ369	108,291.67	1	174
45350, 45398	hemorrhoidal banding system	SA115	223.50	4	3
5039D, 5039M	Nephroureteral Catheter	SD306	117.90	1	70
657XG	suture, nylon, 10–0	SC104	12.17	2	
657XG	intrastromal corneal ring	SA120	1,145	7	
657XG	patient/laser interface (single—use, disposable).	SD307	172.50	1	
657XG	femtosecond laser	ES048	293,000	2	
657XG	incision programming software	ES049	10,012.50	1	
692XX	earwash bottle disposable tips	SD308	1.72	1	
77385, 77386, 77402, 77407, 77412.	Power Conditioner	ER102	26,400	2	2,198,441
7778A, 7778B, 7778C, 7778D, 7778E.	brachytherapy treatment vault	ES052	175,000	1	24,936
88104, 88106, 88108	fixative spray for cytospin	SL503	1.53	1	62,552
88108	Shannon cyto funnel, cytospin	SD298	2.27	1	48,740
88108	slide, microscope coated cytospin (single circle).	SL504	0.39	1	48,740
88182	Protease	SL506	0.43	1	568
88346, 8835X	Immunofluorescent mounting media	SD309	3.50	1	114,211
88346, 8835X	Zeus medium	SL518	0.85	2	114,211
88346, 8835X	Hydrophobic PAP Pen	SK120	1.76 (100 uses)	1	114,211
88360, 88361	Antibody Estrogen Receptor monoclonal	SL493	13.89	3	116,718

TABLE 10—INVOICES RECEIVED FOR EXISTING DIRECT PE INPUTS

CPT/HCPCS Codes	Item name	CMS Code	Current price	Updated price	Percent change	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
31300, 31320, 31360, 31365, 31367, 31368, 31370, 31375, 31380, 31382, 31390, 31395, 31628, 31632, 31750, 31755, 31800, 41120, 41130, 41135, 41140, 41145, 41150, 41153, 41155, 41500, 41510, 41512, 41530, 42120, 42842, 42844, 42845, 42870, 42890, 42892, 42894, 42950, 42953, 42955, 43215, 43247, 58555, 58558, 58562, 58563, 60605, 92511, 92612.	endosheath	SD070	9.50	17.25	82	1	65,318
41530, 43228, 43229, 43270, 64633, 64634, 64635, 64636.	radiofrequency generator (NEURO).	EQ214	32,900	10,000	−70	1	265,270
88341, 88342, 88343, 88344, 88360, 88361.	Benchmark ULTRA automated slide preparation system.	EP112	134,000	150,000	12	1	3,279,993
8835X	antibody IgA FITC	SL012	71.40	41.18	−42	1	93,520
95018	benzylpenicilloyl polylysine (eg, PrePen) 0.25ml uou.	SH103	72.45	83.00	15	1	60,683

TABLE 10—INVOICES RECEIVED FOR EXISTING DIRECT PE INPUTS—Continued

CPT/HCPCS Codes	Item name	CMS Code	Current price	Updated price	Percent change	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
95923	kit, electrode, iontophoresis.	SA014	11.99	4.01	−67	3	96,189

6. CY 2016 Valuation of Specific Codes

TABLE 11—CY 2016 PROPOSED WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
11750	Removal of nail	2.5	1.99	1.58	No.
20240	Biopsy of bone, open procedure	3.28	3.73	2.61	No.
27280	Arthrodesis, open, sacroiliac joint including obtaining bone graft	14.64	20	20	No.
3160A	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (eg, aspiration[s]/biopsy[ies]), one or two mediastinal and/or hilar lymph node stat.	NEW	5	4.71	No.
3160B	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with endobronchial ultrasound (EBUS) guided transtracheal and/or transbronchial sampling (eg, aspiration[s]/biopsy[ies]), 3 or more mediastinal and/or hilar lymph node stati.	NEW	5.5	5.21	No.
3160C	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transendoscopic endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) for peripheral lesion(s) (List separately in addition to.	NEW	1.7	1.4	No.
31622	Diagnostic examination of lung airways using an endoscope	2.78	2.78	2.78	No.
31625	Biopsy of lung airways using an endoscope	3.36	3.36	3.36	No.
31626	Insertion of radiation therapy markers into lung airways using an endoscope.	4.16	4.16	4.16	No.
31628	Biopsy of one lobe of lung using an endoscope	3.8	3.8	3.8	No.
31629	Needle biopsy of windpipe cartilage, airway, and/or lung using an endoscope.	4.09	4	4	No.
31632	Biopsy of lung using an endoscope	1.03	1.03	1.03	No.
31633	Needle biopsy of lung using an endoscope	1.32	1.32	1.32	No.
3347A	Transcatheter pulmonary valve implantation, percutaneous approach, including pre-stenting of the valve delivery site, when performed.	NEW	25	25	No.
37215	Transcatheter placement of intravascular stent(s), cervical carotid artery, percutaneous; with distal embolic protection.	19.68	18	18	No.
3725A	Intravascular ultrasound (noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation; initial non-coronary vessel (List separately in addition to code for primary procedure).	NEW	1.8	1.8	No.
3725B	Intravascular ultrasound (noncoronary vessel) during diagnostic evaluation and/or therapeutic intervention, including radiological supervision and interpretation; each additional noncoronary vessel (List separately in addition to code for primary procedure.	NEW	1.44	1.44	No.
38570	Removal of abdominal cavity lymph nodes using an endoscope	9.34	9.34	8.49	No.
38571	Removal of total lymph nodes of both sides of pelvis using an endoscope.	14.76	12	12	No.
38572	Removal of total lymph nodes of both sides of pelvis and abdominal lymph node biopsy using an endoscope.	16.94	15.6	15.6	No.
3940A	Mediastinoscopy; includes biopsy(ies) of mediastinal mass (eg, lymphoma), when performed.	NEW	5.44	5.44	No.
3940B	Mediastinoscopy; with lymph node biopsy(ies) (eg, lung cancer staging).	NEW	7.5	7.25	No.
43775	Stomach reduction procedure with partial removal of stomach using an endoscope.	C	21.4	20.38	No.
44380	Ileoscopy, through stoma; diagnostic, including collection of specimen(s) by brushing or washing, when performed.	1.05	0.97	0.9	No.
44381	Ileoscopy, through stoma; with transendoscopic balloon dilation	N/A	1.48	1.48	Yes
44382	Ileoscopy, through stoma; with biopsy, single or multiple	1.27	1.27	1.2	No.
44384	Ileoscopy, through stoma; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed).	N/A	3.11	2.88	No.

TABLE 11—CY 2016 PROPOSED WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
44385	Endoscopic evaluation of small intestinal pouch (eg, Kock pouch, ileal reservoir [S or J]); diagnostic, including collection of specimen(s) by brushing or washing, when performed.	1.82	1.3	1.23	No.
44386	Endoscopic evaluation of small intestinal pouch (eg, Kock pouch, ileal reservoir [S or J]); with biopsy, single or multiple.	2.12	1.6	1.53	No.
44388	Colonoscopy through stoma; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure).	2.82	2.82	2.75	No.
44389	Colonoscopy through stoma; with biopsy, single or multiple	3.13	3.12	3.05	No.
44390	Colonoscopy through stoma; with removal of foreign body	3.82	3.82	3.77	No.
44391	Colonoscopy through stoma; with control of bleeding, any method	4.31	4.22	4.22	No.
44392	Colonoscopy through stoma; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps or bipolar cautery.	3.81	3.63	3.63	No.
44394	Colonoscopy through stoma; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique.	4.42	4.13	4.13	No.
44401	Colonoscopy through stoma; with ablation of tumor(s), polyp(s), or other lesion (includes pre-and post-dilation and guide wire passage, when performed).	N/A	4.44	4.44	No.
44402	Colonoscopy through stoma; with endoscopic stent placement (including pre- and post-dilation and guidewire passage, when performed).	N/A	4.96	4.73	No.
44403	Colonoscopy through stoma; with endoscopic mucosal resection	N/A	5.81	5.53	No.
44404	Colonoscopy through stoma; with directed submucosal injection(s), any substance.	N/A	3.13	3.05	No.
44405	Colonoscopy through stoma; with transendoscopic balloon dilation	N/A	3.33	3.33	No.
44406	Colonoscopy through stoma; with endoscopic ultrasound examination, limited to the sigmoid, descending, transverse, or ascending colon and cecum and adjacent structures.	N/A	4.41	4.13	No.
44407	Colonoscopy through stoma; with transendoscopic ultrasound guided intramural or transmural fine needle aspiration/biopsy(s), includes endoscopic ultrasound examination limited to the sigmoid, descending, transverse, or ascending colon and cecum and adjace.	N/A	5.06	5.06	No.
44408	Colonoscopy through stoma; with decompression (for pathologic distention) (eg, volvulus, megacolon), including placement of decompression tube, when performed.	N/A	4.24	4.24	No.
45330	Sigmoidoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing when performed.	0.96	0.84	0.77	No.
45331	Sigmoidoscopy, flexible; with biopsy, single or multiple	1.15	1.14	1.07	No.
45332	Sigmoidoscopy, flexible; with removal of foreign body	1.79	1.85	1.79	No.
45333	Sigmoidoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps.	1.79	1.65	1.65	No.
45334	Sigmoidoscopy, flexible; with control of bleeding, any method	2.73	2.1	2.1	No.
45335	Sigmoidoscopy, flexible; with directed submucosal injection(s), any substance.	1.46	1.15	1.07	No.
45337	Sigmoidoscopy, flexible; with decompression (for pathologic distention) (eg, volvulus, megacolon), including placement of decompression tube, when performed.	2.36	2.2	2.2	No.
45338	Sigmoidoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique.	2.34	2.15	2.15	No.
45340	Sigmoidoscopy, flexible; with transendoscopic balloon dilation	1.89	1.35	1.35	No.
45341	Sigmoidoscopy, flexible; with endoscopic ultrasound examination	2.6	2.43	2.15	No.
45342	Sigmoidoscopy, flexible; with transendoscopic ultrasound guided intramural or transmural fine needle aspiration/biopsy(s).	4.05	3.08	3.08	No.
45346	Sigmoidoscopy, flexible; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed).	N/A	2.97	2.84	No.
45347	Sigmoidoscopy, flexible; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed).	N/A	2.98	2.75	No.
45349	Sigmoidoscopy, flexible; with endoscopic mucosal resection	N/A	3.83	3.55	No.
45350	Sigmoidoscopy, flexible;with banding (eg, hemorrhoids)	N/A	1.78	1.78	No.
45378	Colonoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed, (separate procedure).	3.69	3.36	3.29	No.
45379	Colonoscopy, flexible; with removal of foreign body	4.68	4.37	4.31	No.
45380	Colonoscopy, flexible, proximal to splenic flexure; with biopsy, single or multiple.	4.43	3.66	3.59	No.
45381	Colonoscopy, flexible; with directed submucosal injection(s), any substance.	4.19	3.67	3.59	No.
45382	Colonoscopy, flexible; with control of bleeding, any method	5.68	4.76	4.76	No.

TABLE 11—CY 2016 PROPOSED WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
45384	Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps or bipolar cautery.	4.69	4.17	4.17	No.
45385	Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique.	5.3	4.67	4.67	No.
45386	Colonoscopy, flexible; with transendoscopic balloon dilation	4.57	3.87	3.87	No.
45388	Colonoscopy, flexible; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed).	N/A	4.98	4.98	No.
45389	Colonoscopy, flexible; with endoscopic stent placement (includes pre- and post-dilation and guide wire passage, when performed).	N/A	5.5	5.27	No.
45390	Colonoscopy, flexible; with endoscopic mucosal resection	N/A	6.35	6.07	No.
45391	Colonoscopy, flexible; with endoscopic ultrasound examination limited to the rectum, sigmoid, descending, transverse, or ascending colon and cecum, and adjacent structures.	5.09	4.95	4.67	No.
45392	Colonoscopy, flexible; with transendoscopic ultrasound guided intramural or transmural fine needle aspiration/biopsy(s), includes endoscopic ultrasound examination limited to the rectum, sigmoid, descending, transverse, or ascending colon and cecum, and a.	6.54	5.6	5.6	No.
45393	Colonoscopy, flexible; with decompression (for pathologic distention) (eg, volvulus, megacolon), including placement of decompression tube, when performed.	N/A	4.78	4.78	No.
45398	Colonoscopy, flexible; with banding, (eg, hemorrhoids)	N/A	4.3	4.3	No.
46500	Injection of hemorrhoids	1.69	1.69	1.42	No.
46601	Anoscopy; diagnostic, with high-resolution magnification	N/A	1.6	1.6	No.
46607	Anoscopy; with high-resolution magnification (hra), with biopsy, single or multiple.	N/A	2.2	2.2	No.
47135	Transplantation of donor liver to anatomic position	83.64	91.78	90	No.
50390	Aspiration and/or injection kidney cyst, accessed through the skin	1.96	1.96	1.96	No.
5039A	Injection procedure for antegrade nephrostogram and/or ureterogram, complete diagnostic procedure including imaging guidance (eg, ultrasound and fluoroscopy) and all associated radiological supervision and interpretation; new access.	NEW	3.15	3.15	No.
5039B	Injection procedure for antegrade nephrostogram and/or ureterogram, complete diagnostic procedure including imaging guidance (eg, ultrasound and fluoroscopy) and all associated radiological supervision and interpretation; existing access.	NEW	1.42	1.1	No.
5039C	Placement of nephrostomy catheter, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation.	NEW	4.7	4.25	No.
5039D	Placement of nephroureteral catheter, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation, new access.	NEW	5.75	5.3	No.
5039E	Exchange nephrostomy catheter, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation.	NEW	2	1.82	No.
5039M	Convert nephrostomy catheter to nephroureteral catheter, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation.	NEW	4.2	4	No.
5069G	Placement of ureteral stent, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; pre-existing nephrostomy.	NEW	4.6	4.21	No.
5069H	Placement of ureteral stent, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; new access, without separate.	NEW	6	5.5	No.
5069I	Placement of ureteral stent, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; new access, with separate.	NEW	7.55	7.05	No.
5443A	Repair of traumatic corporeal tear(s)	NEW	11.5	11.5	No.
5443B	Replantation, penis, complete amputation including urethral repair	NEW	24.5	22.1	No.

TABLE 11—CY 2016 PROPOSED WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES—Continued

HCPCS	Descriptor	Current work RVU	RUC work RVU	CMS work RVU	CMS time refinement
63045	Laminectomy, facetectomy and foraminotomy; cervical	17.95	17.95	17.95	No.
63046	Laminectomy, facetectomy and foraminotomy; thoracic	17.25	17.25	17.25	No.
657XG	Implantation of intrastromal corneal ring segments	NEW	5.93	5.39	No.
68801	Dilation of tear-drainage opening	1	1	0.82	No.
68810	Insertion of probe into the tear duct	2.15	1.54	1.54	No.
68811	Insertion of probe into the tear duct under anesthesia	2.45	2.03	1.74	No.
68815	Probing of nasal-tear duct with insertion of tube or stent	3.3	3	2.7	No.
68816	Probing of nasal-tear duct with balloon catheter dilation	3.06	2.35	2.1	No.
71100	Radiologic examination, ribs, unilateral; 2 views	0.22	0.22	0.22	No.
72070	Radiologic examination, spine; thoracic, 2 views	0.22	0.22	0.22	No.
7208A	Entire spine x ray, one view	NEW	0.3	0.26	No.
7208B	Entire spine x-ray; 2 or 3 views	NEW	0.35	0.31	No.
7208C	Entire spine x-ray; 4 or 5 views	NEW	0.39	0.35	No.
7208D	Entire spine x-ray; min 6 views	NEW	0.45	0.41	No.
73060	Radiologic examination; humerus, minimum of 2 views	0.17	0.16	0.16	No.
73560	Radiologic examination, knee; 1 or 2 views	0.17	0.16	0.16	No.
73562	Radiologic examination, knee; 3 views	0.18	0.18	0.18	No.
73564	Radiologic examination, knee; complete, 4 or more views	0.22	0.22	0.22	No.
73565	Radiologic examination, knee; both knees, standing, anteroposterior.	0.17	0.16	0.16	No.
73590	Radiologic examination; tibia and fibula, 2 views	0.17	0.16	0.16	No.
73600	Radiologic examination, ankle; 2 views	0.16	0.16	0.16	No.
76999	Ultrasound procedure	C	C	C	N/A
77387	Guidance for localization of target volume for delivery of radiation treatment delivery, includes intrafraction tracking when performed.	N/A	0.58	0.58	No.
7778B	Remote afterloading high dose rate radionuclide skin surface brachytherapy, includes basic dosimetry, when performed; lesion diameter over 2.0 cm and 2 or more channels, or multiple lesions.	NEW	1.4	1.4	No.
7778C	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; 1 channel.	NEW	1.95	1.95	No.
7778D	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; 2–12 channels.	NEW	3.8	3.8	No.
7778E	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; over 12 channels.	NEW	5.4	5.4	No.
88346	Antibody evaluation	0.86	0.74	0.56	No.
8835X	Immunofluorescence, per specimen; each additional single antibody stain procedure (List separately in addition to code for primary procedure).	NEW	0.7	0.53	No.
88367	Morphometric analysis, in situ hybridization (quantitative or semiquantitative), using computer-assisted technology, per specimen: initial single probe stain procedure.	0.73	0.86	0.73	No.
88368	Morphometric analysis, in situ hybridization (quantitative or semiquantitative) manual, per specimen; initial single probe stain procedure.	0.88	0.88	0.88	No.
91299	Procedure for gastrointestinal diagnosis	C	C	C	N/A
9254A	Caloric vestibular test with recording, bilateral; bithermal (ie, one warm and one cool irrigation in each ear for a total of four irrigations).	NEW	0.8	0.6	No.
9254B	Caloric vestibular test with recording, bilateral; monothermal (ie, one irrigation in each ear for a total of two irrigations).	NEW	0.55	0.3	No.
99174	Instrument-based ocular screening (eg, photoscreening, automated-refraction), bilateral.	N	0	N	No.
9917X	Instrument-based ocular screening (eg, photoscreening, automated-refraction), bilateral; with on-site analysis.	NEW	0	N	No.
G0104	Colorectal cancer screening; flexible sigmoidoscopy	0.96	0.84	0.77	No.
G0105	Colorectal cancer screening; colonoscopy on individual at high risk	3.36	3.36	3.29	No.
G0121	Colorectal cancer screening; colonoscopy on individual not meeting criteria for high risk.	3.36	3.36	3.29	No.

TABLE 12—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITHOUT REFINEMENT

HCPCS	Descriptor
20245	Bone biopsy excisional.
20697	Comp ext fixate strut change.
27280	Fusion of sacroiliac joint.
3160A	Bronch ebus 141 gmt. 141 ng 1/2 node.
3160B	Bronch ebus 141 gmt. 141 ng 3/> node.
3160C	Bronch ebus ivntj perph les.
31622	Dx bronchoscope/wash.
31625	Bronchoscopy w/biopsy(s).
31626	Bronchoscopy w/markers.
31628	Bronchoscopy/lung bx each.
31629	Bronchoscopy/needle bx each.
31632	Bronchoscopy/lung bx addl.
31633	Bronchoscopy/needle bx addl.
3347A	Implant tcat pulm vlv perq.
37215	Transcath stent cca w/eps.
3725A	Intrvasc us noncoronary 1st.
3725B	Intrvasc us noncoronary addl.
38570	Laparoscopy lymph node biop.

TABLE 12—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITHOUT REFINEMENT—Continued

HCPCS	Descriptor
38571	Laparoscopy lymphadenectomy.
3940A	Mediastinoscpy w/medstnl bx.
3940B	Mediastinoscpy w/lmph nod bx.
44384	Small bowel endoscopy.
44402	Colonoscopy w/stent plcmt.
44403	Colonoscopy w/resection.
44406	Colonoscopy w/ultrasound.
44407	Colonoscopy w/ndl aspir/bx.
44408	Colonoscopy w/decompression.
45337	Sigmoidoscopy & decompress.
45341	Sigmoidoscopy w/ultrasound.
45342	Sigmoidoscopy w/us guide bx.
45347	Sigmoidoscopy w/plcmt stent.
45349	Sigmoidoscopy w/resection.
45389	Colonoscopy w/stent plcmt.
45390	Colonoscopy w/resection.
45391	Colonoscopy w/endoscope us.
45392	Colonoscopy w/endoscopic fnb.
45393	Colonoscopy w/decompression.
47135	Transplantation of liver.

TABLE 12—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITHOUT REFINEMENT—Continued

HCPCS	Descriptor
5443B	Replantation of penis.
63045	Remove spine lamina 1 crvl.
63046	Remove spine lamina 1 thrc.
68811	Probe nasolacrimal duct.
68815	Probe nasolacrimal duct.
692XX	Remove impacted ear wax uni.
76948	Echo guide ova aspiration.
7778A	Hdr rdncl skn surf brachytx.
7778B	Hdr rdncl skn surf brachytx.
7778C	Hdr rdncl ntrstl/icav brchtx.
7778D	Hdr rdncl ntrstl/icav brchtx.
7778E	Hdr rdncl ntrstl/icav brchtx.
88346	Immunofluorescent study.
8835X	Immunofluor antb addl stain.
9254A	Caloric vstblr test w/rec.
9254B	Caloric vstblr test w/rec.
9935A	Prolong clincl staff svc.
9935B	Prolong clincl staff svc add.

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
10021	Fna w/o image	EF015	mayo stand	NF		24	28	Refined equipment time to conform to established policies for non-highly technical equipment.	
		EF023	table, exam	NF		29	28	Refined equipment time to conform to established policies for non-highly technical equipment.	
		L037D	RN/LPN/MTA	NF	Greet patient, provide gowning, ensure appropriate medical records are available.	1	0	Typically billed with an E/M or other evaluation service.	(0.37)
11750	Removal of nail bed.	EF015	mayo stand	NF		27	45	Refined equipment time to conform to established policies for non-highly technical equipment.	0.02
		EF031	table, power	NF		54	62	Refined equipment time to conform to established policies for non-highly technical equipment.	0.13
		EQ137	instrument pack, basic ($500–$1,499).	NF		34	45	Refined equipment time to conform to established policies for non-highly technical equipment.	0.03
		EQ168	light, exam	NF		54	62	Refined equipment time to conform to established policies for non-highly technical equipment.	0.03
		L037D	RN/LPN/MTA	NF	Provide pre-service education/obtain consent.	0	2	Refined time to standard time for this clinical labor task.	0.74
		SG067	penrose drain (0.25in x 4in).	NF		1	0	Removed supply not typically used in this service.	(0.50)
11760	Repair of nail bed.	EF014	light, surgical	NF		45	43	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.02)
		EF015	mayo stand	NF		45	43	Refined equipment time to conform to established policies for non-highly technical equipment.	

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		EF031	table, power	NF		72	70	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.03)
		EQ137	instrument pack, basic ($500–$1,499).	NF		52	47	Refined equipment time to conform to established policies for instrument packs.	(0.01)
		EQ168	light, exam	NF		72	70	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.01)
		L037D	RN/LPN/MTA	F	Discharge day management.	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
		L037D	RN/LPN/MTA	NF	Complete pre-service diagnostic & referral forms.	5	0	Emergency procedure, input would not typically be used.	(1.85)
		L037D	RN/LPN/MTA	NF	Coordinate pre-surgery services.	3	0	Emergency procedure, input would not typically be used.	(1.11)
		L037D	RN/LPN/MTA	NF	Provide pre-service education/obtain consent.	5	0	Duplication with other clinical labor task.	(1.85)
12005	Rpr s/n/a/gen/trk12.6–20.0cm.	EF023	table, exam	NF		40	44	Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF		40	44	Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
		EQ168	light, exam	NF		40	44	Refined equipment time to conform to established policies for non-highly technical equipment.	0.02
		L037D	RN/LPN/MTA	F	Discharge day management.	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
		L037D	RN/LPN/MTA	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	7	3	Refined time to standard time for this clinical labor task.	(1.48)
12006	Rpr s/n/a/gen/trk20.1–30.0cm.	EF031	table, power	NF		45	49	Refined equipment time to conform to established policies for non-highly technical equipment.	0.07
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF		45	49	Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
		EQ168	light, exam	NF		45	49	Refined equipment time to conform to established policies for non-highly technical equipment.	0.02
		L037D	RN/LPN/MTA	F	Discharge day management.	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
		L037D	RN/LPN/MTA	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	7	3	Refined time to standard time for this clinical labor task.	(1.48)
12007	Rpr s/n/ax/gen/trnk >30.0 cm.	EF031	table, power	NF		50	54	Refined equipment time to conform to established policies for non-highly technical equipment.	0.07

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF	.....	50	54	Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
		EQ168	light, exam	NF	.....	50	54	Refined equipment time to conform to established policies for non-highly technical equipment.	0.02
		L037D	RN/LPN/MTA	F	Discharge day management.	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
		L037D	RN/LPN/MTA	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	7	3	Refined time to standard time for this clinical labor task.	(1.48)
12013 ...	Rpr f/e/e/n/l/m 2.6–5.0 cm.	EF031	table, power	NF	.....	27	33	Refined equipment time to conform to established policies for non-highly technical equipment.	0.10
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF	.....	27	33	Refined equipment time to conform to established policies for non-highly technical equipment.	0.02
		EQ168	light, exam	NF	.....	27	33	Refined equipment time to conform to established policies for non-highly technical equipment.	0.03
		L037D	RN/LPN/MTA	F	Discharge day management.	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
		L037D	RN/LPN/MTA	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	5	3	Refined time to standard time for this clinical labor task.	(0.74)
12014 ...	Rpr f/e/e/n/l/m 5.1–7.5 cm.	EF031	table, power	NF	.....	32	38	Refined equipment time to conform to established policies for non-highly technical equipment.	0.10
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF	.....	32	38	Refined equipment time to conform to established policies for non-highly technical equipment.	0.02
		EQ168	light, exam	NF	.....	32	38	Refined equipment time to conform to established policies for non-highly technical equipment.	0.03
		L037D	RN/LPN/MTA	F	Discharge day management.	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
		L037D	RN/LPN/MTA	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	5	3	Refined time to standard time for this clinical labor task.	(0.74)
12015 ...	Rpr f/e/e/n/l/m 7.6–12.5 cm.	EF031	table, power	NF	.....	37	43	Refined equipment time to conform to established policies for non-highly technical equipment.	0.10
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF	.....	37	43	Refined equipment time to conform to established policies for non-highly technical equipment.	0.02
		EQ168	light, exam	NF	.....	37	43	Refined equipment time to conform to established policies for non-highly technical equipment.	0.03

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		L037D	RN/LPN/MTA	F	Discharge day management.	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
		L037D	RN/LPN/MTA	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	5	3	Refined time to standard time for this clinical labor task.	(0.74)
12016	Rpr fe/e/en/l/m 12.6–20.0 cm.	EF031	table, power	NF		42	48	Refined equipment time to conform to established policies for non-highly technical equipment.	0.10
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF		42	48	Refined equipment time to conform to established policies for non-highly technical equipment.	0.02
		EQ168	light, exam	NF		42	48	Refined equipment time to conform to established policies for non-highly technical equipment.	0.03
		L037D	RN/LPN/MTA	F	Discharge day management.	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
		L037D	RN/LPN/MTA	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	5	3	Refined time to standard time for this clinical labor task.	(0.74)
12041	Intmd rpr n-hf/genit 2.5cm/<.	ED004	camera, digital (6 mexapixel).	F		0	27	Input added to maintain consistency with all other codes within family.	0.10
		ED004	camera, digital (6 mexapixel).	NF		60	27	Refined equipment time to conform to office visit duration.	(0.12)
		EF014	light, surgical	NF		33	42	Refined equipment time to conform to established policies for non-highly technical equipment.	0.09
		EF015	mayo stand	NF		33	42	Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
		EF023	table, exam	NF		60	27	Refined equipment time to conform to office visit duration.	(0.10)
		EF031	table, power	NF		33	42	Refined equipment time to conform to established policies for non-highly technical equipment.	0.15
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF		33	42	Refined equipment time to conform to established policies for non-highly technical equipment.	0.02
		EQ137	instrument pack, basic ($500–$1,499).	NF		0	46	Equipment item replaces another item (EQ138); see preamble.	0.11
		EQ138	instrument pack, medium ($1,500 and up).	NF		40	0	Equipment item replaced by another item (EQ137); see preamble.	(0.28)
		EQ168	light, exam	NF		60	27	Refined equipment time to conform to office visit duration.	(0.14)
		L037D	RN/LPN/MTA	F	Discharge day management.	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
		L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent.	2	0	Intraservice direct PE inputs are not included in the facility setting; See preamble text.	(0.74)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		L037D	RN/LPN/MTA	NF	Complete pre-service diagnostic & referral forms.	5	0	Emergency procedure, input would not typically be used.	(1.85)
		L037D	RN/LPN/MTA	NF	Coordinate pre-surgery services.	3	0	Emergency procedure, input would not typically be used.	(1.11)
		L037D	RN/LPN/MTA	NF	Follow-up phone calls and prescriptions.	3	0	Emergency procedure, input would not typically be used.	(1.11)
12054	Intmd rpr face/mm 7.6–12.5cm.	ED004	camera, digital (6 mexapixel).	NF		90	27	Refined equipment time to conform to office visit duration.	(0.24)
		EF014	light, surgical	NF		63	71	Refined equipment time to conform to established policies for non-highly technical equipment.	0.08
		EF015	mayo stand	NF		63	71	Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
		EF023	table, exam	NF		90	27	Refined equipment time to conform to office visit duration.	(0.19)
		EF031	table, power	NF		63	71	Refined equipment time to conform to established policies for non-highly technical equipment.	0.13
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF		63	71	Refined equipment time to conform to established policies for non-highly technical equipment.	0.02
		EQ138	instrument pack, medium ($1,500 and up).	NF		75	80	Refined equipment time to conform to established policies for instrument packs.	0.03
		EQ168	light, exam	NF		90	27	Refined equipment time to conform to office visit duration.	(0.27)
		L037D	RN/LPN/MTA	F	Discharge day management.	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
		L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent.	2	0	Intraservice direct PE inputs are not included in the facility setting; See preamble text.	(0.74)
		L037D	RN/LPN/MTA	NF	Complete pre-service diagnostic & referral forms.	5	0	Emergency procedure, input would not typically be used.	(1.85)
		L037D	RN/LPN/MTA	NF	Coordinate pre-surgery services.	3	0	Emergency procedure, input would not typically be used.	(1.11)
		L037D	RN/LPN/MTA	NF	Follow-up phone calls and prescriptions.	3	0	Emergency procedure, input would not typically be used.	(1.11)
12055	Intmd rpr face/mm 12.6–20 cm.	ED004	camera, digital (6 mexapixel).	NF		136	63	Refined equipment time to conform to office visit duration.	(0.27)
		EF014	light, surgical	NF		73	81	Refined equipment time to conform to established policies for non-highly technical equipment.	0.08
		EF015	mayo stand	NF		73	81	Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
		EF023	table, exam	NF		136	63	Refined equipment time to conform to office visit duration.	(0.22)
		EF031	table, power	NF		73	81	Refined equipment time to conform to established policies for non-highly technical equipment.	0.13

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF	.....	73	81	Refined equipment time to conform to established policies for non-highly technical equipment.	0.02
		EQ138	instrument pack, medium ($1,500 and up).	NF	.....	85	90	Refined equipment time to conform to established policies for instrument packs.	0.03
		EQ168	light, exam	NF	.....	136	63	Refined equipment time to conform to office visit duration.	(0.32)
		L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent.	2	0	Intraservice direct PE inputs are not included in the facility setting; See preamble text.	(0.74)
		L037D	RN/LPN/MTA	NF	Complete pre-service diagnostic & referral forms.	5	0	Emergency procedure, input would not typically be used.	(1.85)
		L037D	RN/LPN/MTA	NF	Coordinate pre-surgery services.	3	0	Emergency procedure, input would not typically be used.	(1.11)
		L037D	RN/LPN/MTA	NF	Follow-up phone calls and prescriptions.	3	0	Emergency procedure, input would not typically be used.	(1.11)
		SA054	pack, post-op incision care (suture).	F	.....	2	1	No rationale was provided for quantity change relative to current value; maintaining current value.	(4.91)
12057 ...	Intmd rpr face/mm >30.0 cm.	ED004	camera, digital (6 mexapixel).	NF	.....	166	63	Refined equipment time to conform to office visit duration.	(0.39)
		EF014	light, surgical	NF	.....	103	111	Refined equipment time to conform to established policies for non-highly technical equipment.	0.08
		EF015	mayo stand	NF	.....	103	111	Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
		EF023	table, exam	NF	.....	166	63	Refined equipment time to conform to office visit duration.	(0.31)
		EF031	table, power	NF	.....	103	111	Refined equipment time to conform to established policies for non-highly technical equipment.	0.13
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF	.....	103	111	Refined equipment time to conform to established policies for non-highly technical equipment.	0.02
		EQ138	instrument pack, medium ($1,500 and up).	NF	.....	115	120	Refined equipment time to conform to established policies for instrument packs.	0.03
		EQ168	light, exam	NF	.....	166	63	Refined equipment time to conform to office visit duration.	(0.45)
		L037D	RN/LPN/MTA	F	Provide pre-service education/obtain consent.	2	0	Intraservice direct PE inputs are not included in the facility setting; See preamble text.	(0.74)
		L037D	RN/LPN/MTA	NF	Complete pre-service diagnostic & referral forms.	5	0	Emergency procedure, input would not typically be used.	(1.85)
		L037D	RN/LPN/MTA	NF	Coordinate pre-surgery services.	3	0	Emergency procedure, input would not typically be used.	(1.11)
		L037D	RN/LPN/MTA	NF	Follow-up phone calls and prescriptions.	3	0	Emergency procedure, input would not typically be used.	(1.11)
		SA054	pack, post-op incision care (suture).	F	.....	2	1	No rationale was provided for quantity change relative to current value; maintaining current value.	(4.91)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		SA054	pack, post-op incision care (suture).	NF		2	1	No rationale was provided for quantity change relative to current value; maintaining current value.	(4.91)
20240	Bone biopsy excisional.	L037D	RN/LPN/MTA	F	Dischrg gmt. same day (0.5 x 99238) (enter 6 min).	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
30300	Remove nasal foreign body.	EF008	chair with headrest, exam, reclining.	NF		59	67	Refined equipment time to conform to established policies for non-highly technical equipment.	0.09
		EF015	mayo stand	NF		22	40	Refined equipment time to conform to established policies for non-highly technical equipment.	0.02
		EQ137	instrument pack, basic ($500–$1,499).	NF		29	47	Refined equipment time to conform to established policies for instrument packs.	0.04
		EQ167	light source, xenon	F		27	0	Redundant when used together with EQ170; see preamble.	(0.72)
		EQ167	light source, xenon	NF		59	0	Redundant when used together with EQ170; see preamble.	(1.57)
		EQ170	light, fiberoptic headlight w-source.	NF		59	67	Refined equipment time to conform to established policies for non-highly technical equipment.	0.06
		EQ234	suction and pressure cabinet, ENT (SMR).	NF		59	67	Refined equipment time to conform to established policies for non-highly technical equipment.	0.07
		ES013	endoscope, rigid, sinoscopy.	NF		71	74	Refined equipment time to conform to established policies for scopes.	0.02
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	NF		59	67	Refined equipment time to conform to established policies for non-highly technical equipment.	1.03
		L037D	RN/LPN/MTA	F	Discharge day management.	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
		SA041	pack, basic injection.	NF		1	0	Supply item replaced by another item (component parts); see preamble.	(11.67)
		SB001	cap, surgical	NF		0	1	Supply item replaces another item (SA041); see preamble.	0.21
		SB012	drape, sterile, for Mayo stand.	NF		0	1	Supply item replaces another item (SA041); see preamble.	1.69
		SB024	gloves, sterile	NF		0	2	Supply item replaces another item (SA041); see preamble.	1.68
		SB027	gown, staff, impervious.	NF		0	2	Supply item replaces another item (SA041); see preamble.	2.37
		SB033	mask, surgical	NF		0	1	Supply item replaces another item (SA041); see preamble.	0.20
		SB044	underpad 2ft x 3ft (Chux).	NF		0	1	Supply item replaces another item (SA041); see preamble.	0.23
		SG009	applicator, sponge-tipped.	NF		0	3	Supply item replaces another item (SA041); see preamble.	0.42
		SG055	gauze, sterile 4in x 4in.	NF		0	2	Supply item replaces another item (SA041); see preamble.	0.32
		SM010	cleaning brush, endoscope.	F		2	1	Refined supply quantity to what is typical for the procedure.	(4.99)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		SM010	cleaning brush, endoscope.	NF	.....	4	2	Refined supply quantity to what is typical for the procedure.	(9.98)
30903 ...	Control of nosebleed.	EF008	chair with headrest, exam, reclining.	NF	.....	54	110	Refined equipment time to conform to established policies for equipment with 4× monitoring time.	0.60
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF	.....	54	50	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.01)
		EQ137	instrument pack, basic ($500–$1,499).	NF	.....	61	54	Refined equipment time to conform to established policies for instrument packs.	(0.02)
		EQ170	light, fiberoptic headlight w-source.	NF	.....	54	50	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.03)
		EQ234	suction and pressure cabinet, ENT (SMR).	NF	.....	54	110	Refined equipment time to conform to established policies for equipment with 4× monitoring time.	0.52
		L037D	RN/LPN/MTA	F	Dischrg gmt. same day (0.5 x 99238) (enter 6 min).	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
30905 ...	Control of nosebleed.	EF008	chair with headrest, exam, reclining.	NF	.....	72	128	Refined equipment time to conform to established policies for equipment with 4× monitoring time.	0.60
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF	.....	72	68	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.01)
		EQ137	instrument pack, basic ($500–$1,499).	NF	.....	79	72	Refined equipment time to conform to established policies for instrument packs.	(0.02)
		EQ170	light, fiberoptic headlight w-source.	NF	.....	72	68	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.03)
		EQ234	suction and pressure cabinet, ENT (SMR).	NF	.....	72	128	Refined equipment time to conform to established policies for equipment with 4× monitoring time.	0.52
		L037D	RN/LPN/MTA	F	Dischrg gmt. same day (0.5 x 99238) (enter 6 min).	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
30906 ...	Repeat control of nosebleed.	EF008	chair with headrest, exam, reclining.	NF	.....	84	140	Refined equipment time to conform to established policies for equipment with 4× monitoring time.	0.60
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF	.....	84	80	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.01)
		EQ137	instrument pack, basic ($500–$1,499).	NF	.....	91	84	Refined equipment time to conform to established policies for instrument packs.	(0.02)
		EQ170	light, fiberoptic headlight w-source.	NF	.....	84	80	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.03)
		EQ234	suction and pressure cabinet, ENT (SMR).	NF	.....	84	140	Refined equipment time to conform to established policies for equipment with 4× monitoring time.	0.52
31295 ...	Sinus endo w/ balloon dil.	EF008	chair with headrest, exam, reclining.	NF	.....	50	103	Refined equipment time to conform to established policies for equipment with 4× monitoring time.	0.57

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		EF015	mayo stand	NF		32	43	Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
		EQ137	instrument pack, basic ($500–$1,499).	NF		42	47	Refined equipment time to conform to established policies for instrument packs.	0.01
		EQ167	light source, xenon	NF		50	0	Redundant when used together with EQ170; see preamble.	(1.33)
		EQ170	light, fiberoptic headlight w-source.	NF		50	43	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.06)
		EQ234	suction and pressure cabinet, ENT (SMR).	NF		50	103	Refined equipment time to conform to established policies for equipment with 4× monitoring time.	0.49
		ES013	endoscope, rigid, sinoscopy.	NF		44	47	Refined equipment time to conform to established policies for scopes.	0.02
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	NF		50	43	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.90)
		L037D	RN/LPN/MTA	F	Dischrg gmt. same day (0.5 × 99238) (enter 6 min).	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
		L037D	RN/LPN/MTA	NF	Complete pre-service diagnostic & referral forms.	5	0	See preamble text	(1.85)
		L037D	RN/LPN/MTA	NF	Provide pre-service education/obtain consent.	7	3	Refined time to standard time for this clinical labor task.	(1.48)
		L037D	RN/LPN/MTA	NF	Sedate/Apply anesthesia.	5	2	Refined time to standard time for this clinical labor task.	(1.11)
		SJ037	oxymetazoline nasal spray (Afrin) (15ml uou).	NF		3	1	Refined supply quantity to what is typical for the procedure.	(3.66)
31296	Sinus endo w/ balloon dil.	EF008	chair with headrest, exam, reclining.	NF		60	113	Refined equipment time to conform to established policies for equipment with 4× monitoring time.	0.57
		EF015	mayo stand	NF		60	53	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.01)
		EQ137	instrument pack, basic ($500–$1,499).	NF		52	57	Refined equipment time to conform to established policies for instrument packs.	0.01
		EQ167	light source, xenon	NF		60	0	Redundant when used together with EQ170; see preamble.	(1.60)
		EQ170	light, fiberoptic headlight w-source.	NF		60	53	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.06)
		EQ234	suction and pressure cabinet, ENT (SMR).	NF		60	113	Refined equipment time to conform to established policies for equipment with 4× monitoring time.	0.49
		ES013	endoscope, rigid, sinoscopy.	NF		54	57	Refined equipment time to conform to established policies for scopes.	0.02
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	NF		60	53	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.90)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		L037D	RN/LPN/MTA	F	Dischrg gmt. same day (0.5 × 99238) (enter 6 min).	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
		L037D	RN/LPN/MTA	NF	Complete pre-service diagnostic & referral forms.	5	0	See preamble text	(1.85)
		L037D	RN/LPN/MTA	NF	Provide pre-service education/obtain consent.	7	3	Refined time to standard time for this clinical labor task.	(1.48)
		L037D	RN/LPN/MTA	NF	Sedate/Apply anesthesia.	5	2	Refined time to standard time for this clinical labor task.	(1.11)
		SJ037	oxymetazoline nasal spray (Afrin) (15ml uou).	NF		3	1	Refined supply quantity to what is typical for the procedure.	(3.66)
31297	Sinus endo w/ balloon dil.	EF008	chair with headrest, exam, reclining.	NF		58	111	Refined equipment time to conform to established policies for equipment with 4× monitoring time.	0.57
		EF015	mayo stand	NF		40	51	Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
		EQ137	instrument pack, basic ($500–$1,499).	NF		47	55	Refined equipment time to conform to established policies for instrument packs.	0.02
		EQ167	light source, xenon	NF		58	0	Redundant when used together with EQ170; see preamble.	(1.55)
		EQ170	light, fiberoptic headlight w-source.	NF		58	51	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.06)
		EQ234	suction and pressure cabinet, ENT (SMR).	NF		58	111	Refined equipment time to conform to established policies for equipment with 4× monitoring time.	0.49
		ES013	endoscope, rigid, sinoscopy.	NF		52	55	Refined equipment time to conform to established policies for scopes.	0.02
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	NF		58	51	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.90)
		L037D	RN/LPN/MTA	F	Dischrg gmt. same day (0.5 × 99238) (enter 6 min).	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
		L037D	RN/LPN/MTA	NF	Complete pre-service diagnostic & referral forms.	5	0	See preamble text	(1.85)
		L037D	RN/LPN/MTA	NF	Provide pre-service education/obtain consent.	7	3	Refined time to standard time for this clinical labor task.	(1.48)
		L037D	RN/LPN/MTA	NF	Sedate/Apply anesthesia.	5	2	Refined time to standard time for this clinical labor task.	(1.11)
		SJ037	oxymetazoline nasal spray (Afrin) (15ml uou).	NF		3	1	Refined supply quantity to what is typical for the procedure.	(3.66)
38572	Laparoscopy lymphadenectomy.	SA051	pack, pelvic exam	F		1	0	Removed supply not typically used in this service.	(1.17)
40804	Removal foreign body mouth.	EF008	chair with headrest, exam, reclining.	NF		74	82	Refined equipment time to conform to established policies for non-highly technical equipment.	0.09
		EQ110	electrocautery-hyfrecator, up to 45 watts.	NF		29	39	Refined equipment time to conform to established policies for non-highly technical equipment.	0.03

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		EQ137	instrument pack, basic ($500–$1,499).	NF	.....	36	38	Refined equipment time to conform to established policies for instrument packs.	—
		EQ170	light, fiberoptic headlight w-source.	NF	.....	74	82	Refined equipment time to conform to established policies for non-highly technical equipment.	0.06
		EQ234	suction and pressure cabinet, ENT (SMR).	F	.....	27	0	Equipment usage not typical for a follow-up office visit.	(0.25)
		EQ234	suction and pressure cabinet, ENT (SMR).	NF	.....	61	39	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.20)
		L037D	RN/LPN/MTA	F	Dischrg gmt. same day (0.5 × 99238) (enter 6 min).	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
		SD009	canister, suction	NF	.....	2	1	Refined supply quantity to what is typical for the procedure.	(3.91)
42809 ...	Remove pharynx foreign body.	EF008	chair with headrest, exam, reclining.	NF	.....	58	74	Refined equipment time to conform to established policies for non-highly technical equipment.	0.17
		EF015	mayo stand	NF	.....	26	47	Refined equipment time to conform to established policies for non-highly technical equipment.	0.02
		EQ137	instrument pack, basic ($500–$1,499).	NF	.....	60	51	Refined equipment time to conform to established policies for instrument packs.	(0.02)
		EQ170	light, fiberoptic headlight w-source.	NF	.....	58	74	Refined equipment time to conform to established policies for non-highly technical equipment.	0.13
		EQ234	suction and pressure cabinet, ENT (SMR).	F	.....	27	0	Equipment usage not typical for a follow-up office visit.	(0.25)
		EQ234	suction and pressure cabinet, ENT (SMR).	NF	.....	58	47	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.10)
		ES020	fiberscope, flexible, rhinolaryngoscopy.	NF	.....	115	128	Refined equipment time to conform to established policies for scopes.	0.47
		L037D	RN/LPN/MTA	F	Dischrg gmt. same day (0.5 × 99238) (enter 6 min).	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
		SA048	pack, minimum multi-specialty visit.	F	.....	2	1	Refined supply quantity to what is typical for the procedure.	(1.14)
44380 ...	Small bowel endoscopy br/wa.	EF018	stretcher	NF	.....	73	77	Standard time for moderate sedation equipment.	0.02
		EF027	table, instrument, mobile.	NF	.....	29	77	Standard time for moderate sedation equipment.	0.07
		EF031	table, power	NF	.....	29	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.47)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	52	77	Standard time for moderate sedation equipment.	0.35
		EQ032	IV infusion pump ...	NF	.....	52	77	Standard time for moderate sedation equipment.	0.16
44381 ...	Small bowel endoscopy br/wa.	EF018	stretcher	NF	.....	83	87	Standard equipment and time for moderate sedation.	0.02
		EF027	table, instrument, mobile.	NF	.....	39	87	Standard equipment and time for moderate sedation.	0.07
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	62	87	Standard equipment and time for moderate sedation.	0.35

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		EQ032	IV infusion pump ...	NF	.....	62	87	Standard equipment and time for moderate sedation.	0.16
44382 ...	Small bowel endoscopy.	EF018	stretcher	NF	.....	78	82	Standard time for moderate sedation equipment.	0.02
		EF027	table, instrument, mobile.	NF	.....	34	82	Standard time for moderate sedation equipment.	0.07
		EF031	table, power	NF	.....	34	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.56)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	57	82	Standard time for moderate sedation equipment.	0.35
		EQ032	IV infusion pump ...	NF	.....	57	82	Standard time for moderate sedation equipment.	0.16
44385 ...	Endoscopy of bowel pouch.	EF027	table, instrument, mobile.	NF	.....	29	77	Standard time for moderate sedation equipment.	0.07
		EF031	table, power	NF	.....	29	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.47)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	52	77	Refined equipment time to conform to established policies for equipment with 4× monitoring time.	0.35
		EQ032	IV infusion pump ...	NF	.....	52	77	Standard time for moderate sedation equipment.	0.16
44386 ...	Endoscopy bowel pouch/biop.	EF027	table, instrument, mobile.	NF	.....	31	79	Standard time for moderate sedation equipment.	0.07
		EF031	table, power	NF	.....	31	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.51)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	54	79	Standard time for moderate sedation equipment.	0.35
		EQ032	IV infusion pump ...	NF	.....	54	79	Standard time for moderate sedation equipment.	0.16
44388 ...	Colonoscopy thru stoma spx.	EF027	table, instrument, mobile.	NF	.....	57	87	Standard time for moderate sedation equipment.	0.04
		EF031	table, power	NF	.....	39	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.64)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	57	87	Standard time for moderate sedation equipment.	0.42
		EQ032	IV infusion pump ...	NF	.....	57	87	Standard time for moderate sedation equipment.	0.19
44389 ...	Colonoscopy with biopsy.	EF027	table, instrument, mobile.	NF	.....	62	92	Standard time for moderate sedation equipment.	0.04
		EF031	table, power	NF	.....	44	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.72)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	62	92	Standard time for moderate sedation equipment.	0.42
		EQ032	IV infusion pump ...	NF	.....	62	92	Standard time for moderate sedation equipment.	0.19
44390 ...	Colonoscopy for foreign body.	EF027	table, instrument, mobile.	NF	.....	67	97	Standard time for moderate sedation equipment.	0.04
		EF031	table, power	NF	.....	49	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.80)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF		67	97	Standard time for moderate sedation equipment.	0.42
		EQ032	IV infusion pump	NF		67	97	Standard time for moderate sedation equipment.	0.19
44391	Colonoscopy for bleeding.	EF027	table, instrument, mobile.	NF		72	102	Standard time for moderate sedation equipment.	0.04
		EF031	table, power	NF		54	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.88)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF		72	102	Standard time for moderate sedation equipment.	0.42
		EQ032	IV infusion pump	NF		72	102	Standard time for moderate sedation equipment.	0.19
44392	Colonoscopy & polypectomy.	EF027	table, instrument, mobile.	NF		62	92	Standard time for moderate sedation equipment.	0.04
		EF031	table, power	NF		44	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.72)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF		62	92	Standard time for moderate sedation equipment.	0.42
		EQ032	IV infusion pump	NF		62	92	Standard time for moderate sedation equipment.	0.19
44394	Colonoscopy w/ snare.	EF027	table, instrument, mobile.	NF		62	92	Standard time for moderate sedation equipment.	0.04
		EF031	table, power	NF		44	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.72)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF		62	92	Standard time for moderate sedation equipment.	0.42
		EQ032	IV infusion pump	NF		62	92	Standard time for moderate sedation equipment.	0.19
44401	Colonoscopy with ablation.	EF027	table, instrument, mobile.	NF		62	92	Standard equipment and time for moderate sedation.	0.04
		EF031	table, power	NF		44	0	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.72)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF		62	92	Standard equipment and time for moderate sedation.	0.42
		EQ032	IV infusion pump	NF		62	92	Standard equipment and time for moderate sedation.	0.19
44404	Colonoscopy w/ injection.	EF027	table, instrument, mobile.	NF		62	92	Standard equipment and time for moderate sedation.	0.04
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF		62	92	Standard equipment and time for moderate sedation.	0.42
		EQ032	IV infusion pump	NF		62	92	Standard equipment and time for moderate sedation.	0.19
44405	Colonoscopy w/ dilation.	EF027	table, instrument, mobile.	NF		40	100	Standard equipment and time for moderate sedation.	0.08
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF		50	100	Standard equipment and time for moderate sedation.	0.70
		EQ032	IV infusion pump	NF		50	100	Standard equipment and time for moderate sedation.	0.32
45330	Diagnostic sigmoidoscopy.	EF027	table, instrument, mobile.	NF		12	0	No moderate sedation	(0.02)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF		18	0	No moderate sedation	(0.25)
		EQ235	suction machine (Gomco).	NF		12	22	Increased to reflect Intra-Service clinical labor tasks.	0.02
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	NF		12	22	Increased to reflect Intra-Service clinical labor tasks.	1.29
		ES043	Video Sigmoidoscope.	NF		42	49	Refined equipment time to conform to established policies for scopes.	0.49
45331	Sigmoidoscopy and biopsy.	EF027	table, instrument, mobile.	NF		12	0	No moderate sedation	(0.02)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF		33	0	No moderate sedation	(0.46)
		EQ235	suction machine (Gomco).	NF		12	27	Matches time spent using endoscope system.	0.03
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	NF		12	27	Increased to reflect Intra-Service clinical labor tasks.	1.93
		ES043	Video Sigmoidoscope.	NF		42	54	Refined equipment time to conform to established policies for scopes.	0.83
45332	Sigmoidoscopy w/fb removal.	EF027	table, instrument, mobile.	NF		34	82	Standard time for moderate sedation equipment.	0.07
		EF031	table, power	NF		34	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.56)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF		57	82	Standard time for moderate sedation equipment.	0.35
		EQ032	IV infusion pump	NF		57	82	Standard time for moderate sedation equipment.	0.16
45333	Sigmoidoscopy & polypectomy.	EF027	table, instrument, mobile.	NF		29	77	Standard time for moderate sedation equipment.	0.07
		EF031	table, power	NF		29	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.47)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF		52	77	Standard time for moderate sedation equipment.	0.35
		EQ032	IV infusion pump	NF		52	77	Standard time for moderate sedation equipment.	0.16
45334	Sigmoidoscopy for bleeding.	EF027	table, instrument, mobile.	NF		34	82	Standard time for moderate sedation equipment.	0.07
		EF031	table, power	NF		34	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.56)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF		57	82	Standard time for moderate sedation equipment.	0.35
		EQ032	IV infusion pump	NF		57	82	Standard time for moderate sedation equipment.	0.16
45335	Sigmoidoscopy w/submuc inj.	EF027	table, instrument, mobile.	NF		29	77	Standard time for moderate sedation equipment.	0.07
		EF031	table, power	NF		29	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.47)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	52	77	Standard time for moderate sedation equipment.	0.35
		EQ032	IV infusion pump ...	NF	.....	52	77	Standard time for moderate sedation equipment.	0.16
45338 ...	Sigmoidoscopy w/tumr remove.	EF027	table, instrument, mobile.	NF	.....	29	77	Standard time for moderate sedation equipment.	0.07
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	52	77	Standard time for moderate sedation equipment.	0.35
		EQ032	IV infusion pump ...	NF	.....	52	77	Standard time for moderate sedation equipment.	0.16
45340 ...	Sig w/tndsc balloon dilation.	EF027	table, instrument, mobile.	NF	.....	34	82	Standard time for moderate sedation equipment.	0.07
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	57	82	Standard time for moderate sedation equipment.	0.35
		EQ032	IV infusion pump ...	NF	.....	57	82	Standard time for moderate sedation equipment.	0.16
45346 ...	Sigmoidoscopy w/ablation.	EF027	table, instrument, mobile.	NF	.....	34	82	Standard equipment and time for moderate sedation.	0.07
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	57	82	Standard equipment and time for moderate sedation.	0.35
		EQ032	IV infusion pump ...	NF	.....	57	82	Standard equipment and time for moderate sedation.	0.16
45350 ...	Sgmdsc w/band ligation.	EF027	table, instrument, mobile.	NF	.....	94	82	Standard equipment and time for moderate sedation.	(0.02)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	94	82	Standard equipment and time for moderate sedation.	(0.17)
		EQ032	IV infusion pump ...	NF	.....	94	82	Standard equipment and time for moderate sedation.	(0.08)
		SH074	water, sterile for irrigation (250–1000ml uou).	NF	.....	1	0	This input is not contained within any other code in this family; maintaining consistency with all other codes within family.	(2.09)
		SK087	water, distilled	NF	.....	0	5	This input is not contained within any other code in this family; maintaining consistency with all other codes within family.	0.07
45378 ...	Diagnostic colonoscopy.	EF027	table, instrument, mobile.	NF	.....	57	87	Standard time for moderate sedation equipment.	0.04
		EF031	table, power	NF	.....	39	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.64)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	57	87	Standard time for moderate sedation equipment.	0.42
		EQ032	IV infusion pump ...	NF	.....	57	87	Standard time for moderate sedation equipment.	0.19
		EQ235	suction machine (Gomco).	NF	.....	72	39	Matches time spent using endoscope system.	(0.07)
45379 ...	Colonoscopy w/fb removal.	EF027	table, instrument, mobile.	NF	.....	67	97	Standard time for moderate sedation equipment.	0.04
		EF031	table, power	NF	.....	49	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.80)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	67	97	Standard time for moderate sedation equipment.	0.42
		EQ032	IV infusion pump ...	NF	.....	67	97	Standard time for moderate sedation equipment.	0.19

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		EQ235	suction machine (Gomco).	NF	.....	92	49	Matches time spent using endoscope system.	(0.08)
45380 ...	Colonoscopy and biopsy.	EF027	table, instrument, mobile.	NF	.....	60	90	Standard time for moderate sedation equipment.	0.04
		EF031	table, power	NF	.....	42	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.69)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	60	90	Standard time for moderate sedation equipment.	0.42
		EQ032	IV infusion pump ...	NF	.....	60	90	Standard time for moderate sedation equipment.	0.19
		EQ235	suction machine (Gomco).	NF	.....	78	42	Matches time spent using endoscope system.	(0.07)
45381 ...	Colonoscopy submucous njx.	EF027	table, instrument, mobile.	NF	.....	60	90	Standard time for moderate sedation equipment.	0.04
		EF031	table, power	NF	.....	42	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.69)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	60	90	Standard time for moderate sedation equipment.	0.42
		EQ032	IV infusion pump ...	NF	.....	60	90	Standard time for moderate sedation equipment.	0.19
		EQ235	suction machine (Gomco).	NF	.....	78	42	Matches time spent using endoscope system.	(0.07)
45382 ...	Colonoscopy w/ control bleed.	EF027	table, instrument, mobile.	NF	.....	72	102	Standard time for moderate sedation equipment.	0.04
		EF031	table, power	NF	.....	54	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.88)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	72	102	Standard time for moderate sedation equipment.	0.42
		EQ032	IV infusion pump ...	NF	.....	72	102	Standard time for moderate sedation equipment.	0.19
		EQ235	suction machine (Gomco).	NF	.....	102	54	Matches time spent using endoscope system.	(0.09)
45384 ...	Colonoscopy w/ lesion removal.	EF027	table, instrument, mobile.	NF	.....	60	90	Standard time for moderate sedation equipment.	0.04
		EF031	table, power	NF	.....	42	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.69)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	60	90	Standard time for moderate sedation equipment.	0.42
		EQ032	IV infusion pump ...	NF	.....	60	90	Standard time for moderate sedation equipment.	0.19
		EQ235	suction machine (Gomco).	NF	.....	78	42	Matches time spent using endoscope system.	(0.07)
45385 ...	Colonoscopy w/ lesion removal.	EF027	table, instrument, mobile.	NF	.....	62	92	Standard time for moderate sedation equipment.	0.04
		EF031	table, power	NF	.....	44	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.72)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	62	92	Standard time for moderate sedation equipment.	0.42
		EQ032	IV infusion pump ...	NF	.....	62	92	Standard time for moderate sedation equipment.	0.19
		EQ235	suction machine (Gomco).	NF	.....	82	44	Matches time spent using endoscope system.	(0.07)
45386 ...	Colonoscopy w/ balloon dilat.	EF027	table, instrument, mobile.	NF	.....	67	97	Standard time for moderate sedation equipment.	0.04

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		EF031	table, power	NF		49	0	Equipment removed due to redundancy when used together with equipment item EF018, stretcher.	(0.80)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF		67	97	Standard time for moderate sedation equipment.	0.42
		EQ032	IV infusion pump	NF		67	97	Standard time for moderate sedation equipment.	0.19
		EQ235	suction machine (Gomco).	NF		92	49	Matches time spent using endoscope system.	(0.08)
45388	Colonoscopy w/ ablation.	EF027	table, instrument, mobile.	NF		67	97	Standard equipment and time for moderate sedation.	0.04
		EF031	table, power	NF		49	0	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.80)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF		67	97	Standard equipment and time for moderate sedation.	0.42
		EQ032	IV infusion pump	NF		67	97	Standard equipment and time for moderate sedation.	0.19
		EQ235	suction machine (Gomco).	NF		92	49	Matches time spent using endoscope system.	(0.08)
45398	Colonoscopy w/ band ligation.	EF027	table, instrument, mobile.	NF		52	82	Standard equipment and time for moderate sedation.	0.04
		EF031	table, power	NF		34	0	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.56)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF		52	82	Standard equipment and time for moderate sedation.	0.42
		EQ032	IV infusion pump	NF		52	82	Standard equipment and time for moderate sedation.	0.19
		EQ235	suction machine (Gomco).	NF		62	34	Matches time spent using endoscope system.	(0.06)
46500	Injection into hemorrhoid(s).	EF014	light, surgical	NF		73	60	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.13)
		EF031	table, power	NF		73	60	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.21)
		EQ235	suction machine (Gomco).	NF		73	60	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.03)
		ES002	anoscope with light source.	NF		78	60	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.07)
		L037D	RN/LPN/MTA	F	Cleaning scope at POV.	5	0	Included in clinical labor task ''Clean room, equipment, and supplies'' included in post-operative visit.	(1.85)
		L037D	RN/LPN/MTA	F	Complete pre-service diagnostic and referral forms.	3	0	Standard 0 day global pre-service times; exception not accepted as service is rarely furnished in the facility.	(1.11)
		L037D	RN/LPN/MTA	F	Coordinate pre-surgery services.	3	0	Standard 0 day global pre-service times; exception not accepted as service is rarely furnished in the facility.	(1.11)
		L037D	RN/LPN/MTA	F	Follow-up phone calls and prescriptions.	3	0	Standard 0 day global pre-service times; exception not accepted as service is rarely furnished in the facility.	(1.11)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		L037D	RN/LPN/MTA	F	Schedule space and equipment in facility.	3	0	Standard 0 day global pre-service times; exception not accepted as service is rarely furnished in the facility.	(1.11)
		L037D	RN/LPN/MTA	F	Setup scope at POV.	5	0	Included in clinical labor task ''Prepare room, equipment, supplies'' included in post-operative visit.	(1.85)
		L037D	RN/LPN/MTA	NF	Clean scope	5	0	Included in clinical labor task ''Clean room, equipment, and supplies''.	(1.85)
		L037D	RN/LPN/MTA	NF	Cleaning scope at POV.	5	0	Included in clinical labor task ''Clean room, equipment, and supplies'' included in post-operative visit.	(1.85)
		L037D	RN/LPN/MTA	NF	Follow-up phone calls and prescriptions.	3	0	Typically billed with an E/M or other evaluation service.	(1.11)
		L037D	RN/LPN/MTA	NF	Setup scope (non facility setting only).	5	0	Included in clinical labor task ''Prepare room, equipment, supplies''.	(1.85)
		L037D	RN/LPN/MTA	NF	Setup scope at POV.	5	0	Included in clinical labor task ''Clean room, equipment, and supplies'' included in post-operative visit.	(1.85)
		SA042	pack, cleaning and disinfecting, endoscope.	NF		2	0	Removed supply associated with equipment item not typically used in this service.	(34.12)
46601	Diagnostic anoscopy.	EF031	table, power	NF		41	33	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.13)
46607	Diagnostic anoscopy & biopsy.	EF031	table, power	NF		49	38	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.18)
5039A	Njx px nfrosgrm &/urtrgrm.	ED050	PACS Workstation Proxy.	NF		58	67	Refined equipment time to conform to clinical labor time.	0.20
		EF027	table, instrument, mobile.	NF		284	277	Standard equipment and time for moderate sedation.	(0.01)
		EL011	room, angiography	NF		44	0	Equipment item replaced by another item; see preamble.	(231.21)
		EL014	room, radiographic-fluoroscopic.	NF		0	44	Equipment item replaces another item; see preamble.	61.30
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF		284	277	Standard equipment and time for moderate sedation.	(0.10)
		EQ032	IV infusion pump	NF		284	277	Standard equipment and time for moderate sedation.	(0.04)
		EQ168	light, exam	NF		44	62	Refined equipment time to conform to established policies for non-highly technical equipment.	0.08
		L037D	RN/LPN/MTA	NF	Monitor pt following service/check tubes, monitors, drains (not related to moderate sedation).	0	45	Clinical labor type replaces another clinical labor type; see preamble.	16.65
		L051A	RN	NF	Monitor pt following service/check tubes, monitors, drains (not related to moderate sedation).	45	0	Clinical labor type replaced by another labor type; see preamble.	(22.95)
		SA019	kit, iv starter	NF		1	0	Duplicative; a similar item is already included in this service.	(1.60)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		SA042	pack, cleaning and disinfecting, endoscope.	NF		1	0	Removed supply associated with equipment item not typically used in this service.	(17.06)
		SB022	gloves, non-sterile	NF		2	0	Duplicative; items included in pack, minimum multi-specialty visit (SA048).	(0.17)
		SB024	gloves, sterile	NF		2	1	Duplicative; items included in pack, moderate sedation (SA044).	(0.84)
		SB028	gown, surgical, sterile.	NF		2	1	Duplicative; items included in pack, moderate sedation (SA044).	(4.67)
		SC049	stop cock, 3-way	NF		1	0	Duplicative; items included in pack, moderate sedation (SA044).	(1.18)
5039B	Njx px nfrosgrm &/urtrgrm.	ED050	PACS Workstation Proxy.	NF		21	45	Refined equipment time to conform to clinical labor time (Full intraservice period minus monitoring time).	0.53
		EF027	table, instrument, mobile.	NF		22	40	Refined equipment time to conform to established policies for non-highly technical equipment.	0.03
		EL011	room, angiography	NF		22	0	Equipment item replaced by another item; see preamble.	(115.60)
		EL014	room, radiographic-fluoroscopic.	NF		0	22	Equipment item replaces another item; see preamble.	30.65
		EQ168	light, exam	NF		22	40	Refined equipment time to conform to established policies for non-highly technical equipment.	0.08
		L037D	RN/LPN/MTA	NF	Assist physician in performing procedure.	15	0	Removed clinical labor associated with moderate sedation; moderate sedation not typical for this procedure.	(5.55)
		SA042	pack, cleaning and disinfecting, endoscope.	NF		1	0	Removed supply associated with equipment item not typically used in this service.	(17.06)
		SB001	cap, surgical	NF		4	3	Aligned supply quantities with changes to number of clinical labor staff.	(0.21)
		SB022	gloves, non-sterile	NF		2	0	Duplicative; items included in pack, minimum multi-specialty visit (SA048).	(0.17)
		SB033	mask, surgical	NF		2	1	Aligned supply quantities with changes to number of clinical labor staff.	(0.20)
		SB039	shoe covers, surgical.	NF		4	3	Aligned supply quantities with changes to number of clinical labor staff.	(0.34)
5039C	Plmt nephrostomy catheter.	ED050	PACS Workstation Proxy.	NF		71	80	Refined equipment time to conform to clinical labor time.	0.20
		EF027	table, instrument, mobile.	NF		300	290	Standard equipment and time for moderate sedation.	(0.01)
		EL011	room, angiography	NF		60	0	Equipment item replaced by another item; see preamble.	(315.28)
		EL014	room, radiographic-fluoroscopic.	NF		0	60	Equipment item replaces another item; see preamble.	83.59
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF		300	290	Standard equipment and time for moderate sedation.	(0.14)
		EQ032	IV infusion pump	NF		300	290	Standard equipment and time for moderate sedation.	(0.06)
		EQ168	light, exam	NF		60	75	Refined equipment time to conform to established policies for non-highly technical equipment.	0.06

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		L037D	RN/LPN/MTA	NF	Monitor pt following service/check tubes, monitors, drains (not related to moderate sedation).	0	45	Clinical labor type replaces another clinical labor type; see preamble.	16.65
		L041B	Radiologic Technologist.	NF	Clean room/equipment by physician staff.	6	3	Refined time to standard time for this clinical labor task.	(1.23)
		L051A	RN	NF	Monitor pt. following service/check tubes, monitors, drains (not related to moderate sedation).	45	0	Clinical labor type replaced by another labor type; see preamble.	(22.95)
		SA019	kit, iv starter	NF		1	0	Duplicative; items included in pack, moderate sedation (SA044).	(1.60)
		SA042	pack, cleaning and disinfecting, endoscope.	NF		1	0	Removed supply associated with equipment item not typically used in this service.	(17.06)
		SB022	gloves, non-sterile	NF		2	0	Duplicative; items included in pack, minimum multi-specialty visit (SA048).	(0.17)
		SB024	gloves, sterile	NF		2	1	Duplicative; items included in pack, moderate sedation (SA044).	(0.84)
		SB028	gown, surgical, sterile.	NF		2	1	Duplicative; items included in pack, moderate sedation (SA044).	(4.67)
		SC049	stop cock, 3-way	NF		1	0	Duplicative; items included in pack, moderate sedation (SA044).	(1.18)
5039D	Plmt nephroureteral catheter.	ED050	PACS Workstation Proxy.	NF		83	92	Refined equipment time to conform to clinical labor time.	0.20
		EF027	table, instrument, mobile.	NF		312	302	Standard equipment and time for moderate sedation.	(0.01)
		EL011	room, angiography	NF		72	0	Equipment item replaced by another item; see preamble.	(378.34)
		EL014	room, radiographic-fluoroscopic.	NF		0	72	Equipment item replaces another item; see preamble.	100.30
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF		312	302	Standard equipment and time for moderate sedation.	(0.14)
		EQ032	IV infusion pump	NF		312	302	Standard equipment and time for moderate sedation.	(0.06)
		EQ168	light, exam	NF		72	87	Refined equipment time to conform to established policies for non-highly technical equipment.	0.06
		L037D	RN/LPN/MTA	NF	Monitor pt. following service/check tubes, monitors, drains (not related to moderate sedation).	0	45	Clinical labor type replaces another clinical labor type; see preamble.	16.65
		L041B	Radiologic Technologist.	NF	Clean room/equipment by physician staff.	6	3	Refined time to standard time for this clinical labor task.	(1.23)
		L051A	RN	NF	Monitor pt. following service/check tubes, monitors, drains (not related to moderate sedation).	45	0	Clinical labor type replaced by another labor type; see preamble.	(22.95)
		SA019	kit, iv starter	NF		1	0	Duplicative; a similar item is already included in this service.	(1.60)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		SA042	pack, cleaning and disinfecting, endoscope.	NF	.....	1	0	Removed supply associated with equipment item not typically used in this service.	(17.06)
		SB022	gloves, non-sterile	NF	.....	2	0	Duplicative; items included in pack, minimum multi-specialty visit (SA048).	(0.17)
		SB024	gloves, sterile	NF	.....	2	1	Duplicative; items included in pack, moderate sedation (SA044).	(0.84)
		SB028	gown, surgical, sterile.	NF	.....	2	1	Duplicative; items included in pack, moderate sedation (SA044).	(4.67)
		SC049	stop cock, 3-way ...	NF	.....	1	0	Duplicative; items included in pack, moderate sedation (SA044).	(1.18)
		SD306	Nephroureteral Catheter.	NF	.....	1	0	Supply not mentioned in SOR work description.	(117.90)
5039E ...	Exchange nephrostomy cath.	ED050	PACS Workstation Proxy.	NF	.....	21	50	Refined equipment time to conform to clinical labor time.	0.64
		EF027	table, instrument, mobile.	NF	.....	90	45	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.06)
		EL011	room, angiography	NF	.....	30	0	Equipment item replaced by another item; see preamble.	(157.64)
		EL014	room, radiographic-fluoroscopic.	NF	.....	0	30	Equipment item replaces another item; see preamble.	41.79
		EQ168	light, exam	NF	.....	30	45	Refined equipment time to conform to established policies for non-highly technical equipment.	0.06
		L037D	RN/LPN/MTA	NF	Assist physician in performing procedure.	20	0	Clinical labor type replaced by another labor type; see preamble.	(7.40)
		L041B	Radiologic Technologist.	NF	Clean room/equipment by physician staff.	6	3	Refined time to standard time for this clinical labor task.	(1.23)
		SA031	kit, suture removal	NF	.....	1	0	Redundant when used together with supply catheter percutaneous fastener (Percu—Stay) (SD146).	(1.05)
		SA042	pack, cleaning and disinfecting, endoscope.	NF	.....	1	0	Removed supply associated with equipment item not typically used in this service.	(17.06)
		SB001	cap, surgical	NF	.....	4	3	Aligned supply quantities with changes to number of clinical labor staff.	(0.21)
		SB022	gloves, non-sterile	NF	.....	2	0	Duplicative; items included in pack, minimum multi-specialty visit (SA048).	(0.17)
		SB033	mask, surgical	NF	.....	2	1	Aligned supply quantities with changes to number of clinical labor staff.	(0.20)
		SB039	shoe covers, surgical.	NF	.....	4	3	Aligned supply quantities with changes to number of clinical labor staff.	(0.34)
5039M ..	Convert nephrostomy catheter.	ED050	PACS Workstation Proxy.	NF	.....	68	77	Refined equipment time to conform to clinical labor time.	0.20
		EF027	table, instrument, mobile.	NF	.....	297	287	Standard equipment and time for moderate sedation.	(0.01)
		EL011	room, angiography	NF	.....	57	0	Equipment item replaced by another item; see preamble.	(299.52)
		EL014	room, radiographic-fluoroscopic.	NF	.....	0	57	Equipment item replaces another item; see preamble.	79.41
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF	.....	297	287	Standard equipment and time for moderate sedation.	(0.14)
		EQ032	IV infusion pump ...	NF	.....	297	287	Standard equipment and time for moderate sedation.	(0.06)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		EQ168	light, exam	NF		57	72	Refined equipment time to conform to established policies for non-highly technical equipment.	0.06
		L037D	RN/LPN/MTA	NF	Monitor pt following service/check tubes, monitors, drains (not related to moderate sedation).	0	45	Clinical labor type replaces another clinical labor type; see preamble.	16.65
		L041B	Radiologic Technologist.	NF	Clean room/equipment by physician staff.	6	3	Refined time to standard time for this clinical labor task.	(1.23)
		L051A	RN	NF	Monitor pt following service/check tubes, monitors, drains (not related to moderate sedation).	45	0	Clinical labor type replaced by another labor type; see preamble.	(22.95)
		SA019	kit, iv starter	NF		1	0	Duplicative; items included in pack, moderate sedation (SA044).	(1.60)
		SA031	kit, suture removal	NF		1	0	Redundant when used together with supply catheter percutaneous fastener (Percu—Stay) (SD146).	(1.05)
		SA042	pack, cleaning and disinfecting, endoscope.	NF		1	0	Removed supply associated with equipment item not typically used in this service.	(17.06)
		SB022	gloves, non-sterile	NF		2	0	Duplicative; items included in pack, minimum multi-specialty visit (SA048).	(0.17)
		SB024	gloves, sterile	NF		2	1	Duplicative; items included in pack, moderate sedation (SA044).	(0.84)
		SB028	gown, surgical, sterile.	NF		2	1	Duplicative; items included in pack, moderate sedation (SA044).	(4.67)
		SC049	stop cock, 3-way	NF		1	0	Duplicative; items included in pack, moderate sedation (SA044).	(1.18)
5069G	Plmt ureteral stent prq.	ED050	PACS Workstation Proxy.	NF		68	77	Refined equipment time to conform to clinical labor time.	0.20
		EF027	table, instrument, mobile.	NF		297	287	Standard equipment and time for moderate sedation.	(0.01)
		EL011	room, angiography	NF		57	0	Equipment item replaced by another item; see preamble.	(299.52)
		EL014	room, radiographic-fluoroscopic.	NF		0	57	Equipment item replaces another item; see preamble.	79.41
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF		297	287	Standard equipment and time for moderate sedation.	(0.14)
		EQ032	IV infusion pump	NF		297	287	Standard equipment and time for moderate sedation.	(0.06)
		EQ168	light, exam	NF		57	72	Refined equipment time to conform to established policies for non-highly technical equipment.	0.06
		L037D	RN/LPN/MTA	NF	Monitor pt. following service/check tubes, monitors, drains (not related to moderate sedation).	0	45	Clinical labor type replaces another clinical labor type; see preamble.	16.65
		L041B	Radiologic Technologist.	NF	Clean room/equipment by physician staff.	6	3	Refined time to standard time for this clinical labor task.	(1.23)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		L051A	RN	NF	Monitor pt. following service/check tubes, monitors, drains (not related to moderate sedation).	45	0	Clinical labor type replaced by another labor type; see preamble.	(22.95)
		SA019	kit, iv starter	NF		1	0	Duplicative; items included in pack, moderate sedation (SA044).	(1.60)
		SA031	kit, suture removal	NF		1	0	Redundant when used together with supply catheter percutaneous fastener (Percu—Stay) (SD146).	(1.05)
		SA042	pack, cleaning and disinfecting, endoscope.	NF		1	0	Removed supply associated with equipment item not typically used in this service.	(17.06)
		SB022	gloves, non-sterile	NF		2	0	Duplicative; items included in pack, minimum multi-specialty visit (SA048).	(0.17)
		SB024	gloves, sterile	NF		2	1	Duplicative; items included in pack, moderate sedation (SA044).	(0.84)
		SB028	gown, surgical, sterile.	NF		2	1	Duplicative; items included in pack, moderate sedation (SA044).	(4.67)
		SC049	stop cock, 3-way	NF		1	0	Duplicative; items included in pack, moderate sedation (SA044).	(1.18)
5069H	Plmt ureteral stent prq.	ED050	PACS Workstation Proxy.	NF		85	94	Refined equipment time to conform to clinical labor time.	0.20
		EF027	table, instrument, mobile.	NF		314	304	Standard equipment and time for moderate sedation.	(0.01)
		EL011	room, angiography	NF		74	0	Equipment item replaced by another item; see preamble.	(388.85)
		EL014	room, radiographic-fluoroscopic.	NF		0	74	Equipment item replaces another item; see preamble.	103.09
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF		314	304	Standard equipment and time for moderate sedation.	(0.14)
		EQ032	IV infusion pump	NF		314	304	Standard equipment and time for moderate sedation.	(0.06)
		EQ168	light, exam	NF		74	89	Refined equipment time to conform to established policies for non-highly technical equipment.	0.06
		L037D	RN/LPN/MTA	NF	Monitor pt. following service/check tubes, monitors, drains (not related to moderate sedation).	0	45	Clinical labor type replaces another clinical labor type; see preamble.	16.65
		L041B	Radiologic Technologist.	NF	Acquire images (75%).	47	46	Rounding error in CL time calculation.	(0.41)
		L041B	Radiologic Technologist.	NF	Clean room/equipment by physician staff.	6	3	Refined time to standard time for this clinical labor task.	(1.23)
		L051A	RN	NF	Monitor pt. following service/check tubes, monitors, drains (not related to moderate sedation).	45	0	Clinical labor type replaced by another labor type; see preamble.	(22.95)
		SA019	kit, iv starter	NF		1	0	Duplicative; items included in pack, moderate sedation (SA044).	(1.60)
		SA042	pack, cleaning and disinfecting, endoscope.	NF		1	0	Removed supply associated with equipment item not typically used in this service.	(17.06)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		SB022	gloves, non-sterile	NF		2	0	Duplicative; items included in pack, minimum multi-specialty visit (SA048).	(0.17)
		SB024	gloves, sterile	NF		2	1	Duplicative; items included in pack, moderate sedation (SA044).	(0.84)
		SB028	gown, surgical, sterile.	NF		2	1	Duplicative; a similar item is already included in this service.	(4.67)
		SC049	stop cock, 3-way	NF		1	0	Duplicative; items included in pack, moderate sedation (SA044).	(1.18)
5069I	Plmt ureteral stent prq.	ED050	PACS Workstation Proxy.	NF		98	107	Refined equipment time to conform to clinical labor time.	0.20
		EF027	table, instrument, mobile.	NF		327	317	Standard equipment and time for moderate sedation.	(0.01)
		EL011	room, angiography	NF		87	0	Equipment item replaced by another item; see preamble.	(457.16)
		EL014	room, radiographic-fluoroscopic.	NF		0	87	Equipment item replaces another item; see preamble.	121.20
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp).	NF		327	317	Standard equipment and time for moderate sedation.	(0.14)
		EQ032	IV infusion pump	NF		327	317	Standard equipment and time for moderate sedation.	(0.06)
		EQ168	light, exam	NF		87	102	Refined equipment time to conform to established policies for non-highly technical equipment.	0.06
		L037D	RN/LPN/MTA	NF	Monitor pt. following service/check tubes, monitors, drains (not related to moderate sedation).	0	45	Clinical labor type replaces another clinical labor type; see preamble.	16.65
		L041B	Radiologic Technologist.	NF	Clean room/equipment by physician staff.	6	3	Refined time to standard time for this clinical labor task.	(1.23)
		L051A	RN	NF	Monitor pt. following service/check tubes, monitors, drains (not related to moderate sedation).	45	0	Clinical labor type replaced by another labor type; see preamble.	(22.95)
		SA019	kit, iv starter	NF		1	0	Duplicative; items included in pack, moderate sedation (SA044).	(1.60)
		SA042	pack, cleaning and disinfecting, endoscope.	NF		1	0	Removed supply associated with equipment item not typically used in this service.	(17.06)
		SB022	gloves, non-sterile	NF		2	0	Duplicative; items included in pack, minimum multi-specialty visit (SA048).	(0.17)
		SB024	gloves, sterile	NF		2	1	Duplicative; items included in pack, moderate sedation (SA044).	(0.84)
		SB028	gown, surgical, sterile.	NF		2	1	Duplicative; items included in pack, moderate sedation (SA044).	(4.67)
		SC049	stop cock, 3-way	NF		1	0	Duplicative; items included in pack, moderate sedation (SA044).	(1.18)
5443A	Repair corporeal tear.	EF031	table, power	F		144	135	Refined equipment time to conform to clinical labor time.	(0.15)
		EF031	table, power	NF		144	135	Refined equipment time to conform to clinical labor time.	(0.15)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		EQ168	light, exam	F		144	135	Refined equipment time to conform to clinical labor time.	(0.04)
		EQ168	light, exam	NF		144	135	Refined equipment time to conform to clinical labor time.	(0.04)
657XG	Impltj ntrstrml crnl rng seg.	L038A	COMT/COT/RN/CST.	F	Discharge day management same day 99238 –6 minutes.	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.28)
68801	Dilate tear duct opening.	L038A	COMT/COT/RN/CST.	F	Discharge day management same day 99238 –6 minutes.	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.28)
68810	Probe nasolacrimal duct.	L038A	COMT/COT/RN/CST.	F	Discharge day management same day 99238 –6 minutes.	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.28)
68816	Probe nl duct w/ balloon.	EL006	lane, screening (oph).	NF		16	47	Refined equipment time to conform to clinical labor time.	2.77
69200	Clear outer ear canal.	EF008	chair with headrest, exam, reclining.	NF		22	27	Refined equipment time to conform to established policies for non-highly technical equipment.	0.05
		EF015	mayo stand	NF		19	27	Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
		EQ137	instrument pack, basic ($500–$1,499).	NF		26	31	Refined equipment time to conform to established policies for instrument packs.	0.01
		EQ170	light, fiberoptic headlight w-source.	NF		22	27	Refined equipment time to conform to established policies for non-highly technical equipment.	0.04
		EQ183	microscope, operating.	NF		22	27	Refined equipment time to conform to established policies for non-highly technical equipment.	0.14
		EQ234	suction and pressure cabinet, ENT (SMR).	NF		22	27	Refined equipment time to conform to established policies for non-highly technical equipment.	0.05
		L037D	RN/LPN/MTA	F	Dischrg gmt. same day (0.5 × 99238) (enter 6 min).	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
		SH047	lidocaine 1%–2% inj (Xylocaine).	NF		5	0	Supply item replaced by another item (SH050); see preamble.	(0.18)
		SH050	lidocaine 4% soln, topical (Xylocaine).	NF		0	3	Supply item replaces another item (SH047); see preamble.	0.46
69220	Clean out mastoid cavity.	EF008	chair with headrest, exam, reclining.	NF		20	25	Refined equipment time to conform to established policies for non-highly technical equipment.	0.05
		EF015	mayo stand	NF		17	25	Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
		EQ137	instrument pack, basic ($500–$1,499).	NF		0	29	Equipment item replaces another item (EQ138); see preamble.	0.07
		EQ138	instrument pack, medium ($1,500 and up).	NF		29	0	Equipment item replaced by another item (EQ137); see preamble.	(0.20)
		EQ183	microscope, operating.	NF		20	25	Refined equipment time to conform to established policies for non-highly technical equipment.	0.14

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		EQ234	suction and pressure cabinet, ENT (SMR).	NF	.....	20	25	Refined equipment time to conform to established policies for non-highly technical equipment.	0.05
		L037D	RN/LPN/MTA	F	Dischrg day gmt. (0.5 × 99238) (enter 6 min).	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
		L037D	RN/LPN/MTA	NF	Clean surgical instrument package.	15	10	Refined time to standard time for this clinical labor task.	(1.85)
		L037D	RN/LPN/MTA	NF	Provide pre-service education/ obtain consent.	0	2	Refined time to standard time for this clinical labor task.	0.74
7208A ...	X-ray exam entire spi 1 vw.	ED050	PACS Workstation Proxy.	NF	.....	21	25	Refined equipment time to conform to clinical labor time.	0.09
7208B ...	X-ray exam entire spi 2/3 vw.	ED050	PACS Workstation Proxy.	NF	.....	36	40	Refined equipment time to conform to clinical labor time.	0.09
7208C ..	X-ray exam entire spi 4/5 vw.	ED050	PACS Workstation Proxy.	NF	.....	44	48	Refined equipment time to conform to clinical labor time.	0.09
7208D ..	X-ray exam entire spi 6/ vw.	ED050	PACS Workstation Proxy.	NF	.....	53	57	Refined equipment time to conform to clinical labor time.	0.09
73565 ...	X-ray exam of knees.	L041B	Radiologic Technologist.	NF	Greet patient and provide gowning.	0	3	Input added to maintain consistency with all other codes within family.	1.23
77385 ...	Ntsty modul rad tx dlvr smpl.	EQ139	intercom (incl. master, pt substation, power, wiring).	NF	.....	27	0	Indirect Practice Expense; not individually allocable to a particular patient for a particular service.	(0.10)
		ER040	laser, diode, for patient positioning (Probe).	NF	.....	29	27	Refined equipment time to conform to established policies for highly technical equipment.	(0.12)
		ER056	radiation treatment vault.	NF	.....	29	27	Refined equipment time to conform to established policies for highly technical equipment.	(3.15)
		ER065	water chiller (radiation treatment).	NF	.....	29	27	Refined equipment time to conform to established policies for highly technical equipment.	(0.13)
		ER089	IMRT accelerator ...	NF	.....	29	27	Refined equipment time to conform to established policies for highly technical equipment.	(16.14)
		ER102	Power conditioner ..	NF	.....	29	27	Refined equipment time to conform to established policies for highly technical equipment.	(0.17)
77386 ...	Ntsty modul rad tx dlvr cplx.	EQ139	intercom (incl. master, pt substation, power, wiring).	NF	.....	42	0	Indirect Practice Expense; not individually allocable to a particular patient for a particular service.	(0.15)
		ER040	laser, diode, for patient positioning (Probe).	NF	.....	44	42	Refined equipment time to conform to established policies for highly technical equipment.	(0.12)
		ER056	radiation treatment vault.	NF	.....	44	42	Refined equipment time to conform to established policies for highly technical equipment.	(3.15)
		ER065	water chiller (radiation treatment).	NF	.....	44	42	Refined equipment time to conform to established policies for highly technical equipment.	(0.13)
		ER089	IMRT accelerator ...	NF	.....	44	42	Refined equipment time to conform to established policies for highly technical equipment.	(16.14)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		ER102	Power conditioner ..	NF	.....	44	42	Refined equipment time to conform to established policies for highly technical equipment.	(0.17)
		L050C	Radiation Therapist	NF	Check dressings & wound/home care instructions/coordinate office visits/prescriptions.	2	1	Refined to conform with identical labor activity in other codes in the family.	(0.50)
77402 ...	Radiation treatment delivery.	EQ139	intercom (incl. master, pt substation, power, wiring).	NF	.....	12	0	Indirect Practice Expense; not individually allocable to a particular patient for a particular service.	(0.04)
		ER040	laser, diode, for patient positioning (Probe).	NF	.....	14	12	Refined equipment time to conform to established policies for highly technical equipment.	(0.12)
		ER056	radiation treatment vault.	NF	.....	14	12	Refined equipment time to conform to established policies for highly technical equipment.	(3.15)
		ER065	water chiller (radiation treatment).	NF	.....	14	12	Refined equipment time to conform to established policies for highly technical equipment.	(0.13)
		ER089	IMRT accelerator ...	NF	.....	14	12	Refined equipment time to conform to established policies for highly technical equipment.	(16.14)
		ER102	Power conditioner ..	NF	.....	14	12	Refined equipment time to conform to established policies for highly technical equipment.	(0.17)
77407 ...	Radiation treatment delivery.	EQ139	intercom (incl. master, pt substation, power, wiring).	NF	.....	17	0	Indirect Practice Expense; not individually allocable to a particular patient for a particular service.	(0.06)
		ER040	laser, diode, for patient positioning (Probe).	NF	.....	19	17	Refined equipment time to conform to established policies for highly technical equipment.	(0.12)
		ER056	radiation treatment vault.	NF	.....	19	17	Refined equipment time to conform to established policies for highly technical equipment.	(3.15)
		ER065	water chiller (radiation treatment).	NF	.....	19	17	Refined equipment time to conform to established policies for highly technical equipment.	(0.13)
		ER089	IMRT accelerator ...	NF	.....	19	17	Refined equipment time to conform to established policies for highly technical equipment.	(16.14)
		ER102	Power conditioner ..	NF	.....	19	17	Refined equipment time to conform to established policies for highly technical equipment.	(0.17)
77412 ...	Radiation treatment delivery.	EQ139	intercom (incl. master, pt substation, power, wiring).	NF	.....	21	0	Indirect Practice Expense; not individually allocable to a particular patient for a particular service.	(0.08)
		ER040	laser, diode, for patient positioning (Probe).	NF	.....	23	21	Refined equipment time to conform to established policies for highly technical equipment.	(0.12)
		ER056	radiation treatment vault.	NF	.....	23	21	Refined equipment time to conform to established policies for highly technical equipment.	(3.15)
		ER065	water chiller (radiation treatment).	NF	.....	23	21	Refined equipment time to conform to established policies for highly technical equipment.	(0.13)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		ER089	IMRT accelerator ...	NF	.....	23	21	Refined equipment time to conform to established policies for highly technical equipment.	(16.14)
		ER102	Power conditioner ..	NF	.....	23	21	Refined equipment time to conform to established policies for highly technical equipment.	(0.17)
88104 ...	Cytopath fl nongyn smears.	EP024	microscope, compound.	NF	.....	60	56	Refined to conform with identical labor activity in other codes in the family.	(0.15)
		L033A	Lab Technician	NF	Order, restock, and distribute specimen containers with requisition forms..	0.5	0	Indirect Practice Expense; not individually allocable to a particular patient for a particular service.	(0.17)
88106 ...	Cytopath fl nongyn filter.	L033A	Lab Technician	NF	Order, restock, and distribute specimen containers with requisition forms..	0.5	0	Indirect Practice Expense; not individually allocable to a particular patient for a particular service.	(0.17)
88108 ...	Cytopath concentrate tech.	L033A	Lab Technician	NF	Order, restock, and distribute specimen containers with requisition forms..	0.5	0	Indirect Practice Expense; not individually allocable to a particular patient for a particular service.	(0.17)
88160 ...	Cytopath smear other source.	EP038	solvent recycling system.	NF	.....	1	0	Refined equipment time to conform to clinical labor time.	(0.05)
		L035A	Lab Tech/ Histotechnologist.	NF	Prepare automated stainer with solutions and load microscopic slides. Set and confirm stainer program. Set and confirm stainer program.	6	4	Refined time to standard time for this clinical labor task.	(0.70)
		L035A	Lab Tech/ Histotechnologist.	NF	Stain air dried slides with modified Wright stain. Review slides for malignancy/high cellularity (cross contamination).	5	0	See preamble text	(1.75)
88161 ...	Cytopath smear other source.	EP038	solvent recycling system.	NF	.....	1	0	Refined equipment time to conform to clinical labor time.	(0.05)
	Cytopath smear other source.	L035A	Lab Tech/ Histotechnologist.	NF	Prepare automated stainer with solutions and load microscopic slides. Set and confirm stainer program. Set and confirm stainer program.	6	4	Refined time to standard time for this clinical labor task.	(0.70)
	Cytopath smear other source.	L035A	Lab Tech/ Histotechnologist.	NF	Stain air dried slides with modified Wright stain. Review slides for malignancy/high cellularity (cross contamination).	5	3	Refined time to standard time for this clinical labor task.	(0.70)
88162 ...	Cytopath smear other source.	EP038	solvent recycling system.	NF	.....	1	0	Refined equipment time to conform to clinical labor time.	(0.05)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
	Cytopath smear other source.	L035A	Lab Tech/ Histotechnologist.	NF	Other Clinical Activity (please specify): Prepare automated stainer with solutions and load microscopic slides.	6	4	Refined time to standard time for this clinical labor task.	(0.70)
88182 ...	Cell marker study.	L033A	Lab Technician	NF	Accession specimen/prepare for examination.	6	4	Refined time to standard time for this clinical labor task.	(0.66)
	Cell marker study.	L033A	Lab Technician	NF	Clean room/ equipment following procedure (including any equipment maintenance that must be done after the procedure).	2	1	Refined time to standard time for this clinical labor task.	(0.33)
		L033A	Lab Technician	NF	Dispose of remaining specimens, spent chemicals/other consumables, and hazardous waste.	2	1	Refined time to standard time for this clinical labor task.	(0.33)
		L033A	Lab Technician	NF	Prepare, pack and transport specimens and records for in-house storage and external storage (where applicable).	2	1	Refined time to standard time for this clinical labor task.	(0.33)
		L045A	Cytotechnologist	NF	Clean room/ equipment following procedure (including any equipment maintenance that must be done after the procedure).	2	1	Refined time to standard time for this clinical labor task.	(0.45)
		L045A	Cytotechnologist	NF	Enter data into laboratory information system, multiparameter analyses and field data en.	2	0	Refined time to standard time for this clinical labor task.	(0.90)
		L045A	Cytotechnologist	NF	Print out histograms, assemble materials with paperwork to pathologists Review histograms and gating with pathologist.	5	2	Refined time to standard time for this clinical labor task.	(1.35)
88184 ...	Flowcytometry/ tc 1 marker.	ED031	printer, dye sublimation (photo, color).	NF	.....	5	1	Refined equipment time to conform to clinical labor time.	(0.04)
		L033A	Lab Technician	NF	Clean room/ equipment following procedure (including any equipment maintenance that must be done after the procedure).	2	1	Refined time to standard time for this clinical labor task.	(0.33)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		L033A	Lab Technician	NF	Enter data into laboratory information system, multiparameter analyses and field data en.	4	0	Refined time to standard time for this clinical labor task.	(1.32)
		L045A	Cytotechnologist	NF	Instrument start-up, quality control functions, calibration, centrifugation, maintaining specimen tracking, logs and labeling.	15	13	Refined to conform with identical labor activity in other codes in the family.	(0.90)
		L045A	Cytotechnologist	NF	Other Clinical Activity (please specify) Load specimen into flow cytometer, run specimen, monitor data acquisition, and.	10	7	Refined to conform with identical labor activity in other codes in the family.	(1.35)
		L045A	Cytotechnologist	NF	Print out histograms, assemble materials with paperwork to pathologists Review histograms and gating with pathologist.	5	2	Refined time to standard time for this clinical labor task.	(1.35)
88185 ...	Flowcytometry/tc add-on.	ED031	printer, dye sublimation (photo, color).	NF	.....	2	1	Refined equipment time to conform to clinical labor time.	(0.01)
		L033A	Lab Technician	NF	Enter data into laboratory information system, multiparameter analyses and field data en.	1	0	Refined time to standard time for this clinical labor task.	(0.33)
88321 ...	Microslide consultation.	L033A	Lab Technician	NF	Accession specimen/prepare for examination.	4	0	Duplication with other clinical labor task.	(1.32)
		L033A	Lab Technician	NF	Register the patient in the information system, including all demographic and billing information. In addition to stand.	13	5	See preamble text	(2.64)
		L037B	Histotechnologist ...	NF	Phone calls for clarifications and/or additional materials.	0	3	Input added to maintain consistency with all other codes within family.	1.11
88323 ...	Microslide consultation.	L033A	Lab Technician	NF	Register the patient in the information system, including all demographic and billing information. In addition to stand.	13	5	Non-standard refinement, see preamble text.	(2.64)
		L037B	Histotechnologist ...	NF	Assemble and deliver slides with paperwork to pathologists.	1	0	Duplication with other clinical labor task.	(0.37)
		L037B	Histotechnologist ...	NF	Clean equipment while performing service.	1	0	Duplication with other clinical labor task.	(0.37)
		SL063	eosin y	NF	.....	8	0	Redundant when used together with SL135.	(6.41)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		SL135	stain, hematoxylin ..	NF	.....	32	8	Refined supply quantity to what is typical for the procedure.	(1.06)
88325 ...	.....	EP019	hood, ventilator with blower.	NF	.....	1	0	See preamble text	—
		EP033	slide coverslipper, robotic.	NF	.....	6	0	See preamble text	(0.57)
		EP034	slide dryer	NF	.....	1	0	See preamble text	—
		EP035	slide etcher-labeler	NF	.....	1	0	See preamble text	(0.05)
		EP036	slide stainer, automated, high-volume throughput.	NF	.....	12	0	See preamble text	(0.55)
		EP038	solvent recycling system.	NF	.....	4	0	See preamble text	(0.18)
		EP043	water bath, general purpose (lab).	NF	.....	6	0	See preamble text	(0.01)
		ER041	microtome	NF	.....	6	0	See preamble text	(0.26)
		L033A	Lab Technician	NF	Prepare room. Filter and replenish stains and supplies. (including OCT blocks, set up grossing station with colored stain.	10	0	Indirect Practice Expense; not individually allocable to a particular patient for a particular service.	(3.30)
		L033A	Lab Technician	NF	Accession specimen/prepare for examination.	4	0	Duplication with other clinical labor task.	(1.32)
		L033A	Lab Technician	NF	Dispose of remaining specimens, spent chemicals/other consumables, and hazardous waste.	1	0	See preamble text	(0.33)
		L033A	Lab Technician	NF	Register the patient in the information system, including all demographic and billing information. In addition to stand.	13	5	See preamble text	(2.64)
		L033A	Lab Technician	NF	prepare, pack and transport specimens and records for in-house storage and external storage.	2	0	See preamble text	(0.66)
		L037B	Histotechnologist ...	NF	Clean equipment while performing service.	1	0	Duplication with other clinical labor task.	(0.37)
		L037B	Histotechnologist ...	NF	Complete workload recording logs. Collate slides and paperwork. Deliver to pathologist.	1	0	See preamble text	(0.37)
		L037B	Histotechnologist ...	NF	Prepare automated coverslipper, remove slides from stainer and place on coverslipper.	1	0	See preamble text	(0.37)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		L037B	Histotechnologist ...	NF	Prepare automated stainer with solutions and load microscopic slides. Set and confirm stainer program. Set and confirm stainer program.	1	0	See preamble text	(0.37)
		L037B	Histotechnologist ...	NF	Slide preparation sectioning and recuts, quality control function, maintaining specimen tracking, logs and labeling.	4	0	See preamble text	(1.48)
		SB023	gloves, non-sterile, nitrile.	NF	.....	2	0	See preamble text	(0.38)
		SB027	gown, staff, impervious.	NF	.....	0.1	0	See preamble text	(0.12)
		SF004	blade, microtome ...	NF	.....	0.2	0	See preamble text	(0.34)
		SL020	bleach	NF	.....	10	0	See preamble text	(0.01)
		SL030	cover slip, glass	NF	.....	2	0	See preamble text	(0.16)
		SL063	eosin y	NF	.....	8	0	See preamble text	(6.41)
		SL078	histology freezing spray (Freeze-It).	NF	.....	0.2	0	See preamble text	(0.29)
		SL085	label for microscope slides.	NF	.....	20	10	See preamble text	(0.26)
		SL095	mounting media (Histomount).	NF	.....	2	0	See preamble text	(0.07)
		SL122	slide, microscope ...	NF	.....	2	0	See preamble text	(0.11)
		SL135	stain, hematoxylin ..	NF	.....	32	0	See preamble text	(1.41)
		SL151	xylenes solvent	NF	.....	60	0	See preamble text	(0.72)
		SL189	ethanol, 100%	NF	.....	60	0	See preamble text	(0.20)
		SL190	ethanol, 70%	NF	.....	8	0	See preamble text	(0.03)
		SL248	ethanol, 95%	NF	.....	36	0	See preamble text	(0.12)
		SM027	wipes, lens cleaning (per wipe) (Kimwipe).	NF	.....	2	0	See preamble text	(0.03)
88329 ...	Path consult introp.	L037B	Histotechnologist ...	NF	Assist pathologist with gross specimen examination.	10	3	Refined time to standard time for this clinical labor task.	(2.59)
		L037B	Histotechnologist ...	NF	Clean room/equipment following procedure (including any equipment maintenance that must be done after the procedure).	5	1	Refined time to standard time for this clinical labor task.	(1.48)
88331 ...	Path consult intraop 1 bloc.	L033A	Lab Technician	NF	Prepare room. Filter and replenish stains and supplies. (including OCT blocks, set up grossing station with colored stai.	10	0	Indirect Practice Expense; not individually allocable to a particular patient for a particular service.	1.48
		L037B	Histotechnologist ...	NF	Accession specimen/prepare for examination.	0	4	Input added to maintain consistency with all other codes within family.	1.48
		L037B	Histotechnologist ...	NF	Assemble and deliver slides with paperwork to pathologists.	2	0.5	Refined time to standard time for this clinical labor task.	(0.56)
		L037B	Histotechnologist ...	NF	Assist pathologist with gross specimen examination.	10	3	Refined time to standard time for this clinical labor task.	(2.59)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		L037B	Histotechnologist ...	NF	Clean room/equipment following procedure (including any equipment maintenance that must be done after the procedure).	10	1	Refined time to standard time for this clinical labor task.	(3.33)
		SL134	stain, frozen section, H&E (1ml per slide).	NF	.....	0	1	Supply item replaces another item (SL231); see preamble.	0.57
		SL231	kit, stain, H&E	NF	.....	0.1	0	Supply item replaced by another item (SL134); see preamble.	(9.80)
88332 ...	Path consult intraop addl.	L037B	Histotechnologist ...	NF	Assemble and deliver slides with paperwork to pathologists.	2	0.5	Refined time to standard time for this clinical labor task.	(0.56)
		L037B	Histotechnologist ...	NF	Assist pathologist with gross specimen examination.	2	3	Refined time to standard time for this clinical labor task.	0.37
		L037B	Histotechnologist ...	NF	Clean room/equipment following procedure (including any equipment maintenance that must be done after the procedure).	0	1	Input added to maintain consistency with all other codes within family.	0.37
		SF047	scalpel, safety, surgical, with blade (#10–20).	NF	.....	0	1	Input added to maintain consistency with all other codes within family.	2.14
		SL134	stain, frozen section, H&E (1ml per slide).	NF	.....	0	1	Supply item replaces another item (SL231); see preamble.	0.57
		SL231	kit, stain, H&E	NF	.....	0.1	0	Supply item replaced by another item (SL134); see preamble.	(9.80)
88333 ...	Intraop cyto path consult 1.	L033A	Lab Technician	NF	Prepare room. Filter and replenish stains and supplies. (including OCT blocks, set up grossing station with colored stai.	10	0	Indirect Practice Expense; not individually allocable to a particular patient for a particular service.	(3.30)
		L037B	Histotechnologist ...	NF	Accession specimen/prepare for examination.	0	4	Input added to maintain consistency with all other codes within family.	1.48
		L037B	Histotechnologist ...	NF	Assemble and deliver slides with paperwork to pathologists.	2	0.5	Refined time to standard time for this clinical labor task.	(1.48)
		L037B	Histotechnologist ...	NF	Assist pathologist with gross specimen examination (including performance of intraoperative frozen sections).	7	3	Refined time to standard time for this clinical labor task.	(1.48)
		L037B	Histotechnologist ...	NF	Clean room/equipment following procedure (including any equipment maintenance that must be done after the procedure).	5	1	Refined time to standard time for this clinical labor task.	(1.48)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		SL122	slide, microscope ...	NF	.....	10	4	Refined supply quantity to what is typical for the procedure.	(0.33)
		SL231	kit, stain, H&E	NF	.....	0.1	0	Removed supply not typically used in this service.	(9.80)
88334 ...	Intraop cyto path consult 2.	L037B	Histotechnologist ...	NF	Assemble and deliver slides with paperwork to pathologists.	2	0.5	Refined time to standard time for this clinical labor task.	(0.56)
		L037B	Histotechnologist ...	NF	Assist pathologist with gross specimen examination (including performance of intraoperative frozen sections).	5	3	Refined time to standard time for this clinical labor task.	(0.74)
		L037B	Histotechnologist ...	NF	Clean room/equipment following procedure (including any equipment maintenance that must be done after the procedure).	0	1	Input added to maintain consistency with all other codes within family.	0.37
		SL122	slide, microscope ...	NF	.....	10	4	Refined supply quantity to what is typical for the procedure.	(0.33)
		SL231	kit, stain, H&E	NF	.....	0.1	0	Removed supply not typically used in this service.	(9.80)
88355 ...	Analysis skeletal muscle.	EP046	freezer, ultradeep (−70 degrees).	NF	.....	30	0	Indirect Practice Expense; not individually allocable to a particular patient for a particular service.	(1.32)
		L033A	Lab Technician	NF	Accession specimen/prepare for examination.	6	4	Refined time to standard time for this clinical labor task.	(0.66)
		L033A	Lab Technician	NF	Assemble and deliver slides with paperwork to pathologists.	2	0.5	Refined time to standard time for this clinical labor task.	(0.50)
		L033A	Lab Technician	NF	Clean room, equipment following procedure including any equipment maintenance that must be done after the procedure.	2	1	Refined time to standard time for this clinical labor task.	(0.33)
		L033A	Lab Technician	NF	Dispose of remaining specimens, spent chemicals/other consumables, and hazardous waste.	2	1	Refined time to standard time for this clinical labor task.	(0.33)
		L033A	Lab Technician	NF	Prepare specimen containers/preload fixative/label containers/distribute requisition form(s) to physician.	9	0.5	Refined time to standard time for this clinical labor task.	(2.81)
		L033A	Lab Technician	NF	Prepare specimen for −70 degree storage, log specimen and place in freezer for retrieval and performance of quantitative.	5	0	Refined time to standard time for this clinical labor task.	(1.65)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		L033A	Lab Technician	NF	Prepare, pack and transport specimens and records for storage.	4	1	Refined time to standard time for this clinical labor task.	(0.99)
		L033A	Lab Technician	NF	Receive phone call from referring laboratory/facility with scheduled procedure to arrange special delivery of specimen p.	7	5	See preamble text	(0.66)
		L037B	Histotechnologist ...	NF	Assist pathologist with gross examination.	7	3	Refined time to standard time for this clinical labor task.	(1.48)
88360 ...	Tumor immunohistochem/manual.	EP024	microscope, compound.	NF	.....	36	25	See preamble text	(0.41)
		L033A	Lab Technician	NF	Recycle xylene from tissue processor and stainer.	1	0	Non-standard clinical labor task.	(0.33)
		L037B	Histotechnologist ...	NF	Enter patient data, computational prep for antibody testing, generate and apply bar codes to slides, and enter data for.	5	1	Refined time to standard time for this clinical labor task.	(1.48)
		L037B	Histotechnologist ...	NF	Verify results and complete work load recording logs.	1	0	Refined time to standard time for this clinical labor task.	(0.37)
88361 ...	Tumor immunohistochem/comput.	L033A	Lab Technician	NF	Recycle xylene from tissue processor and stainer.	1	0	Non-standard clinical labor task.	(0.33)
		L037B	Histotechnologist ...	NF	Enter patient data, computational prep for antibody testing, generate and apply bar codes to slides, and enter data for.	5	1	Refined time to standard time for this clinical labor task.	(1.48)
		L037B	Histotechnologist ...	NF	Verify results and complete work load recording logs.	1	0	Refined time to standard time for this clinical labor task.	(0.37)
88362 ...	Nerve teasing preparations.	L033A	Lab Technician	NF	Assemble and deliver cedar mounted slides with paperwork to pathologists.	2	0.5	Refined time to standard time for this clinical labor task.	(0.50)
		L033A	Lab Technician	NF	Assemble other light microscopy slides, epon nerve biopsy slides, and clinical history, and present to pathologist to pr.	5	0.5	Refined time to standard time for this clinical labor task.	(1.49)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		L033A	Lab Technician	NF	Clean room/equipment following procedure (including dissecting microscope and dissection work area. Cedar oil specific c.	7	1	Refined time to standard time for this clinical labor task.	(1.98)
		L033A	Electrodiagnostic Technologist.	NF	Preparation: labeling of blocks and containers and document location and processor used.	2	0.5	Refined time to standard time for this clinical labor task.	(0.50)
		L037B	Histotechnologist ...	NF	Accession specimen and prepare for examination.	10	4	Refined time to standard time for this clinical labor task.	(2.22)
		L037B	Histotechnologist ...	NF	Assist pathologist with gross specimen examination including the following; A ; Selection of fresh unfixed tissue samp.	10	5	Non-standard refinement, see preamble text.	(1.85)
		L037B	Histotechnologist ...	NF	Consult with pathologist regarding representation needed, block selection and appropriate technique.	7	0	Task would not be required for the typical procedure.	(2.59)
		L037B	Histotechnologist ...	NF	Dispose of remaining specimens, spent chemicals/other consumables, and hazardous waste.	2	1	Refined time to standard time for this clinical labor task.	(0.37)
		L037B	Histotechnologist ...	NF	Manage any relevant utilization review/quality assurance activities and regulatory compliance documentation.	2	0	Refined time to standard time for this clinical labor task.	(0.74)
		L037B	Histotechnologist ...	NF	Prepare specimen containers preload fixative label containers distribute requisition form(s) to physician.	12	0.5	Refined time to standard time for this clinical labor task.	(4.26)
		L037B	Histotechnologist ...	NF	Prepare, pack and transport cedar oiled glass slides and records for in-house special storage (need to be stored flat).	10	0	Refined time to standard time for this clinical labor task.	(3.70)
		L037B	Histotechnologist ...	NF	Prepare, pack and transport specimens and records for in-house storage and external storage (where applicable).	2	1	Refined time to standard time for this clinical labor task.	(0.37)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		L037B	Histotechnologist ...	NF	Storage remaining specimen. (Osmicated nerve strands, potential for additional teased specimens).	5	0	Refined time to standard time for this clinical labor task.	(1.85)
92511 ...	Nasopharyngoscopy.	EF008	chair with headrest, exam, reclining.	NF	.....	19	26	Refined equipment time to conform to established policies for non-highly technical equipment.	0.08
		EQ167	light source, xenon	NF	.....	19	0	Redundant when used together with EQ170; see preamble.	(0.51)
		EQ170	light, fiberoptic headlight w-source.	NF	.....	19	26	Refined equipment time to conform to established policies for non-highly technical equipment.	0.06
		ES020	fiberscope, flexible, rhinolaryngoscopy.	NF	.....	46	53	Refined equipment time to conform to established policies for scopes.	0.26
		ES031	video system, endoscopy (processor, digital capture, monitor, printer, cart).	NF	.....	19	26	Refined equipment time to conform to established policies for non-highly technical equipment.	0.90
		L037D	RN/LPN/MTA	F	Dischrge Day mgmt. (0.5 × 99238) (enter 6 min).	6	0	Aligned clinical labor discharge day management time with the work time discharge day code.	(2.22)
		SB006	drape, non-sterile, sheet 40in x 60in.	NF	.....	1	0	Removed supply not typically used in this service.	(0.22)
		SB027	gown, staff, impervious.	NF	.....	2	0	Removed supply not typically used in this service.	(2.37)
		SB033	mask, surgical	NF	.....	2	0	Removed supply not typically used in this service.	(0.39)
		SD070	endosheath	NF	.....	1	0	Removed supply not typically used in this service.	(17.25)
95812 ...	Eeg 41–60 minutes.	EF003	bedroom furniture (hospital bed, table, reclining chair).	NF	.....	124	99	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.15)
		EQ017	EEG, digital, prolonged testing system (computer w-remote camera).	NF	.....	133	99	Refined equipment time to conform to established policies for non-highly technical equipment.	(4.99)
		L047B	REEGT	NF	Assist physician in performing procedure.	79	50	Refined clinical labor time to match physician intraservice time.	(13.63)
		L047B	REEGT	NF	Enter patient information into laboratory log book.	2	0	Refined to conform with identical labor activity in other codes in the family.	(0.94)
		L047B	REEGT	NF	Provide pre-service education/obtain consent.	2	0	Duplication with other clinical labor task.	(0.94)
		L047B	REEGT	NF	Transfer data to reading station & archive data.	4	2	Refined time to standard time for this clinical labor task.	(0.94)
95813 ...	Eeg over 1 hour	EF003	bedroom furniture (hospital bed, table, reclining chair).	NF	.....	147	129	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.11)
		EQ017	EEG, digital, prolonged testing system (computer w-remote camera).	NF	.....	156	129	Refined equipment time to conform to established policies for non-highly technical equipment.	(3.96)
		L047B	REEGT	NF	Assist physician in performing procedure.	102	80	Refined clinical labor time to match physician intraservice time.	(10.34)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		L047B	REEGT	NF	Enter patient information into laboratory log book.	2	0	Refined to conform with identical labor activity in other codes in the family.	(0.94)
		L047B	REEGT	NF	Provide pre-service education/obtain consent.	2	0	Duplication with other clinical labor task.	(0.94)
		L047B	REEGT	NF	Transfer data to reading station & archive data.	4	2	Refined time to standard time for this clinical labor task.	(0.94)
95863	Muscle test 3 limbs.	EF023	table, exam	NF		52	55	Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
		EQ024	EMG–NCV–EP system, 8 channel.	NF		52	55	Refined equipment time to conform to established policies for non-highly technical equipment.	0.44
		L037A	Electrodiagnostic Technologist.	NF	Clean room/equipment by physician staff.	0	3	Refined to conform with identical labor activity in other codes in the family.	1.11
95864	Muscle test 4 limbs.	EF023	table, exam	NF		62	65	Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
		EQ024	EMG–NCV–EP system, 8 channel.	NF		62	65	Refined equipment time to conform to established policies for non-highly technical equipment.	0.44
		L037A	Electrodiagnostic Technologist.	NF	Other Clinical Activity—specify:Prepare technician report, summarize clinical and electrodiagnostic data, and interpre.	6	0	Refined to conform with identical labor activity in other codes in the family.	(2.22)
95869	Muscle test thor paraspinal.	EF023	table, exam	NF		27	30	Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
		EQ024	EMG–NCV–EP system, 8 channel.	NF		27	30	Refined equipment time to conform to established policies for non-highly technical equipment.	0.44
		L037A	Electrodiagnostic Technologist.	NF	Clean room/equipment by physician staff.	0	3	Refined to conform with identical labor activity in other codes in the family.	1.11
95870	Muscle test nonparaspinal.	EF023	table, exam	NF		27	30	Refined equipment time to conform to established policies for non-highly technical equipment.	0.01
		EQ024	EMG–NCV–EP system, 8 channel.	NF		27	30	Refined equipment time to conform to established policies for non-highly technical equipment.	0.44
		L037A	Electrodiagnostic Technologist.	NF	Clean room/equipment by physician staff.	0	3	Refined to conform with identical labor activity in other codes in the family.	1.11
		SD275	Disposable electrode pack.	NF		6	1	Refined supply quantity to what is typical for the procedure.	(13.75)
95923	Autonomic nrv syst funj test.	EF023	table, exam	NF		51	43	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.02)
		EQ035	QSART acquisition system (Q-Sweat).	NF		46	43	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.33)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		EQ124	stimulator, constant current, w-stimulating and grounding electrodes (Grass Telefactor).	NF	.....	46	43	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.01)
		EQ171	light, infra-red, ceiling mount.	NF	.....	46	43	Refined equipment time to conform to established policies for non-highly technical equipment.	.....
		L037A	Electrodiagnostic Technologist.	NF	Clean room/equipment by physician staff.	5	0	Typically billed with an E/M or other evaluation service.	(1.85)
		L037A	Electrodiagnostic Technologist.	NF	Complete diagnostic forms, lab & X-ray requisitions.	5	0	Typically billed with an E/M or other evaluation service.	(1.85)
		L037A	Electrodiagnostic Technologist.	NF	Complete pre-service diagnostic & referral forms.	5	2	Refined to conform with identical labor activity in other codes in the family.	(1.11)
		L037A	Electrodiagnostic Technologist.	NF	Prepare room, equipment, supplies.	0	2	Refined time to standard time for this clinical labor task.	0.74
		SA014	kit, electrode, iontophoresis.	NF	.....	4	3	See preamble text	(4.01)
		SA048	pack, minimum multi-specialty visit.	NF	.....	1	0	Typically billed with an E/M or other evaluation service.	(1.14)
95928 ...	C motor evoked uppr limbs.	EF023	table, exam	NF	.....	65	45	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.06)
		EQ024	EMG–NCV–EP system, 8 channel.	NF	.....	65	45	Refined equipment time to conform to established policies for non-highly technical equipment.	(2.95)
		EQ178	magnetic stimulator hand coil (70–90mm).	NF	.....	65	45	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.16)
		EQ180	magnetic stimulator system (BiStim).	NF	.....	65	45	Refined equipment time to conform to established policies for non-highly technical equipment.	(1.43)
		L047B	REEGT	NF	Assist physician in performing procedure.	60	40	Refined clinical labor time to match physician intraservice time.	(9.40)
		L047B	REEGT	NF	Other Clinical Activity—specify: Review requisition. Assess for special needs. Give patient instructions for test prepa.	3	0	Duplication with other clinical labor task.	(1.41)
		SA048	pack, minimum multi-specialty visit.	NF	.....	1	0	Typically billed with an E/M or other evaluation service.	(1.14)
95929 ...	C motor evoked lwr limbs.	EF023	table, exam	NF	.....	65	45	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.06)
		EQ024	EMG–NCV–EP system, 8 channel.	NF	.....	65	45	Refined equipment time to conform to established policies for non-highly technical equipment.	(2.95)
		EQ179	magnetic stimulator leg coil (110mm).	NF	.....	65	45	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.24)
		EQ180	magnetic stimulator system (BiStim).	NF	.....	65	45	Refined equipment time to conform to established policies for non-highly technical equipment.	(1.43)

TABLE 13—CY 2016 PROPOSED CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITH REFINEMENTS—Continued

HCPCS code	HCPCS code description	Input code	Input code description	NF/F	Labor activity (where applicable)	RUC recommendation or current value (min or qty)	CMS refinement (min or qty)	Comment	Direct costs change ($)
		L047B	REEGT	NF	Assist physician in performing procedure.	60	40	Refined clinical labor time to match physician intraservice time.	(9.40)
		L047B	REEGT	NF	Other Clinical Activity—specify:Review requisition. Assess for special needs. Give patient instructions for test prepa.	3	0	Duplication with other clinical labor task.	(1.41)
95933	Blink reflex test	L037A	Electrodiagnostic Technologist.	NF	Clean room/equipment by physician staff.	5	3	Refined time to standard time for this clinical labor task.	(0.74)
		L037A	Electrodiagnostic Technologist.	NF	Prepare room, equipment, supplies.	0	2	Refined time to standard time for this clinical labor task.	0.74
95956	Eeg monitor technol attended.	EF003	bedroom furniture (hospital bed, table, reclining chair).	NF		772	769	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.02)
		EQ017	EEG, digital, prolonged testing system (computer w-remote camera).	NF		772	769	Refined equipment time to conform to established policies for non-highly technical equipment.	(0.44)
		EQ047	air compressor, safety.	NF		52	49	Refined equipment time to conform to established policies for non-highly technical equipment.	
		L047B	REEGT	NF	Other Clinical Activity—specify: Coordinate pretesting services/review test/exam results.	3	0	Duplication with other clinical labor task.	(1.41)
		L047B	REEGT	NF	Provide pre-service education/obtain consent.	2	0	Duplication with other clinical labor task.	(0.94)

TABLE 14—CROSSWALK FOR ESTABLISHING CY 2016 NEW, REVISED, AND POTENTIALLY MISVALUED CODES MALPRACTICE RVUS

CY 2016 New, Revised or Potentially Misvalued Code		Malpractice Risk Factor Crosswalk Code	
11750	Removal of nail bed	11750	Removal of nail bed.
20240	Bone biopsy excisional	20240	Bone biopsy excisional.
27280	Fusion of sacroiliac joint	27280	Fusion of sacroiliac joint.
31622	Dx bronchoscope/wash	31622	Dx bronchoscope/wash.
3160A	Bronch ebus sampling 1/2 node	31620	Endobronchial us add-on.
3160B	Bronch ebus samplng 3/≤ node	31620	Endobronchial us add-on.
31625	Bronchoscopy w/biopsy(s)	31625	Bronchoscopy w/biopsy(s).
31626	Bronchoscopy w/markers	31626	Bronchoscopy w/markers.
31628	Bronchoscopy/lung bx each	31628	Bronchoscopy/lung bx each.
31629	Bronchoscopy/needle bx each	31629	Bronchoscopy/needle bx each.
3160C	Bronch ebus ivntj perph les	31620	Endobronchial us add-on.
31632	Bronchoscopy/lung bx addl	31632	Bronchoscopy/lung bx addl.
31633	Bronchoscopy/needle bx addl	31633	Bronchoscopy/needle bx addl.
3347A	Implant tcat pulm vlv perq	93581	Transcath closure of vsd.
3725A	Intrvasc us noncoronary 1st	37250	Iv us first vessel add-on.
3725B	Intrvasc us noncoronary addl	37251	Iv us each add vessel add-on.
38570	Laparoscopy lymph node biop	38570	Laparoscopy lymph node biop.
38571	Laparoscopy lymphadenectomy	38571	Laparoscopy lymphadenectomy.
38572	Laparoscopy lymphadenectomy	38572	Laparoscopy lymphadenectomy.
3940A	Mediastinoscpy w/medstnl bx	33924	Remove pulmonary shunt.
3940B	Mediastinoscpy w/lmph nod bx	32606	Thoracoscopy w/bx med space.
44380	Small bowel endoscopy br/wa	44380	Small bowel endoscopy br/wa.
44381	Small bowel endoscopy br/wa	45340	Sig w/tndsc balloon dilation.
44382	Small bowel endoscopy	44382	Small bowel endoscopy.

TABLE 14—CROSSWALK FOR ESTABLISHING CY 2016 NEW, REVISED, AND POTENTIALLY MISVALUED CODES MALPRACTICE RVUS—Continued

44384	Small bowel endoscopy	44383	Ileoscopy w/stent.
44385	Endoscopy of bowel pouch	44385	Endoscopy of bowel pouch.
44386	Endoscopy bowel pouch/biop	44386	Endoscopy bowel pouch/biop.
44388	Colonoscopy thru stoma spx	44388	Colonoscopy thru stoma spx.
44389	Colonoscopy with biopsy	44389	Colonoscopy with biopsy.
44390	Colonoscopy for foreign body	44390	Colonoscopy for foreign body.
44391	Colonoscopy for bleeding	44391	Colonoscopy for bleeding.
44392	Colonoscopy & polypectomy	44392	Colonoscopy & polypectomy.
44394	Colonoscopy w/snare	44394	Colonoscopy w/snare.
44401	Colonoscopy with ablation	44393	Colonoscopy lesion removal.
44402	Colonoscopy w/stent plcmt	44397	Colonoscopy w/stent.
44403	Colonoscopy w/resection	44392	Colonoscopy & polypectomy.
44404	Colonoscopy w/injection	44389	Colonoscopy with biopsy.
44405	Colonoscopy w/dilation	44390	Colonoscopy for foreign body.
44406	Colonoscopy w/ultrasound	44394	Colonoscopy w/snare.
45330	Diagnostic sigmoidoscopy	45330	Diagnostic sigmoidoscopy.
45331	Sigmoidoscopy and biopsy	45331	Sigmoidoscopy and biopsy.
45332	Sigmoidoscopy w/fb removal	45332	Sigmoidoscopy w/fb removal.
45333	Sigmoidoscopy & polypectomy	45333	Sigmoidoscopy & polypectomy.
45334	Sigmoidoscopy for bleeding	45334	Sigmoidoscopy for bleeding.
45335	Sigmoidoscopy w/submuc inj	45335	Sigmoidoscopy w/submuc inj.
45337	Sigmoidoscopy & decompress	45337	Sigmoidoscopy & decompress.
45338	Sigmoidoscopy w/tumr remove	45338	Sigmoidoscopy w/tumr remove.
45340	Sig w/tndsc balloon dilation	45340	Sig w/tndsc balloon dilation.
45341	Sigmoidoscopy w/ultrasound	45341	Sigmoidoscopy w/ultrasound.
45342	Sigmoidoscopy w/us guide bx	45342	Sigmoidoscopy w/us guide bx.
45346	Sigmoidoscopy w/ablation	45339	Sigmoidoscopy w/ablate tumr.
45347	Sigmoidoscopy w/plcmt stent	45345	Sigmoidoscopy w/stent.
45349	Sigmoidoscopy w/resection	45338	Sigmoidoscopy w/tumr remove.
45350	Sgmdsc w/band ligation	45334	Sigmoidoscopy for bleeding.
45378	Diagnostic colonoscopy	45378	Diagnostic colonoscopy.
45379	Colonoscopy w/fb removal	45379	Colonoscopy w/fb removal.
45380	Colonoscopy and biopsy	45380	Colonoscopy and biopsy.
45381	Colonoscopy submucous njx	45381	Colonoscopy submucous njx.
45382	Colonoscopy w/control bleed	45382	Colonoscopy w/control bleed.
45384	Colonoscopy w/lesion removal	45384	Colonoscopy w/lesion removal.
45385	Colonoscopy w/lesion removal	45385	Colonoscopy w/lesion removal.
45386	Colonoscopy w/balloon dilat	45386	Colonoscopy w/balloon dilat.
45388	Colonoscopy w/ablation	45383	Lesion removal colonoscopy.
45389	Colonoscopy w/stent plcmt	45387	Colonoscopy w/stent.
45390	Colonoscopy w/resection	45385	Colonoscopy w/lesion removal.
45391	Colonoscopy w/endoscope us	45391	Colonoscopy w/endoscope us.
45392	Colonoscopy w/endoscopic fnb	45392	Colonoscopy w/endoscopic fnb.
45393	Colonoscopy w/decompression	45382	Colonoscopy w/control bleed.
45398	Colonoscopy w/band ligation	45382	Colonoscopy w/control bleed.
46500	Injection into hemorrhoid(s)	46500	Injection into hemorrhoid(s).
47135	Transplantation of liver	47135	Transplantation of liver.
5039A	Njx px nfrosgrm &/urtrgrm	50390	Drainage of kidney lesion.
5039B	Njx px nfrosgrm &/urtrgrm	50394	Injection for kidney x-ray.
5039C	Plmt nephrostomy catheter	50392	Insert kidney drain.
5039D	Plmt nephroureteral catheter	50393	Insert ureteral tube.
5039M	Convert nephrostomy catheter	50393	Insert ureteral tube.
5039E	Exchange nephrostomy cath	50398	Change kidney tube.
5069G	Plmt ureteral stent prq	50398	Change kidney tube.
5069H	Plmt ureteral stent prq	50393	Insert ureteral tube.
5069I	Plmt ureteral stent prq	50393	Insert ureteral tube.
5443A	Repair corporeal tear	54406	Remove muti-comp penis pros.
5443B	Replantation of penis	53448	Remov/replc ur sphinctr comp.
657XG	Impltj ntrstrml crnl rng seg	65426	Removal of eye lesion.
7208A	X-ray exam entire spi 1 vw	72050	X-ray exam neck spine 4/5vws.
7208B	X-ray exam entire spi 2/3 vw	72052	X-ray exam neck spine 6/>vws.
7208C	X-ray exam entire spi 4/5 vw	72052	X-ray exam neck spine 6/> vws.
7208D	X-ray exam entire spi 6/> vw	72052	X-ray exam neck spine 6/> vws.
73560	X-ray exam of knee 1 or 2	73560	X-ray exam of knee 1 or 2.
73562	X-ray exam of knee 3	73562	X-ray exam of knee 3.
73564	X-ray exam knee 4 or more	73564	X-ray exam knee 4 or more.
73565	X-ray exam of knees	73565	X-ray exam of knees.
73590	X-ray exam of lower leg	73590	X-ray exam of lower leg.
73600	X-ray exam of ankle	73600	X-ray exam of ankle.
77402	Radiation treatment delivery	G6003	Radiation treatment delivery.
77407	Radiation treatment delivery	G6007	Radiation treatment delivery.
77412	Radiation treatment delivery	G6011	Radiation treatment delivery.
77385	Ntsty modul rad tx dlvr smpl	G6015	Radiation tx delivery imrt.

TABLE 14—CROSSWALK FOR ESTABLISHING CY 2016 NEW, REVISED, AND POTENTIALLY MISVALUED CODES MALPRACTICE RVUS—Continued

77386	Ntsty modul rad tx dlvr cplx	G6015	Radiation treatment delivery.
77387	Guidance for radiaj tx dlvr	77014	Ct scan for therapy guide.
76948	Echo guide ova aspiration	76948	Echo guide ova aspiration.
7778A	Hdr rdncl skn surf brachytx	77785	Hdr brachytx 1 channel.
7778B	Hdr rdncl skn surf brachytx	77786	Hdr brachytx 2–12 channel.
7778C	Hdr rdncl ntrstl/icav brchtx	77785	Hdr brachytx 1 channel.
7778D	Hdr rdncl ntrstl/icav brchtx	77786	Hdr brachytx 2–12 channel.
7778E	Hdr rdncl ntrstl/icav brchtx	77787	Hdr brachytx over 12 chan.
88346	Immunofluorescent study	88346	Immunofluorescent study.
8835X	Immunofluor antb addl stain	88346	Immunofluorescent study.
88367	Insitu hybridization auto	88367	Insitu hybridization auto.
88368	Insitu hybridization manual	88368	Insitu hybridization manual.
91200	Liver elastography	91200	Liver elastography.
9254A	Caloric vestibular test with recording	92540	Basic vestibular evaluation.
9254B	Caloric vestibular test with recording	92540	Basic vestibular evaluation.
99497	Advncd care plan 30 min	99214	Office/outpatient visit est.
99498	Advncd care plan addl 30 min	99214	Office/outpatient visit est.

Note: For any codes not included in Table 14, we are proposing to use the utilization crosswalk, when a crosswalk exists, in order to calculate the malpractice risk factor for these services, as discussed in the preamble text.

a. Lower GI Endoscopy Services

CPT revised the lower gastrointestinal endoscopy code set for CY 2015 following identification of some of the codes as potentially misvalued and the affected specialty society's contention that this code set did not allow for accurate reporting of services based upon current medical practice. The RUC subsequently provided recommendations to us for valuing these services. In the CY 2015 PFS final rule with comment period, we delayed valuing the lower GI codes and indicated that we would propose values for these codes in the CY 2016 proposed rule, citing the new process for including proposed values for new, revised and potentially misvalued codes in the proposed rule as one of the reasons for the delay.

(1) Gastrointestinal (GI) Endoscopy (CPT Codes 43775, 44380–46607 and HCPCS Codes G0104, G0105, and G0121)

In the CY 2014 PFS final rule with comment period, we indicated that we used what we called an ''incremental difference methodology'' in valuing the upper GI codes for that year. We explained that the RUC made extensive use of a methodology that uses the incremental difference in codes to determine values for many of these services. This methodology uses a base code or other comparable code and considers what the difference should be between that code and another code by comparing the differentials to those for other sets of similar codes. As with the esophagoscopy subfamily, many of the procedures described within the colonoscopy subfamily have identical counterparts in the esophagogastroduodenoscopy (EGD) subfamily. For instance, the base colonoscopy CPT code 45378 is described as ''Colonoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing when performed, (separate procedure).'' The base EGD CPT code 43235 is described as ''Esophagogastroduodenoscopy, flexible, transoral; diagnostic, with collection of specimen(s) by brushing or washing, when performed.'' In valuing other codes within both subfamilies, the RUC frequently used the difference between these two base codes as an increment for measuring the difference in work involved in doing a similar procedure utilizing colonoscopy versus utilizing EGD. For example, the EGD CPT code 43239 includes a biopsy in addition to the base diagnostic EGD CPT code 43235. The RUC valued this by adding the incremental difference in the base colonoscopy code over the base EGD CPT code to the value it recommended for the esophagoscopy biopsy, CPT code 43202. With some variations, the RUC used this incremental difference methodology extensively in valuing subfamilies of codes. We have made use of similar methodologies in establishing work RVUs for codes in this family.

We agreed with several of the RUC recommendations for codes in this family. Where we did not agree, we consistently applied the incremental difference methodology. Table I7 reflects how we applied this methodology and the values we are proposing. To calculate the base RVU for the colonoscopy subfamily, we looked at the current intraservice time for CPT code 45378, which is 30 minutes, and the current work RVU, which is 3.69. The RUC recommended an intraservice time of 25 minutes and 3.36 RVUs. We then compared that service to the base EGD CPT code 43235 for which the RUC recommended a work RVU of 2.26, giving an increment between EGD and colonoscopy of 1.10 RVUs. We added that increment to our proposed work RVU for CPT 43235 of 2.19 to arrive at our proposed work RVU for the base colonoscopy CPT code 45378 of 3.29. We use this value as the base code in the incremental methodology for establishing the work value for the other base codes in the colonoscopy subfamilies which were then used to value the other codes in that subfamily.

TABLE 15—APPLICATION OF THE INCREMENTAL DIFFERENCE METHODOLOGY

HCPCS	Descriptor	Current WRVU	RUC WRVU	Base procedure	Base RVU	Increment	Increment value	Calculated WRVU
44380	Ileoscopy, through stoma; diagnostic, including collection of specimen(s) by brushing or washing, when performed.	1.05	0.97	Colonoscopy	3.29	Colonoscopy to Ileoscopy.	−2.39	0.9

TABLE 15—APPLICATION OF THE INCREMENTAL DIFFERENCE METHODOLOGY—Continued

HCPCS	Descriptor	Current WRVU	RUC WRVU	Base procedure	Base RVU	Increment	Increment value	Calculated WRVU
44382	Ileoscopy, through stoma; with biopsy, single or multiple.	1.27	1.27	Ileoscopy	0.9	Biopsy	0.3	1.2
44384	Ileoscopy, through stoma; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed).	NA	3.11	Ileoscopy	0.9	Stent	1.98	2.88
44385	Endoscopic evaluation of small intestinal pouch (eg, Kock pouch, ileal reservoir [S or J]); diagnostic, including collection of specimen(s) by brushing or washing, when performed.	1.82	1.3	Colonoscopy	3.29	Colonoscopy to endo. eval.	−2.06	1.23
44386	Endoscopic evaluation of small intestinal pouch (eg, Kock pouch, ileal reservoir [S or J]); with biopsy, single or multiple.	2.12	1.6	Endo. Eval.	1.23	Biopsy	0.3	1.53
44388	Colonoscopy through stoma; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure).	2.82	2.82	Colonoscopy	3.29	Colonoscopy to Colonoscopy through stoma.	−0.54	2.75
44389	Colonoscopy through stoma; with biopsy, single or multiple.	3.13	3.12	Colonoscopy through stoma.	2.75	Biopsy	0.3	3.05
44390	Colonoscopy through stoma; with removal of foreign body.	3.82	3.82	Colonoscopy through stoma.	2.75	Foreign body	1.02	3.77
44402	Colonoscopy through stoma; with endoscopic stent placement (including pre- and post-dilation and guidewire passage, when performed).	4.7	4.96	Colonoscopy through stoma.	2.75	Stent	1.98	4.73
44403	Colonoscopy through stoma; with endoscopic mucosal resection.	NA	5.81	Colonoscopy through stoma.	2.75	Endoscopic mucosal resection.	2.78	5.53
44404	Colonoscopy through stoma; with directed submucosal injection(s), any substance.	NA	3.13	Colonoscopy through stoma.	2.75	Submucosal injection	0.3	3.05
45330	Sigmoidoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing when performed.	0.96	0.84	Colonoscopy	3.29	Colonoscopy to Sigmoidoscopy.	−2.52	0.77
45331	Sigmoidoscopy, flexible; with biopsy, single or multiple.	1.15	1.14	Sigmoidoscopy	0.77	Biopsy	0.3	1.07
45332	Sigmoidoscopy, flexible; with removal of foreign body.	1.79	1.85	Sigmoidoscopy	0.77	Foreign body	1.02	1.79
45335	Sigmoidoscopy, flexible; with directed submucosal injection(s), any substance.	1.46	1.15	Sigmoidoscopy	0.77	Submucosal injection	0.3	1.07
45341	Sigmoidoscopy, flexible; with endoscopic ultrasound examination.	2.6	2.43	Sigmoidoscopy	0.77	Endoscopic ultrasound	1.38	2.15

TABLE 15—APPLICATION OF THE INCREMENTAL DIFFERENCE METHODOLOGY—Continued

HCPCS	Descriptor	Current WRVU	RUC WRVU	Base procedure	Base RVU	Increment	Increment value	Calculated WRVU
45346	Sigmoidoscopy, flexible; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre- and post-dilation and guide wire passage, when performed).	NA	2.97	Sigmoidoscopy	0.77	Ablation	2.07	2.84
45347	Sigmoidoscopy, flexible; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed).	NA	2.98	Sigmoidoscopy	0.77	Stent	1.98	2.75
45349	Sigmoidoscopy, flexible; with endoscopic mucosal resection.	NA	3.83	Sigmoidoscopy	0.77	Endoscopic mucosal resection.	2.78	3.55
45378	Colonoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed, (separate procedure).	3.69	3.36	Colonoscopy	3.29			
45379	Colonoscopy, flexible; with removal of foreign body.	4.68	4.37	Colonoscopy	3.29	Foreign body	1.02	4.31
45380	Colonoscopy, flexible, proximal to splenic flexure; with biopsy, single or multiple.	4.43	3.66	Colonoscopy	3.29	Biopsy	0.3	3.59
45381	Colonoscopy, flexible; with directed submucosal injection(s), any substance.	4.19	3.67	Colonoscopy	3.29	Submucosal injection	0.3	3.59
45389	Colonoscopy, flexible; with endoscopic stent placement (includes pre- and post-dilation and guide wire passage, when performed).	NA	5.5	Colonoscopy	3.29	Stent	1.98	5.27
45390	Colonoscopy, flexible; with endoscopic mucosal resection.	NA	6.35	Colonoscopy	3.29	Endoscopic mucosal resection.	2.78	6.07
45391	Colonoscopy, flexible; with endoscopic ultrasound examination limited to the rectum, sigmoid, descending, transverse, or ascending colon and cecum, and adjacent structures.	5.09	4.95	Colonoscopy	3.29	Endoscopic ultrasound	1.38	4.67

(2) Laparoscopic Sleeve Gastrectomy (CPT Code 43775)

Prior to CY 2013, CPT code 43775 described a non-covered service. For CY 2013, this service was covered as part of the bariatric surgery National Coverage Determination (NCD) and has been contractor-priced since 2013. We are now proposing to establish national pricing for CPT code 43775. To establish a work RVU, we are crosswalking this code to CPT code 37217 (Transcatheter placement of an intravascular stent(s), intrathoracic common carotid artery or innominate artery by retrograde treatment, via open ipsilateral cervical carotid artery exposure, including angioplasty, when performed, and radiological supervision and interpretation), due to their identical intraservice times, similar total times, and similar levels of intensity. Therefore, we are proposing a work RVU of 20.38 for CPT code 43775.

(3) Incomplete Colonoscopy (CPT codes 44388, 45378, G0105, and G0121)

Prior to CY 2015, according to CPT instruction, an incomplete colonoscopy was defined as a colonoscopy that did not evaluate the colon past the splenic flexure (the distal third of the colon). In accordance with that definition, the Medicare Claims Processing Manual (pub. 100–04, chapter 12, section 30.1.B., available at *http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items*) states that physicians should report an incomplete colonoscopy with 45378 and append modifier -53, which is paid at the same rate as a sigmoidoscopy.

In CY 2015, the CPT instruction changed the definition of an incomplete colonoscopy to a colonoscopy that does not evaluate the entire colon. The 2015 CPT Manual states, ''When performing a diagnostic or screening endoscopic procedure on a patient who is scheduled and prepared for a total colonoscopy, if the physician is unable to advance the colonoscope to the

cecum or colon-small intestine anastomosis due to unforeseen circumstances, report 45378 (colonoscopy) or 44388 (colonoscopy through stoma) with modifier -53 and provide appropriate documentation.''

Given that the new definition of an incomplete colonoscopy also includes colonoscopies where the colonoscope is advanced past the splenic flexure but not to the cecum, we are proposing to establish new values for the incomplete colonoscopies, reported with the -53 modifier. At present, we crosswalk the RVUs for the incomplete colonoscopies from the values of the corresponding sigmoidoscopy. Given that the new CPT instructions will reduce the number of reported complete colonoscopies and increase the number of colonoscopies that proceeded further toward completion reported with the -53 modifier, we believe CPT code 45378 reported with the -53 modifier will now describe a more resource-intensive group of services than were previously reported. Therefore, we are proposing to develop RVUs for these codes reported with the -53 modifier by using one-half the value of the inputs for the corresponding codes reported without the -53 modifier.

In addition to this proposed change in input values, we are also seeking comment on how to address the disparity of resource costs among the broader range of services now described by the colonoscopy codes billed with the -53 modifier. We believe that it may be appropriate for practitioners to report the sigmoidoscopy CPT code 45330 under circumstances when a beneficiary is scheduled and prepared for a total colonoscopy (diagnostic colonoscopy, screening colonoscopy or colonoscopy through stoma), but the practitioner is unable to advance the colonoscope beyond the splenic flexure. We are seeking comment and recommendations on that possibility, as well as more generally, the typical resource costs of these incomplete colonoscopy services under CPT's new definition. Finally, we are seeking information regarding the number of colonoscopies that will be considered incomplete under CPT's new definition relative to the old definition, as well as the number of incomplete colonoscopies where the practitioner is unable to advance the colonoscope beyond the splenicflexure. This information will help us determine whether or not differential payment is required, and if it is, how to make the appropriate utilization assumptions within our ratesetting process.

(4) Malpractice (MP) Crosswalk

We examined the RUC's recommended MP crosswalk for this family of codes. The MP crosswalks are used to identify the presumed mix of specialties that furnish particular services until there is Medicare claims data for the new codes. We direct the reader to section II.B.1. of this proposed rule for further explanation regarding these crosswalks. In reviewing the recommended MP crosswalks for CPT codes 43775, 44407, 44408, 46601, and 46607, we noted that the RUC-recommended MP crosswalk codes are inconsistent with our analysis of the specialties likely to furnish the service based on the description of the services and our review of the RUC-recommended utilization crosswalk. The inconsistency between the RUC's recommended MP and utilization crosswalks is not altogether unusual. However when there are discrepancies between the MP and utilization crosswalk recommendations, they generally reflect the RUC's expectation that due to changes in coding, there will be a different mix of specialties reporting a new code than might be reflected in the claims data for the code previously used to report that service. This often occurs when the new coding structure for a particular family of services is either more or less specific than the old set of codes. In most of these cases, we could identify a rationale for why the RUC's recommended MP crosswalks for these codes were likely to be more accurate than the RUC's recommended utilization crosswalk. But in the case of these codes, the reason for the discrepancies were neither apparent nor explained as part of the recommendation. Since the specialty mix in the claims data is used to determine the specialty mix for each HCPCS code for the purposes of calculating MP RVUs, and that data will be used to set the MP RVUs once it is available, we believe using a specialty mix derived from the claims data of the predecessor codes is more likely to be accurate than the RUC-recommended MP crosswalk as well as more likely to result in stable MP RVUs for these services over several years. Therefore, until claims data under the new set of codes is available, we are proposing to use the specialty mix of the source code(s) in the RUC-recommended utilization crosswalk in order to calculate the malpractice risk factor for these services instead of the RUC-recommended MP crosswalk. Once claims data are available, those data will be incorporated into the calculation of MP RVUs for these services under the MP RVU methodology.

b. Radiation Treatment and Related Image Guidance Services

For CY 2015, the CPT Editorial Panel revised the set of codes that describe radiation treatment delivery services based in part on the CMS identification of these services as potentially misvalued in CY 2012. We identified these codes as potentially misvalued under a screen called ''Services with Stand-Alone PE Procedure Time.'' We proposed this screen following our discovery of significant discrepancies between the RUC-recommended 60 minute procedure time assumptions for intensity modulated radiation therapy (IMRT) and information available to the public suggesting that the procedure typically took between 5 and 30 minutes per treatment.

The CPT Editorial Panel's revisions included the addition and deletion of several codes and the development of new guidelines and coding instructions. Four treatment delivery codes (77402, 77403, 77404, and 77406) were condensed into 77402 (Radiation Treatment Delivery, Simple), three treatment delivery codes (77407, 77408, 77409) were condensed into 77407 (Radiation treatment delivery, intermediate), and four treatment codes (77412, 77413, 77414, 77416) were condensed into 77412 (Radiation treatment delivery, complex). Intensity Modulated Radiation Therapy (IMRT) treatment delivery, previously reported under a single code, was split into two codes, 77385 (IMRT treatment delivery, simple) and 77386 (IMRT treatment delivery, complex). The CPT Editorial Panel also created a new image guidance code, 77387 (Guidance for localization of target volume for delivery of treatment, includes intrafraction tracking when performed) to replace 77014 (computed tomography guidance for placement of radiation therapy fields), 77421 (stereoscopic X-ray guidance for localization of target volume for the delivery of radiation therapy,) and 76950 (ultrasonic guidance for placement of radiation therapy fields) when any of these services were furnished in conjunction with radiation treatment delivery.

In response to stakeholder concerns regarding the magnitude of the coding changes and in light of the process changes we adopted for valuing new and revised codes, we did not implement interim final values for the new codes and delayed implementing the new code set until 2016. To address the valuation of the new code set through proposed rulemaking, and

continue making payment based the previous valuations even though CPT deleted the prior radiation treatment delivery codes for CY 2015, we created G-codes that mimic the predecessor CPT codes (79 FR 67667).

We propose to establish values for the new codes based on RUC recommendations, subject to standard CMS refinements that appear in Table 15 in section II.B.4. of this proposed rule. We also note that because the invoices used to price the capital equipment included ''on-board imaging,'' the cost of that equipment is already reflected in the price per minute associated with the capital equipment. Therefore, we have not included it as a separate item in the proposed direct PE inputs for these codes, even though it appeared as a separate item on the PE worksheet included with the RUC recommendations for these codes. The direct PE inputs for these codes are reflected in the proposed direct PE input database available on the CMS Web site under the supporting data files for the CY 2016 PFS proposed rule with comment period at *http://www.cms.gov/PhysicianFeeSched/*. The RVUs that result from the use of these proposed direct PE inputs (and work RVUs and work time, as applicable) are displayed in Addendum B on the CMS Web site.

In addition to the refinements addressed above, there are three additional issues for which we are seeking comment and/or making specific proposals related to these services: image guidance, equipment utilization rate assumptions for linear accelerators, and superficial radiation treatment services.

(1) Image Guidance Services

Under the previous CPT coding structure, image guidance was separately billable when furnished in conjunction with the radiation treatment delivery services. The image guidance was reported using different CPT codes, depending on which image guidance modality was used. These codes were split into professional and/or technical components that allowed practitioners to report a single component or the global service. The professional component of each of these codes included the work of the physician furnishing the image guidance. CPT code 77014, used to report CT guidance, had a work RVU of 0.85; CPT code 77421, used to report stereotactic guidance, had a work RVU of 0.39, and CPT code 76950, used to report ultrasonic guidance, had a work RVU of 0.58. The technical component of these codes incorporated the resource costs of the image guidance capital equipment (such as CT, ultrasound, or stereotactic) and the clinical staff involved in furnishing the image guidance associated with the radiation treatment. When billed globally, the RVUs reflected the sum of the professional and technical components. In the revised coding structure, one new image guidance code is to be reported regardless of the modality used, and in developing its recommended values, the RUC assumed that CT guidance would be typical.

However, the 2013 Medicare claims data for separately reported image guidance indicates that stereotactic guidance for radiation treatment services was furnished more frequently than CT guidance. The RUC has recommended a work RVU of 0.58 and associated work times of 3 pre-service minutes, 10 intraservice minutes, and 3 post-service minutes for image guidance CPT code 77387. We reviewed this recommendation considering the discrepancy between the modality the RUC assumed to be typical in the vignette and the modality typically reported in the Medicare claims data. Given that the recommended work RVU for the new single code is similar to the work RVUs of the predecessor codes, roughly prorated based on their distribution in Medicare claims data, we agree with the RUC-recommended work RVU for the service. However, the RUC also recommended an increase in overall work time associated with image guidance consistent with the survey data used to value the new services. If accurate, this increase in time and maintenance of total work would suggest a decrease in the overall intensity for image guidance relative to the current codes. Given this implication, we are seeking comment as to the appropriate work time associated with CPT code 77387.

Although 77421 (stereotactic guidance) and 76950 (ultrasonic guidance) have been deleted, we note that CPT maintained CPT code 77014 (Computed tomography guidance for placement of radiation therapy fields) and the RUC recommendation states that CPT did so based on concerns that without this option, some practitioners might have no valid CPT alternative than to use higher valued diagnostic CT codes when they used this CT guidance. The RUC recommendation also includes a statement that utilization of this code is expected to drop to negligible levels by 2015, assuming that practitioners would use the new codes that are not differentiated based on imaging modality. Once all the new codes are implemented for Medicare, we anticipate that CPT and/or the RUC will address the continued use of 77014 and, if it continues to be part of the code set, provide recommendations as to the appropriate values given changes in utilization.

Regarding the reporting of the new image guidance codes, CPT guidance instructs that the technical portion of image guidance is now bundled into the IMRT and Stereotactic Radiation Treatment delivery codes, but it is not bundled into the simple, intermediate, and complex radiation treatment delivery codes. CPT guidance states that the technical component of the image guidance code can be reported with codes 77402, 77407, and 77412 (simple, intermediate, and complex radiation treatment) when furnished, which means that the technical component of the image guidance code should not be reported with the IMRT or Stereotactic Radiation Treatment delivery codes. The RUC recommendation, however, incorporates the same capital cost of image guidance equipment (a linear accelerator, or linac), for all these radiation treatment delivery codes, including the codes that describe IMRT and Stereotactic Radiation Treatment delivery services. The RUC explains that the recommendations were done this way because the older lower-dose external beam radiation machines are no longer manufactured and the image guidance technology is integrated into the single kind of linear accelerator used for all the radiation treatment services. In reviewing the new code structure and the RUC recommendations, we assume that the CPT editorial panel did not foresee that the RUC would recommend that we develop PE RVUs for all the radiation treatment delivery codes based on the assumption that the same capital equipment is typically used in furnishing the entire range of external beam radiation treatments. Because the RUC recommendations incorporate the more extensive capital equipment in the lower dose treatment codes as well, a portion of the resource costs of the technical portion of imaging guidance are already allocated into the PE RVUs for all of the treatment delivery codes, not just the IMRT and Stereotactic Radiation Treatment delivery codes as CPT guidance would suggest.

In order to avoid incorporating the cost of this equipment into both the treatment delivery codes (77402, 77407, and 77412) and the technical component of the new imaging guidance code (77387–TC), we considered valuing 77387 as a professional service only and not creating the professional/technical component splits envisioned by CPT. In the context of the budget neutral PFS, incorporating a duplicative

direct input with a cost of more than six dollars per minute has significant impacts on the PE RVUs for all other services. However, we also noted that the RUC did not address this apparent contradiction in its recommendation and not all of the recommended direct PE inputs for the technical component of 77387 are capital equipment costs. Therefore, we are proposing to allow for professional and technical component billing for these services, as reflected in CPT guidance, and we are proposing to use the RUC recommended direct PE inputs for these services (refined as described in Table 15). However, we are also seeking comment on the apparent contradiction between technical component billing for image guidance in the context of the inclusion of a single linac with integrated imaging guidance technology being included for all external beam treatment codes.

(2) Equipment Utilization Rate for Linear Accelerators

The cost of the capital equipment is the primary determining factor in the payment rates for these services. For each CPT code, the equipment costs are estimated based on multiplying the assumed number of minutes the equipment is used for that procedure by the per minute cost of the particular equipment item. Under our PE methodology, we currently use two default equipment usage assumptions in allocating capital equipment costs to calculate PE RVUs. The first is that each equipment item is only available to be used during what are assumed to be regular business hours for a physician's office: 10 hours per day, 5 days per week (50 hours per week) and 50 weeks per year. The second assumption is that the equipment is in use only 50 percent of the time that it is available for use. The current default 50 percent utilization rate assumption translates into 25 hours per week out of a 50-hour work week.

We have previously addressed the accuracy of these default assumptions as they apply to particular equipment resources and particular services. In the CY 2008 PFS proposed rule (72 FR 38132) we discussed the 50 percent utilization assumption and acknowledged that the default 50 percent usage assumption is unlikely to capture the actual usage rates for all equipment. However, we stated that we did not believe that we had strong empirical evidence to justify any alternative approaches. We indicated that we would continue to monitor the appropriateness of the equipment utilization assumption, and evaluate whether changes should be proposed in light of the data available.

Subsequently, a 2009 report on equipment utilization by MedPAC included studies that suggested a higher utilization rate for diagnostic imaging equipment costing more than $1 million. These studies cited by MedPAC suggested that for Magnetic Resonance Imaging equipment, a utilization rate of 92 percent on a 50-hour week would be most accurate. Similarly, another MedPAC cited study suggested that for Computed Tomography scanners, 45 hours was more accurate and that is equivalent to a 90 percent utilization rate on a 50-hour work week. For the CY 2010 PFS proposed rule, we proposed to increase the equipment usage rate to 90 percent for all services containing equipment that cost in excess of $1 million dollars. We stated that the studies cited by MedPAC suggested that physicians and suppliers would not typically make huge capital investments in equipment that would only be utilized 50 percent of the time (74 FR 33532).

In response to comments to that proposal, we finalized a 90 percent utilization rate assumption for MRI and CT to be transitioned over a 4-year period. Regarding the utilization assumptions for other equipment priced over $1 million, we stated that we would continue to explore data sources regarding use of the most accurate utilization rates possible (74 FR 61755). Congress subsequently specified the utilization rate to be assumed for MRI and CT by successive amendments to Section 1848(b)(4)(C) of the Act. Section 3135(a) of the Affordable Care Act (Pub. L. 111–148) set the assumed utilization rate for expensive diagnostic imaging equipment to 75 percent, effective for 2011 and subsequent years. Section 635 of the American Taxpayer Relief Act (ATRA) (Pub. L. 112–240) set the assumed equipment utilization rate to 90%, effective for 2014 and subsequent years. Both of these changes were exempted from the budget neutrality requirements described in section 1848(c)(2)(B)(ii)(II) of the Act.

We have also made other adjustments to the default assumptions regarding the number of hours for which the equipment is available to be used. For example, some equipment used in furnishing services to Medicare beneficiaries is available to be used on a 24-hour/day, 7 days/per week basis. For these items, we develop the rate per minute by amortizing the cost over the extended period of time the equipment is in use.

Based on the RUC recommendations for the new codes that describe radiation treatment services, we do not believe our default assumptions regarding equipment usage are accurate for the capital equipment used in radiation treatment services. As we noted above, the RUC recommendations assume that the same type of linear accelerator is now typically used to furnish all levels and types of external beam radiation treatment services because the machines previously used to furnish these services are no longer manufactured. In valuing the previous code set and making procedure time assumptions, different equipment items were assumed to be used to furnish the different levels and types of radiation treatment. With the current RUC-recommended inputs, we can then assume that the same equipment item is used to furnish more services. If we assume the RUC recommendation to include the same kind of capital equipment for all of these codes is accurate, we believe that it is illogical to continue to assume that the equipment is only used for 25 out of a possible 50 hours per week. In order to estimate the difference between the previous number of minutes the linear accelerator was assumed to be in use under the previous valuation and the number of minutes now being recommended, we applied the change in assumptions to the services reported in the most recent year of Medicare claims data. Under the assumptions reflected in the previous direct PE inputs, the kind of linear accelerator used for IMRT made up a total of 44.8 million out of 65 million minutes of external beam treatments furnished to Medicare beneficiaries. Under the new code set, however, a single kind of linear accelerator would be used for all of the 65 million minutes furnished to Medicare beneficiaries. This represents a 45 percent increase in the aggregate amount of time that this kind of linac is in use. Of course, the utilization rate that corresponds with that increase in minutes is not necessarily precise since the current utilization rate only reflects the default assumption and is not itself rooted in empirical data. Additionally, in some cases, individual practices that already use linear accelerators for IMRT may have replaced the now-obsolete capital equipment with new, additional linear accelerators instead of increasing the use of capital equipment already owned. However, we do not believe that the latter scenario is likely to be common in cases where the linear accelerators had previously been used only 25 hours per week.

Therefore, we are proposing to adjust the equipment utilization rate

assumption for the linear accelerator to account for the significant increase in usage. Instead of applying our default 50 percent assumption, we are proposing to use a 70 percent assumption based on the recognition that the item is now being typically used in a significantly broader range of services, and that would increase its overall usage in comparison to the previous assumption. We note that we developed the 70 percent rate based on a rough reconciliation between the number of minutes the equipment is being used according to the new recommendations versus the current number of minutes based on an analysis of claims data. We continue to seek evidence to ensure that the usage assumptions, both the utilization rate and number of available hours, used to calculate equipment costs are as accurate as possible. We believe that comparing the changes in direct PE input recommendations and using the Medicare claims data indicates that the utilization assumption to 70 percent is more accurate than the default utilization assumption of 50 percent. However, we have reviewed other information that suggests this utilization rate may be higher than 70 percent and that the number of available hours per week is greater than 50.

For example, as part of the 2014 RUC recommendations for the Radiation Treatment Delivery codes, the RUC submitted a 2011 staffing survey conducted by the American Society for Radiology Technicians (ASRT). Using the 2014 version of the same study, we noted that there are an average of 2.3 linacs per radiation treatment facility and 52.7 patients per day treated per radiation treatment facility. These data suggest that an average of 22.9 patients is treated on each linac per day. Using an average of the RUC-recommended procedure times for CPT codes 77385, 77386, 77402, 77407, and 77412 weighted by the annual volume of procedures derived from Medicare claims data yielded a total of 670.39 minutes or 11.2 hours that a single linac is in use per day. This is in contrast to both the number of hours of use reflected in our default assumptions (5 of the 10 available business hours per day) and in our proposed revision to the equipment utilization rate assumption (7 hours out of 10 available business hours per day).

For advanced diagnostic imaging services, we finalized a policy to change the equipment utilization assumption only by 10 percent per year, in response to suggestions from commenters. Because capital equipment costs are amortized over several years, we believe it is reasonable to transition changes to the default assumptions for particular items over several years. We note that the change from one kind of capital equipment to another is likely to occur over a number of years, roughly equivalent to the useful life of particular items as they become obsolete. In the case of most of these items, we have assumed a 7-year useful life, and therefore, we assume that the transition to use of the single kind of capital equipment would likely take place over 7 years as individual pieces of equipment age into obsolescence. However, in the case of this transition in capital equipment, we have reasons to believe that the transition to the new capital equipment has already occurred. First, we note that the specialty societies concluded that the single linear accelerator was typical for these services at the time that the current recommendations were developed in 2013. Therefore, we believe it is logical to assume that, at a minimum, the first several years of the transition to new capital equipment had already taken place by 2013. This would account for the linear accelerator being typically used at that time. This would not be surprising, given that prior to the 2013 review by the RUC, the codes describing the non-IMRT external beam radiation treatments had last been reviewed in 2002. Second, because we are proposing to use the 2013 recommendations for 2016 PFS payment rates, we believe it would be reasonable to assume that in the years between 2013 and 2016, the majority of the rest of the obsolete machines would have been replaced with the single linear accelerator.

Nonetheless, we recognize that there would be value in following precedent to transition changes in utilization assumptions over several years.

Given the fact that it is likely that the transition to the linear accelerator began prior to the 2013 revaluation of the radiation treatment delivery codes by CPT and that the useful life of the newest generation of linear accelerator is 7 years, we believe a 2-year transition to the 70 percent utilization rate assumption would account for any remaining time to transition to the new equipment. Therefore, in developing PE RVUs for these services, we are proposing to use a 60 percent utilization rate assumption for CY 2016 and a 70 percent utilization rate assumption for CY 2017. The PE RVUs displayed in addendum B on the CMS Web site were calculated using the proposed 60 percent equipment utilization rate for the linac as displayed in the CY 2016 direct PE input database.

Additionally, we continue to seek empirical data on the capital equipment costs, including equipment utilization rates, for the linac and other capital-intensive machines, and seek comment on how to most accurately address issues surrounding those costs within the PE methodology.

(3) Superficial Radiation Treatment Delivery

In the CY 2015 PFS final rule with comment period, we noted that changes to the CPT prefatory language modify the services that are appropriately billed with CPT code 77401 (radiation treatment delivery, superficial and/or ortho voltage, per day). The changes effectively meant that many other procedures supporting superficial radiation therapy were bundled with 77401. The RUC, however, did not review the inputs for superficial radiation therapy procedures, and therefore, did not assess whether changes in its valuation were appropriate in light of this bundling. Some stakeholders suggested that the change in the prefatory language precluded them from billing for codes that were previously frequently billed in addition to this code and expressed concern that as a result there would be significant reduction in their overall payments. In the CY 2015 PFS final rule with comment period, we requested information on whether the new radiation therapy code set combined with modifications in prefatory text allowed for appropriate reporting of the services associated with superficial radiation and whether the payment continued to reflect the relative resources required to furnish superficial radiation therapy services.

In response to our request, we received a recommendation from a stakeholder to make adjustments to both the physician work and PE components for code 77401. The stakeholder suggested that since crucial aspects of the service, such as treatment planning and device design and construction, were not currently reflected in 77401, and practitioners were precluded from reporting these activities separately, that physician work should be included for CPT code 77401. Additionally, the stakeholders suggested that the current inputs used to value the code are not accurate because the inputs include zero physician work and minutes for a radiation therapist to provide the service directly to the patient. The stakeholders suggested, alternatively, that physicians, not radiation therapists, typically provide superficial radiation services directly. Therefore, we are seeking recommendations from other stakeholders, including the RUC, regarding whether or not it would be

appropriate to add physician work for this service and remove minutes for the radiation therapists, even though physician work is not included in other radiation treatment services.

The stakeholder also suggested that we amend the direct PE inputs by including nurse time and updating the price of the capital equipment used in furnishing the service. We believe it would be most appropriate to address the clinical labor assigned to the code in the context of the information regarding the physician work that might be associated with the service. Therefore, we seek information on the possible inclusion of nurse time for this service as part of the comments and/or recommendations regarding physician work for the service. However, we reviewed the submitted invoices for the request to update the capital equipment for the service. We are proposing to update the equipment item ER045 ''orthovoltage radiotherapy system'' by renaming it ''SRT–100 superficial radiation therapy system'' and updating the price from $140,000 to $216,000, on the basis of the submitted invoices. The PE RVUs displayed in Addendum B on the CMS Web site were calculated with this proposed modification that is displayed in the CY 2016 direct PE input database.

c. Advance Care Planning Services

For CY 2015, the CPT Editorial Panel created two new codes describing advance care planning (ACP) services: CPT code 99497 (Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health professional; first 30 minutes, face-to-face with the patient, family member(s) and/or surrogate); and an add-on CPT code 99498 (Advance care planning including the explanation and discussion of advance directives such as standard forms (with completion of such forms, when performed), by the physician or other qualified health professional; each additional 30 minutes (List separately in addition to code for primary procedure)). In the CY 2015 PFS final rule with comment period (79 FR 67670–71), we assigned a PFS interim final status indicator of ''I'' (Not valid for Medicare purposes. Medicare uses another code for the reporting and payment of these services) to CPT codes 99497 and 99498 for CY 2015. We said that we would consider whether to pay for CPT codes 99497 and 99498 after we had the opportunity to go through notice and comment rulemaking.

We received many public comments to the final rule recommending that we recognize these two CPT codes and make separate payment for ACP services, in view of the time required to furnish the services and their importance for the quality of care and treatment of the patient. For CY 2016, we are proposing to assign CPT codes 99497 and 99498 PFS status indicator ''A,'' which is defined as: ''Active code. These codes are separately payable under the PFS. There will be RVUs for codes with this status.'' The presence of an ''A'' indicator does not mean that Medicare has made a national coverage determination regarding the service. Contractors remain responsible for local coverage decisions in the absence of a national Medicare policy. We are proposing to adopt the RUC-recommended values (work RVUs, time, and direct PE inputs) for CPT codes 99497 and 99498 beginning in CY 2016 and will consider all public comments that we receive on this proposal.

Physicians' services are covered and paid by Medicare in accordance with section 1862(a)(1)(A) of the Act. Therefore, CPT code 99497 (and CPT code 99498 when applicable) should be reported when the described service is reasonable and necessary for the diagnosis or treatment of illness or injury. For example, this could occur in conjunction with the management or treatment of a patient's current condition, such as a 68 year old male with heart failure and diabetes on multiple medications seen by his physician for the evaluation and management of these two diseases, including adjusting medications as appropriate. In addition to discussing the patient's short-term treatment options, the patient expresses interest in discussing long-term treatment options and planning, such as the possibility of a heart transplant if his congestive heart failure worsens and advance care planning including the patient's desire for care and treatment if he suffers a health event that adversely affects his decision-making capacity. In this case the physician would report a standard E/M code for the E/M service and one or both of the ACP codes depending upon the duration of the ACP service. However, the ACP service as described in this example would not necessarily have to occur on the same day as the E/M service.

We seek comment on this proposal, including whether payment is needed and what type of incentives this proposal creates. In addition, we seek comment on whether payment for advance care planning is appropriate in other circumstances such as an optional element, at the beneficiary's discretion, of the annual wellness visit (AWV) under section 1861(hhh)(2)(G) of the Act.

d. Proposed Valuation of Other Codes for CY 2016

(1) Excision of Nail Bed (CPT Code 11750)

The RUC's review of 10-day global services identified 18 services currently valued with greater than 1.5 office visits and 2012 Medicare utilization data over 1,000, including CPT code 11750. As a result, the RUC requested this service be surveyed for work and reviewed for CY 2016.

The RUC recommended a work RVU of 1.99 for CPT code 11750, despite a decrease in the associated post-operative visits. We believe the recommendation for this service overstates the work involved in performing this procedure specifically given the decrease in post-operative visits. Due to similarity in service and time, we believe a direct crosswalk of the work RVUs for CPT code 10140 (Drainage of blood or fluid accumulation), which is also a 10 day global service with one post-operative visit, to CPT code 11750 more accurately reflects the time and intensity of furnishing the service. Therefore, for CY 2016 we are proposing a work RVU of 1.58 for CPT code 11750.

(2) Bone Biopsy Excisional (CPT Code 20240)

In the same review of 10-day global services, the RUC identified CPT code 20240 as potentially misvalued. As a result, the RUC requested this service be surveyed and reviewed for CY 2016. Subsequent to this identification, the RUC also requested and we approved a global period change from a 10-day to a 0-day global period for this procedure. Based on the survey data, the RUC recommended a decrease in the intraservice time from 39 to 30 minutes, removal of two postoperative visits (one 99238 and one 99212), and an increase in the work RVUs for CPT code 20240 from 3.28 to 3.73. We do not believe this recommendation accurately reflects the work involved in this procedure, especially given the decrease in intraservice time and post-operative visits. Therefore, for CY 2016, we are proposing a work RVU of 2.61 for CPT code 20240 based on the reductions in time for the service.

(3) Endobronchial Ultrasound (CPT Codes 31622, 3160A, 3160B, 31625, 31626, 31628, 31629, 3160C, 31632 and 31633)

For CY 2016, the CPT Editorial Panel deleted one code, CPT 31620 (Ultrasound of lung airways using an endoscope), and created three new codes, CPT 3160A–3160C, to describe bronchoscopic procedures that are inherently performed with endobronchial ultrasound (EBUS).

In their review of the newly revised EBUS family, the RUC recommended a change in the work RVU for CPT code 31629 from 4.09 to 4.00. The RUC also recommended maintaining the current work RVUs for CPT codes 31622, 31625, 31626, 31628, 31632 and 31633. We are proposing to use those values for CY 2016.

For the newly created codes, the RUC recommended a work RVU of 5.00 for CPT code 3160A, 5.50 for CPT code 3160B and 1.70 for CPT code 3160C. We believe the recommended work RVUs for these services overstate the work involved in furnishing the procedures. In order to develop proposed work RVUs for CPT code 3160A, we compared the service described by the new code to deleted CPT codes 31620 and 31629, because this new code describes a service that combines services described by 31620 and 31629. Specifically, we took the sum of the current work RVU of CPT code 31629 (WRVU=4.09) and the CY 2015 work RVU of CPT code 31620 (WRVU=1.40) and multiplied it by the quotient of CPT code 3160A's RUC-recommended intraservice time (INTRA=60 min) and the sum of CPT codes 31620 and 31629's current and CY 2015 intraservice times (INTRA=70 min), respectively. This resulted in a work RVU of 4.71 and we are proposing that value. To value CPT code 3160B, we used the RUC-recommended increment of 0.5 work RVU between this service and CPT code 3160A to calculate for CPT code 3160B our proposed work RVUs of 5.21. Lastly, because the service described by new CPT code 3160C is very similar to deleted CPT code 31620, we believe a direct crosswalk of the previous values for 31620 accurately reflects the time and intensity of furnishing the service described by 3160C. Therefore, we are proposing a work RVUs of 1.40 for CPT code 3160C.

(4) Laparoscopic Lymphadenectomy (CPT Codes 38570, 38571 and 38572)

The RUC identified three laparoscopic lymphadenectomy codes as potentially misvalued: CPT code 38570 (Laparoscopy, surgical; with retroperitoneal lymph node sampling (biopsy), single or multiple); CPT code 38571 (Laparoscopy, surgical; with retroperitoneal lymph node sampling (biopsy), single or multiple with bilateral total pelvic lymphadenectomy); and CPT code 38572 (Laparoscopy, surgical; with retroperitoneal lymph node sampling (biopsy), single or multiple with bilateral total pelvic lymphadenectomy and periaortic lymph node sampling (biopsy), single or multiple). Accordingly, the specialty society resurveyed these 10-day global codes, and the survey results indicated decreases in intraservice and total work times. After reviewing the survey responses, the RUC recommended that CMS maintain the current work RVU for CPT code 38570 of 9.34; reduce the work RVU for CPT code 38571 from 14.76 to 12.00; and reduce the work RVU for CPT code 38572 from 16.94 to 15.60. We propose to accept the RUC recommendations for CPT codes 38571 and 38572, as the RUC is recommending reductions in the work RVUs that correspond with marked decreases in intraservice time and decreases in total time. However, we do not agree with the RUC's recommendation to maintain the current work RVU for CPT code 38570 in spite of similar changes in intraservice and total times as were shown in the RUC recommendations for CPT codes 38571 and 38572. Therefore, we propose to reduce the work RVU for CPT code 38570 to 8.49, which reflects the ratio of the reduction in total time for this code and would maintain rank order among the three codes.

(5) Mediastinoscopy With Biopsy (CPT Codes 3940A and 3940B)

The RUC identified CPT code 39400 (Mediastinoscopy, including biopsy(ies) when performed) as a potentially misvalued code due to an unusually high preservice time and Medicare utilization over 10,000. In reviewing the code's history, it became apparent that the code has been used to report two distinct procedural variations although the code was valued using a vignette for only one of them. As a result, CPT code 39400 is being deleted and replaced with CPT codes 3940A and 3940B to describe each of the two mediastinoscopy procedures.

We are proposing to accept the RUC-recommended work RVU of 5.44 for code 3940A. We agree with the RUC that the crosswalk from CPT code 52235 (Cystourethroscopy, with fulguration) appropriately estimates the overall work for CPT code 3940A. For CPT code 3940B, we disagree with the RUC recommended work RVU of 7.50. We believe that the work value for CPT code 3940A establishes an accurate baseline for this family of codes, so we are scaling the work RVU of CPT code 3940B in accordance with the change in the intraservice times between CPT codes 3940A and 3940B. Applying this ratio in the intraservice time to the work value of CPT code 3940A yields a total work RVU of 7.25 for CPT code 3940B. We also note that the RUC recommendation for CPT code 3940A represents a decrease in value by 0.64 work RVUs, which is roughly proportionate to the reduction from a full hospital discharge visit (99238) to a half discharge visit assumed to be typical in the post-operative period. The RUC recommendation for CPT code 3940B had the same reduction in the post-operative work without a corresponding decrease in its recommended work RVU. In order to reflect the reduction in post-operative work and to maintain relativity between the two codes in the family, we are proposing 7.25 as the work RVU for CPT code 3940B.

(6) Hemorrhoid(s) Injection (CPT Code 46500)

The RUC also identified CPT code 46500 (Injection of sclerosing solution, hemorrhoids) as potentially misvalued, and the specialty society resurveyed this 10-day global code. The survey showed a significant decrease in the reported intraservice and total work times. After reviewing the survey responses, the RUC recommended that CMS should maintain the current work RVU of 1.69 in spite of these drops in intraservice and total times. We propose to instead reduce the work RVU to 1.42, which reduces the work RVU by the same ratio as the reduction in total time.

We are also proposing to refine the recommended PE inputs by removing the inputs associated with cleaning the scope. As recommended by the RUC, we are proposing to include a scope as a direct PE input that is disposable, and therefore, does not require cleaning.

(7) Liver Allotransplantation (CPT Code 47135)

The RUC also identified CPT code 47135 (Liver allotransplantation; orthotopic, partial or whole, from cadaver or living donor, any age) as potentially misvalued, and the specialty society resurveyed this 90-day global code. The survey showed a significant decrease in reported intraservice work time, but a significant increase in total work time (the number of post-operative visits significantly declined while the level of visits increased). After reviewing the survey responses, the

RUC recommended an increase in the work RVU from 83.64 to 91.78, which is the median of the survey, as well as the exact value for CPT code 33935 (Heart-lung transplant with recipient cardiectomy-pneumonectomy). However, we do not believe this crosswalk is the most accurate from among the group of transplant codes. CPT code 32854 (Lung transplant, double (bilateral sequential or en bloc); with cardiopulmonary bypass) has intraservice and total times that are closer to those the RUC recommended for CPT code 47135, and CPT code 32854 has a work RVU of 90.00 which is the 25th percentile of the survey for CPT code 47135. Therefore, we propose to increase the work RVU of CPT code 47135 to 90.00.

(8) Genitourinary Catheter Procedures (CPT Codes 5039A, 5039B, 5039C, 5039D, 5039M, 5039E, 5069G, 5069H, 5069I)

For CY 2016, the CPT Editorial Panel is deleting six codes (50392, 50393, 50394, 50398, 74475, and 74480) that were commonly reported together, and are creating 12 new codes both to describe these genitourinary catheter procedures more accurately and to bundle inherent imaging services. Three of these codes (506XF, 507XK, and 507XL) were referred back to CPT to be resurveyed as add-on codes. The other nine codes were reviewed at the January 2015 RUC meeting and assigned recommended work RVUs and direct PE inputs.

We are proposing to use the RUC-recommended work RVU of 3.15 for CPT code 5039A. We agree that this is an appropriate value, and that the code should be used as a basis for establishing relativity with the rest of the family. As a result, we began by making comparisons between the service times of CPT code 5039A and the other codes in the family in order to determine the appropriate proposed work value of each procedure.

For CPT code 5039B, we disagree with the RUC recommended work RVU of 1.42, and we are instead proposing a work RVU of 1.10, based on three separate data points. First, the RUC summary of recommendations stated that CPT code 5039B describes work previously described by a combination of CPT codes 50394 and 74425. These two codes have work RVUs of 0.76 and 0.36, respectively, which sum together to 1.12. Second, we noted that the work of CPT code 49460 (Mechanical removal of obstructive material from gastrostomy) is similar, with the same intraservice time of 15 minutes and same total time of 55 minutes but a work RVU of 0.96. Finally, we observed that the minimum survey result had a work RVU of 1.10, and we believe this value appropriately reflects the total work for the service. Accordingly, we are proposing 1.10 as the work RVU for CPT code 5039B.

We employed a similar methodology to develop a proposed work RVU of 4.25 for CPT code 5039C. The three previously established codes are being combined in CPT code 5039C; these had respective work values of 3.37 (CPT code 50392), 0.54 (CPT code 74475), and 0.36 (CPT code 74425); together these sum to 4.27 work RVUs. We also looked at valuing CPT code 5039C based on relativity with other codes in the family. The ratio of the intraservice time of 35 minutes for CPT code 5039A and the intraservice time of 48 minutes for CPT code 5039C; applied to the work RVU of base code 5039A (3.15) results in a potential work RVU of 4.32. The total time compared to CPT code 5039A also went from 91 minutes to 107 minutes and this ratio applied to the base work RVU results in a work RVU of 3.70. We utilized these data to inform our choice of an appropriate crosswalk. We believe CPT code 31660 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance) is an appropriate reference crosswalk for CPT code 5039C. CPT code 31660 has an intraservice time of 50 minutes, total time of 105 minutes, and a work RVU of 4.25. Therefore, we propose to establish the work RVU for CPT code 5039C at the crosswalked value of 4.25 work RVUs.

According to the RUC recommendations, CPT codes 5039C and 5039D are very similar procedures, with CPT code 5039D making use of a nephroureteral catheter instead of a nephrostomy catheter. The RUC valued the added difficulty of CPT code 5039D at 1.05 work RVUs compared to code CPT code 5039C. We are maintaining the relative difference in work between these two codes by proposing a value of 5.30 for CPT code 5039D. (This is the work RVU of 4.25 for CPT code 5039C plus 1.05 RVUs.) Additionally, we are using CPT code 57155 (Insertion of uterine tandem and/or vaginal ovoids for clinical brachytherapy) as our reference crosswalk. CPT code 57155 has a work RVU of 5.40 and an identical intraservice time of 60 minutes, but it also has fourteen additional minutes of total time, 133 minutes compared to 119 minutes for CPT code 5039D, which supports the difference of 0.10 RVUs. For these reasons, we are proposing the value of CPT code 5039D at 5.30 work RVUs.

As with the other genitourinary codes, we developed the proposed work value of CPT code 5039M in order to preserve relativity within the family. CPT code 5039M has 15 fewer minutes of intraservice time compared to CPT code 5039D (45 minutes compared to 60 minutes). This is a ratio of 0.75, applied to the based work RVU of CPT code 5039D (5.30) resulted in a potential work RVU of 3.98. CPT code 5039C was another close match within the family, with 3 more minutes of intraservice time compared to 5039M, 48 minutes of intraservice time instead of 45 minutes. This ratio (0.94) applied to the base work RVU of CPT code 5039C (4.25) also resulted in a potential work RVU of 3.98. Based on this information, we identified CPT code 31634 (Bronchoscopy, rigid or flexible, with balloon occlusion) as an appropriate crosswalk, and propose a work RVU of 4.00 for CPT code 5039M. The two codes share an identical intraservice time of 45 minutes, though the latter possesses a lower total time of 90 minutes.

For CPT code 5039E, we considered how the code and work RVU would fit within the family in comparison to our proposed values for CPT codes 5039A and 5039C. CPT code 5039A serves as the base code for this group; it has 35 minutes of intraservice time in comparison to 20 minutes for CPT code 5039E. This intraservice time ratio of 0.57 resulted in a potential work RVU of 1.80 for CPT code 5039E when applied to the work RVU of CPT code 5039A (3.15). Similarly, CPT code 5039C is the most clinically similar procedure to CPT code 5039E. CPT code 5039C has 48 minutes of intraservice time compared to 20 minutes of intraservice time for CPT code 5039E. This ratio of 0.42 applied to the base work RVU of CPT code 5039C (4.25) results in a potential work RVU of 1.77. We also made use of two crosswalks to help determine a proposed value for CPT code 5039E. CPT code 64416 (Injection, anesthetic agent; brachial plexus) also includes 20 minutes of intraservice time and has a work RVU of 1.81. CPT code 36569 (Insertion of peripherally inserted central venous catheter) has the same intraservice and total time as CPT code 5039E, with a work RVU of 1.82. Accordingly, we are crosswalking the work RVU for CPT code 5039E to CPT code 36569 and proposing a work RVU of 1.82 for CY 2016.

The remaining three codes all utilize ureteral stents and form their own small subfamily within the larger group of genitourinary catheter procedures. For CPT code 5069G, we are proposing a

work RVU of 4.21, which is the 25th percentile result from the survey information. We believe that the 25th percentile provides a more accurate value for CPT code 5069G based on the work involved in the procedure and within the context of other codes in the family. We are also referencing CPT code 31648 (Bronchoscopy, rigid or flexible, with removal of bronchial valve), which shares 45 minutes of intraservice time and has a work RVU of 4.20, as an appropriate crosswalk for CPT code 5069G.

For CPT code 5069H, we compared its intraservice time to the code within the family that had the most similar duration, CPT code 5039D. This code has 60 minutes of intraservice time compared to 62 minutes for CPT code 5069H. This is a ratio of 1.03 applied to the base work RVU of CPT code 5039D (5.30) resulted in a potential work RVU of 5.48. We also looked to crosswalks with similar numbers, in particular CPT code 50382 (Removal and replacement of internally dwelling ureteral stent). This code has 60 minutes of intraservice time, 125 minutes of total time, and a work RVU of 5.50. For these reasons, we are crosswalking CPT code 5069H to CPT code 50382 and proposing a work RVU of 5.50.

Finally, we developed the proposed value for CPT code 5069I using three related methods. CPT codes 5069H and 5069I describe very similar procedures, with 5069I adding the use of a nephrostomy tube. The RUC addressed the additional difficulty of this procedure by recommending 1.55 more work RVUs for CPT code 5069I than for CPT code 5069H. Adding the 1.55 work RVUs to the proposed work RVU for CPT code 5069H (5.50) would produce a work RVU of 7.05 for CPT code 5069I. We also looked at the ratio of intraservice times for CPT code 5069I (75 minutes) and the base code in the subfamily, CPT code 5069G (45 minutes). The intraservice time ratio between these two codes is 1.67 when applied to the base work RVU of CPT code 5069G (4.21) resulted in a potential work RVU of 7.02. We also identified an appropriate crosswalk reference in CPT code 36481 (Percutaneous portal vein catheterization by any method) which shares the same intraservice time as CPT code 5069I and has a work RVU of 6.98. Accordingly, to maintain relativity among this subfamily of codes, we are proposing a work RVU of 7.05 for CPT code 5069I based on an incremental increase of 1.55 RVUs from CPT code 5069H.

In reviewing the direct PE inputs for this family of codes, we refined a series of the RUC- recommended inputs in order to maintain relativity with current standards. All of the following refinements refer to the non-facility setting for this family of codes. Under the clinical labor inputs, we are proposing to remove the RN/LPN/MTA (L037D) (intraservice time for assisting physician in performing procedure) for CPT codes 5039B and 5039E. This amounts to 15 minutes for CPT code 5039B and 20 minutes for CPT code 5039E. Moderate sedation is not inherent in these procedures and, therefore, we do not believe that this clinical labor task would typically be completed in the course of this procedure. We are also reducing the RadTech (L041B) intraservice time for acquiring images from 47 minutes to 46 minutes for CPT code 5069H. This procedure contains 62 minutes of intraservice time, with clinical labor assigned for acquiring images (75 percent) and a circulator (25 percent). The exact time for these clinical labor tasks multiplies out to 46.5 minutes and 15.5 minutes, respectively. The RUC recommendation for CPT code 5069H rounded both of these values upwards, assigning 47 minutes for acquiring images and 16 minutes for the circulator, which together sum to 63 minutes. We are reducing the clinical labor time for acquiring images to 46 minutes to preserve the 62 minutes of total intraservice time for CPT code 5069H.

During the post-service portion of the clinical labor service period, we are proposing to change the labor type for the ''patient monitoring following service/check tubes, monitors, drains (not related to moderate sedation)'' input. There are 45 minutes of clinical labor time assigned under this category to CPT codes 5039A, 5039C, 5039D, 5039M, 5069G, 5069H, and 5069I. Although we agree that the 45 minutes are appropriate for these procedures as part of moderate sedation, we are changing the clinical labor type from the recommended RN (L051A) to RN/LPN/MTA (L037D) to reflect the staff that will typically be doing the monitoring for these procedures. Even though the CPT Editorial Committee's description of post-service work for CPT code 5039E includes a recovery period for sedation, we recognize that according to the recommendation, CPT codes 5039B and 5039E do not use moderate sedation, so we did not propose to include moderate sedation inputs for these codes.

The RUC recommendation for CPT code 5039D includes a nephroureteral catheter as a new supply input with an included invoice. However, in the RUC summary of recommendations for this code, there is no mention of a nephroureteral catheter in the intraservice work description. CPT code 5039D does mention the use of a nephroureteral stent in this description, but there is no request for a nephroureteral stent supply item on the PE worksheet for this code. We are therefore seeking clarification from stakeholders regarding the use of the nephroureteral catheter for CPT code 5039D. We have not proposed to add the nephroureteral catheter as a supply item for CPT code 5039D pending this information. We are also requesting a clarification to the intraservice work description in the summary of recommendations for this code to explain the use, if any, of the nephroureteral catheter in this procedure.

The RUC recommended the inclusion of ''room, angiography'' (EL011) for this family of codes. We do not agree with the RUC that an angiography room would be used in the typical case for these procedures, as there are other rooms available which can provide fluoroscopic guidance. Most of the codes that make use of an angiography room are cardiovascular codes, and much of the equipment listed for this room would not be used for non-cardiovascular procedures. We are therefore proposing to replace equipment item ''room, angiography'' (EL011) with equipment item ''room, radiographic-fluoroscopic'' (EL014) for the same number of minutes. We are requesting public comment regarding the typical room type used to furnish the services described by these CPT codes, as well as the more general question of the typical room type used for GU and GI procedures. In the past, the RUC has developed broad recommendations regarding the typical uses of rooms for particular procedures, including the radiographic-fluoroscopy room. We believe that such a recommendation from the RUC concerning all of these codes could be useful in ensuring relativity across the PFS.

(9) Penile Trauma Repair (CPT Codes 5443A and 5443B)

CPT created these two new codes because there are no existing codes to capture penile traumatic injury that includes penile fracture, also known as traumatic corporal tear, and complete penile amputation. CPT code 5443A will describe a repair of traumatic corporeal tear(s) while CPT code 5443B will describe a replantation, penis, complete amputation. For CPT code 5443B, we disagree with the RUC recommendation of a work RVU of 24.50. We believe that the 25th

percentile work RVU of 22.10 provides a more accurate value based on the work involved in the procedure and within the context of other codes in the same family, since CPT code 5443A was also valued using the 25th percentile. We find further support for this valuation through a crosswalk to CPT code 43334 (Repair, paraesophageal hiatal hernia via thoracotomy, except neonatal) which has an identical intraservice time and a work RVU of 22.12. Therefore we are proposing a work RVU of 22.10 for CPT code 5443B.

Because CPT codes 5443A and 5443B are typically performed on an emergency basis, we question the appropriateness of the standard 60 minutes of preservice clinical labor in the facility setting, as the typical procedure would not make use of office-based clinical labor. For example, we do not believe that the typical case would require 8 minutes to schedule space in the facility for an emergency procedure, or 20 minutes to obtain consent. We are seeking further public comment on this issue from the RUC and other stakeholders.

(10) Intrastromal Corneal Ring Implantation (CPT Code 657XG)

CPT code 657XG is a new code describing insertion of prosthetic ring segments into the corneal stroma for treatment of keratoconus in patients whose disease has progressed to a degree that they no longer tolerate contact lens wear for visual rehabilitation.

We disagree with the RUC recommendation of a work RVU of 5.93 for CPT code 657XG. Although we appreciated the extensive list of other codes the RUC provided as references, we are concerned that the recommended value for CPT code 657XG overestimates the work involved in furnishing this service relative to other PFS services. We did not find a single code with comparable intraservice and total time that had a higher work RVU. The recommended crosswalk, CPT code 67917 (Repair of ectropion; extensive), appears to have the highest work RVU of any 90-day global surgery service in this range of work time values. It also has longer intraservice time and total time than the code in question, making a direct crosswalk inappropriate.

As a result, we are proposing a new value for CPT code 657XG based on the intraservice time ratio in relation to the recommended crosswalk. We compared the 33 minutes of intraservice time in CPT code 67917 to the 30 minutes of intraservice time in CPT code 657XG. The intraservice time ratio between these two codes is 0.91, and when multiplied by the work RVU of CPT code 67917 (5.93) resulted in a potential work RVU of 5.39. We also considered CPT code 58605 (Ligation or transection of fallopian tube(s)), which has the same intraservice time, seven additional minutes of total time, and a work RVU of 5.28. We believe that CPT 58605 is a closer fit for a direct crosswalk because it shares the same intraservice time of 30 minutes with CPT code 657XG. Accordingly, we are proposing a work RVU of 5.39 for CPT code 657XG.

The RUC recommendation for CPT code 657XG includes a series of invoices for several new supplies and equipment items. One of these was the 10–0 nylon suture with two submitted invoice prices of $245.62 per box of 12, or $20.47 per suture, and another was priced at $350.62 per box of 12, or $29.22 per suture. Given the range of prices between these two invoices, we sought publicly available information and identified numerous sutures that appear to be consistent with those recommended by the specialty society, at lower prices, which we believe are more likely to be typical since we assume that the typical practitioner would seek the best price. One example is ''Surgical Suture, Black Monofilament, Nylon, Size: 10–0, 12''/30cm, Needle: DSL6, 12/bx'' for $146. Therefore, we are proposing to establish a new supply code for ''suture, nylon 10–0'' and price that item at $12.17 each. We welcome comments from stakeholders regarding this supply item.

(11) Dilation and Probing of Lacrimal and Nasolacrimal Duct (CPT Codes 66801, 68810, 68811, 68815 and 68816)

The RUC's review of 10-day global services identified 18 services with greater than 1.5 office visits and 2012 Medicare utilization data over 1,000, including CPT codes 66801, 68810, 68811, 68815, and 68816. As a result, the RUC requested these services be surveyed reviewed for CY 2016.

The RUC recommended a work RVU of 1.00 for CPT code 68801 and a work RVU of 1.54 for CPT code 68810. While we are proposing to use the RUC-recommended work RVU for CPT code 68810, we do not believe the recommendation for CPT code 68801 best reflects the work involved in the procedure because of a discrepancy between the post-operative work time and work RVU. Specifically, the RUC recommendation for the procedure included the removal of a 99211 visit, but the RUC-recommended work RVU did not reflect any corresponding adjustment. As a result, we are proposing to accept the RUC's recommendation to remove the 99211 visit from the service but are proposing to further reduce the work RVU for CPT code 68801 by removing the RVUs associated with CPT code 99211. Therefore, for CY 2016, we are proposing a work RVUs of 0.82 to CPT code 68801 and 1.54 to CPT code 68810.

The RUC recommended a work RVU of 2.03, 3.00, and 2.35 for CPT codes 68811, 68815 and 68816, respectively. We do not believe the RUC recommendations for these services best reflect the work involved in performing these procedures. To value these services, we calculated a total time ratio by dividing the code's current total time by the RUC-recommended total time, and then applying that ratio to the current work RVU. This produces our CY 2016 proposed work RVUs of 1.74, 2.70, and 2.10 for CPT codes 68811, 68815, and 68816, respectively.

(12) Spinal Instability (CPT Code 7208A, 7208B, 7208C, and 7208D)

For CY 2015, the CPT Editorial Panel deleted codes 72010 (radiologic examination, spine, entire, survey study, anteroposterior and lateral), 72069 (radiologic examination, spine, thorocolumbar, standing (scoliosis)), and 72090 (radiological examination, spine; scoliosis study, including supine and erect studies), revised one code, 72080 (Radiologic examination, spine; thoracolumbar junction, minimum of 2 views) and created four new codes which cover radiologic examination of the entire thoracic and lumbar spine, including the skull, cervical and sacral spine if performed. The new codes were organized by number of views, ranging from one view in 7208A, two to three views in 7208B, four to five views in 7208C, and minimum of 6 views in 7208D.

We disagree with the RUC's work RVU recommendations for these four codes. For 7208A, we noted that the one minute increase in time resulted in a larger work RVU than would be expected when taking the ratio between time and RVU in the source code and comparing that to the time and work RVU ratio in the new code. Using the relationship between time and RVU from deleted code 72069, we are proposing a work RVU of 0.26 for 7208A, which differs from the RUC-recommended value of 0.30. Using an incremental methodology based on the relationship between work and time in the first code we are proposing to adjust the RUC-recommended work RVUs for CPT codes 7208B, 7208C and 7208D to, respectively, 0.31, 0.35, and 0.41.

(13) Echo Guidance for Ova Aspiration (CPT Code 76948)

In the CY 2014 PFS final rule with comment period, we requested additional information to assist us in the valuation of ultrasound guidance codes. We nominated these codes as potentially misvalued based on the extent to which standalone ultrasound guidance codes were billed separately from services where ultrasound guidance was an integral part of the procedure. CPT code 76948 was among the codes considered potentially misvalued. CPT code 76948 was surveyed by the specialty societies and the RUC issued a recommendation for CY 2016. We have concerns about valuation this code, considering that it is a guidance code used only for a single procedure: 58970 (aspiration of ova), and we believe that these two codes are almost always billed concurrently. We believe codes 76948 and 58970 should be bundled to accurately reflect how the service is furnished.

We are proposing to use work times based on refinements of the RUC-recommended values by removing the 3 minutes of pre and post service time since these times are reflected in the 58970 procedure code. We are proposing work and time values for 76948 based on a crosswalk from 76945 (Ultrasonic guidance for chorionic villus sampling, imaging supervision and interpretation) which has a physician work time of 30 minutes and an RVU of 0.56. Therefore we are proposing to maintain 25 minutes of intraservice time for 76948 and proposing a work RVU of 0.56.

(14) Immunohistochemistry (CPT Codes 88341, 88342, and 88344)

In establishing interim final direct PE inputs for CY 2015 for CPT codes 88341, 88342, and 88344, we replaced the RUC-recommended supply item ''UltraView Universal DAB Detection Kit'' (SL488) with ''Universal Detection Kit'' (SA117), since the RUC did not provide an explanation for the required use of a more expensive kit. We also adjusted the equipment time for equipment item ''microscope, compound'' (EP024). We re-examined these codes when valuing the immunofluorescence family of codes for CY 2016, and reviewed information received by commenters that explained the need for these supply items. Specifically, commenters explained that the universal detection kit that CMS included in place of the RUC-recommended kit was not typically used in these services as it was not clinically appropriate. We are proposing to include the RUC-recommended supply item, SL488, for CPT codes 88341, 88342, and 88344, as well as the RUC-recommended equipment time for ''microscope, compound'' for CY 2016.

(15) Immunofluorescent Studies (CPT Codes 88346 and 8835X)

For CY 2016, the CPT Editorial Panel deleted one code, CPT 88347 (Antibody evaluation), created a new add-on service, CPT 8835X, and revised CPT code 88346 to describe immunofluorescent studies. The RUC recommended a work RVU of 0.74 for CPT code 88346 and 0.70 for CPT code 8835X. While we are accepting the RUC recommendation for CPT code 88346, we do not believe the recommendation for CPT code 8835X best reflects the work involved in the procedure due to our concerns with the relationship between the RUC-recommended intraservice times for the base code and the newly created add-on code. We examined intraservice time relationships between other base codes and add-on codes and found that two codes in the Intravascular ultrasound family, CPT 37250 (Ultrasound evaluation of blood vessel during diagnosis or treatment) and 37251(Ultrasound evaluation of blood vessel during diagnosis or treatment), share a similar base code/add-on code intraservice time relationship, and are also diagnostic in nature, as are CPT codes 88346 and 8835X. Due to these similarities, we believe it is appropriate to apply the relationship, which is a 24 percent difference, between CPT codes 37250 and 37251 in calculating work RVUs for CPT codes 88346 and 8835X. Multiplying the RVU of CPT code 88346, 0.74, by 24 percent, and then subtracted the product from 0.74 results in a work RVU of 0.56 for CPT code 8835X. Therefore, for CY 2016, we are proposing a work RVU of 0.74 for CPT code 88346 and 0.56 for CPT code 8835X.

(16) Morphometric Analysis (CPT Codes 88364, 88365, 88366, 88367, 88373, 88374, 88377, 88368, and 88369)

CPT codes 88367 and 88368 were reviewed and valued in the CY 2015 PFS final rule with comment period (79 FR 67668 through 67669). Since then, the RUC has re-reviewed these services for CY 2016 due to the specialty society's initially low survey response rate. In our review of these codes, we noticed that the latest RUC recommendation is identical to the RUC recommendation provided for CY 2015 rulemaking. As a result, we do not believe there is any reason to modify our CY 2015 work RVUs or work time for these procedures. Therefore, we are proposing to retain the CY 2015 work RVUs and work time for CPT codes 88367 and 88368 for CY 2016.

In establishing interim final direct PE inputs for CY 2015 for CPT codes 88364, 88365, 88366, 88367, 88373, 88374, 88377, 88368, and 88369, we refined the RUC-recommended direct PE inputs as follows. We refined the units of several supply items, including ''ethanol, 100%'' (SL189), ''ethanol, 70%'' (SL190), ''ethanol, 85%'' (SL191), ''ethanol, 95%'' (SL248), ''kit, FISH paraffin pretreatment'' (SL195), ''kit, HER–2/neu DNA Probe'' (SL196), positive and negative control slides (SL112, SL118, SL119, SL184, SL185, SL508, SL509, SL510, SL511), ''(EBER) DNA Probe Cocktail'' (SL497),''Kappa probe cocktails'' (SL498) and ''Lambda probe cocktails'' (SL499), to maintain consistency within the codes in the family, and adjusted the quantities included in these codes to align with the code descriptors and better reflect the typical resources used in furnishing these services. We also adjusted the equipment time for equipment items ''water bath, FISH procedures (lab)'' (EP054), ''chamber, Hybridization'' (EP045), ''microscope, compound'' (EP024), ''instrument, microdissection (Veritas)'' (EP087), and ''ThermoBrite'' (EP088), to reflect the typical time the equipment is used, among other common refinements.

We re-examined these codes when valuing the immunofluorescence family of codes for CY 2016, and reviewed information received from commenters that described the typical batch size for each of these services, thereby explaining the apparent inconsistencies and discrepancies in the quantity of units among the codes in the family. We are proposing to include the RUC-recommended quantities for each of these supply items for the CPT codes 88364, 88365, 88366, 88367, 88373, 88374, 88377, 88368, and 88369 for CY 2016. With regard to the equipment items, we received information explaining that the recommended equipment times already accounted for the typical batch size, and thus, the recommended times were already reflective of the typical case. Therefore, we are proposing to adjust the equipment time for equipment items EP054, EP045, and EP087 to align with the RUC-recommended times. We also received comments explaining the need for equipment item EP088. Based on that information, we are proposing to include this equipment item consistent with the RUC recommendations for CPT code 88366.

We note that the information we received regarding the typical batch size

was critical in determining the appropriate direct PE inputs for these pathology services. We also note that we usually do not have information regarding the typical batch size or block size when we are reviewing the direct PE inputs for pathology services. The supply quantity and equipment minutes are often a direct function of the number of tests processed at once. Given the importance of the typical number of tests being processed by a laboratory in determining the direct PE inputs, which often include expensive supplies, we are very concerned that the direct PE inputs included in many pathology services may not reflect the typical resource costs involved in furnishing the typical service.

In particular, we note that since laboratories of various sizes furnish pathology tests and that, depending on the test, a large laboratory may be at least as likely to have furnished a test to a Medicare beneficiary compared to a small laboratory, we believe that an equipment item included in a recommendation that is commercially available to a small laboratory may not be the same equipment item that is used in the typical case. If the majority of services billed under the PFS for a particular CPT code are furnished by laboratories that run many of these tests each day, then assumptions informed by commercially available products may significantly underestimate the typical number of tests processed together, and thus the assumptions underlying current valuations for per-test cost of supplies and equipment may be much higher than the typical resources used in furnishing the service. We invite stakeholders to provide us with information about the equipment and supply inputs used in the typical case for particular pathology services.

(17) Vestibular Caloric Irrigation (CPT Codes 9254A and 9254B)

For CY 2016, the CPT Editorial Panel deleted CPT code 92543 (Assessment and recording of balance system during irrigation of both ears) and created two new CPT codes, 9254A and 9254B, to report caloric vestibular testing for bithermal and monothermal testing procedures, respectively. The RUC recommended a work RVU of 0.80 for CPT code 9254A and a work RVU of 0.55 for CPT code 9254B. We believe the recommendations for these services overstate the work involved in performing these procedures. Due to similarity in service and time, we believe a direct crosswalk of CPT code 97606 (Negative pressure wound therapy, surface area greater than 50 square centimeters, per session) to CPT code 9254A is appropriate. To value CPT code 9254B, we divided the proposed work RVU for 9254A in half since the code descriptor for this procedure describes the service as having two irrigations as opposed to the four involved in 9254A. Therefore, for CY 2016, we are proposing a work RVUs of 0.60 to 9254A and 0.30 to 9254B.

(18) Instrument-Based Ocular Screening (CPT Codes 99174 and 9917X)

For CY 2015, the CPT Editorial Panel created a new code, CPT code 9917X, to describe instrument-based ocular screening with on-site analysis and also revised existing CPT code 99174, which describes instrument-based ocular screening with remote analysis and report. Currently, CPT code 99174 is assigned a status indicator of N (non-covered service) which we believe should be maintained due to its nature as a screening service. After review of CPT code 9917X, we believe this service is also a screening service and should be assigned a status indicator of N (non-covered service). Therefore, for CY 2016, we are proposing to assign a PFS status indicator of N (non-covered service) for CPT codes 99174 and 9917X.

(19) Low-Dose Computer Tomography, Lung, Screening (GXXX1) and Lung Cancer Screening Counseling and Shared Decision Making Visit (GXXX2)

We have issued national coverage determination (NCD) for the coverage of a lung cancer screening counseling and shared decision making visit and, for appropriate beneficiaries, annual screening with low dose computed tomography (LDCT) as an additional preventive benefit. The American College of Radiology (ACR) submitted recommendations for work and direct PE inputs. The ACR recommended that we crosswalk GXXX1 to 71250 (computed tomography, thorax; without contrast material) with additional physician work added to account for the added intensity of the service. After reviewing this recommendation, we believe that the physician work (time and intensity) is identical in both GXXX1 and 71250, and therefore, we are proposing a work RVU of 1.02 for GXXX1.

We are proposing to value the lung cancer screening counseling and shared decision making visit (GXXX2) using a crosswalk from the work value for G0443 (Brief face-to-face counseling for alcohol misuse, 15 minutes) which has a work RVU of 0.45. We added 2 minutes of pre-service time, and 1 minute post-service time which we valued at 0.0224 RVU per minute yielding a total of 0.062 additional RVUs which we then added to 0.45, bringing the total proposed work RVUs for GXXX2 to 0.52. The direct PE input recommendations from the ACR were refined according to CMS standard refinements and appear in the CY 2016 proposed direct PE input database.

7. Direct PE Input-Only Recommendations

In CY 2014, we proposed to limit the nonfacility PE RVUs for individual codes so that the total nonfacility PFS payment amount would not exceed the total combined amount that Medicare would pay for the same code in the facility setting. In developing the proposal, we sought a reliable means for Medicare to set upper payment limits for office-based procedures given our several longstanding concerns regarding the accuracy of certain aspects of the direct PE inputs, including both items and procedure time assumptions, and prices of individual supplies and equipment (78 FR 74248 through 74250). After considering the many comments we received regarding our proposal, the majority of which urged us to withdraw the proposal for a variety of reasons, we decided not to finalize the policy. However, we continue to believe that using practice expense data that are auditable, comprehensive, and regularly updated would contribute to the accuracy of practice expense calculations.

Subsequent to our decision not to finalize the proposal, the RUC forwarded direct PE input recommendations for a subset of codes with nonfacility PE RVUs that would have been limited by the policy. Some of these codes also include work values, but the RUC recommendations did not address the accuracy of those values.

We generally believe that combined reviews of work and PE for each code under the potentially misvalued codes initiative leads to more accurate and appropriate assignment of RVUs. We also believe, and have previously stated, that our standard process for evaluating potentially misvalued codes is unlikely to be the most effective means of addressing our concerns regarding the accuracy of some aspects of the direct PE inputs (79 FR 74248).

However, we also believe it is important to use the most accurate and up-to-date information available to us when developing PFS RVUs for individual services. Therefore, we have reviewed the RUC-recommended direct PE inputs for these services and are proposing to use them, with the refinements addressed in this section. However, we are also identifying these

codes as potentially misvalued because their direct PE inputs were not reviewed alongside review of their work RVUs and time. We considered not addressing these recommendations until such time as comprehensive reviews could occur, but we recognized the public interest in using the updated recommendations regarding the PE inputs until such time as the work RVUs and time can be addressed. Therefore, we note that while we are proposing adjusted PE inputs for these services based on these recommendations, we would anticipate addressing any corresponding change to direct PE inputs once the work RVUs and time are addressed.

a. Repair of Nail Bed (CPT Code 11760)

This recommendation includes 22 minutes of clinical labor time assigned for ''Assist physician in performing procedure.'' Because CPT code 11760 has 33 minutes of work intraservice time, we believe that this clinical labor input was intended to be calculated at 67 percent of work time. However, the equipment times are also calculated based on the 22 minutes of intraservice time. We are seeking comment on whether or not it would be appropriate to include the full 33 minutes of work intraservice time for the equipment.

b. Submucosal Ablation of the Tongue Base (CPT Code 41530)

We did not review CPT code 41530 for direct PE inputs, because we noted that the RUC anticipates making recommendations regarding the work RVU and direct PE inputs for this service in the near future.

c. Cytopathology Fluids, Washings or Brushings (CPT Codes 88104, 88106, 88108)

We are proposing to update the Millipore filter supply (SL502) based on stakeholder submission of new information following the RUC's original recommendation. As requested, we are proposing to crosswalk the price of the Millipore filter to the cytology specimen filter (Transcyst) supply (SL041) and assign a value of $4.15. This change is reflected in the proposed direct PE input database.

d. Cytopathology Smears, Screening and Interpretation (CPT Codes 88160, 88161, 88162)

We are concerned that there is a lack of clarity and the possibility for confusion contained in the CPT descriptors of CPT codes 88160 and 88161. The CPT descriptor for the first code refers to the ''screening and interpretation'' of Cytopathology smears, while the descriptor for the second code refers to the ''preparation, screening and interpretation'' of Cytopathology smears. We believe that there is currently the potential for duplicative counting of direct PE inputs due to the overlapping nature of these two codes. We are concerned that the same procedure may be billed multiple times under both CPT code 88160 and 88161. We believe that these codes are potentially misvalued, and we are seeking a full review of this family of codes for both work and PE, given the potential for overlap. We recognize that the ideal solution may involve revisions by the CPT Editorial Panel.

With regard to the current direct PE input recommendations, we are proposing to remove the clinical labor minutes recommended for ''Stain air dried slides with modified Wright stain'' for CPT code 88160 since staining slides would not be a typical clinical labor task if there is no slide preparation taking place, as the descriptor for this code suggests.

We are proposing to update the protease solution supply (SL506) based on stakeholder submission of new information following the RUC's original recommendation. As requested, we are proposing to change the name of the supply to ''Protease'', alter the unit of measurement from milliliters to milligrams, change the quantity assigned to CPT code 88182 from 1 to 1.12, and update the price from $0.47 to $0.4267. These changes are reflected in the proposed direct PE input database.

We are requesting additional information regarding the use of the desktop computer with monitor (ED021) for CPT code 88182. We have made no change to the current equipment time value pending the submission of additional information.

e. Flow Cytometry, Cytoplasmic Cell Surface (CPT Code 88184, 88185)

We are requesting additional information regarding the specific use of the desktop computer with monitor (ED021) for CPT codes 88184 and 88185 since the recommendation does not specify how it is used.

f. Consultation on Referred Slides and Materials (CPT Codes 88321, 88323, 88325)

We are proposing to remove the clinical labor time for ''Accession specimen/prepare for examination'' for CPT codes 88321 and 88325. These codes do not involve the preparation of slides, so this clinical labor task is duplicative with the labor carried out under ''Open shipping package, remove and sort slides based on outside number.'' We are proposing to maintain the recommended 4 minutes for this clinical labor task for CPT code 88323, since it does require slide preparation.

We are proposing to refine the clinical labor time for ''Register the patient in the information system, including all demographic and billing information'' from 13 minutes to 5 minutes for all three codes. As indicated in Table 6, our proposed standard clinical labor time for entering patient data is 4 minutes for pathology codes, and we believe that the extra tasks involving label preparation described in this clinical labor task would typically require an additional 1 minute to complete. We also believe that the additional recommended time likely reflects administrative tasks that are appropriately accounted for in the indirect PE methodology.

We are proposing to refine the clinical labor time from 7 minutes to 5 minutes for the new task ''Receive phone call from referring laboratory/facility with scheduled procedure to arrange special delivery of specimen procurement kit, including muscle biopsy clamp as needed. Review with sender instructions for preservation of specimen integrity and return arrangements. Contact courier and arrange delivery to referring laboratory/facility.'' Based on the description of this task, we believe that this task would typically take 5 minutes to be performed by the Lab Technician.

We are proposing to remove the eosin solution supply (SL063) from CPT code 88323. We do not agree that this supply would be typically used in this procedure, and the eosin solution is redundant when used together with the hematoxylin stain supply (SL135). We are also refining the quantity of the hematoxylin stain from 32 to 8 for CPT code 88323, to be consistent with its use in other related Pathology codes.

We are proposing to remove many of the inputs for clinical labor, supplies, and equipment for CPT code 88325. The descriptor for this code indicates that it does not involve slide preparation, and therefore we are proposing labor, supplies, and equipment inputs to match the inputs recommended for CPT code 88321, which also does not include the preparation of slides.

g. Morphometric Analysis, Tumor Immunohistochemistry (CPT Codes 88360, 88361)

We are proposing to update the pricing for the Benchmark ULTRA automated slide preparation system (EP112) and the E-Bar II Barcode Slide Label System (EP113). Based on stakeholder submission of information subsequent to the original RUC recommendation, we are reclassifying

these two pieces of equipment as a single item with a price of $150,000. CPT codes 88360 and 88361 have been valued using this new price. The equipment time values remain unchanged.

The RUC recommendation for CPT codes 88360 and 88361 included an invoice for the Antibody Estrogen Receptor monoclonal supply (SL493). The submitted invoice has a price of $694.70 per box of 50, or $13.89 per test. We sought publically available information regarding this supply and identified numerous monoclonal antibody estrogen receptors that appear to be consistent with those recommended by the specialty society, at publicly available lower prices, which we believe are more likely to be typical since we assume that the typical practitioner would seek the best price available to the public. One example is Estrogen Receptor Antibody (h-151) [DyLight 405], priced at 100 tests per box for $319. Therefore, we are proposing to establish a new supply code for ''Antibody Estrogen Receptor monoclonal'' and price that item at $3.19 each. We welcome comments from stakeholders regarding this supply item.

h. Nerve Teasing Preparations (CPT Code 88362)

We are proposing to refine the recommended clinical labor time for ''Assist pathologist with gross specimen examination including the following; Selection of fresh unfixed tissue sample; selection of tissue for formulant fixation for paraffin blocking and epon blocking. Reserve some specimen for additional analysis'' from 10 minutes to 5 minutes. We note that the 5 minutes includes 3 minutes for assisting the pathologist with the gross specimen examination (as listed in Table 6) and an additional 2 minutes for the additional tasks due to the work taking place on a fresh specimen.

i. Nasopharyngoscopy With Endoscope (CPT Code 92511)

We are proposing to remove the endosheath (SD070) from this procedure, because we do not believe it would be typically used and it was not included in the recommendations for any of the other related codes in the same tab. If the endosheath were included as a supply with the presentation of additional clinical information, then we believe it would be appropriate to remove all of the clinical labor and equipment time currently assigned to cleaning the scope.

j. Needle Electromyography (CPT Codes 95863, 95864, 95869, 95870)

We are proposing to reduce the quantity of the iontophoresis electrode kit (SA014) supply from 4 to 3. According to the description of this code, the procedure typically uses 2–4 electrodes, and therefore we believe that a supply quantity of 3 would better reflect the typical case. We are requesting further information regarding the typical number of electrodes used in this procedure; if the maximum of 4 electrodes is in fact typical for the procedure, then we recommend that the code descriptor be referred to CPT for further clarification.

J. Medicare Telehealth Services

1. Billing and Payment for Telehealth Services

Several conditions must be met for Medicare to make payments for telehealth services under the PFS. The service must be on the list of Medicare telehealth services and meet all of the following additional requirements:

- The service must be furnished via an interactive telecommunications system.
- The service must be furnished by a physician or authorized practitioner.
- The service must be furnished to an eligible telehealth individual.
- The individual receiving the service must be located in a telehealth originating site.

When all of these conditions are met, Medicare pays a facility fee to the originating site and makes a separate payment to the distant site practitioner furnishing the service.

Section 1834(m)(4)(F)(i) of the Act defines Medicare telehealth services to include consultations, office visits, office psychiatry services, and any additional service specified by the Secretary, when furnished via a telecommunications system. We first implemented this statutory provision, which was effective October 1, 2001, in the CY 2002 PFS final rule with comment period (66 FR 55246). We established a process for annual updates to the list of Medicare telehealth services as required by section 1834(m)(4)(F)(ii) of the Act in the CY 2003 PFS final rule with comment period (67 FR 79988).

As specified at § 410.78(b), we generally require that a telehealth service be furnished via an interactive telecommunications system. Under § 410.78(a)(3), an interactive telecommunications system is defined as multimedia communications equipment that includes, at a minimum, audio and video equipment permitting two-way, real-time interactive communication between the patient and distant site physician or practitioner.

Telephones, facsimile machines, and stand-alone electronic mail systems that are not integrated into an electronic health record system do not meet the definition of an interactive telecommunications system. An interactive telecommunications system is generally required as a condition of payment; however, section 1834(m)(1) of the Act allows the use of asynchronous ''store-and-forward'' technology when the originating site is part of a federal telemedicine demonstration program in Alaska or Hawaii. As specified in § 410.78(a)(1), asynchronous store-and-forward is the transmission of medical information from an originating site for review by the distant site physician or practitioner at a later time.

Medicare telehealth services may be furnished to an eligible telehealth individual notwithstanding the fact that the practitioner furnishing the telehealth service is not at the same location as the beneficiary. An eligible telehealth individual is an individual enrolled under Part B who receives a telehealth service furnished at an originating site.

Practitioners furnishing Medicare telehealth services are reminded that these services are subject to the same non-discrimination laws as other services, including the effective communication requirements for persons with disabilities of section 504 of the Rehabilitation Act and language access for persons with limited English proficiency, as required under Title VI of the Civil Rights Act of 1964. For more information, see *http://www.hhs.gov/ocr/civilrights/resources/specialtopics/hospitalcommunication.*

Practitioners furnishing Medicare telehealth services submit claims for telehealth services to the Medicare Administrative Contractors that process claims for the service area where their distant site is located. Section 1834(m)(2)(A) of the Act requires that a practitioner who furnishes a telehealth service to an eligible telehealth individual be paid an amount equal to the amount that the practitioner would have been paid if the service had been furnished without the use of a telecommunications system.

Originating sites, which can be one of several types of sites specified in the statute where an eligible telehealth individual is located at the time the service is being furnished via a telecommunications system, are paid a fee under the PFS a facility fee for each Medicare telehealth service. The statute

specifies both the types of entities that can serve as originating sites and the geographic qualifications for originating sites. With regard to geographic qualifications, § 410.78(b)(4) limits originating sites to those located in rural health professional shortage areas (HPSAs) or in a county that is not included in a metropolitan statistical areas (MSAs).

Historically, we have defined rural HPSAs to be those located outside of MSAs. Effective January 1, 2014, we modified the regulations regarding originating sites to define rural HPSAs as those located in rural census tracts as determined by the Office of Rural Health Policy (ORHP) of the Health Resources and Services Administration (HRSA) (78 FR 74811). Defining ''rural'' to include geographic areas located in rural census tracts within MSAs allows for broader inclusion of sites within HPSAs as telehealth originating sites. Adopting the more precise definition of ''rural'' for this purpose expands access to health care services for Medicare beneficiaries located in rural areas. HRSA has developed a Web site tool to provide assistance to potential originating sites to determine their geographic status. To access this tool, see the CMS Web site at *www.cms.gov/teleheath/*.

An entity participating in a federal telemedicine demonstration project that has been approved by, or received funding from, the Secretary as of December 31, 2000 is eligible to be an originating site regardless of its geographic location.

Effective January 1, 2014, we also changed our policy so that geographic status for an originating site would be established and maintained on an annual basis, consistent with other telehealth payment policies (78 FR 74400). Geographic status for Medicare telehealth originating sites for each calendar year is now based upon the status of the area as of December 31 of the prior calendar year.

For a detailed history of telehealth payment policy, see 78 FR 74399.

2. Adding Services to the List of Medicare Telehealth Services

As noted previously, in the December 31, 2002 **Federal Register** (67 FR 79988), we established a process for adding services to or deleting services from the list of Medicare telehealth services. This process provides the public with an ongoing opportunity to submit requests for adding services. Under this process, we assign any qualifying request to make additions to the list of telehealth services to one of two categories. Revisions to criteria that we use to review requests in the second category were finalized in the November 28, 2011 **Federal Register** (76 FR 73102). The two categories are:

- *Category 1:* Services that are similar to professional consultations, office visits, and office psychiatry services that are currently on the list of telehealth services. In reviewing these requests, we look for similarities between the requested and existing telehealth services for the roles of, and interactions among, the beneficiary, the physician (or other practitioner) at the distant site and, if necessary, the telepresenter, a practitioner who is present with the beneficiary in the originating site. We also look for similarities in the telecommunications system used to deliver the proposed service; for example, the use of interactive audio and video equipment.
- *Category 2:* Services that are not similar to the current list of telehealth services. Our review of these requests includes an assessment of whether the service is accurately described by the corresponding code when furnished via telehealth and whether the use of a telecommunications system to deliver the service produces demonstrated clinical benefit to the patient. In reviewing these requests, we look for evidence indicating that the use of a telecommunications system in furnishing the candidate telehealth service produces clinical benefit to the patient. Submitted evidence should include both a description of relevant clinical studies that demonstrate the service furnished by telehealth to a Medicare beneficiary improves the diagnosis or treatment of an illness or injury or improves the functioning of a malformed body part, including dates and findings, and a list and copies of published peer reviewed articles relevant to the service when furnished via telehealth. Our evidentiary standard of clinical benefit does not include minor or incidental benefits.

Some examples of clinical benefit include the following:

- Ability to diagnose a medical condition in a patient population without access to clinically appropriate in-person diagnostic services.
- Treatment option for a patient population without access to clinically appropriate in-person treatment options.
- Reduced rate of complications.
- Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).
- Decreased number of future hospitalizations or physician visits.
- More rapid beneficial resolution of the disease process treatment.
- Decreased pain, bleeding, or other quantifiable symptom.
- Reduced recovery time.

For the list of covered telehealth services, see the CMS Web site at *www.cms.gov/teleheath/*. Requests to add services to the list of Medicare telehealth services must be submitted and received no later than December 31 of each calendar year to be considered for the next rulemaking cycle. For example, qualifying requests submitted before the end of CY 2015 will be considered for the CY 2017 proposed rule. Each request to add a service to the list of Medicare telehealth services must include any supporting documentation the requester wishes us to consider as we review the request. Because we use the annual PFS rulemaking process as a vehicle for making changes to the list of Medicare telehealth services, requestors should be advised that any information submitted is subject to public disclosure for this purpose. For more information on submitting a request for an addition to the list of Medicare telehealth services, including where to mail these requests, see the CMS Web site at *www.cms.gov/telehealth/*.

3. Submitted Requests to the List of Telehealth Services for CY 2016

Under our existing policy, we add services to the telehealth list on a category 1 basis when we determine that they are similar to services on the existing telehealth list with respect to the roles of, and interactions among, the beneficiary, physician (or other practitioner) at the distant site and, if necessary, the telepresenter. As we stated in the CY 2012 final rule with comment period (76 FR 73098), we believe that the category 1 criteria not only streamline our review process for publicly requested services that fall into this category, the criteria also expedite our ability to identify codes for the telehealth list that resemble those services already on this list.

a. Submitted Requests

We received several requests in CY 2014 to add various services as Medicare telehealth services effective for CY 2016. The following presents a discussion of these requests, and our proposals for additions to the CY 2016 telehealth list. Of the requests received, we find that the following services are sufficiently similar to psychiatric diagnostic procedures or office/outpatient visits currently on the telehealth list to qualify on a category one basis. Therefore, we propose to add the following services to the telehealth list on a category 1 basis for CY 2016:

• CPT code 99356 (prolonged service in the inpatient or observation setting, requiring unit/floor time beyond the usual service; first hour (list separately in addition to code for inpatient evaluation and management service); and 99357 (prolonged service in the inpatient or observation setting, requiring unit/floor time beyond the usual service; each additional 30 minutes (list separately in addition to code for prolonged service).

The prolonged service codes can only be billed in conjunction with hospital inpatient and skilled nursing facility evaluation & management (E/M) codes, and of these, only subsequent hospital and subsequent nursing facility visit codes are on list of Medicare telehealth services. Therefore, CPT codes 99356 and 99357 would only be reportable with codes for which limits of one subsequent hospital visit every three days via telehealth, and one subsequent nursing facility visit every thirty days, would continue to apply.

• CPT codes 90963 (end-stage renal disease (ESRD) related services for home dialysis per full month, for patients younger than 2 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents); 90964 (end-stage renal disease (ESRD) related services for home dialysis per full month, for patients 2–11 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents); 90965 (end-stage renal disease (ESRD) related services for home dialysis per full month, for patients 12–19 years of age to include monitoring for the adequacy of nutrition, assessment of growth and development, and counseling of parents); and 90966 (end-stage renal disease (ESRD) related services for home dialysis per full month, for patients 20 years of age and older).

Although these services are for home-based dialysis, and a patient's home is not an authorized originating site for telehealth, we recognize that many components of these services would be furnished from an authorized originating site and, therefore, can be furnished via telehealth.

The required clinical examination of the catheter access site must be furnished face-to-face ''hands on'' (without the use of an interactive telecommunications system) by a physician, certified nurse specialist (CNS), nurse practitioner (NP), or physician's assistant (PA). An interactive telecommunications system may be used for providing additional visits required under the 2 to 3 visit Monthly Capitation Payment (MCP) code and the 4 or more visit MCP code. See the final rule for CY 2005 (69 FR 66276) for further information on furnishing ESRD services via telehealth.

We also received requests to add services to the telehealth list that do not meet our criteria for Medicare telehealth services. We are not proposing to add the following procedures for the reasons noted:

• All evaluation and management services, telerehabilitation services, and palliative care, pain management and patient navigation services for cancer patients.

None of these requests identified the specific codes that were being requested for addition as telehealth services, and two of the requests did not include evidence of any clinical benefit when the services are furnished via telehealth. Since we did not have information on the specific codes requested for addition or evidence of clinical benefit for these requests, we cannot evaluate whether the services are appropriate for addition to the Medicare telehealth services list.

• CPT codes 99291 (critical care, evaluation and management of the critically ill or critically injured patient; first 30–74 minutes); and 99292 (critical care, evaluation and management of the critically ill or critically injured patient; each additional 30 minutes (list separately in addition to code for primary service).

We previously considered and rejected adding these codes to the list of Medicare telehealth services in the CY 2009 PFS final rule (74 FR 69744) on a category 1 basis because, due to the acuity of critically ill patients, we did not consider critical care services similar to any services on the current list of Medicare telehealth services. In that rule, we said that critical care services must be evaluated as category 2 services. Because we would consider critical care services under category 2, we needed to evaluate whether these are services for which telehealth can be an adequate substitute for a face-to-face encounter. We had no evidence suggesting that the use of telehealth could be a reasonable surrogate for the face-to-face delivery of this type of care.

The American Telemedicine Association (ATA) submitted a request, which cited several studies to support adding these services on a category 2 basis. To qualify under category 2, we would need evidence that the service produces a clinical benefit for the patient. However, in reviewing the information provided by the ATA and a study entitled, ''Impact of an Intensive Care Unit Telemedicine Program on Patient Outcomes in an Integrated Health Care System,'' published July 2014, in ''JAMA Internal Medicine,'' which found no evidence that the implementation of ICU TM significantly reduced mortality rates or hospital length of stay, we do not believe that the evidence demonstrates a clinical benefit to patients. Therefore, we are not proposing to add these services on a category 2 basis to the list of Medicare telehealth services for CY 2016.

• CPT code 99358 (prolonged evaluation and management service before and/or after direct patient care; first hour) and 99359 (prolonged evaluation and management service before and/or after direct patient care; each additional 30 minutes (list separately in addition to code for prolonged service).

As we indicated in the CY 2015 PFS final rule with comment period (79 FR 67600), these services are not separately payable by Medicare. It would be inappropriate to include a service as a telehealth service when Medicare does not otherwise make a separate payment for it. Therefore, we are not proposing to add these non-payable services to the list of Medicare telehealth services for CY 2016.

• CPT code 99444 (online evaluation and management service provided by a physician or other qualified health care professional who may report an evaluation and management services provided to an established patient or guardian, not originating from a related E/M service provided within the previous 7 days, using the internet or similar electronic communications network).

As we indicated in the CY 2014 PFS final rule with comment period (78 FR 74403), we assigned a status indicator of ''N'' (Noncovered service) to this service because: (1) this service is non-face-to-face; and (2) the code descriptor includes language that recognizes the provision of services to parties other than the beneficiary and for whom Medicare does not provide coverage (for example, a guardian). Under section 1834(m)(2)(A) of the Act, Medicare pays the physician or practitioner furnishing a telehealth service an amount equal to the amount that would have been paid if the service was furnished without the use of a telecommunications system. Because CPT code 99444 is currently noncovered, there would be no Medicare payment if this service was furnished without the use of a telecommunications system. Since this service is noncovered under Medicare, we are not proposing to add it to the list of Medicare telehealth services for CY 2016.

• CPT code 99490 (chronic care management services, at least 20 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month, with the following required elements: multiple (two or more) chronic conditions expected to last at least 12 months, or until the death of the patient; chronic conditions place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline; comprehensive care plan established, implemented, revised, or monitored).

This service is one that can be furnished without the beneficiary's face-to-face presence, and using any number of non-face-to-face means of communication. Therefore, the service is not appropriate for consideration as a Medicare telehealth service. It is unnecessary to add this service to the list of Medicare telehealth services. Therefore, we are not proposing to add it to the list of Medicare telehealth services for CY 2016.

• CPT codes 99605 (medication therapy management service(s) provided by a pharmacist, individual, face-to-face with patient, with assessment and intervention if provided; initial 15 minutes, new patient); 99606 (medication therapy management service(s) provided by a pharmacist, individual, face-to-face with patient, with assessment and intervention if provided; initial 15 minutes, established patient); and 99607 (medication therapy management service(s) provided by a pharmacist, individual, face-to-face with patient, with assessment and intervention if provided; each additional 15 minutes (list separately in addition to code for primary service).

These codes are noncovered services for which no payment may be made under the PFS. Therefore, we are not proposing to add these services to the list of Medicare telehealth services for CY 2016.

In summary, we are proposing to add the following codes to the list of Medicare telehealth services beginning in CY 2016 on a category 1 basis: Prolonged service inpatient CPT codes 99356 and 99357 and ESRD-related services 90933 through 90936. As indicated above, the prolonged service codes can only be billed in conjunction with subsequent hospital and subsequent nursing facility codes. Limits of one subsequent hospital visit every three days, and one subsequent nursing facility visit every thirty days, would continue to apply when the services are furnished as telehealth services. For the ESRD related services, the required clinical examination of the catheter access site must be furnished face-to-face ''hands on'' (without the use of an interactive telecommunications system) by a physician, certified nurse specialist (CNS), nurse practitioner (NP), or physician's assistant (PA).

We remind all interested stakeholders that we are currently soliciting public requests to add services to the list of Medicare telehealth services. To be considered during PFS rulemaking for CY 2017, these requests must be submitted and received by December 31, 2015. Each request to add a service to the list of Medicare telehealth services must include any supporting documentation the requester wishes us to consider as we review the request. For more information on submitting a request for an addition to the list of Medicare telehealth services, including where to mail these requests, we refer readers to the CMS Web site at *www.cms.gov/telehealth/.*

4. Proposal To Amend § 410.78 To Include Certified Registered Nurse Anesthetists as Practitioners for Telehealth Services

Under section 1834(m)(1) of the Act, Medicare makes payment for telehealth services furnished by physicians and practitioners. Section 1834(m)(4)(E) of the Act specifies that, for purposes of furnishing Medicare telehealth services, the term ''practitioner'' has the meaning given that term in section 1842(b)(18)(C), which includes a certified registered nurse anesthetist (CRNA) as defined in section 1861 (bb)(2).

We initially omitted CRNAs from the list of distant site practitioners for telehealth services in the regulation because we did not believe these practitioners would furnish any of the service on the list of Medicare telehealth services. However, CRNAs in some states are licensed to furnish certain services on the telehealth list, including E/M services. Therefore, we propose to revise the regulation at § 410.78(b)(2) to include a CRNA, as described under § 410.69, to the list of distant site practitioners who can furnish Medicare telehealth services.

K. Incident to Proposals: Billing Physician as the Supervising Physician and Ancillary Personnel Requirements

1. Background

Section 1861(s)(2)(A) of the Act establishes the benefit category for services and supplies furnished as ''incident to'' the professional services of a physician. The statute specifies that services and supplies furnished as an incident to a physician's professional service (hereinafter ''incident to services'') are ''of kinds which are commonly furnished in physicians' offices and are commonly either rendered without charge or included in physicians' bills.'' In addition to the requirements of the statute, § 410.26 sets forth specific requirements that must be met for physicians and other practitioners to bill Medicare for incident to services. Section 410.26(a)(7) limits incident to services to those included under section 1861(s)(2)(A) of the Act and that are not covered under another benefit category. Section 410.26(b) specifies (in part) that in order for services and supplies to be paid as incident to services under Medicare Part B, the services or supplies must be:

• Furnished in a noninstitutional setting to noninstitutional patients.

• An integral, though incidental, part of the service of a physician (or other practitioner) in the course of diagnosis or treatment of an injury or illness.

• Furnished under direct supervision (as specified under § 410.26(a)(2)) of a physician or other practitioner eligible to bill and directly receive Medicare payment.

• Furnished by a physician, a practitioner with an incident to benefit, or auxiliary personnel.

In addition to § 410.26, there are regulations specific to each type of practitioner who is allowed to bill for incident to services as specified in § 410.71(a)(2) (clinical psychologist services), § 410.74(b) (physician assistants' services), § 410.75(d) (nurse practitioners' services), § 410.76(d) (clinical nurse specialists' services), and § 410.77(c) (certified nurse-midwives' services). When referring to practitioners who can bill for services furnished incident to their professional services, we are referring to physicians and these practitioners.

Incident to services are treated as if they were furnished by the billing physician or other practitioner for purposes of Medicare billing and payment. Consistent with this terminology, in this discussion when referring to the physician or other practitioner furnishing the service, we are referring to the physician or other practitioner who is billing for the incident to service. When we refer to the ''auxiliary personnel'' or the person who provides the service, we are referring to an individual who is personally performing the service or some aspect of it as distinguished from the physician or other practitioner who bills for the incident to service.

Since we treat incident to services as services furnished by the billing physician or other practitioner for

purposes of Medicare billing and payment, payment is made to the billing physician or other practitioner under the PFS, and all relevant Medicare rules apply including, but not limited to, requirements regarding medical necessity, documentation, and billing. Those practitioners who can bill Medicare for incident to services are paid at their applicable Medicare payment rate as if they personally furnished the service. For example, when incident to services are billed by a physician, they are paid at 100 percent of the fee schedule amount, and when the services are billed by a nurse practitioner or clinical nurse specialist, they are paid at 85 percent of the fee schedule amount. Payments are subject to the usual deductible and coinsurance amounts.

In the CY 2014 PFS final rule with comment period, we amended § 410.26 by adding a paragraph (b)(7) to require that, as a condition for Medicare Part B payment, all incident to services must be furnished in accordance with applicable state law. Additionally, we amended the definition of auxiliary personnel at § 410.26(a)(1) to require that the individual who provides the incident to services must meet any applicable requirements to provide such services (including licensure) imposed by the state in which the services are furnished. These requirements for compliance with applicable state laws apply to any individual providing incident to services as a means to protect the health and safety of Medicare beneficiaries in the delivery of health care services, and to provide the Medicare program with additional recourse for denying or recovering Part B payment for incident to services that are not furnished in compliance with state law (78 FR 74410). Revisions to § 410.26(a)(1) and (b)(7) were intended to clarify the longstanding payment policy of paying only for services that are furnished in compliance with any applicable state or federal requirements. The amended regulations also provide the Medicare program with additional recourse for denying or recovering Part B payment for incident to services that are not furnished in compliance with applicable requirements.

2. Billing Physician as the Supervising Physician

In addition to the CY 2014 revisions to the regulations for incident to services, we believe that additional requirements for incident to services should be explicitly and unambiguously stated in the regulations. As described in this proposed rule, incident to a physician's or other practitioner's professional services means that the services or supplies are furnished as an integral, although incidental, part of the physician's or other practitioner's personal professional services in the course of diagnosis or treatment of an injury or illness (§ 410.26(b)(2)). Incident to services require direct supervision of the auxiliary personnel providing the service by the physician or other practitioner (§ 410.26(b)(5)).

We are proposing to revise the regulations specifying the requirements for which physicians or other practitioners can bill for incident to services. In the CY 2002 PFS final rule, in response to a comment seeking clarification regarding what physician billing number should be used on the claim form for an incident to service, at 66 FR 55267, we stated that when a claim is submitted to Medicare under the billing number of a physician or other practitioner for an 'incident to' service, the physician or other practitioner is stating that he or she performed the service or directly supervised the auxiliary personnel performing the service. Accordingly, the Medicare billing number of the ordering physician or other practitioner should not be used if that person did not directly supervise the auxiliary personnel.

Section 410.26(b)(5) currently states that the physician (or other practitioner) supervising the auxiliary personnel need not be the same physician (or other practitioner) upon whose professional service the incident to service is based. To be certain that the incident to services furnished to a beneficiary are in fact an integral, although incidental, part of the physician's or other practitioner's personal professional service that is billed to Medicare, we believe that the physician or other practitioner who bills for the incident to service must also be the physician or other practitioner who directly supervises the service. It has been our position that billing practitioners should have a personal role in, and responsibility for, furnishing services for which they are billing and receiving payment as an incident to their own professional services. This is consistent with the requirements that all physicians and billing practitioners attest on each Medicare claim that he or she ''personally furnished'' the services for which he or she is billing. Without this requirement, there could be an insufficient nexus with the physician's or other practitioner's services being billed on a claim to Medicare as incident to services and the actual services being furnished to the Medicare beneficiary by the auxiliary personnel. Therefore, we are proposing to amend § 410.26(b)(5) to state that the physician or other practitioner who bills for incident to services must also be the physician or other practitioner who directly supervises the auxiliary personnel who provide the incident to services. Also, to further clarify the meaning of the proposed amendment to this regulation, we are proposing to remove the last sentence from § 410.26(b)(5) specifying that the physician (or other practitioner) supervising the auxiliary personnel need not be the same physician (or other practitioner) upon whose professional service the incident to service is based.

3. Auxiliary Personnel Who Have Been Excluded or Revoked From Medicare

As a condition of Medicare payment, auxiliary personnel who, under the direct supervision of a physician or other practitioner, provide incident to services to Medicare beneficiaries must comply with all applicable Federal and State laws. This includes not having been excluded from Medicare, Medicaid and all other federally funded health care programs by the Office of Inspector General. We are proposing to amend the regulation to explicitly prohibit auxiliary personnel from providing incident to services who have either been excluded from Medicare, Medicaid and all other federally funded health care programs by the Office of Inspector General or who have had their enrollment revoked for any reason. These excluded or revoked individuals are already prohibited from providing services to Medicare beneficiaries, so this proposed revision is an additional safeguard to ensure that these excluded or revoked individuals are not providing incident to services and supplies under the direct supervision of a physician or other authorized supervising practitioner. These proposed revisions to the incident to regulations will provide the Medicare program with additional recourse for denying or recovering Part B payment for incident to services and supplies that are not furnished in compliance with our program requirements.

4. Compliance and Oversight

We recognize that there are many ways in which compliance with these requirements could be consistently and fairly assured across the Medicare program. In considering implementation of these proposals, we wish to be mindful of the need to minimize or eliminate any practitioner administrative burden while at the same time ensuring that practitioners are not subjected to unnecessary audits or

placed at risk of inadvertent non-compliance. Therefore, while we believe that the initial responsibility of compliance rests with the practitioner, we invite comments through this proposed rule about possible approaches we could take to improve our ability ensure that incident to services are provided to beneficiaries by qualified individuals in a manner consistent with Medicare statute and regulations. We invite commenters to consider the options we will consider, such as creating new categories of enrollment, implementing a mechanism for registration short of full enrollment, requiring the use of claim elements such as modifiers to identify the types of individuals providing services, or relying on post-payment audits, investigations and recoupments by CMS contractors such as Recovery Auditors or Program Integrity Contractors. We will consider these comments in the course of implementing the proposals we finalize in rulemaking for CY 2016, and further, if we decide in the future that additional regulations or guidance will be necessary to monitor compliance with these or other requirements surrounding incident to services.

L. Portable X-ray: Billing of the Transportation Fee

Portable X-ray suppliers receive a transportation fee for transporting portable X-ray equipment to the location where portable X-rays are taken. If more than one patient at the same location is X-rayed, the portable X-ray transportation fee is allocated among the patients. We have received feedback that some portable x-ray suppliers have been operating under the assumption that the prorated transportation payment when more than one patient is receiving portable X-ray services at the same location refers to only a subset of patients. The Medicare Claims Processing Manual (Pub. 100–4, Chapter 13, Section 90.3) currently states:

> Carriers shall allow only a single transportation payment for each trip the portable X-ray supplier makes to a particular location. When more than one Medicare patient is X-rayed at the same location, e.g., a nursing home, prorate the single fee schedule transportation payment among all patients receiving the services. For example, if two patients at the same location receive X-rays, make one-half of the transportation payment for each.

In some jurisdictions, Medicare contractors have been allowing the portable X-ray transportation fee to be allocated only among Medicare Part B beneficiaries. In other jurisdictions, Medicare contractors have required the transportation fee to be allocated among all Medicare patients (Parts A and B). We believe it would be more appropriate to allocate the transportation fee among all patients who receive portable X-ray services in a single trip. Medicare should not pay for more than its share of the transportation costs for portable X-ray services.

We are proposing to revise the Medicare Claims Processing Manual (Pub. 100–4, Chapter 13, Section 90.3) to remove the word ''Medicare'' before ''patient'' in section 90.3. We are also proposing to clarify that this subregulatory guidance means that, when more than one patient is X-rayed at the same location, the single transportation payment under the PFS is to be prorated among all patients (Medicare Parts A and B, and non-Medicare) receiving portable X-ray services during that trip, regardless of their insurance status.

For example, for portable x-ray services furnished at a SNF, we believe that the transportation fee should be allocated among all patients receiving portable X-ray services at the same location in a single trip irrespective of whether the patient is in a Part A stay, a Part B patient, or not a Medicare beneficiary at all. If the patient is in a Part A SNF stay, payment for the allocated portion of the transportation fee (and the X-ray) would be the SNF's responsibility. For a privately insured patient, it would be the responsibility of that patient's insurer. For a Medicare Part B patient, payment would be made under Part B for the share of the transportation fee attributable to that patient. We welcome comments on this proposal to determine Medicare Part B's portion of the transportation payment by prorating the single fee among all patients.

M. Technical Correction: Waiver of Deductible for Anesthesia Services Furnished on the Same Date as a Planned Screening Colorectal Cancer Test

Section 1833(b)(1) of the Act waives the deductible for colorectal cancer screening tests regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as the screening test. To implement this statutory provision, we amended our regulation at § 410.160 to add to the list of services to which the deductible does not apply, beginning January 1, 2011, a surgical service furnished in connection with, as a result of, and in the same clinical encounter as a planned colorectal cancer screening test. A surgical service furnished in connection with, as a result of, and in the same clinical encounter as a colorectal cancer screening test means a surgical service furnished on the same date as a planned colorectal cancer screening test as described in § 410.37.

In the CY 2015 PFS final rule with comment period, we modified the regulatory definition of colorectal cancer screening test with regard to colonoscopies to include anesthesia services whether billed as part of the colonoscopy service or separately. (See § 410.37(a)(1)(iii) of our regulations). In the preamble to the final rule, we stated that the statutory waiver of deductible would apply to anesthesia services furnished in conjunction with a colorectal cancer screening test even when a polyp or other tissue is removed during a colonoscopy (79 FR 67731). We also indicated that practitioners should report anesthesia services with the PT modifier in such circumstances. The final policy was implemented for services furnished during CY 2015. While we modified the definition of colorectal cancer screening services in the regulation at § 410.37(a)(1)(iii) to include anesthesia furnished with a screening colonoscopy, we did not make a conforming change to our regulations to expressly reflect the inapplicability of the deductible to those anesthesia services.

To better reflect our policy in the regulations, we propose a technical correction to amend § 410.160(b)(8) to expressly recognize anesthesia services. Specifically, we propose to amend § 410.160(b)(8) to add ''and beginning January 1, 2015, for an anesthesia service,'' following the first use of the phrase ''a surgical service'' and to add ''or anesthesia'' following the word ''surgical'' each time it is used in the second sentence of § 410.160(b)(8). This amendment to our regulation will ensure that both surgical or anesthesia services furnished in connection with, as a result of, and in the same clinical encounter as a colorectal cancer screening test will be exempt from the deductible requirement when furnished on the same date as a planned colorectal cancer screening test as described in § 410.37.

III. Other Provisions of the Proposed Regulations

A. Proposed Provisions associated with the Ambulance Fee Schedule

1. Overview of Ambulance Services

a. Ambulance Services

Under the ambulance fee schedule, the Medicare program pays for ambulance transportation services for Medicare beneficiaries when other means of transportation are contraindicated by the beneficiary's medical condition and all other coverage requirements are met. Ambulance services are classified into different levels of ground (including water) and air ambulance services based on the medically necessary treatment provided during transport.

These services include the following levels of service:

- For Ground—
++ Basic Life Support (BLS) (emergency and non-emergency)
++ Advanced Life Support, Level 1 (ALS1) (emergency and non-emergency)
++ Advanced Life Support, Level 2 (ALS2)
++ Paramedic ALS Intercept (PI)
++ Specialty Care Transport (SCT)
- For Air—
++ Fixed Wing Air Ambulance (FW)
++ Rotary Wing Air Ambulance (RW)

b. Statutory Coverage of Ambulance Services

Under sections 1834(l) and 1861(s)(7) of the Act, Medicare Part B (Supplemental Medical Insurance) covers and pays for ambulance services, to the extent prescribed in regulations, when the use of other methods of transportation would be contraindicated by the beneficiary's medical condition.

The House Ways and Means Committee and Senate Finance Committee Reports that accompanied the 1965 Social Security Amendments suggest that the Congress intended that—

- The ambulance benefit cover transportation services only if other means of transportation are contraindicated by the beneficiary's medical condition; and
- Only ambulance service to local facilities be covered unless necessary services are not available locally, in which case, transportation to the nearest facility furnishing those services is covered (H.R. Rep. No. 213, 89th Cong., 1st Sess. 37 and Rep. No. 404, 89th Cong., 1st Sess. Pt 1, 43 (1965)).

The reports indicate that transportation may also be provided from one hospital to another, to the beneficiary's home, or to an extended care facility.

c. Medicare Regulations for Ambulance Services

Our regulations relating to ambulance services are set forth at 42 CFR part 410, subpart B and 42 CFR part 414, subpart H. Section 410.10(i) lists ambulance services as one of the covered medical and other health services under Medicare Part B. Therefore, ambulance services are subject to basic conditions and limitations set forth at § 410.12 and to specific conditions and limitations included at § 410.40 and § 410.41. Part 414, subpart H, describes how payment is made for ambulance services covered by Medicare.

2. Ambulance Extender Provisions

a. Amendment to Section 1834(l)(13) of the Act

Section 146(a) of the MIPPA amended section 1834(l)(13)(A) of the Act to specify that, effective for ground ambulance services furnished on or after July 1, 2008 and before January 1, 2010, the ambulance fee schedule amounts for ground ambulance services shall be increased as follows:

- For covered ground ambulance transports that originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 3 percent.
- For covered ground ambulance transports that do not originate in a rural area or in a rural census tract of a metropolitan statistical area, the fee schedule amounts shall be increased by 2 percent.

The payment add-ons under section 1834(l)(13)(A) of the Act have been extended several times. Most recently, section 203(a) of the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10, enacted on April 16, 2015) amended section 1834(l)(13)(A) of the Act to extend the payment add-ons through December 31, 2017. Thus, these payment add-ons apply to covered ground ambulance transports furnished before January 1, 2018. We are proposing to revise § 414.610(c)(1)(ii) to conform the regulations to this statutory requirement. (For a discussion of past legislation extending section 1834(l)(13) of the Act, please see the CY 2014 PFS final rule with comment period (78 FR 74438 through 74439)).

This statutory requirement is self-implementing. A plain reading of the statute requires only a ministerial application of the mandated rate increase, and does not require any substantive exercise of discretion on the part of the Secretary.

b. Amendment to Section 1834(l)(12) of the Act

Section 414(c) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (Pub. L. 108–173, enacted on December 8, 2003) (MMA) added section 1834(l)(12) to the Act, which specified that, in the case of ground ambulance services furnished on or after July 1, 2004, and before January 1, 2010, for which transportation originates in a qualified rural area (as described in the statute), the Secretary shall provide for a percent increase in the base rate of the fee schedule for such transports. The statute requires this percent increase to be based on the Secretary's estimate of the average cost per trip for such services (not taking into account mileage) in the lowest quartile of all rural county populations as compared to the average cost per trip for such services (not taking into account mileage) in the highest quartile of rural county populations. Using the methodology specified in the July 1, 2004 interim final rule (69 FR 40288), we determined that this percent increase was equal to 22.6 percent. As required by the MMA, this payment increase was applied to ground ambulance transports that originated in a ''qualified rural area,'' that is, to transports that originated in a rural area included in those areas comprising the lowest 25th percentile of all rural populations arrayed by population density. For this purpose, rural areas included Goldsmith areas (a type of rural census tract). This rural bonus is sometimes referred to as the ''Super Rural Bonus'' and the qualified rural areas (also known as ''super rural'' areas) are identified during the claims adjudicative process via the use of a data field included in the CMS-supplied ZIP code file.

The Super Rural Bonus under section 1834(l)(12) of the Act has been extended several times. Most recently, section 203(b) of the Medicare Access and CHIP Reauthorization Act of 2015 amended section 1834(l)(12)(A) of the Act to extend this rural bonus through December 31, 2017. Therefore, we are continuing to apply the 22.6 percent rural bonus described above (in the same manner as in previous years) to ground ambulance services with dates of service before January 1, 2018 where transportation originates in a qualified rural area. Accordingly, we are proposing to revise § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement. (For a discussion of past legislation extending section 1834(l)(12) of the Act, please see the CY 2014 PFS

final rule with comment period (78 FR 74439 through 74440)).

This statutory provision is self-implementing. It requires an extension of this rural bonus (which was previously established by the Secretary) through December 31, 2017, and does not require any substantive exercise of discretion on the part of the Secretary.

3. Changes in Geographic Area Delineations for Ambulance Payment

a. Background

In the CY 2015 PFS final rule with comment period (79 FR 67744 through 67750) as amended by the correction issued December 31, 2014 (79 FR 78716 through 78719), we adopted, beginning in CY 2015, the revised OMB delineations as set forth in OMB's February 28, 2013 bulletin (No. 13–01) and the most recent modifications of the Rural-Urban Commuting Area (RUCA) codes for purposes of payment under the ambulance fee schedule. With respect to the updated RUCA codes, we designated any census tracts falling at or above RUCA level 4.0 as rural areas. In addition, we stated that none of the super rural areas would lose their status upon implementation of the revised OMB delineations and updated RUCA codes. After publication of the CY 2015 PFS final rule with comment period and the correction, we received feedback and comments from stakeholders expressing concerns about the implementation of the new geographic area delineations finalized in that rule (as corrected). In response to these concerns, we are clarifying our implementation of the revised OMB delineations and the updated RUCA codes in CY 2015, and reproposing the implementation of the revised OMB delineations and updated RUCA codes for CY 2016 and subsequent calendar years. We are requesting public comment on our proposals, as further discussed in section III A.3.b. of this proposed rule.

b. Provisions of the Proposed Rule

Under section 1834(l)(2)(C) of the Act, the Secretary is required to consider appropriate regional and operational differences in establishing the ambulance fee schedule. Historically, the Medicare ambulance fee schedule has used the same geographic area designations as the acute care hospital inpatient prospective payment system (IPPS) and other Medicare payment systems to take into account appropriate regional (urban and rural) differences. This use of consistent geographic standards for Medicare payment purposes provides for consistency across the Medicare program.

The geographic areas used under the ambulance fee schedule effective in CY 2007 were based on OMB standards published on December 27, 2000 (65 FR 82228 through 82238), Census 2000 data, and Census Bureau population estimates for 2007 and 2008 (OMB Bulletin No. 10–02). For a discussion of OMB's delineation of Core-Based Statistical Areas (CBSAs) and our implementation of the CBSA definitions under the ambulance fee schedule, we refer readers to the preamble of the CY 2007 Ambulance Fee Schedule proposed rule (71 FR 30358 through 30361) and the CY 2007 PFS final rule with comment period (71 FR 69712 through 69716). On February 28, 2013, OMB issued OMB Bulletin No. 13–01, which established revised delineations for Metropolitan Statistical Areas (MSAs), Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. A copy of this bulletin may be obtained at *http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-01.pdf.* According to OMB, this bulletin provides the delineations of all Metropolitan Statistical Areas, Metropolitan Divisions, Micropolitan Statistical Areas, Combined Statistical Areas, and New England City and Town Areas in the United States and Puerto Rico based on the standards published on June 28, 2010, in the **Federal Register** (75 FR 37246–37252) and Census Bureau data. OMB defines an MSA as a CBSA associated with at least one urbanized area that has a population of at least 50,000, and a Micropolitan Statistical Area (referred to in this discussion as a Micropolitan Area) as a CBSA associated with at least one urban cluster that has a population of at least 10,000 but less than 50,000 (75 FR 37252). Counties that do not qualify for inclusion in a CBSA are deemed ''Outside CBSAs.'' We note that, when referencing the new OMB geographic boundaries of statistical areas, we are using the term ''delineations'' consistent with OMB's use of the term (75 FR 37249).

Although the revisions OMB published on February 28, 2013 were not as sweeping as the changes made when we adopted the CBSA geographic designations for CY 2007, the February 28, 2013 OMB bulletin did contain a number of significant changes. For example, there are new CBSAs, urban counties that became rural, rural counties that became urban, and existing CBSAs that were split apart. As we stated in the CY 2015 PFS final rule with comment period (79 FR 67745), we reviewed our findings and impacts relating to the new OMB delineations, and found no compelling reason to further delay implementation. We stated in the CY 2015 final rule with comment period, and we continue to believe, that it is important for the ambulance fee schedule to use the latest labor market area delineations available as soon as reasonably possible to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts.

Additionally, in the FY 2015 IPPS final rule (79 FR 49952), we adopted OMB's revised delineations to identify urban areas and rural areas for purposes of the IPPS wage index. For the reasons discussed in this section above, we believe that it would be appropriate to adopt the same geographic area delineations for use under the ambulance fee schedule as are used under the IPPS and other Medicare payment systems. Thus, we are proposing to continue implementation of the new OMB delineations as described in the February 28, 2013 OMB Bulletin No. 13–01 for CY 2016 and subsequent CYs to more accurately identify urban and rural areas for ambulance fee schedule payment purposes. We continue to believe that the updated OMB delineations more realistically reflect rural and urban populations, and that the use of such delineations under the ambulance fee schedule would result in more accurate payment. Under the ambulance fee schedule, consistent with our current definitions of urban and rural areas (§ 414.605), in CY 2016 and subsequent CYs, MSAs would continue to be recognized as urban areas, while Micropolitan and other areas outside MSAs, and rural census tracts within MSAs (as discussed below in this section), would continue to be recognized as rural areas. We invite public comments on this proposal.

In addition to the OMB's statistical area delineations, the current geographic areas used in the ambulance fee schedule also are based on rural census tracts determined under the most recent version of the Goldsmith Modification. These rural census tracts within MSAs are considered rural areas under the ambulance fee schedule (see § 414.605). For certain rural add-on payments, section 1834(l) of the Act requires that we use the most recent version of the Goldsmith Modification to determine rural census tracts within MSAs. In the CY 2007 PFS final rule with comment period (71 FR 69714 through 69716), we adopted the most recent (at that time) version of the

Goldsmith Modification, designated as RUCA codes. RUCA codes use urbanization, population density, and daily commuting data to categorize every census tract in the country. For a discussion about RUCA codes, we refer the reader to the CY 2007 PFS final rule with comment period (71 FR 69714 through 69716) and the CY 2015 PFS final rule with comment period (79 FR 67745 through 67746). As stated previously, on February 28, 2013, OMB issued OMB Bulletin No. 13–01, which established revised delineations for Metropolitan Statistical Areas, Micropolitan Statistical Areas, and Combined Statistical Areas, and provided guidance on the use of the delineations of these statistical areas. Several modifications of the RUCA codes were necessary to take into account updated commuting data and the revised OMB delineations. We refer readers to the U.S. Department of Agriculture's Economic Research Service Web site for a detailed listing of updated RUCA codes found at *http://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes.aspx*. The updated RUCA code definitions were introduced in late 2013 and are based on data from the 2010 decennial census and the 2006–2010 American Community Survey. Information regarding the American Community Survey can be found at *http://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes.aspx*. We believe that the most recent RUCA codes provide more accurate and up-to-date information regarding the rurality of census tracts throughout the country. Accordingly, we are proposing to continue to use the most recent modifications of the RUCA codes for CY 2016 and subsequent CYs, to recognize levels of rurality in census tracts located in every county across the nation, for purposes of payment under the ambulance fee schedule. If we continue to use the most recent RUCA codes, many counties that are designated as urban at the county level based on population would continue to have rural census tracts within them that would be recognized as rural areas through our use of RUCA codes.

As we stated in the CY 2015 PFS final rule with comment period (79 FR 67745), the 2010 Primary RUCA codes are as follows:

(1) Metropolitan area core: primary flow with an urbanized area (UA).

(2) Metropolitan area high commuting: primary flow 30 percent or more to a UA.

(3) Metropolitan area low commuting: primary flow 10 to 30 percent to a UA.

(4) Micropolitan area core: primary flow within an Urban Cluster of 10,000 to 49,999 (large UC).

(5) Micropolitan high commuting: primary flow 30 percent or more to a large UC.

(6) Micropolitan low commuting: primary flow 10 to 30 percent to a large UC.

(7) Small town core: primary flow within an Urban Cluster of 2,500 to 9,999 (small UC).

(8) Small town high commuting: primary flow 30 percent or more to a small UC.

(9) Small town low commuting: primary flow 10 to 30 percent to a small UC.

(10) Rural areas: primary flow to a tract outside a UA or UC.

Based on this classification, and consistent with our current policy as set forth in the CY 2015 PFS final rule with comment period (79 FR 67745), we are proposing to continue to designate any census tracts falling at or above RUCA level 4.0 as rural areas for purposes of payment for ambulance services under the ambulance fee schedule. As discussed in the CY 2007 PFS final rule with comment period (71 FR 69715) and the CY 2015 PFS final rule with comment period (79 FR 67745), the Office of Rural Health Policy within the Health Resources and Services Administration (HRSA) determines eligibility for its rural grant programs through the use of the RUCA code methodology. Under this methodology, HRSA designates any census tract that falls in RUCA level 4.0 or higher as a rural census tract. In addition to designating any census tracts falling at or above RUCA level 4.0 as rural areas, under the updated RUCA code definitions, HRSA has also designated as rural census tracts those census tracts with RUCA codes 2 or 3 that are at least 400 square miles in area with a population density of no more than 35 people. We refer readers to HRSA's Web site at *ftp://ftp.hrsa.gov/ruralhealth/Eligibility2005.pdf* for additional information. Consistent with the HRSA guidelines discussed above and the policy we adopted in the CY 2015 PFS final rule with comment period (79 FR 67750), we are proposing for CY 2016 and subsequent CYs, to designate as rural areas those census tracts that fall at or above RUCA level 4.0. We continue to believe that this HRSA guideline accurately identifies rural census tracts throughout the country, and thus would be appropriate to apply for ambulance fee schedule payment purposes.

Also, consistent with the policy we finalized in the CY 2015 PFS final rule with comment period (79 FR 67749), we would not designate as rural areas those census tracts that fall in RUCA levels 2 or 3 that are at least 400 square miles in area with a population density of no more than 35 people. We have determined that it is not feasible to implement this guideline due to the complexities of identifying these areas at the ZIP code level. We do not have sufficient information available to identify the ZIP codes that fall in these specific census tracts. Also, payment under the ambulance fee schedule is based on the ZIP codes; therefore, if the ZIP code is predominantly metropolitan but has some rural census tracts, we do not split the ZIP code areas to distinguish further granularity to provide different payments within the same ZIP code. We believe that payment for all ambulance transportation services at the ZIP code level provides for a more consistent and administratively feasible payment system. For example, if we were to pay based on ZIP codes for some areas and counties or census tracts for other areas, there are circumstances where ZIP codes cross county or census tract borders and where counties or census tracts cross ZIP code borders. Such overlaps in geographic designations would complicate our ability to appropriately assign ambulance transportation services to geographic areas for payment under the ambulance fee schedule. Therefore, under the ambulance fee schedule, we would not designate as rural areas those census tracts that fall in RUCA levels 2 or 3 that are at least 400 square miles in area with a population density of no more than 35 people.

We invite public comments on our proposals, as discussed in this proposed rule, to continue to use the updated RUCA codes under the ambulance fee schedule for CY 2016 and subsequent CYs.

As we stated in the CY 2015 PFS proposed rule (79 FR 40374), the adoption of the most current OMB delineations and the updated RUCA codes would affect whether certain areas are recognized as rural or urban. The distinction between urban and rural is important for ambulance payment purposes because urban and rural transports are paid differently. The determination of whether a transport is urban or rural is based on the point of pick-up for the transport; thus, a transport is paid differently depending on whether the point of pick-up is in an urban or a rural area. During claims processing, a geographic designation of urban, rural, or super rural is assigned to each claim for an ambulance

transport based on the point of pick-up ZIP code that is indicated on the claim.

The continued implementation of the revised OMB delineations and the updated RUCA codes would continue to affect whether or not transports would be eligible for rural adjustments under the ambulance fee schedule statute and regulations. For ground ambulance transports where the point of pick-up is in a rural area, the mileage rate is increased by 50 percent for each of the first 17 miles (§ 414.610(c)(5)(i)). For air ambulance services where the point of pick-up is in a rural area, the total payment (base rate and mileage rate) is increased by 50 percent (§ 414.610(c)(5)(i)).

Section 1834(l)(12) of the Act (as amended most recently by section 203(b) of the Medicare Access and CHIP Reauthorization Act of 2015) specifies that, for services furnished during the period July 1, 2004 through December 31, 2017, the payment amount for the ground ambulance base rate is increased by a ''percent increase'' (Super Rural Bonus) where the ambulance transport originates in a ''qualified rural area,'' which is a rural area that we determine to be in the lowest 25th percentile of all rural populations arrayed by population density (also known as a ''super rural area''). We implement this Super Rural Bonus in § 414.610(c)(5)(ii). As discussed in section III.A.2.b. of this proposed rule, we are proposing to revise § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement. As we stated in the CY 2015 PFS proposed rule (79 FR 40374) and final rule with comment period (79 FR 67746), adoption of the revised OMB delineations and the updated RUCA codes would have no negative impact on ambulance transports in super rural areas, as none of the current super rural areas would lose their status due to the revised OMB delineations and the updated RUCA codes. Furthermore, under section 1834(l)(13) of the Act (as amended most recently by section 203(a) of the Medicare Access and CHIP Reauthorization Act of 2015), for ground ambulance transports furnished through December 31, 2017, transports originating in rural areas are paid based on a rate (both base rate and mileage rate) that is 3 percent higher than otherwise is applicable. (See also § 414.610(c)(1)(ii)). As discussed in section III.A.2.a. of this proposed rule, we are proposing to revise § 414.610(c)(1)(ii) to conform the regulations to this statutory requirement.

Similar to our discussion in the CY 2015 PFS proposed rule (79 FR 40374) and final rule with comment period (79 FR 67746), if we continue to use OMB's revised delineations and the updated RUCA codes for CY 2016 and subsequent CYs, ambulance providers and suppliers that pick up Medicare beneficiaries in areas that would be Micropolitan or otherwise outside of MSAs based on OMB's revised delineations or in a rural census tract of an MSA based on the updated RUCA codes (but were within urban areas under the geographic delineations in effect in CY 2014) would continue to experience increases in payment for such transports (as compared to the CY 2014 geographic delineations) because they may be eligible for the rural adjustment factors discussed above in this section. In addition, those ambulance providers and suppliers that pick up Medicare beneficiaries in areas that would be urban based on OMB's revised delineations and the updated RUCA codes (but were previously in Micropolitan Areas or otherwise outside of MSAs, or in a rural census tract of an MSA under the geographic delineations in effect in CY 2014) would continue to experience decreases in payment for such transports (as compared to the CY 2014 geographic delineations) because they would no longer be eligible for the rural adjustment factors discussed above in this section.

The continued use of the revised OMB delineations and the updated RUCA codes for CY 2016 and subsequent CYs would mean the continued recognition of urban and rural boundaries based on the population migration that occurred over a 10-year period, between 2000 and 2010. As discussed above in this section, we are proposing to continue to use the updated RUCA codes to identify rural census tracts within MSAs, such that any census tracts falling at or above RUCA level 4.0 would continue to be designated as rural areas. In order to determine which ZIP codes are included in each such rural census tract, we are proposing to continue to use the ZIP code approximation file developed by HRSA. This file includes the 2010 RUCA code designation for each ZIP code and can be found at *http://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes.aspx*. If ZIP codes are added over time to the USPS ZIP code file (and thus are not included in the 2010 ZIP code approximation file provided to us by HRSA) or if ZIP codes are revised over time, we would determine the appropriate urban/rural designation for such ZIP code based on any updates provided on the HRSA and OMB Web sites, located at *http://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes.aspx* and *http://www.whitehouse.gov/sites/default/files/omb/bulletins/2013/b-13-01.pdf*.

Based on the April 2015 USPS ZIP code file that we are using in this proposed rule to assess the impacts of the revised geographic delineations, there are a total of 42,925 ZIP codes in the U.S. Table 16 sets forth an analysis of the number of ZIP codes that changed urban/rural status in each U.S. state and territory after CY 2014 due to our implementation of the revised OMB delineations and the updated RUCA codes beginning in CY 2015, using the April 2015 USPS ZIP code file, the revised OMB delineations, and the updated RUCA codes (including the RUCA ZIP code approximation file discussed above). Based on this data, the geographic designations for approximately 95.22 percent of ZIP codes are unchanged by OMB's revised delineations and the updated RUCA codes. Similar to the analysis set forth in the CY 2015 PFS final rule with comment period, as corrected (79 FR 78716 through 78719), as reflected in Table 16, more ZIP codes have changed from rural to urban (1,600 or 3.73 percent) than from urban to rural (451 or 1.05 percent). In general, it is expected that ambulance providers and suppliers in 451 ZIP codes within 42 states, may continue to experience payment increases under the revised OMB delineations and the updated RUCA codes, as these areas have been redesignated from urban to rural. The state of Ohio has the most ZIP codes that changed from urban to rural with a total of 54, or 3.63 percent. Ambulance providers and suppliers in 1,600 ZIP codes within 44 states and Puerto Rico may continue to experience payment decreases under the revised OMB delineations and the updated RUCA codes, as these areas have been redesignated from rural to urban. The state of West Virginia has the most ZIP codes that changed from rural to urban (149 or 15.92 percent). As discussed above, these findings are illustrated in Table 16.

TABLE 16—ZIP CODE ANALYSIS BASED ON OMB'S REVISED DELINEATIONS AND UPDATED RUCA CODES

State/Territory *	Total ZIP codes	Total ZIP codes changed rural to urban	Percentage of total ZIP codes	Total ZIP codes changed urban to rural	Percentage of total ZIP codes	Total ZIP codes not changed	Percentage of total ZIP codes not changed
AK	276	0	0.00	0	0.00	276	100.00
AL	854	43	5.04	8	0.94	803	94.03
AR	725	19	2.62	9	1.24	697	96.14
AS	1	0	0.00	0	0.00	1	100.00
AZ	569	21	3.69	7	1.23	541	95.08
CA	2723	85	3.12	43	1.58	2595	95.30
CO	677	4	0.59	9	1.33	664	98.08
CT	445	37	8.31	0	0.00	408	91.69
DC	303	0	0.00	0	0.00	303	100.00
DE	99	6	6.06	0	0.00	93	93.94
EK	63	0	0.00	0	0.00	63	100.00
EM	857	35	4.08	4	0.47	818	95.45
FL	1513	69	4.56	9	0.59	1435	94.84
FM	4	0	0.00	0	0.00	4	100.00
GA	1032	47	4.55	4	0.39	981	95.06
GU	21	0	0.00	0	0.00	21	100.00
HI	143	9	6.29	3	2.10	131	91.61
IA	1080	20	1.85	3	0.28	1057	97.87
ID	335	0	0.00	0	0.00	335	100.00
IL	1629	68	4.17	7	0.43	1554	95.40
IN	1000	33	3.30	20	2.00	947	94.70
KY	1030	30	2.91	5	0.49	995	96.60
LA	739	69	9.34	1	0.14	669	90.53
MA	751	8	1.07	9	1.20	734	97.74
MD	630	69	10.95	0	0.00	561	89.05
ME	505	5	0.99	12	2.38	488	96.63
MH	2	0	0.00	0	0.00	2	100.00
MI	1185	22	1.86	21	1.77	1142	96.37
MN	1043	31	2.97	7	0.67	1005	96.36
MP	3	0	0.00	0	0.00	3	100.00
MS	541	14	2.59	1	0.18	526	97.23
MT	411	0	0.00	3	0.73	408	99.27
NC	1102	87	7.89	10	0.91	1005	91.20
ND	419	2	0.48	0	0.00	417	99.52
NE	632	7	1.11	6	0.95	619	97.94
NH	292	0	0.00	2	0.68	290	99.32
NJ	748	1	0.13	2	0.27	745	99.60
NM	438	4	0.91	2	0.46	432	98.63
NV	257	1	0.39	2	0.78	254	98.83
NY	2246	84	3.74	42	1.87	2120	94.39
OH	1487	23	1.55	54	3.63	1410	94.82
OK	791	5	0.63	7	0.88	779	98.48
OR	496	26	5.24	9	1.81	461	92.94
PA	2244	129	5.75	38	1.69	2077	92.56
PR	177	21	11.86	0	0.00	156	88.14
PW	2	0	0.00	0	0.00	2	100.00
RI	91	2	2.20	1	1.10	88	96.70
SC	544	47	8.64	2	0.37	495	90.99
SD	418	0	0.00	1	0.24	417	99.76
TN	814	52	6.39	12	1.47	750	92.14
TX	2726	64	2.35	32	1.17	2630	96.48
UT	360	2	0.56	0	0.00	358	99.44
VA	1277	98	7.67	19	1.49	1160	90.84
VI	16	0	0.00	0	0.00	16	100.00
VT	309	3	0.97	0	0.00	306	99.03
WA	744	17	2.28	6	0.81	721	96.91
WI	919	19	2.07	5	0.54	895	97.39
WK	711	11	1.55	7	0.98	693	97.47
WM	342	2	0.58	3	0.88	337	98.54
WV	936	149	15.92	3	0.32	784	83.76
WY	198	0	0.00	1	0.51	197	99.49
TOTALS	42,925	1600	3.73	451	1.05	40,874	95.22

* ZIP code analysis includes U.S. States and Territories (FM—Federated States of Micronesia, GU—Guam, MH—Marshall Islands, MP—Northern Mariana Islands, PW—Palau, AS—American Samoa; VI—Virgin Islands; PR—Puerto Rico). Missouri is divided into east and west regions due to work distribution of the Medicare Administrative Contractors (MACs): EM—East Missouri, WM—West Missouri. Johnson and Wyandotte counties in Kansas were changed as of January 2010 to East Kansas (EK) and the rest of the state is West Kansas (WK).

For more detail on the impact of our proposals, in addition to Table 16, the following files are available through the Internet on the Ambulance Fee Schedule Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AmbulanceFeeSchedule/index.html:* ZIP Codes By State Changed From Urban To Rural: ZIP Codes By State Changed From Rural To Urban: List of ZIP Codes With RUCA Code Designations: and Complete List of ZIP Codes.

As discussed in the CY 2015 PFS final rule with comment period (79 FR 67750), we believe the most current OMB statistical area delineations, coupled with the updated RUCA codes, more accurately reflect the contemporary urban and rural nature of areas across the country, and thus we believe the use of the most current OMB delineations and RUCA codes under the ambulance fee schedule will enhance the accuracy of ambulance fee schedule payments. As we discussed in the CY 2015 PFS final rule with comment period (79 FR 67750), we considered, as alternatives, whether it would be appropriate to delay the implementation of the revised OMB delineations and the updated RUCA codes, or to phase in the implementation of the new geographic delineations over a transition period for those ZIP codes losing rural status. We determined that it would not be appropriate to implement a delay or a transition period for the revised geographic delineations for the reasons set forth in the CY 2015 PFS final rule. Similarly, we considered whether a delay in implementation or a transition period would be appropriate for CY 2016 and subsequent CYs. We continue to believe that it is important to use the most current OMB delineations and RUCA codes available as soon as reasonably possible to maintain a more accurate and up-to-date payment system that reflects the reality of population shifts. Because we believe the revised OMB delineations and updated RUCA codes more accurately identify urban and rural areas and enhance the accuracy of the Medicare ambulance fee schedule, we do not believe a delay in implementation or a transition period would be appropriate for CY 2016 and subsequent CYs. Areas that have lost their rural status and become urban have become urban because of recent population shifts. We believe it is important to base payment on the most accurate and up-to-date geographic area delineations available. Furthermore, we believe a delay in implementation of the revised OMB delineations and the updated RUCA codes would be a disadvantage to the ambulance providers or suppliers experiencing payment increases based on these updated and more accurate OMB delineations and RUCA codes. Thus, we are not proposing a delay in implementation or a transition period for the revised OMB delineations and updated RUCA codes for CY 2016 and subsequent CYs.

We invite public comments on our proposals to continue implementation of the revised OMB delineations as set forth in OMB's February 28, 2013 bulletin (No. 13–01) and the most recent modifications of the RUCA codes as discussed above for CY 2016 and subsequent CYs for purposes of payment under the ambulance fee schedule. In addition, we invite public comments on any alternative methods for implementing the revised OMB delineations and the updated RUCA codes.

4. Proposed Changes to the Ambulance Staffing Requirement

Under section 1861(s)(7) of the Act, Medicare Part B covers ambulance services when the use of other methods of transportation is contraindicated by the individual's medical condition, but only to the extent provided in regulations. Section 410.41(b)(1) requires that a vehicle furnishing ambulance services at the Basic Life Support (BLS) level must be staffed by at least two people, one of whom must meet the following requirements: (1) be certified as an emergency medical technician by the state or local authority where the services are furnished, and (2) be legally authorized to operate all lifesaving and life-sustaining equipment on board the vehicle.

Section 410.41(b)(2) states that, for vehicles furnishing ambulance services at the Advanced Life Support (ALS) level, ambulance providers and suppliers must meet the staffing requirements for vehicles furnishing services at the BLS level. In addition, one of the two staff members must be certified as a paramedic or an emergency medical technician, by the state or local authority where the services are being furnished, to perform one or more ALS services. These staffing requirements are further explained in the Medicare Benefit Policy Manual (Pub. No. 100–02), Chapter 10 (see sections 10.1.2 and 30.1.1)

In its July 24, 2014 Management Implication Report, 13–0006, entitled ''Medicare Requirements for Ambulance Crew Certification,'' the Office of Inspector General (OIG) discussed its investigation of ambulance suppliers in a state that requires a higher level of training than Medicare requires for ambulance staff. In some instances, OIG found that second crew members: (1) possessed a lower level of training than required by state law, or (2) had purchased or falsified documentation to establish their credentials. The OIG expressed its concern that our current regulations and manual provisions do not set forth licensure or certification requirements for the second crew member. The OIG was informed by federal prosecutors that prosecuting individuals who had purchased or falsified documentation to establish their credentials would be difficult because Medicare had no requirements regarding the second ambulance staff member and the ambulance transports complied with the relevant Medicare regulations and manual provisions for ambulance staffing.

The OIG recommended that Medicare revise its regulations and manual provisions related to ambulance staffing to parallel the standard used for vehicle requirements at § 410.41(a), which requires that ambulances be equipped in ways that comply with state and local laws. Specifically, the OIG recommended that our regulation and manual provisions addressing ambulance vehicle staffing should indicate that, for Medicare to cover ambulance services furnished to a Medicare beneficiary, the ambulance crew must meet the requirements currently set forth in § 410.41(b) or the state and local requirements, whichever are more stringent. Currently, § 410.41(b) does not require that ambulance vehicle staff comply with all applicable state and local laws. We agree with OIG's concerns and believe that requiring ambulance staff to also comply with state and local requirements would enhance the quality and safety of ambulance services furnished to Medicare beneficiaries.

Accordingly, we are proposing to revise § 410.41(b) to require that all Medicare-covered ambulance transports must be staffed by at least two people who meet both the requirements of applicable state and local laws where the services are being furnished, and the current Medicare requirements under § 410.41(b). We believe that this would, in effect, require both of the required ambulance vehicle staff to also satisfy any applicable state and local requirements that may be more stringent than those currently set forth at § 410.41(b), consistent with OIG's recommendation. In addition, we are proposing to revise the definition of Basic Life Support (BLS) in § 414.605 to include the proposed revised staffing requirements discussed above for

§ 410.41(b). These proposed revisions to § 410.41(b) and § 414.605 would account for differences in individual state or local staffing and licensure requirements, better accommodating state or local laws enacted to ensure beneficiaries' health and safety. Likewise, these proposed revisions would strengthen the federal government's ability to prosecute violations associated with such requirements and recover inappropriately or fraudulently received funds from ambulance companies found to be operating in violation of state or local laws. Furthermore, as discussed above, we believe that these proposals would enhance the quality and safety of ambulance services provided to Medicare beneficiaries.

In addition, we are proposing to revise § 410.41(b) and the definition of Basic Life Support (BLS) in § 414.605 to clarify that, for BLS vehicles, at least one of the staff members must be certified at a minimum as an emergency medical technician-basic (EMT-Basic), which we believe would more clearly state our current policy. Currently, these regulations require that, for BLS vehicles, one staff member be certified as an EMT (§ 410.41(b)) or EMT-Basic (§ 414.605). These proposed revisions to the regulations do not change our current policy, but clarify that one of the BLS vehicle staff members must be certified at the minimum level of EMT-Basic, but may also be certified at a higher level, for example, EMT-intermediate or EMT paramedic.

Finally, we are proposing to revise the definition of Basic Life Support (BLS) in § 414.605 to delete the last sentence, which sets forth examples of certain state law provisions. This sentence (''For example, only in some states is an EMT-Basic permitted to operate limited equipment on board the vehicle, assist more qualified personnel in performing assessments and interventions, and establish a peripheral intravenous (IV) line''), has been included in the definition of BLS since the ambulance fee schedule was finalized in 2002 (67 FR 9100, Feb. 27, 2002). Because state laws may change over the course of time, we are concerned that this sentence may not accurately reflect the status of the relevant state laws over time. Therefore, we are proposing to delete the last sentence of this definition. Furthermore, we do not believe that the examples set forth in this sentence are necessary to convey the definition of BLS for Medicare coverage and payment purposes.

We invite public comments on our proposals to revise the ambulance vehicle staffing requirements in § 410.41(b) and § 414.605 as discussed above. If we finalize these proposals, we will revise our manual provisions addressing ambulance vehicle staffing as appropriate, consistent with our finalized policy.

B. Chronic Care Management (CCM) Services for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

1. Background

a. Primary Care and Care Coordination

Over the last several years, we have been increasing our focus on primary care, and have explored ways in which care coordination can improve health outcomes and reduce expenditures.

In the CY 2012 PFS proposed rule (76 FR 42793 through 42794, and 42917 through 42920), and the CY 2012 PFS final rule (76 FR 73063 through 73064), we discussed how primary care services have evolved to focus on preventing and managing chronic disease, and how refinements for payment for post-discharge care management services could improve care management for a beneficiary's transition from the hospital to the community setting. We acknowledged that the care coordination included in services such as office visits does not always describe adequately the non-face-to-face care management work involved in primary care and may not reflect all the services and resources required to furnish comprehensive, coordinated care management for certain categories of beneficiaries, such as those who are returning to a community setting following discharge from a hospital or skilled nursing facility (SNF) stay. We initiated a public discussion on primary care and care coordination services, and stated that we would consider payment enhancements in future rulemaking as part of a multiple year strategy exploring the best means to encourage primary care and care coordination services.

In the CY 2013 PFS proposed rule (77 FR 44774 through 44775), we noted several initiatives and programs designed to improve payment for, and encourage long-term investment in, care management services. These include the Medicare Shared Savings Program; testing of the Pioneer Accountable Care Organization (ACO) and the Advance Payment ACO model; the Primary Care Incentive Payment (PCIP) Program; the patient-centered medical home model in the Multi-payer Advanced Primary Care Practice (MAPCP) Demonstration; the Federally Qualified Health Center (FQHC) Advanced Primary Care Practice demonstration; the Comprehensive Primary Care (CPC) initiative; and the HHS Strategic Framework on Multiple Chronic Conditions. We also noted that we were monitoring the progress of the AMA Chronic Care Coordination Workgroup in developing codes to describe care transition and care coordination activities, and proposed refinement of the PFS payment for post discharge care management services.

In the CY 2013 PFS final rule (77 FR 68978 through 68994), we finalized policies for payment of Transitional Care Management (TCM) services, effective January 1, 2013. We adopted two CPT codes (99495 and 99496) to report physician or qualifying nonphysician practitioner care management services for a patient following a discharge from an inpatient hospital or SNF, an outpatient hospital stay for observation or partial hospitalization services, or partial hospitalization in a community mental health center. As a condition for receiving TCM payment, a face-to-face visit was required.

In the CY 2014 PFS proposed rule (78 FR 43337 through 43343), we proposed to establish separate payment under the PFS for chronic care management (CCM) services and proposed a scope of services and requirements for billing and supervision. In the CY 2014 PFS final rule (78 74414 through 74427), we finalized policies to establish separate payment under the PFS for CCM services furnished to patients with multiple chronic conditions that are expected to last at least 12 months or until the death of the patient, and that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline. In the CY 2015 PFS final rule (79 FR 67715 through 67730), additional billing requirements were finalized, including the requirement to furnish CCM services using a certified electronic health record or other electronic technology. Payment for CCM services was effective beginning on January 1, 2015, for physicians billing under the PFS.

b. RHC and FQHC Payment Methodologies

A RHC or FQHC visit must be a face-to-face encounter between the patient and a RHC or FQHC practitioner (physician, nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist, or clinical social worker, and under certain conditions, an RN or LPN furnishing care to a homebound RHC or FQHC patient) during which time one or more RHC or FQHC services are furnished. A TCM service can also be a RHC or FQHC visit. A Diabetes Self-Management Training

(DSMT) service or a Medical Nutrition Therapy (MNT) service furnished by a certified DSMT or MNT provider may also be a FQHC visit.

RHCs are paid an all-inclusive rate (AIR) for medically-necessary medical and mental health services, and qualified preventive health services furnished on the same day (with some exceptions). In general, the A/B MAC calculates the AIR for each RHC by dividing total allowable costs by the total number of visits for all patients. Productivity, payment limits, and other factors are also considered in the calculation. Allowable costs must be reasonable and necessary and may include practitioner compensation, overhead, equipment, space, supplies, personnel, and other costs incident to the delivery of RHC services. The AIR is subject to a payment limit, except for those RHCs that have an exception to the payment limit. Services furnished incident to a RHC professional service are included in the per-visit payment and are not billed separately.

FQHCs have also been paid under the AIR methodology; however, on October 1, 2014, FQHCs began to transition to a FQHC PPS system in which they are paid based on the lesser of a national encounter-based rate or their total adjusted charges. The FQHC PPS rate is adjusted for geographic differences in the cost of services by the FQHC geographic adjustment factor. It is also increased by 34 percent when a FQHC furnishes care to a patient that is new to the FQHC or to a beneficiary receiving an Initial Preventive Physical Examination (IPPE) or an Annual Wellness Visit (AWV). Both the AIR and FQHC PPS payment rates were designed to reflect all the services that a RHC or FQHC furnishes in a single day, regardless of the length or complexity of the visit or the number or type of practitioners seen.

c. Payment for CCM Services

To address the concern that the non-face-to-face care management work involved in furnishing comprehensive, coordinated care management for certain categories of beneficiaries is not adequately paid for as part of an office visit, beginning on January 1, 2015, practitioners billing under the PFS are paid separately for CCM services under CPT code 99490 when CCM service requirements are met.

RHCs and FQHCs cannot bill under the PFS for RHC or FQHC services and individual practitioners working at RHCs and FQHCs cannot bill under the PFS for RHC or FQHC services while working at the RHC or FQHC. While many RHCs and FQHCs coordinate services within their own facilities, and may sometimes help to coordinate services outside their facilities, the type of structured care management services that are now payable under the PFS for patients with multiple chronic conditions, particularly for those who are transitioning from a hospital or SNF back into their communities, are not included in the RHC or FQHC payment. This proposed rule proposes to provide an additional payment for the costs of CCM services that are not already captured in the RHC AIR or the FQHC PPS payment, beginning on January 1, 2016. Services that are currently being furnished and paid under the RHC AIR or FQHC PPS payment methodology will not be affected by the ability of the RHC or FQHC to receive payment for additional services that are not included in the RHC AIR or FQHC PPS.

d. Solicitation of Comments on Payment for CCM Services in RHCs and FQHCs

In the May 2, 2014 ''Medicare Program: Prospective Payment System for Federally Qualified Health Centers; Changes to Contracting Policies for Rural Health Clinics; and Changes to Clinical Laboratory Improvement Amendments of 1988 Enforcement Actions for Proficiency Testing Referral; Final Rule'' (79 FR 25447), we discussed ways to achieve the Affordable Care Act goal of furnishing integrated and coordinated services, and specifically noted the CCM services program beginning in 2015 for physicians billing under the PFS. We encouraged RHCs and FQHCs to review the CCM services information in the CY 2014 PFS final rule with comment period and submit comments to us on how the CCM services payment could be adapted for RHCs and FQHCs to promote integrated and coordinated care in RHCs and FQHCs.

All of the comments we received in response to this request were strongly supportive of payment to RHCs and FQHCs for CCM services. Some commenters were concerned that the requirements for electronic exchange of information and interoperability with other providers would be difficult for some entities, and that some patients do not have the resources to receive secure messages via the internet. One commenter suggested that the additional G-codes for CCM services should be sufficient to cover the associated costs of documenting care coordination in FQHCs, and another commenter suggested that we develop a risk-adjusted CCM services fee. We also received subsequent recommendations from the National Association of Rural Health Clinics on various payment options for CCM services in RHCs. These comments were very helpful in forming the basis for this proposal, and we thank the commenters for their comments.

2. Proposed Payment Methodology and Billing for CCM Services in RHCs and FQHCs

a. Proposed Payment Methodology and Billing Requirements

The requirements we are proposing for RHCs and FQHCs to receive payment for CCM services are consistent with those finalized in the CY 2015 PFS final rule with comment period for practitioners billing under the PFS and are summarized in Table 17. We propose to establish payment, beginning on January 1, 2016, for RHCs and FQHCs who furnish a minimum of 20 minutes of qualifying CCM services during a calendar month to patients with multiple (two or more) chronic conditions that are expected to last at least 12 months or until the death of the patient, and that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline. The CPT code descriptor sets forth the eligibility guidelines for CCM services and will serve as the basis for potential medical review. In accordance with both the CPT instructions and Medicare policy, only one practitioner can bill this code per month, and there are restrictions regarding the billing of other overlapping care management services during the same service period. The following section discusses these aspects of our proposal in more detail and additional information will be communicated in subregulatory guidance.

We propose that a RHC or FQHC can bill for CCM services furnished by, or incident to, a RHC or FQHC physician, nurse practitioner, physician assistant, or certified nurse midwife for a RHC or FQHC patient once per month, and that only one CCM payment per beneficiary per month can be paid. If another practice furnishes CCM services to a beneficiary, the RHC or FQHC cannot bill for CCM services for the same beneficiary for the same service period. We also propose that TCM and any other program that provides additional payment for care management services (outside of the RHC AIR or FQHC PPS payment) cannot be billed during the same service period.

For purposes of meeting the minimum 20-minute requirement, the RHC or FQHC could count the time of only one practitioner or auxiliary staff (for example, a nurse, medical assistant, or

other individual working under the supervision of a RHC or FQHC physician or other practitioner) at a time, and could not count overlapping intervals such as when two or more RHC or FQHC practitioners are meeting about the patient. Only conversations that fall under the scope of CCM services would be included towards the time requirement.

We noted that for billing under the PFS, the care coordination included in services such as office visits do not always describe adequately the non-face-to-face care management work involved in primary care. We also noted that payment for office visits may not reflect all the services and resources required to furnish comprehensive, coordinated care management for certain categories of beneficiaries, such as those who are returning to a community setting following discharge from a hospital or SNF stay. In considering CCM payment for RHCs and FQHCs, we believe that the non-face-to-face time required to coordinate care is also not captured in the RHC AIR or the FQHC PPS payment, particularly for the rural and/or low-income populations served by RHCs and FQHCs. Allowing separate payment for CCM services in RHCs and FQHCs is intended to reflect the additional resources necessary for the unique services that are required in order to furnish CCM services that are not already captured in the RHC AIR or the FQHC PPS payment.

We propose that payment for CCM services be based on the PFS national average non-facility payment rate when CPT code 99490 is billed alone or with other payable services on a RHC or FQHC claim. (For the first quarter of 2015, the national average payment rate is $42.91 per beneficiary per calendar month.) CCM payment to RHCs and FQHCs would be based on the PFS amount, but would be paid as part of the RHC and FQHC benefit, using the CPT code to identify that the requirements for payment are met and a separate payment should be made. We also propose to waive the RHC and FQHC face-to-face requirements when CCM services are furnished to a RHC or FQHC patient. Coinsurance would be applied as applicable to FQHC claims, and coinsurance and deductibles would apply as applicable to RHC claims. RHCs and FQHCs would continue to be required to meet the RHC and FQHC Conditions of Participation and any additional RHC or FQHC payment requirements. We intend to provide detailed billing instructions in subregulatory guidance following publication of a final rule.

b. Other Options Considered

We considered adding CCM services as a RHC or FQHC covered stand-alone service and removing the RHC/FQHC policy requiring a face-to-face visit requirement for this service. Under this option, payment for RHCs would be at the AIR, payment for FQHCs would be the lesser of total charges or the PPS rate, and if CCM services are furnished on the same day as another payable medical visit, only one visit would be paid. We are not proposing this payment option because it would result in a significant overpayment if no other services were furnished on the same day, and would result in no additional payment if furnished on the same day as another medical visit.

We also considered allowing RHCs and FQHCs to carve out CCM services and bill them separately to the PFS. We are not proposing this payment option because CCM services are a RHC and FQHC service and only non-RHC/FQHC services can be billed through the PFS.

We also considered developing a modifier that could be added to the claim for additional payment when CCM services are furnished. We are not proposing this option because it would require that payment for CCM services be made only when furnished along with a billable service that qualifies as an RHC or FQHC service.

We also considered establishing payment for CCM costs on a reasonable cost basis though the cost report. We are not proposing this option because payment for CCM services through the cost report would complicate coinsurance and/or deductible accountability, whereas it is more administratively feasible to apply coinsurance and/or deductible on a RHC/FQHC claim, as applicable. For example, section 1833(a)(3) of the Act specifies that influenza and pneumococcal vaccines and their administration are exempt from payment at 80 percent of reasonable costs and payment to RHCs and FQHCs for such services is at 100 percent of reasonable cost. Since influenza and pneumococcal vaccines and their administration are not subject to copayment, it is administratively feasible to pay these services through the cost report.

3. Proposed Requirements for CCM Payment in RHCs and FQHCs

a. Proposed Beneficiary Eligibility for CCM Services

Consistent with beneficiary eligibility requirements under the PFS, we propose that RHCs and FQHCs receive payment for furnishing CCM services to patients with multiple chronic conditions that are expected to survive at least 12 months or until the death of the patient, and that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline. RHCs and FQHCs are encouraged to focus on patients with high acuity and high risk when furnishing CCM services to eligible patients, including those who are returning to a community setting following discharge from a hospital or SNF.

b. Proposed Beneficiary Agreement Requirements

Not all patients who are eligible for separately payable CCM services may necessarily want these services to be provided, and some patients who receive CCM services may wish to discontinue them. A beneficiary who declines to receive CCM services from the RHC or FQHC, or who accepts the services and then chooses to revoke his/her agreement, would continue to be able to receive care from the RHC or FQHC and receive any care management services that are currently being furnished under the RHC AIR or FQHC PPS payment system.

Consistent with beneficiary notification and consent requirements under the PFS, we propose that the following requirements be met before the RHC or FQHC can furnish or bill for CCM services:

- The eligible beneficiary must be informed about the availability of CCM services from the RHC or FQHC and provide his or her written agreement to have the services provided, including the electronic communication of the patient's information with other treating providers as part of care coordination. This would include a discussion with the patient about what CCM services are, how they differ from any care management services the RHC or FQHC currently offers, how these services are accessed, how the patient's information will be shared among others, that a non RHC or FQHC cannot furnish or bill for CCM services during the same calendar month that the RHC or FQHC furnishes CCM services, the applicability of coinsurance even when CCM services are not delivered face-to-face in the RHC or FQHC, and that any care management services that are currently provided will continue even if the patient does not agree to have CCM services provided.
- The RHC or FQHC must document in the patient's medical record that all of the CCM services were explained and offered to the patient, and note the patient's decision to accept these services.

• At the time the agreement is obtained, the eligible beneficiary must be informed that the agreement for CCM services could be revoked by the beneficiary at any time either verbally or in writing, and the RHC or FQHC practitioner must explain the effect of a revocation of the agreement for CCM services. If the revocation occurs during a CCM 30-day period, the revocation would be effective at the end of that period. The eligible beneficiary must also be informed that the RHC or FQHC is able to be separately paid for these services during the 30-day period only if no other practitioner or eligible entity, including another RHC or FQHC that is not part of the RHC's or FQHC's organization, has already billed for this service. Since only one CCM payment can be paid per beneficiary per month, the RHC or FQHC would need to ask the patient if they are already receiving CCM services from another practitioner. Revocation by the beneficiary of the agreement must also be noted by recording the date of the revocation in the beneficiary's medical record and by providing the beneficiary with written confirmation that the RHC or FQHC would not be providing CCM services beyond the current 30-day period. A beneficiary who has revoked the agreement for CCM services from a RHC or FQHC may choose instead to receive these services from a different practitioner (including another RHC or FQHC), beginning at the conclusion of the 30-day period.

• The RHC or FQHC must provide a written or electronic copy of the care plan to the beneficiary and record this in the beneficiary's electronic medical record.

c. Proposed Scope of CCM Services in RHCs and FQHCs

We propose that all of the following scope of service requirements must be met to bill for CCM services:

• Initiation of CCM services during a comprehensive Evaluation/Management (E/M), AWV, or IPPE visit. The time spent furnishing these services would not be included in the 20 minute monthly minimum required for CCM billing.

• Continuity of care with a designated RHC or FQHC practitioner with whom the patient is able to get successive routine appointments.

• Care management for chronic conditions, including systematic assessment of a patient's medical, functional, and psychosocial needs; system-based approaches to ensure timely receipt of all recommended preventive care services; medication reconciliation with review of adherence and potential interactions; and oversight of patient self-management of medications.

• A patient-centered plan of care document created by the RHC or FQHC practitioner furnishing CCM services in consultation with the patient, caregiver, and other key practitioners treating the patient to assure that care is provided in a way that is congruent with patient choices and values. The plan would be a comprehensive plan of care for all health issues based on a physical, mental, cognitive, psychosocial, functional and environmental (re)assessment and an inventory of resources and supports. It would typically include, but not be limited to, the following elements: problem list, expected outcome and prognosis, measurable treatment goals, symptom management, planned interventions, medication management, community/social services ordered, how the services of agencies and specialists unconnected to the practice will be directed/coordinated, the individuals responsible for each intervention, requirements for periodic review and, when applicable, revision, of the care plan. A complete list of problems, medications, and medication allergies would be in the electronic health record to inform the care plan, care coordination, and ongoing clinical care.

• Creation of an electronic care plan that would be available 24 hours a day and 7 days a week to all practitioners within the RHC or FQHC who are furnishing CCM services whose time counts towards the time requirement for billing the CCM code, and to other practitioners and providers, as appropriate, who are furnishing care to the beneficiary, to address a patient's urgent chronic care needs. No specific electronic solution or format is required to meet this scope of service element. However, we encourage RHCs and FQHCs who wish to learn more about currently available electronic standards for care planning to refer to the proposed rulemaking for the 2015 Edition of Health Information Technology Certification Criteria, which includes a proposal to enable users of certified health IT to create and receive care plan information in accordance with the C–CDA Release 2.0 standard (80 FR 16842).

• Management of care transitions within health care including referrals to other clinicians, visits following a patient visit to an emergency department, and visits following discharges from hospitals and SNFs. The RHC or FQHC must be able to facilitate communication of relevant patient information through electronic exchange of a summary care record with other health care providers regarding these transitions. The RHC or FQHC must also have qualified personnel who are available to deliver transitional care services to a patient in a timely way to reduce the need for repeat visits to emergency departments and readmissions to hospitals and SNFs.

• Coordination with home and community based clinical service providers required to support a patient's psychosocial needs and functional deficits. Communication to and from home and community based providers regarding these clinical patient needs must be documented in the RHC's or FQHC's medical record system.

• Secure messaging, internet or other asynchronous non-face-to-face consultation methods for a patient and caregiver to communicate with the provider regarding the patient's care in addition to the use of the telephone. We would note that the faxing of information would not meet this requirement. These methods would be required to be available, but would not be required to be used by every practitioner or for every patient receiving CCM services.

d. Proposed Electronic Health Records (EHR) Requirements

We believe that the use of EHR technology that allows data sharing is necessary to assure that RHCs and FQHCs can effectively coordinate services with other practitioners for patients with multiple chronic conditions. Therefore, we propose the following requirements:

• Certified health IT must be used for the recording of demographic information, health-related problems, medications, and medication allergies; a clinical summary record; and other scope of service requirements that reference a health or medical record.

• RHCs and FQHCs must use technology certified to the edition(s) of certification criteria that is, at a minimum, acceptable for the EHR Incentive Programs as of December 31st of the year preceding each CCM payment year to meet the following core technology capabilities: structured recording of demographics, problems, medications, medication allergies, and the creation of a structured clinical summary. For example, technology used to furnish CCM services beginning on January 1, 2016, would be required to meet, at a minimum, the requirements included in the 2014 Edition certification criteria. For the purposes of the scope of services, we refer to technology meeting these requirements as ''CCM Certified Technology.''

• Applicable HIPAA standards would apply to electronic sharing of patient information.

TABLE 17—SUMMARY OF PROPOSED CCM SCOPE OF SERVICE ELEMENTS AND BILLING REQUIREMENTS

CCM Scope of service/billing requirements	Health IT requirements
Initiation of CCM services at an AWV, IPPE, or a comprehensive E/M visi.	None.
Structured recording of demographics, problems, medications, medication allergies, and the creation of a structured clinical summary record. A full list of problems, medications and medication allergies in the EHR must inform the care plan, care coordination, and ongoing clinical care.	Structured recording of demographics, problems, medications, medication allergies, and creation of structured clinical summary records using CCM certified technology.
Access to CCM services 24/7 (providing the beneficiary with a means to make timely contact with the RHC or FQHC to address his or her urgent chronic care needs regardless of the time of day or day of the week.	None.
Continuity of care with a designated RHC or FQHC practitioner with whom the beneficiary is able to get successive routine appointment.	None.
CCM services for chronic conditions including systematic assessment of the beneficiary's medical, functional, and psychosocial needs; system-based approaches to ensure timely receipt of all recommended preventive care services; medication reconciliation with review of adherence and potential interactions; and oversight of beneficiary self-management of medication.	None.
Creation of a patient-centered care plan based on a physical, mental, cognitive, psychosocial, functional and environmental (re)assessment and an inventory of resources and supports; a comprehensive care plan for all health issues. Share the care plan as appropriate with other practitioners and providers.	Must at least electronically capture care plan information; make this information available on a 24/7 basis to all practitioners within the RHC or FQHC whose time counts towards the time requirement for the practice to bill for CCM services; and share care plan information electronically (other than by fax) as appropriate with other practitioners, providers, and caregivers.
Provide the beneficiary with a written or electronic copy of the care plan and document its provision in the electronic medical record.	Document provision of the care plan as required to the beneficiary in the EHR using CCM certified technology.
Management of care transitions between and among health care providers and settings, including referrals to other clinicians; follow-up after an emergency department visit; and follow-up after discharges from hospitals, skilled nursing facilities or other health care facilities.	Format clinical summaries according to CCM certified technology. Not required to use a specific tool or service to exchange/transmit clinical summaries, as long as they are transmitted electronically (other than by fax).
Coordination with home and community based clinical service providers	Communication to and from home and community based providers regarding the patient's psychosocial needs and functional deficits must be documented in the patient's medical record using CCM certified technology.
Enhanced opportunities for the beneficiary and any caregiver to communicate with the RHC or FQHC regarding the beneficiary's care through not only telephone access, but also through the use of secure messaging, internet or other asynchronous non face-to-face consultation methods.	None.
Beneficiary consent—Inform the beneficiary of the availability of CCM services and obtain his or her written agreement to have the services provided, including authorization for the electronic communication of his or her medical information with other treating providers.	
Document in the beneficiary's medical record that all of the CCM services were explained and offered, and note the beneficiary's decision to accept or decline these services.	
Document the beneficiary's written consent and authorization in the EHR using CCM certified technology.	Document the beneficiary's written consent and authorization in the EHR using CCM certified technology.
Beneficiary consent—Inform the beneficiary of the right to stop the CCM services at any time (effective at the end of the calendar month) and the effect of a revocation of the agreement on CCM services.	None.
Beneficiary consent—Inform the beneficiary that only one practitioner can furnish and be paid for these services during a calendar month.	None.

We invite public comments on all aspects of the proposed payment methodology and billing for CCM services in RHCs and FQHCs, the proposed CCM requirements for RHCs and FQHCs, and any other aspect of our proposal.

C. Healthcare Common Procedure Coding System (HCPCS) Coding for Rural Health Clinics (RHCs)

1. RHC Payment Methodology and Billing Requirements

RHCs are paid an all-inclusive rate (AIR) per visit for medically necessary primary health services and qualified preventive health services furnished face-to-face by a RHC practitioner to a Medicare beneficiary. The all-inclusive payment system was designed to minimize reporting requirements, and as such, the rate includes all costs associated with the services that a RHC furnishes in a single day to a Medicare

beneficiary, regardless of the length or complexity of the visit or the number or type of RHC practitioners seen. Except for certain preventive services that are not subject to coinsurance requirements, it has not been necessary for RHCs to submit reporting of medical and procedure codes, such as level I and level II of the HCPCS, on claims for services that were furnished during the visit to determine Medicare payment. Generally, the services reported using the appropriate site of service revenue code on a RHC claim receives payment under the AIR, with coinsurance and deductible applied based upon the associated charges on that line, notwithstanding other Medicare requirements.

Historically, billing instructions for RHCs and Federally Qualified Health Centers (FQHCs) have been similar. Beginning on April 1, 2005, through December 31, 2010, RHCs and FQHCs were no longer required to report HCPCS when billing for RHC and FQHC services rendered during an encounter, absent a few exceptions. CMS Transmittal 371, dated November 19, 2004, eliminated HCPCS coding for FQHCs and eliminated the additional line item reporting of preventive services for RHCs and FQHCs for claims with dates of service on or after April 1, 2005. CMS Transmittal 1719, dated April 24, 2009, effective October 1, 2009, required RHCs and FQHCs to report HCPCS codes for a few services, such as certain preventive services eligible for a waiver of deductible, services subject to frequency limits, and services eligible for payments in addition to the all-inclusive rate.

Section 1834(o)(1)(B) of the Act, as added by the Affordable Care Act, required that FQHCs begin reporting services using HCPCS codes to develop and implement the FQHC PPS. Since January 1, 2011, FQHCs have been required to report all services furnished during an encounter by specifically listing the appropriate HCPCS code(s) for each line item, along with the site of service revenue code(s), when billing Medicare. As of October 1, 2014, HCPCS coding is used to calculate payment for FQHCs that are paid under the FQHC PPS.

Section 4104 of the Affordable Care Act waived the coinsurance and deductible for the initial preventive physical examination (IPPE), the annual wellness visit (AWV), and other Medicare covered preventive services recommended by the United States Preventive Services Task Force (USPSTF) with a grade of A or B. Since January 1, 2011, HCPCS coding has been required for these preventive services when reported by RHCs. When billing for an approved preventive service, RHCs must report an additional line with the appropriate site of service revenue code with the approved preventive service HCPCS code and the associated charges. Although HCPCS coding is currently required for approved preventive services on RHC claims, HCPCS coding is not used to determine RHC payment.

2. Proposed Requirement for Reporting of HCPCS Coding for All Services Furnished by RHCs During a Medicare Visit

For payment under Medicare Part B, the statute requires health transactions to be exchanged electronically, subject to certain exceptions, using standards specified by the Secretary. Specifically, section 1862(a)(22) of the Act requires that no payment may be made under part A or part B for any expenses incurred for items or services, subject to exceptions under section 1862(h), for which a claim is submitted other than in an electronic form specified by the Secretary. Further, section 1173 of the Act, added by section 262 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), requires the Secretary to adopt standards for transactions, and data elements for such transactions, to enable health information to be exchanged electronically, that are appropriate for transactions. These include but are not limited to health claims or equivalent encounter information. As a result of the HIPAA amendments, HHS adopted regulations pertaining to data standards for health care related transactions. The regulations at 45 CFR 160.103 define a covered entity to include a provider of medical or health services (as defined in section 1861(s) of the Act), and define the types of standard transactions. When conducting a transaction, under 45 CFR 162.1000, a covered entity must use the applicable medical data code sets described in § 162.1002 that are valid at the time the health care is furnished, and these regulations define the standard medical data code sets adopted by the Secretary as HCPCS and CPT (Current Procedural Terminology–Fourth Edition) for physician services and other health care services.

Under section 1861(s)(2)(E) of the Act, a RHC is a supplier of ''medical or health services.'' As such, our regulations require these covered entities to report a standard medical code set for electronic health care transactions, although our program instructions have directed RHCs to submit HCPCS codes only for preventive services. We believe reporting of HCPCS coding for all services furnished by a RHC would be consistent with the health transactions requirements, and would provide useful information on RHC patient characteristics, such as level of acuity and frequency of services furnished, and the types of services being furnished by RHCs. This information would also allow greater oversight of the program and inform policy decisions.

We propose that all RHCs must report all services furnished during an encounter using standardized coding systems, such as level I and level II of the HCPCS, for dates of service on or after January 1, 2016. In accordance with section 1862(h) of the Act, in limited situations RHCs that are unable to submit electronic claims and RHCs with fewer than 10 full time equivalent employees are exempt from submitting claims electronically. We propose that RHCs exempt from electronic reporting under 1862(h) of the Act must also report all services furnished during an encounter using HCPCS coding via paper claims for dates of services on or after January 1, 2016. This proposal would necessitate new billing practices for such RHCs, but we believe there would be no significant burden for the limited number of RHCs exempt from electronic billing.

Under this proposal, a HCPCS code would be reported along with the presently required Medicare revenue code for each service furnished by the RHC to a Medicare patient. Although HCPCS coding is currently used to determine FQHC payment under the FQHC PPS, under this proposal, RHCs would continue to be paid under the AIR and there would be no change in their payment methodology.

Accordingly, we are proposing to remove the requirement at § 405.2467(b) pertaining to HCPCS coding for FQHCs and redesignate paragraphs (c) and (d) as paragraphs (b) and (c), respectively. We are also proposing to add a new paragraph (g)(3) to § 405.2462 to require FQHCs and RHCs, whether or not exempt from electronic reporting under § 424.32(d)(3), to report on Medicare claims all service(s) furnished during each FQHC and RHC visit (as defined in § 405.2463) using HCPCS and other codes as required.

We propose to require reporting of HCPCS coding for all services furnished by RHCs to Medicare beneficiaries effective for dates of service on or after January 1, 2016. We are aware that many RHCs already record this information through their billing software or electronic health record systems; however, we recognize there may be some RHCs that need to make

changes in their systems. We invite RHCs to submit comments on the feasibility of updating their billing systems to meet this implementation date of January 1, 2016.

As part of the implementation of the HCPCS coding requirement, we plan to provide instructions on how RHCs are to report HCPCS and other coding and clarify other appropriate billing procedures through program instruction. CMS' Medicare claims processing system would be revised to accept the addition of the new RHC reporting requirements effective January 1, 2016.

D. Payment to Grandfathered Tribal FQHCs That Were Provider-Based Clinics on or Before April 7, 2000

1. Background

a. Health Services to American Indians and Alaskan Natives (AI/AN)

There is a special government-to-government relationship between the federal government and federally recognized tribes based on U.S. treaties, laws, Supreme Court decisions, Executive Orders and the U.S. Constitution. This government-to-government relationship forms the basis for federal health services to American Indians/Alaska Natives (AI/AN) in the U.S.

In 1976, the Indian Health Care Improvement Act (IHCIA, P.L. 94–437) amended the statute to permit payment by Medicare and Medicaid for services provided to AI/ANs in Indian Health Service (IHS) and tribal health care facilities that meet the applicable requirements. Under this authority, Medicare services to AI/ANs may be furnished by IHS operated facilities and programs and tribally-operated facilities and programs under Title I or Title V of the Indian Self Determination Education Assistance Act, as amended (ISDEAA, P.L 93–638).

According to the IHS Year 2015 Profile, the IHS healthcare delivery system currently consists of 46 hospitals, with 28 of those hospitals operated by the IHS and 18 of them operated by tribes under the ISDEAA.

Payment rates for inpatient and outpatient medical care furnished by the IHS and tribal facilities is set annually by the IHS under the authority of sections 321(a) and 322(b) of the Public Health Service (PHS) Act (42 U.S.C. 248 and 249(b)), Public Law 83–568 (42 U.S.C. 2001(a)), and the Indian Health Care Improvement Act (IHCIA) (25 U.S.C. 1601 et seq.), based on the previous year's cost reports from federal and tribal hospitals. The 1976 IHCIA provided the authority for CMS (then HCFA) to pay IHS for its hospital services to Medicare eligible patients, and in 1978 CMS agreed to use a Medicare all-inclusive payment rate for IHS hospitals and IHS hospital-based clinics.

There is an outpatient visit rate for Medicare visits in Alaska and an outpatient visit rate for Medicare visits in the lower 48 States. The Medicare outpatient rate is only applicable for those IHS or tribal facilities that meet the definition of a provider-based department as described at § 413.65(a), or a ''grandfathered'' facility as described at § 413.65(m). For calendar year 2015, the Medicare outpatient encounter rate is $564 for Alaska and $307 for the rest of the country (80 FR 18639, April 7, 2015).

b. Provider-Based Entities and the ''Grandfathering'' Provision

In 2000, we adopted regulations at § 413.65 that established criteria for facilities to be considered provider-based to a hospital for Medicare payment purposes. The provider-based rules apply to facilities located both on and off the main hospital campus for which provider-based status is sought.

In the CY 2001 Hospital Outpatient PPS final rule with comment period (65 FR 18507), we addressed comments on the proposed provider-based rules. In regard to IHS facilities, commenters expressed concern that the proposed rule would undermine the ISDEAA contracting and compacting relationships between the IHS and tribes because provider-based clinics must be clinically and administratively integrated into the hospital, and a tribe that assumes the operation of a provider-based clinic but not the operation of the hospital would not be able to meet this requirement. They were also concerned that the proposed proximity requirements would threaten the status of many IHS and tribal facilities that frequently were located in distant remote areas.

In response to these comments and the special provisions of law referenced above governing health care for IHS and the tribes, we recognized the special relationship between tribes and the United States government, and did not apply the general provider-based criteria to IHS and tribally-operated facilities. The regulations currently include a grandfathering provision at § 413.65(m) for IHS and tribal facilities that were provider-based to a hospital on or prior to April 7, 2000. This section states that facilities and organizations operated by the IHS or tribes will be considered to be departments of hospitals operated by the IHS or tribes if, on or before April 7, 2000, they furnished only services that were billed as if they had been furnished by a department of a hospital operated by the IHS or a tribe and they are:

- Owned and operated by the IHS;
- Owned by the tribe but leased from the tribe by the IHS under the ISDEAA in accordance with applicable regulations and policies of the IHS in consultation with tribes; or
- Owned by the IHS but leased and operated by the tribe under the ISDEAA in accordance with applicable regulations and policies of the IHS in consultation with tribes.

Under the authority of the ISDEAA, a tribe may assume control of an IHS hospital and the provider-based clinics affiliated with the hospital, or may only assume responsibility of the provider-based clinic. On August 11, 2003, we issued a letter to Trailblazer Health Enterprises, LLC, stating that changes in the status of a hospital or facility from IHS to tribal operation, or vice versa, or the realignment of a facility from one IHS or tribal hospital to another IHS or tribal hospital, would not affect the facility's grandfathered status if the resulting configuration is one which would have qualified for grandfathering under § 413.65(m) if it had been in effect on April 7, 2000.

The Medicare Conditions of Participation (CoPs) for Medicare-participating hospitals at § 482.12 require administrative and clinical integration between a hospital and its clinics, departments, and provider-based entities. A tribal clinic billing under an IHS hospital's CMS Certification Number (CCN), without any additional administrative or clinical relationship with the IHS hospital, could put that hospital at risk for non-compliance with the CoPs.

Consequently, we believe that a different structure is needed to maintain access to care for AI/AN populations served by these hospitals and clinics, while also ensuring that these facilities are in compliance with our health and safety rules. The FQHC program may provide an alternative structure that meets the needs of these tribal clinics and the populations they serve, while also ensuring the IHS hospitals are not at risk for non-compliance with the requirements in § 482.12.

c. Federally Qualified Health Centers (FQHCs)

FQHCs were established in 1990 by section 4161 of the Omnibus Budget Reconciliation Act of 1990 and were effective beginning on October 1, 1991. They are facilities that furnish services

that are typically furnished in an outpatient clinic setting.

The statutory requirements that FQHCs must meet to qualify for the Medicare benefit are in section 1861(aa)(4) of the Act. All FQHCs are subject to Medicare regulations at 42 CFR part 405, subpart X, and 42 CFR part 491. Based on these provisions, the following three types of organizations that are eligible to enroll in Medicare as FQHCs:

- Health Center Program grantees: Organizations receiving grants under section 330 of the PHS Act (42 U.S.C. 254b).
- Health Center Program ''look-alikes'': Organizations that have been identified by the Health Resources and Services Administration as meeting the requirements to receive a grant under section 330 of the PHS Act, but which do not receive section 330 grant funding.
- Outpatient health programs or facilities operated by a tribe or tribal organization under the ISDEAA, or by an urban Indian organization receiving funds under Title V of the IHCIA.

FQHCs are also entities that were treated by the Secretary for purposes of Medicare Part B as a comprehensive federally funded health center as of January 1, 1990 (see section 1861(aa)(4)(C) of the Act).

Section 1834 of the Act was amended by section 10501(i)(3)(A) of the Affordable Care Act by adding a new subsection (o), ''Development and Implementation of Prospective Payment System''. Section 1834(o)(1)(A) of the Act requires that the system include a process for appropriately describing the services furnished by FQHCs, and establish payment rates based on such descriptions of services, taking into account the type, intensity, and duration of services furnished by FQHCs. It also stated that the new system may include adjustments (such as geographic adjustments) as determined appropriate by the Secretary.

Section 1833(a)(1)(Z) was added by the Affordable Care Act to require that Medicare payment for FQHC services under section 1834(o) of the Act shall be 80 percent of the lesser of the actual charge or the PPS amount determined under section 1834(o) of the Act.

In accordance with the requirements in the Affordable Care Act, beginning on October 1, 2014, payment to FQHCs is based on the lesser of the national encounter-based FQHC PPS rate, or the FQHC's total charges, for primary health services and qualified preventive health services furnished to Medicare beneficiaries. The FQHC PPS rate is adjusted by the FQHC geographic adjustment factor (GAF), which is based on the Geographic Practice Cost Index used under the PFS. The FQHC PPS rate is also adjusted when the FQHC furnishes services to a patient that is new to the FQHC, and when the FQHC furnishes an IPPE or an AWV. The FQHC PPS base rate for the period from October 1, 2014 to December 31, 2015 is $158.85. The rate will be adjusted in calendar year 2016 by the Medicare Economic Index (MEI), as defined at section 1842(i)(3) of the Act, and subsequently by either the MEI or a FQHC market basket (which would be determined pursuant to CMS regulations).

To assure that FQHCs receive appropriate payment for services furnished, we established a new set of five HCPCS G-codes for FQHCs to report Medicare visits. These G-codes include all the services in a typical bundle of services that would be furnished per diem to a Medicare patient at the FQHC. The five FQHC G-codes are:

G0466–FQHC visit, new patient
G0467–FQHC visit, established patient
G0468–FQHC visit, IPPE or AWV
G0469–FQHC visit, mental health, new patient
G0470–FQHC visit, mental health, established patient

FQHCs establish charges for the services they furnish to FQHC patients, including Medicare beneficiaries, and charges must be uniform for all patients, regardless of insurance status. The FQHC would determine the services that are included in each of the 5 FQHC G-codes, and the sum of the charges for each of the services associated with the G-code would be the G-code payment amount. Payment to the FQHC for a Medicare visit is the lesser of the FQHC's charges (as established by the G-code), or the PPS rate.

2. Proposed Payment Methodology and Requirements

We are proposing that IHS and tribal facilities and organizations that met the conditions of section 413.65(m) on or before April 7, 2000, and have a change in their status on or after April 7, 2000 from IHS to tribal operation, or vice versa, or the realignment of a facility from one IHS or tribal hospital to another IHS or tribal hospital such that the organization no longer meets the CoPs, may seek to become certified as grandfathered tribal FQHCs. To help avoid any confusion, we refer to these tribal FQHCs as grandfathered tribal FQHCs to distinguish them from freestanding tribal FQHCs that are currently being paid the lesser of their charges or the adjusted national FQHC PPS rate of $158.85, and from provider-based tribal clinics that may have begun operations subsequent to April 7, 2000.

Under the authority in 1834(o) of the Affordable Care Act to ''include adjustments . . . determined appropriate by the Secretary,'' we are proposing that these grandfathered tribal FQHCs be paid the lesser of their charges or a grandfathered tribal FQHC PPS rate of $307, which equals the Medicare outpatient per visit payment rate paid to them as a provider-based department, as set annually by the IHS, rather than the FQHC PPS per visit base rate of $158.85, and that coinsurance would be 20 percent of the lesser of the actual charge or the grandfathered tribal FQHC PPS rate. These grandfathered tribal FQHCs would be required to meet all FQHC certification and payment requirements. This FQHC PPS adjustment for grandfathered tribal clinics would not apply to a currently certified tribal FQHC, a tribal clinic that was not provider-based as of April 7, 2000, or an IHS-operated clinic that is no longer provider-based to a tribally-operated hospital. This provision would also not apply in those instances where both the hospital and its provider-based clinic(s) are operated by the tribe or tribal organization.

Since we are proposing that these grandfathered tribal FQHCs would be paid based on the IHS payment rates and not the FQHC PPS payment rates, we are also proposing that the payment rate would not be adjusted by the FQHC PPS GAF, or be eligible for the special payment adjustments under the FQHC PPS for new patients, patients receiving an IPPE or an AWV. They would also not be eligible for the exceptions to the single per diem payment that is available to FQHCs paid under the FQHC PPS. As the IHS outpatient rate for Medicare is set annually, we also propose not to apply the MEI or a FQHC market basket adjustment that is applied annually to the FQHC PPS base rate. We are proposing that these adjustments not be applied because we believe that the special status of these grandfathered tribal clinics, and the enhanced payment they would receive under the FQHC PPS system, would make further adjustments unnecessary and/or duplicative of adjustments already made by IHS in deriving the rate. While we are proposing in this proposed rule an adjustment to the FQHC PPS rate to reflect the IHS rate for these grandfathered tribal clinics, if adopted as final, we will monitor future costs and claims data of these tribal clinics and reconsider options as appropriate.

Grandfathered tribal FQHCs would be paid for services included in the FQHC benefit, even if those services are not included in the IHS Medicare outpatient all-inclusive rate. Services that are included in the IHS outpatient all-inclusive rate but not in the FQHC benefit would not be paid. Information on the FQHC benefit is available in Chapter 13 of the Medicare Benefit Policy Manual.

Grandfathered tribal FQHCs will be subject to Medicare regulations at part 405, subpart X, and part 491, except as noted in section III.D.2. of this proposed rule.

We therefore propose to revise § 405.2462, § 405.2463, § 405.2464, and § 405.2469 to specify the requirements for payment as a grandfathered tribal FQHC, and to specify payment provisions, adjustments, rates, and other requirements for grandfathered tribal FQHCs.

3. Transition

To become certified as a FQHC, an eligible tribe or tribal organization must submit a Form 855A and all required accompanied documentation, including an attestation of compliance with the Medicare FQHC Conditions for Coverage at part 491, to the Jurisdiction H Medicare Administrative Contractor (A/B MAC). After reviewing the application and determining that it is complete and approvable, the MAC would forward the application with its recommendation for approval to the CMS Regional Office (RO) that has responsibility for the geographic area in which the tribal clinic is located. The RO would issue a Medicare FQHC participation agreement to the tribal FQHC, including a CMS Certification Number (CCN), and would advise the MAC of the CCN number, to facilitate the MAC's processing of FQHC claims submitted by the tribal FQHC. Payment to grandfathered tribal FQHCs would begin on the first day of the month in the first quarter of the year subsequent to receipt of a Medicare CCN.

4. Conforming Changes

In addition, to the changes proposed in § 405.2462, § 405.2463, § 405.2464, and § 405.2469, we are proposing to: remove obsolete language from § 405.2410 regarding FQHCs that bill on the basis of the reasonable cost system, add a section heading to § 405.2415, and remove obsolete language from § 405.2448 regarding employment requirements.

E. Part B Drugs

1. Payment for Biosimilar Biological Products Under Section 1847A

Section 3139 of the Affordable Care Act amended section 1847A of the Act to define a biosimilar biological product and a reference biological product, and to provide for Medicare payment of biosimilar biological products using the average sale price (ASP) methodology.

Section 1847A(c)(6)(H) of the Act, as added by section 3139 of the Affordable Care Act, defines a biosimilar biological product as a biological product approved under an abbreviated application for a license of a biological product that relies in part on data or information in an application for another biological product licensed under section 351 of the Public Health Service Act (PHSA). Section 1847A(c)(6)(I) of the Act, as added by section 3139 of the Affordable Care Act, defines the reference biological product for a biosimilar biological product as the biological product licensed under such section 351 of the PHSA that is referred to in the application of the biosimilar biological product.

Section 3139 of the Affordable Care Act also amended section 1847A(b) of the Act by adding a new paragraph (8) to specify that the payment amount for a biosimilar biological product will be the sum of the following two amounts: the ASP as determined using the methodology described under paragraph 1847A(b)(6) applied to a biosimilar biological product for all National Drug Codes (NDCs) assigned to such product in the same manner as such paragraph is applied to drugs described in such paragraph; and 6 percent of the payment amount determined using the methodology in section 1847A(b)(4) of the Act for the corresponding reference biological product. The effective date for ASP statutory provisions on biosimilars was July 1, 2010. Separate sections of the Affordable Care Act also established a licensing pathway for biosimilar biological products.

To implement these provisions, we published CY 2011 PFS final rule with comment period (75 FR 73393 and 73394) in the **Federal Register** on November 29, 2010. The relevant regulation text is found at § 414.902 and § 414.904. At the time that the CY 2011 PFS final rule with comment period was published, it was not apparent how or when the new FDA abbreviated approval pathway would be implemented or when biosimilar products would be approved for marketing in the United States. The FDA approved the first biosimilar product under the new biosimilar approval pathway required by the Affordable Care Act on March 6, 2015.

Since 2010, we have continued to follow the implementation of the FDA biosimilar approval process and the emerging biosimilar marketplace. As biosimilars are now beginning to enter the marketplace, we have also reviewed the existing guidance on Medicare payment for these products. Our review has revealed a potential inconsistency between our interpretation of the statutory language at section 1847A(b)(8) of the Act and regulation text at § 414.904(j). To make the regulation text more consistent with our interpretation of the statutory language, we are proposing to amend the regulation text at § 414.904(j) to make clear that the payment amount for a biosimilar biological product is based on the ASP of all NDCs assigned to the biosimilar biological products included within the same billing and payment code. We are also proposing to amend the regulation text at § 414.914(j) to update the effective date of this provision from July 1, 2010 to January 1, 2016, the anticipated effective date of the CY 2016 Physician Fee Schedule Final Rule with Comment Period. We welcome comments about these proposals.

We would also like to take this opportunity to discuss and clarify some other details of Part B biosimilar payment policy. First, we plan to use a single ASP payment limit for biosimilar products that are assigned to a specific HCPCS code. In general, this means that products that rely on a common reference product's biologics license application will be grouped into the same payment calculation. This approach, which is similar to the ASP calculation for multiple source drugs, is authorized by section 1847A(b)(8)(A) of the Act, which states that the payment determination for a biosimilar biological product is determined using the methodology in paragraph 1847A(b)(6) applied to a biosimilar biological product for all NDCs assigned to such product in the same manner as such paragraph is applied to drugs described in such paragraph.

Second, we would like to describe how payment for newly approved biosimilars will be determined. As we stated in the CY 2011 PFS final rule with comment period (75 FR 73393 and 73394), we anticipate that as subsequent biosimilar biological products are approved, we will receive manufacturers' ASP sales data through the ASP data submission process and publish national payment amounts in a manner that is consistent with our current approach to other drugs and

biologicals that are paid under section 1847A of the Act and set forth in 42 CFR part 414 subpart J. Until we have collected sufficient sales data as reported by manufacturers, payment limits will be determined in accordance with the provisions in section 1847A(c)(4) of the Act. If no manufacturer data is collected, prices will be determined by local contractors using any available pricing information, including provider invoices. As with newly approved drugs and biologicals (including biosimilars), Medicare part B payment would be available once the product is approved by the FDA. Payment for biosimilars (and other drugs and biologicals that are paid under part B) may be made before a HCPCS code has been released, provided that the claim is reasonable and necessary, and meets applicable coverage and claims submission criteria.

We would also like to clarify how wholesale acquisition cost (WAC) data may be used by CMS for Medicare payment of biosimilars in accordance with the provisions in section 1847A(c)(4) of the Act. Section 1847A(c)(4) of the Act authorizes the use of a WAC-based payment amount in cases where the ASP during the first quarter of sales is not sufficiently available from the manufacturer to compute an ASP-based payment amount. Once the wholesale acquisition cost (WAC) data is available from the pharmaceutical pricing compendia and when WAC-based payment amounts are utilized by CMS to determine the national payment limit for a biosimilar product, the payment limit will be 106 percent of the WAC of the biosimilar product; the reference biological product will not be factored into the WAC-based payment limit determination. This approach is consistent with partial quarter pricing that was discussed in rulemaking in the CY 2011 PFS final rule with comment period (75 FR 73465 and 73466) and with statutory language at section 1847A(c)(4) of the Act. Once ASP information is available for a biosimilar product, and when partial quarter pricing requirements no longer apply, the Medicare payment limit for a biosimilar product will be determined based on ASP data.

F. Productivity Adjustment for the Ambulance, Clinical Laboratory, and DMEPOS Fee Schedules

Section 3401 of the Affordable Care Act requires that the update factor under certain payment systems be annually adjusted by changes in economy-wide productivity. The year that the productivity adjustment is effective varies by payment system. Specifically, section 3401 of the Affordable Care Act requires that in CY 2011 (and in subsequent years) update factors under the ambulance fee schedule (AFS), the clinical laboratory fee schedule (CLFS) and the DMEPOS fee schedule be adjusted by changes in economy-wide productivity. Section 3401(a) of the Affordable Care Act amends section 1886(b)(3)(B) of the Act to add clause (xi)(II), which sets forth the definition of this productivity adjustment. The statute defines the productivity adjustment to be equal to the 10-year moving average of changes in annual economy-wide private nonfarm business multifactor productivity (MFP) (as projected by the Secretary for the 10-year period ending with the applicable fiscal year, year, cost reporting period, or other annual period). Historical published data on the measure of MFP is available on the Bureau of Labor Statistics (BLS) Web site at *http://www.bls.gov/mfp.*

MFP is derived by subtracting the contribution of labor and capital inputs growth from output growth. The projection of the components of MFP are currently produced by IHS Global Insight, Inc. (IGI), a nationally recognized economic forecasting firm with which we contract to forecast the components of MFP. To generate a forecast of MFP, IGI replicates the MFP measure calculated by the BLS using a series of proxy variables derived from IGI's U.S. macroeconomic models. In the CY 2011 and CY 2012 PFS final rules with comment period (75 FR 73394 through 73396, 76 FR 73300 through 73301), we set forth the current methodology to generate a forecast of MFP. We identified each of the major MFP component series employed by the BLS to measure MFP as well as provided the corresponding concepts determined to be the best available proxies for the BLS series. Beginning with CY 2016, for the AFS, CLFS and DMEPOS fee schedule, the MFP adjustment is calculated using a revised series developed by IGI to proxy the aggregate capital inputs. Specifically, IGI has replaced the Real Effective Capital Stock used for Full Employment GDP with a forecast of BLS aggregate capital inputs recently developed by IGI using a regression model. This series provides a better fit to the BLS capital inputs, as measured by the differences between the actual BLS capital input growth rates and the estimated model growth rates over the historical time period. Therefore, we are using IGI's most recent forecast of the BLS capital inputs series in the MFP calculations beginning with CY 2016. A complete description of the MFP projection methodology is available on our Web site at *http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MedicareProgramRatesStats/MarketBasketResearch.html.* Although we discuss the IGI changes to the MFP proxy series in this proposed rule, in the future, when IGI makes changes to the MFP methodology, we will announce them on our Web site rather than in the annual rulemaking.

G. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

Section 218(b) of the PAMA amended Title XVIII of the Act to add section 1834(q) directing us to establish a program to promote the use of appropriate use criteria (AUC) for advanced diagnostic imaging services. This proposed rule outlines the initial component of the new Medicare AUC program and our plan for implementing the remaining components.

1. Background

In general, AUC are a set of individual criteria that present information in a manner that links a specific clinical condition or presentation, one or more services, and an assessment of the appropriateness of the service(s). Evidence-based AUC for imaging can assist clinicians in selecting the imaging study that is most likely to improve health outcomes for patients based on their individual context.

We believe the goal of this statutory AUC program is to promote the evidence-based use of advanced diagnostic imaging to improve quality of care and reduce inappropriate imaging. Professional medical societies, health systems, and academic institutions have been designing and implementing AUC for decades. Experience and published studies alike show that results are best when AUC are built on an evidence base that considers patient health outcomes, weighing the benefits and harms of alternative care options, and integrated into broader care management and continuous quality improvement (QI) programs. Successful QI programs in turn have provider-led multidisciplinary teams collectively identify key clinical processes and then develop bottom-up, evidence-based AUC or guidelines that are embedded into clinical workflows, and become the organizing principle of care delivery (Aspen 2013). Feedback loops, an essential component, compare provider performance and patient health outcomes to individual, regional and national benchmarks.

There is also consensus that AUC programs built on evidence-based medicine and applied in a QI context are the best method to identify appropriate care and eliminate inappropriate care, and are preferable to across-the-board payment reductions that do not differentiate interventions that add value from those that cause harm or add no value.

2. Previous AUC Experience

The first CMS experience with AUC, the Medicare Imaging Demonstration (MID), was required by section 135(b) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). Designed as an alternative to prior authorization, the MID's purpose was to examine whether provider exposure to appropriateness guidelines would reduce inappropriate utilization of advanced imaging services. In the 2-year demonstration which began in October 2011, nearly 4,000 physicians, grouped into one of five conveners across geographically and organizationally diverse practice settings, ordered a total of nearly 50,000 imaging studies.[1]

In addition to the outcomes of the MID (*http://www.rand.org/content/dam/rand/pubs/research_reports/RR700/RR706/RAND_RR706.pdf*), we considered others' experiences and results from implementation of imaging AUC and other evidence-based clinical guidelines at healthcare organizations such as Brigham & Women's, Intermountain Healthcare, Kaiser, Massachusetts General Hospital, and Mayo, and in states such as Minnesota. From these experiences, and analyses of them by medical societies and others, general agreement on at least two key points has emerged. First, AUC, and the clinical decision support (CDS) mechanisms through which providers access AUC, must be integrated into the clinical workflow and facilitate, not obstruct, evidence-based care delivery. Second, the ideal AUC is an evidence-based guide that starts with a patient's specific clinical condition or presentation (symptoms) and assists the provider in the overall patient workup, treatment and follow-up. Imaging would appear as key nodes within the clinical management decision tree. The end goal of using AUC is to improve patient health outcomes. In reality, however, many providers may encounter AUC through a CDS mechanism for the first time at the point of image ordering. The CDS would ideally bring the provider back to that specific clinical condition and work-up scenario to ensure and simultaneously document the appropriateness of the imaging test.

However, there are different views about how best to roll out AUC into clinical practice. One opinion is that it is best to start with as comprehensive a library of individual AUC as possible to avoid the frustration, experienced and voiced by many practitioners participating in the MID, of spending time navigating the CDS tool only to find that, about 40 percent of the time, no AUC for their patient's specific clinical condition existed. The other opinion is that, based on decades of experience rolling out AUC in the context of robust QI programs, it is best to focus on a few priority clinical areas (for example, low back pain) at a time, to ensure that providers fully understand the AUC they are using, including when they do not apply to a particular patient. This same group also believes, based on experience with the MID, that too many low-evidence alerts or rules simply create ''alert fatigue.'' They envision that, rather than navigating through a CDS to find relevant AUC, providers would simply enter the patient's condition and a message would pop up stating whether AUC existed for that condition.

We believe there is merit to both approaches, and it has been suggested to us that the best approach may depend on the particular care setting. The second, ''focused'' approach may work better for a large health system that produces and uses its own AUC. The first, ''comprehensive'' approach may in turn work better for a smaller practice with broad image ordering patterns and fewer resources that wants to simply adopt and start using from day one a complete AUC system developed elsewhere. We believe a successful program would allow flexibility, and under section 1834(q) of the Act, we foresee competing sets of AUC developed by different provider-led entities, and competing CDS mechanisms, from which providers may choose.

3. Statutory Authority

Section 218(b) of the PAMA amended the Medicare Part B statute by adding a new section 1834(q) of the Act entitled, ''Recognizing Appropriate Use Criteria for Certain Imaging Services,'' which directs us to establish a new program to promote the use of AUC. In section 1834(q)(1)(B) of the Act, AUC are defined as criteria that are evidence-based (to the extent feasible) and assist professionals who order and furnish applicable imaging services to make the most appropriate treatment decision for a specific clinical condition for an individual.

4. Discussion of Statutory Requirements

There are four major components of the AUC program under section 1834(q) of the Act, each with its own implementation date: (1) Establishment of AUC by November 15, 2015 (section 1834(q)(2)); (2) mechanisms for consultation with AUC by April 1, 2016 (section 1834(q)(3)); (3) AUC consultation by ordering professionals and reporting on AUC consultation by furnishing professionals by January 1, 2017 (section 1834(q)(4)); and (4) annual identification of outlier ordering professionals for services furnished after January 1, 2017 (section 1834(q)(5)). In this proposed rule, we primarily address the first component under section 1834(q)(2)—the process for establishment of AUC, along with relevant aspects of the definitions under section 1834(q)(1).

Section 1834(q)(1) of the Act describes the program and provides definitions of terms. The program is required to promote the use of AUC for applicable imaging services furnished in an applicable setting by ordering professionals and furnishing professionals. Section 1834(q)(1) of the Act provides definitions for AUC, applicable imaging service, applicable setting, ordering professional, and furnishing professional. An ''applicable imaging service'' under section 1834(q)(1)(C) of the Act must be an advanced imaging service as defined in section 1834(e)(1)(B) of the Act, which defines ''advanced diagnostic imaging services'' to include diagnostic magnetic resonance imaging, computed tomography, and nuclear medicine (including positron emission tomography); and other diagnostic imaging services we may specify in consultation with physician specialty organizations and other stakeholders, but excluding x-ray, ultrasound and fluoroscopy services.

Section 1834(q)(2)(A) of the Act requires the Secretary to specify applicable AUC for applicable imaging services, through rulemaking and in consultation with physicians, practitioners and other stakeholders, by November 15, 2015. Applicable AUC may be specified only from among AUC developed or endorsed by national professional medical specialty societies or other provider-led entities. Section 1834(q)(2)(B) of the Act identifies certain considerations the Secretary must take into account when specifying applicable AUC including whether the AUC have stakeholder consensus, are scientifically valid and evidence-based,

[1] Timbie J, Hussey P, Burgette L, et al. Medicare Imaging Demonstration Final Evaluation: Report to Congress. 2014 The Rand Corporation

and are based on studies that are published and reviewable by stakeholders. Section 1834(q)(2)(C) of the Act requires the Secretary to review the specified applicable AUC each year to determine whether there is a need to update or revise them, and to make any needed updates or revisions through rulemaking. Section 1834(q)(2)(D) of the Act specifies that, if the Secretary determines that more than one AUC applies for an applicable imaging service, the Secretary shall apply one or more AUC for the service.

The PAMA was enacted into law on April 1, 2014. Implementation of many aspects of the amendments made by section 218(b) requires consultation with physicians, practitioners, and other stakeholders, and notice and comment rulemaking. We believe the PFS rulemaking process is the most appropriate and administratively feasible implementation vehicle. Given the timing, we were not able to include proposals in the PFS proposed rule to begin implementation in the same year the PAMA was enacted. The PFS proposed rule is published in late June or early July each year. For the new Medicare AUC program to have been a part of last year's proposed rule (CY 2015), we would have had to interpret and analyze the new statutory language, and develop proposed plans for implementation in under one month. Additionally, given the complexity of the program to promote the use of AUC for advanced imaging services established under section 1834(q) of the Act, we believed it was imperative to consult with physicians, practitioners and other stakeholders in advance of developing proposals to implement the program. In the time since the legislation was enacted, we have met extensively with stakeholders to gain insight and hear their comments and concerns about the AUC program. Having this open door with stakeholders has greatly informed our proposed policy. In addition, before AUC can be specified as directed by section 1834(q)(2)(A) of the Act, there is first the need to define what AUC are and to specify the process for developing them. To ensure transparency and meet the requirements of the statute, we are proposing to implement section 1834(q)(2) of the Act by first establishing through rulemaking a process for specifying applicable AUC and proposing the requirements for AUC development. Under our proposal, the specification of AUC under section 1834(q)(2)(A) of the Act will flow from this process.

We are also proposing to define the term, ''provider-led entity,'' which is included in section 1834(q)(1)(B) of the Act so that the public has an opportunity to comment, and entities meeting the definition are aware of the process by which they may become qualified under Medicare to develop or endorse AUC. Under our proposed process, once a provider-led entity is qualified (which includes rigorous AUC development requirements involving evidence evaluation, as provided in section 1834(q)(2)(B) of the Act and proposed in this proposed rule) the AUC that are developed or endorsed by the entity would be considered to be specified applicable AUC under section 1834(q)(2)(A) of the Act.

The second major component of the Medicare AUC program is the identification of qualified CDS mechanisms that could be used by ordering professionals for consultation with applicable AUC under section 1834(q)(3) of the Act. We envision a CDS mechanism for consultation with AUC as an interactive tool that communicates AUC information to the user. The ordering professional would input information regarding the clinical presentation of the patient into the CDS tool, which may be a feature of or accessible through an existing system, and the tool would provide immediate feedback to the ordering professional on the appropriateness of one or more imaging services. Ideally, multiple CDS mechanisms would be available that could integrate directly into, or be seamlessly interoperable with, existing health information technology (IT) systems. This would minimize burden on provider teams and avoid duplicate documentation.

Section 1834(q)(3)(A) of the Act states that the Secretary must specify qualified CDS mechanisms in consultation with physicians, practitioners, health care technology experts, and other stakeholders. This paragraph authorizes the Secretary to specify mechanisms that could include: CDS modules within certified EHR technology; private sector CDS mechanisms that are independent of certified EHR technology; and a CDS mechanism established by the Secretary.

However, all CDS mechanisms must meet the requirements under section 1834(q)(3)(B) of the Act which specifies that a mechanism must: Make available to the ordering professional applicable AUC and the supporting documentation for the applicable imaging service that is ordered; where there is more than one applicable AUC specified for an applicable imaging service, indicate the criteria it uses for the service; determine the extent to which an applicable imaging service that is ordered is consistent with the applicable AUC; generate and provide to the ordering professional documentation to demonstrate that the qualified CDS was consulted by the ordering professional; be updated on a timely basis to reflect revisions to the specification of applicable AUC; meet applicable privacy and security standards; and perform such other functions as specified by the Secretary (which may include a requirement to provide aggregate feedback to the ordering professional). Section 1834(q)(3)(C) of the Act specifies that the Secretary must publish an initial list of specified mechanisms no later than April 1, 2016, and that the Secretary must identify on an annual basis the list of specified qualified CDS mechanisms.

We are not including proposals to implement section 1834(q)(3) of the Act in this proposed rule. We need to first establish, through notice and comment rulemaking, the process for specifying applicable AUC. Specified applicable AUC would serve as the inputs to any qualified CDS mechanism, therefore, these must first be identified so that prospective tool developers are able to establish relationships with AUC developers. In addition, we anticipate that in PFS rulemaking for CY 2017, we will provide clarifications, develop definitions and establish the process by which we will specify qualified CDS mechanisms. The requirements for qualified CDS mechanisms set forth in section 1834(q)(3)(B) of the Act will also be vetted through PFS rulemaking for CY 2017 so that mechanism developers have a clear understanding and notice regarding the requirements for their tools. The CY 2017 proposed rule would be published at the end of June or in early July of 2016, be open for a period of public comment, and then the final rule would be published by November 1, 2016. We anticipate that the initial list of specified applicable CDS mechanisms will be published sometime after the CY 2017 PFS final rule. In advance of these actions, we will continue to work with stakeholders to understand how to ensure that appropriate mechanisms are available, particularly with respect to standards for certified health IT, including EHRs, that can enable interoperability of AUC across systems.

The third major component of the AUC program is in section 1834(q)(4) of the Act, Consultation with Applicable Appropriate Use Criteria. This section establishes, beginning January 1, 2017, the requirement for an ordering professional to consult with a listed qualified CDS mechanism when ordering an applicable imaging service that would be furnished in an

applicable setting and paid for under an applicable payment system; and for the furnishing professional to include on the Medicare claim information about the ordering professional's consultation with a qualified CDS mechanism. The statute distinguishes between the ordering and furnishing professional, recognizing that the professional who orders the imaging service is usually not the same professional who bills Medicare for the test when furnished. Section 1834(q)(4)(C) of the Act provides for certain exceptions to the AUC consultation and reporting requirements including in the case of certain emergency services, inpatient services paid under Medicare Part A, and ordering professionals who obtain a hardship exemption. Section 1834(q)(4)(D) of the Act specifies that the applicable payment systems for the AUC consultation and reporting requirements are the physician fee schedule, hospital outpatient prospective payment system, and the ambulatory surgical center payment system.

We are not including proposals to implement section 1834(q)(4) of the Act in this proposed rule. Again, it is important that we first establish through notice and comment rulemaking the process by which applicable AUC will be specified as well as the CDS mechanisms through which ordering providers would access them. We anticipate including further discussion and adopting policies regarding claims-based reporting requirements in the CY 2017 and CY 2018 rulemaking cycles.

The fourth component of the AUC program is in section 1834(q)(5) of the Act, Identification of Outlier Ordering Professionals. The identification of outlier ordering professionals under this paragraph facilitates a prior authorization requirement for outlier professionals beginning January 1, 2020, as specified under section 1834(q)(6) of the Act. Although, we are not including proposals to implement these sections in this proposed rule, we are proposing to identify outlier ordering professionals from within priority clinical areas that would be established through subsequent rulemaking. In this rule, we propose a process to provide clarity around priority clinical areas.

The concept of priority clinical areas allows CMS to implement an AUC program that combines two approaches to implementation. Under our proposed policy, while potentially large volumes of AUC would become specified across clinical conditions and advanced imaging technologies, we believe this rapid roll out of specified AUC should be balanced with a more focused approach to identifying outlier ordering professionals. We believe this will provide an opportunity for physicians and practitioners to become familiar with AUC in identified priority clinical areas prior to Medicare claims for those services being part of the input for calculating outlier ordering professionals.

In future rulemaking, with the benefit of public comments, we will establish priority clinical areas and expand them over time. Also in future rulemaking, we will develop and clarify our policy to identify outlier ordering professionals.

5. Proposals for Implementation

We are proposing to amend our regulations to add a new § 414.94, ''Appropriate Use Criteria for Certain Imaging Services.''

a. Definitions

In § 414.94 (b), we are proposing to codify and add language to clarify some of the definitions provided in section 1834(q)(1) of the Act as well as define terms that were not defined in statute but for which a definition would be helpful for program implementation. In this section of the proposed rule, we provide a description of the terms we are proposing to codify to facilitate understanding and encourage public comment on the proposed AUC program.

Due to circumstances unique to imaging, it is important to note that there is an ordering professional (the physician or practitioner that orders that the imaging service be performed) and a furnishing professional (the physician or practitioner that actually performs the imaging service and provides the radiologic interpretation of the image) involved in imaging services. In some cases the ordering professional and the furnishing professional are the same.

This proposed AUC program only applies in applicable settings. An applicable setting would include a physician's office, a hospital outpatient department (including an emergency department) and an ambulatory surgical center. The inpatient hospital setting, for example, is not an applicable setting. Further, the proposed program only applies to applicable imaging services. These are advanced diagnostic imaging services for which one or more applicable AUC apply, one or more qualified CDS mechanisms is available, and one of those mechanisms is available free of charge.

We are proposing to clarify the definition for appropriate use criteria, which is defined in statute to include only criteria developed or endorsed by national professional medical specialty societies or other provider-led entities, to assist ordering professionals and furnishing professionals in making the most appropriate treatment decision for a specific clinical condition for an individual. To the extent feasible, such criteria shall be evidence-based. To further describe AUC, we are proposing to add the following language to this definition: AUC are a collection of individual appropriate use criteria. Individual criteria are information presented in a manner that links: A specific clinical condition or presentation; one or more services; and, an assessment of the appropriateness of the service(s).

For the purposes of implementing this program, we are proposing to define new terms in § 414.94(b). A provider-led entity would include national professional medical specialty societies (for example the American College of Radiology and the American Academy of Family Physicians) or an organization that is comprised primarily of providers and is actively engaged in the practice and delivery of healthcare (for example hospitals and health systems). Applicable AUC become specified when they are developed, modified or endorsed by a qualified provider-led entity. A provider-led entity is not considered qualified until CMS makes a determination via the qualification process discussed in this proposal. We are introducing priority clinical areas to inform ordering professionals and furnishing professionals of the clinical topics, clinical topics and imaging modalities or imaging modalities that may be identified by the agency through annual rulemaking and in consultation with stakeholders which may be used in the identification of outlier ordering professionals.

The proposed definitions in § 414.94 are important in understanding our proposals for implementation. Only AUC developed, modified or endorsed by organizations meeting the definition of provider-led entity would be considered specified applicable AUC. As required by the statute, specified applicable AUC, which encompass all AUC developed, modified or endorsed by qualified provider-led entities, must be consulted and such consultation must be reported on the claim for applicable imaging services. To assist in identification of outlier ordering professionals, we propose to focus on priority clinical areas. Priority clinical areas would be associated with a subset of specified AUC.

b. AUC Development by Provider-Led Entities

In § 414.94, we are proposing to include regulations to implement the first component of the Medicare AUC program—specification of applicable AUC. We are first proposing a process by which provider-led entities (including national professional medical specialty societies) become qualified by Medicare to develop or endorse AUC. The cornerstone of this process is for provider-led entities to demonstrate that they engage in a rigorous evidence-based process for developing, modifying, or endorsing AUC. It is through this demonstration that we propose to meet the requirements of section 1834(q)(2)(B) of the Act to take into account certain considerations for the AUC. Section 1834(q)(2)(B) specifies that the Secretary must consider whether AUC have stakeholder consensus, are scientifically valid and evidence-based, and are based on studies that are published and reviewable by stakeholders. It is not feasible for us to review every individual criterion. Rather, we propose to establish a qualification process and requirements for qualified provider-led entities in order to ensure that the AUC development or endorsement processes used by a provider-led entity result in high quality, evidence-based AUC in accordance with section 1834(q)(2)(B). Therefore, we propose that AUC developed, modified, or endorsed by qualified provider-led entities will constitute the specified applicable AUC that ordering professionals would be required to consult when ordering applicable imaging services.

In order to become and remain a qualified provider-led entity, we propose to require a provider-led entity to demonstrate adherence to specific requirements when developing, modifying or endorsing AUC. The first proposed requirement is related to the evidentiary review process for individual criteria. Entities must engage in a systematic literature review of the clinical topic and relevant imaging studies. We would expect the literature review to include evidence on analytical validity, clinical validity, and clinical utility of the specific imaging study. In addition, the provider-led entity must assess the evidence using a formal, published, and widely recognized methodology for grading evidence. Consideration of relevant published evidence-based guidelines and consensus statements by professional medical specialty societies must be part of the evidence assessment. Published consensus statements may form part of the evidence base of AUC and would be subject to the evidentiary grading methodology as any other evidence identified as part of a systematic review.

In addition, we propose that the provider-led entity's AUC development process must be led by at least one multidisciplinary team with autonomous governance that is accountable for developing, modifying, or endorsing AUC. At a minimum, the team must be composed of three members including one with expertise in the clinical topic related to the criterion and one with expertise in imaging studies related to the criterion. We encourage such teams to be larger, and include experts in each of the following domains: Statistical analysis (such as biostatics, epidemiology, and applied mathematics); clinical trial design; medical informatics; and quality improvement. A given team member may be the team's expert in more than one domain. These experts should contribute substantial work to the development of the criterion, not simply review the team's work.

Another important area to address that provides additional assurance regarding quality and evidence-based AUC development is the disclosure of conflicts of interest. We believe it is appropriate to impose relatively stringent requirements for public transparency and disclosure of potential conflicts of interest for anyone participating with a provider-led entity in the development of AUC. We propose that the provider-led entity must have a publicly transparent process for identifying and disclosing potential conflicts of interest of members on the multidisciplinary AUC development team. The provider-led entity must disclose any direct or indirect relationships, as well as ownership or investment interests, among the multidisciplinary team members or immediate family members and organizations that may financially benefit from the AUC that are being considered for development, modification or endorsement.

For individual criteria to be available for practitioners to review prior to incorporation into a CDS mechanism, we propose that the provider-led entity must maintain on its Web site each criterion that is part of the AUC that the entity has considered or is considering for development, modification, or endorsement. This public transparency of individual criteria is critical not only to ordering and furnishing professionals, but also to patients and other health care providers who may wish to view all available AUC.

Although evidence should be the foundation for the development, modification and endorsement of AUC, we recognize that not all aspects of a criterion will be evidence-based, and that a criterion does not exist for every clinical scenario. We believe it is important for AUC users to understand which aspects of a criterion are evidence-based and which are consensus-based. Therefore, we propose that key decision points in individual criteria be graded in terms of strength of evidence using a formal, published, and widely recognized methodology. This level of detail must be part of each AUC posted to the entity's Web site.

It is critical that as provider-led entities develop large collections of AUC, they have a transparent process for the timely and continual review of each criterion, as there are sometimes rapid changes in the evidence base for certain clinical conditions and imaging studies.

Finally, we propose that a provider-led entity's process for developing, modifying, or endorsing AUC (which would be inclusive of the requirements being proposed in this rule) must be publicly posted on the entity's Web site.

We believe it is important to fit AUC to local circumstances and populations, while also ensuring a rigorous due process for doing so. Under our proposed AUC program, local adaptation of AUC might happen in three ways. First, compatibility with local practice is something that ordering professionals can assess when selecting AUC for consultation. Second, professional medical societies (many of which have state chapters) and large health systems (which incorporate diverse practice settings, both urban and rural) that become qualified provider-led entities can get local feedback at the outset and build alternative options into the design of their AUC. Third, local provider-led entities can themselves become qualified to develop, modify, or endorse AUC.

c. Process for Provider-Led Entities To Become Qualified To Develop, Endorse or Modify AUC

We are proposing that provider-led entities must apply to CMS to become qualified. We are proposing that entities that believe they meet the definition of provider-led submit applications to us that document adherence to each of the qualification requirements. The application must include a statement as to how the entity meets the definition of a provider-led entity. Applications will be accepted each year but must be received by January 1. A list of all applicants that we determine to be

qualified provider-led entities will be posted to our Web site by the following June 30 at which time all AUC developed or endorsed by that provider-led entity will be considered to be specified AUC. All qualified provider-led entities must re-apply every 6 years and their applications must be received by January 1 during the 5th year of their approval. Note that the application is not a CMS form; rather it is created by the applicant entity.

d. Identifying Priority Clinical Areas

Section 1834(q)(4) of the Act requires that, beginning January 1, 2017, ordering professionals must consult applicable AUC using a qualified CDS mechanism when ordering applicable imaging services for which payment is made under applicable payment systems, and that furnishing professionals must report the results of this consultation on Medicare claims. Section 1834(q)(5) of the Act further provides for the identification of outlier ordering professionals based on a low adherence to applicable AUC. We are proposing to identify priority clinical areas of AUC that we will use in identifying outlier ordering professionals. Although there is no consequence to being identified as an outlier ordering professional until January 2020, it is important to allow ordering and furnishing professionals as much time as possible to use and familiarize themselves with the specified applicable AUC that will eventually become the basis for identifying outlier ordering professionals.

To identify these priority clinical areas, we may consider incidence and prevalence of diseases, as well as the volume, variability of utilization, and strength of evidence for imaging services. We may also consider applicability of the clinical area to a variety of care settings, and to the Medicare population. We are proposing to annually solicit public comment and finalize clinical priority areas through the PFS rulemaking process beginning in CY 2017. To further assist us in developing the list of proposed priority clinical areas, we are proposing to convene the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC), a CMS FACA compliant committee, as needed to examine the evidence surrounding certain clinical areas.

Specified applicable AUC falling within priority clinical areas may factor into the low-adherence calculation when identifying outlier ordering professionals for the prior authorization component of this statute, which is slated to begin in 2020. Future rulemaking will address further details.

e. Identification of Non-Evidence Based AUC

Despite our proposed provider-led entity qualification process that should ensure evidence-based AUC development, we remain concerned that non-evidence based criteria may be developed or endorsed by qualified provider-led entities. Therefore, we are proposing a process by which we would identify and review potentially non-evidence-based criteria that fall within one of our identified priority clinical areas. We are proposing to accept public comment through annual PFS rulemaking so that the public can assist in identifying AUC that potentially are not evidence-based. We foresee this being a standing request for comments in all future rules regarding AUC. We are proposing to use the MEDCAC to further review the evidentiary basis of these identified AUC, as needed. The MEDCAC has extensive experience in reviewing, interpreting, and translating evidence. If through this process, a number of criteria from an AUC library are identified as being insufficiently evidence-based, and the provider-led entity that produced the library does not make a good faith attempt to correct these in a timely fashion, this information could be considered when the provider-led entity applies for re-qualification.

6. Summary

Section 1834(q) of the Act includes rapid timelines for establishing a new Medicare AUC program for advanced imaging services. The number of clinicians impacted by the scope of this program is massive as it will apply to every physician and practitioner who orders applicable diagnostic imaging services. This crosses almost every medical specialty and could have a particular impact on primary care physicians since their scope of practice can be quite vast.

We believe the best implementation approach is one that is diligent, maximizes the opportunity for public comment and stakeholder engagement, and allows for adequate advance notice to physicians and practitioners, beneficiaries, AUC developers, and CDS mechanism developers. It is for these reasons we are proposing a stepwise approach, adopted through rulemaking, to first define and lay out the process for the Medicare AUC program. However, we also recognize the importance of moving expeditiously to accomplish a fully implemented program.

In summary, we are proposing definitions of terms necessary to implement the AUC program. We are particularly seeking comment on the proposed definition of provider-led entity as these are the organizations that have the opportunity to become qualified to develop, modify or endorse specified AUC. We are also proposing an AUC development process which allows some flexibility for provider-led entities but sets standards including an evidence-based development process and transparency. In addition, we are proposing the concept and definition of priority clinical areas and how they may contribute to the identification of outlier ordering professionals. Lastly, we are proposing to develop a process by which non-evidence-based AUC will be identified and discussed in the public domain. We invite the public to submit comments on these proposals.

H. Physician Compare Web Site

1. Background and Statutory Authority

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 eligible professionals (EPs) who participate in the Physician Quality Reporting System (PQRS) under section 1848 of the Act. We launched the first phase of Physician Compare on December 30, 2010 (*http://www.medicare.gov/physiciancompare*). In the initial phase, we posted the names of EPs that satisfactorily submitted quality data for the 2009 PQRS, as required by section 1848(m)(5)(G) of the Act.

We also implemented, consistent with section 10331(a)(2) of the Affordable Care Act, a plan for making publicly available through Physician Compare information on physician performance that provides comparable information on quality and patient experience measures for reporting periods beginning no earlier than January 1, 2012. We met this requirement in advance of the statutory deadline of January 1, 2013, as outlined below, and plan to continue addressing elements of the plan through rulemaking.

To the extent that scientifically sound measures are developed and are available, we are required to include, to the extent practicable, the following types of measures for public reporting:

- Measures collected under the Physician Quality Reporting System (PQRS).

- An assessment of patient health outcomes and functional status of patients.
- An assessment of the continuity and coordination of care and care transitions, including episodes of care and risk-adjusted resource use.
- An assessment of efficiency.
- An assessment of patient experience and patient, caregiver, and family engagement.
- An assessment of the safety, effectiveness, and timeliness of care.
- Other information as determined appropriate by the Secretary.

In developing and implementing the plan, section 10331(b) requires that we include, to the extent practicable, the following:

- Processes to ensure that data made public are statistically valid, reliable, and accurate, including risk adjustment mechanisms used by the Secretary.
- Processes for physicians and EPs whose information is being publicly reported to have a reasonable opportunity, as determined by the Secretary, to review their results before posting to Physician Compare. We have established a 30-day preview period for all measurement performance data that will allow physicians and other EPs to view their data as it will appear on the Web site in advance of publication on Physician Compare (77 FR 69166, 78 FR 74450, and 79 FR 67770). Details of the preview process will be communicated directly to those with measures to preview and will also be published on the Physician Compare Initiative page (*http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/physician-compare-initiative/*) in advance of the preview period.
- Processes to ensure the data published on Physician Compare provides a robust and accurate portrayal of a physician's performance.
- Data that reflects the care provided to all patients seen by physicians, under both the Medicare program and, to the extent applicable, other payers, to the extent such information would provide a more accurate portrayal of physician performance.
- Processes to ensure appropriate attribution of care when multiple physicians and other providers are involved in the care of the patient.
- Processes to ensure timely statistical performance feedback is provided to physicians concerning the data published on Physician Compare.
- Implementation of computer and data infrastructure and systems used to support valid, reliable and accurate reporting activities.

Section 10331(d) of the Affordable Care Act requires us to consider input from multi-stakeholder groups, consistent with sections 1890(b)(7) and 1890A of the Act, when selecting quality measures for Physician Compare. We also continue to get 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.).

We submitted a report to the Congress in advance of the January 1, 2015 deadline, as required by section 10331(f) of the Affordable Care Act, on Physician Compare development, including information on the efforts and plans to collect and publish data on physician quality and efficiency and on patient experience of care in support of value-based purchasing and consumer choice.

We believe section 10331 of the Affordable Care Act supports our overarching goals of providing consumers with quality of care 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, we plan to continue to publicly report physician performance information on Physician Compare.

2. Public Reporting of Performance and Other Data

Since the initial launch of the Web site, we have continued to build on and improve Physician Compare, including a full redesign in 2013. Currently, Web site users can view information about approved Medicare professionals such as name, 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) board certification information. In addition, for group practices, users can view group practice names, specialties, practice locations, Medicare assignment status, and affiliated professionals.

In addition, there is a section on each Medicare professional's profile page indicating with a green check mark the quality programs under which the EP satisfactorily or successfully reported. The Web site will continue to post annually the names of individual EPs who satisfactorily report under PQRS, EPs who successfully participate in the Medicare Electronic Health Record (EHR) Incentive Program as authorized by section 1848(o)(3)(D) of the Act, and EPs who report PQRS measures in support of Million Hearts (79 FR 67763). A proposed change to the Million Hearts indicator for 2016 data is discussed below.

With the 2013 redesign of the Physician Compare Web site, we added a quality programs section to each group practice profile page, as well. We will continue to indicate which group practices are satisfactorily reporting in the Group Practice Reporting Option (GPRO) under PQRS (79 FR 67763). The Physician Compare Web site also contains a link to the Physician Compare downloadable database (*https://data.medicare.gov/data/physician-compare*), including information on this quality program participation.

We continue to implement our plan for a phased approach to public reporting performance information on the Physician Compare Web site. Under the first phase of this plan, we established that GPRO measures collected under PQRS through the Web Interface for 2012 would be publicly reported on Physician Compare (76 FR 73419 through 73420). We further expanded the plan by including on the Physician Compare Web site the 2013 group practice-level PQRS measures for Diabetes Mellitus (DM) and Coronary Artery Disease (CAD) reported via the Web Interface, and planned to report composite measures for DM and CAD in 2014, as well (77 FR 69166).

The 2012 GPRO measures were publicly reported on Physician Compare in February 2014. The 2013 PQRS GPRO DM and GPRO CAD measures collected via the Web Interface that met the minimum sample size of 20 patients and proved to be statistically valid and reliable were publicly reported on Physician Compare in December 2014. The composite measures were not reported, however, as some items included in the composites were no longer clinically relevant. If the minimum threshold is not met for a particular measure, or the measure is otherwise deemed not to be suitable for public reporting, the performance rate on that measure is not publicly reported. On the Physician Compare Web site, we only publish those measures that are statistically valid and reliable, and therefore, most likely to help consumers make informed decisions about the Medicare professionals they choose to meet their health care needs. In addition, we do not publicly report first year measures, meaning new PQRS and non-PQRS measures that have been available for

reporting for less than one year, regardless of reporting mechanism. 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.

Measures must be based on reliable and valid data elements to be useful to consumers. Therefore, for all proposed measures available for public reporting, including both group and individual EP level measures—regardless of reporting mechanism, only those proposed measures that prove to be valid, reliable, and accurate upon analysis and review at the conclusion of data collection and that meet the established public reporting criteria of a minimum sample size of 20 patients will be included on Physician Compare. For information on how we determine the validity and reliability of data and other statistical analyses we perform, refer to the CY 2015 PFS final rule with comment period (79 FR 67764 through 79 FR 67765).

We will also continue to include an indicator of which reporting mechanism was used and to only include on the site measures deemed statistically comparable.[2] We will continue to publicly report all measures submitted and reviewed and found to be statistically valid and reliable in the Physician Compare downloadable file. However, not all of these measures would necessarily be included on the Physician Compare profile pages. Consumer testing has shown profile pages with too much information and measures that are not well understood by consumers can negatively impact a consumer's ability to make informed decisions. Our analysis of the collected measure data, along with consumer testing and stakeholder feedback, will determine specifically which measures are published on Web site profile pages. Statistical analyses, like those specified above, will ensure the measures included are statistically valid and reliable and comparable across data collection mechanisms. Stakeholder feedback will help us to ensure that all publicly reported measures meet current clinical standards. When measures are finalized in advance of the time period in which they are collected, it is possible that clinical guidelines can change rendering a measure no longer relevant. Publishing that measure can lead to consumer confusion regarding what best practices their health care professional should be subscribing to. We will continue to reach out to stakeholders in the professional community, such as specialty societies, to ensure that the measures under consideration for public reporting remain clinically relevant and accurate.

The primary goal of Physician Compare is to help consumers make informed health care decisions. If a consumer does not properly interpret a quality measure and thus misunderstands what the quality score represents, the consumer cannot use this information to make an informed decision. Through concept testing, we will test with consumers how well they understand measures presented using plain language. Such consumer testing will help us gauge how measures are understood and the kinds of measures that are most relevant to consumers. This will be done to help ensure that the information included on Physician Compare is as consumer friendly and consumer focused as possible.

As is the case for all measures published on Physician Compare, individual EPs and group practices will be given a 30-day preview period to view their measures as they will appear on Physician Compare prior to the measures being published. As in previous years, we will fully explain the process for the 30-day preview and provide a detailed timeline and instructions for preview in advance of the start of the preview period.

We also report certain Accountable Care Organization (ACO) quality measures on Physician Compare (76 FR 67802, 67948). Because EPs that bill under the TIN of an ACO participant are considered to be a group practice for purposes of qualifying for a PQRS incentive under the Medicare Shared Savings Program (Shared Savings Program), we publicly report ACO performance on quality measures on the Physician Compare Web site in the same way as we report performance on quality measures for group practices participating under PQRS. Public reporting of performance on these measures is presented at the ACO level only. The first subset of ACO measures was also published on the Web site in February 2014. ACO measures can be viewed by following the ''Accountable Care Organization (ACO) Quality Data'' link on the homepage of the Physician Compare Web site (*http://medicare.gov/physiciancompare/aco/search.html*).

ACOs will be able to preview their quality data that will be publicly reported on Physician Compare through the ACO Quality Reports, which will be made available to ACOs for review at least 30 days prior to the start of public reporting on Physician Compare. The quality reports will indicate the measures that are available for public reporting. ACO measures will be publicly reported in plain language, so a crosswalk linking the technical language included in the Quality Report and the plain language that will be publicly reported will be provided to ACOs at least 30 days prior to the start of public reporting.

As part of our public reporting plan for Physician Compare, we also have available for public reporting patient experience measures, specifically reporting the CAHPS for PQRS measures, which relate to the Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CG–CAHPS) data, for group practices of 100 or more EPs reporting data in 2013 under PQRS and for ACOs participating in the Shared Savings Program (77 FR 69166 and 69167). The 2013 CAHPS data for ACOs were publicly reported on Physician Compare in December 2014.

We continued to expand our plan for publicly reporting data on Physician Compare in 2015. We plan to make all group practice-level measures collected through the Web Interface for groups of 25 or more EPs participating in 2014 under the PQRS and for ACOs participating in the Shared Savings Program available for public reporting in CY 2015 (78 FR 74449). We also plan to publicly report performance on certain measures that group practices report via registries and EHRs for the 2014 PQRS GPRO (78 FR 74451). Specifically, we finalized a decision to make available for public reporting on Physician Compare performance on 16 registry measures and 13 EHR measures in CY 2015 (78 FR 74451). These measures are consistent with the measures available for public reporting via the Web Interface.

In CY 2015, CAHPS measures for group practices of 100 or more EPs who participate in PQRS, regardless of data submission method, and for Shared Savings Program ACOs reporting through the Web Interface or other CMS-approved tool or interface are available for public reporting (78 FR 74452). In addition, twelve 2014 summary survey measures for groups of 25 to 99 EPs collected via any certified CAHPS vendor regardless of PQRS participation are available for public reporting (78 FR 74452). For ACOs participating in the Shared Savings Program, the patient experience measures that are included in the Patient/Caregiver Experience domain of the Quality Performance Standard under the Shared Savings Program will be available for public reporting in CY 2015 (78 FR 74452).

[2] By statistically comparable, CMS means that the quality measures are analyzed and proven to measure the same phenomena in the same way regardless of the mechanism through which they were collected.

In late CY 2015, certain 2014 individual PQRS measure data reported by individual EPs are also available for public reporting. Specifically, we will make available for public reporting 20 individual measures collected through a registry, EHR, or claims (78 FR 74453 through 74454). These are measures that are in line with those measures reported by groups via the Web Interface.

Finally, in support of the HHS-wide Million Hearts initiative, performance rates on measures in the PQRS Cardiovascular Prevention measures group at the individual EP level for data collected in 2014 for the PQRS are available for public reporting in CY 2015 (78 FR 74454).

We continue to expand public reporting on Physician Compare by making an even broader set of quality measures available for publication on the Web site in CY 2016. All 2015 group-level PQRS measures across all group reporting mechanisms—Web Interface, registry, and EHR—are available for public reporting on Physician Compare in CY 2016 for groups of 2 or more EPs (79 FR 67769). Similarly, we decided that all measures reported by ACOs participating in the Shared Savings Program will be available for public reporting on Physician Compare.

Understanding the value of patient experience data for Physician Compare, CMS decided to report twelve 2015 CAHPS for PQRS summary survey measures for all group practices of two or more EPs, who meet the specified sample size requirements and collect data via a CMS-specified certified CAHPS vendor, are available for public reporting in CY 2016 (79 FR 67772).

To provide the opportunity for more EPs to have measures included on Physician Compare, and to provide more information to consumers to make informed decisions about their health care, we will make available for public reporting in CY 2016 on Physician Compare all 2015 PQRS measures for individual EPs collected through a registry, EHR, or claims (79 FR 67773).

Furthermore, in support of the HHS-wide Million Hearts initiative, we will publicly report the performance rates on the four, 2015 PQRS measures reported by individual EPs in support of Million Hearts with a minimum sample size of 20 patients.

To further support the expansion of quality measure data available for public reporting on Physician Compare and to provide more quality data to consumers to help them make informed decisions, CMS finalized 2015 Qualified Clinical Data Registry (QCDR) PQRS and non-PQRS measure data collected at the individual EP level are available for public reporting. The QCDR is required to declare during their self-nomination if they plan to post data on their own Web site and allow Physician Compare to link to it or if they will provide data to CMS for public reporting on Physician Compare. Measures collected via QCDRs must also meet the established public reporting criteria. Both PQRS and non-PQRS measures that are in their first year of reporting by a QCDR will not be available for public reporting (79 FR 67774 through 67775).

See Table 18 for a summary of our previously finalized policies for public reporting data on Physician Compare.

TABLE 18—SUMMARY OF PREVIOUSLY FINALIZED POLICIES FOR PUBLIC REPORTING ON PHYSICIAN COMPARE

Data collection year	Public reporting year	Reporting mechanism(s)	Quality measures and data for public reporting
2012	2013	Web Interface (WI), EHR, Registry, Claims.	Include an indicator for satisfactory reporters under PQRS, successful e-prescribers under eRx Incentive Program, and participants in the EHR Incentive Program.
2012	February 2014	WI	5 Diabetes Mellitus (DM) and Coronary Artery Disease (CAD) measures collected via the WI for group practices reporting under PQRS with a minimum sample size of 25 patients and Shared Savings Program ACOs.
2013	2014	WI, EHR, Registry, Claims.	Include an indicator for satisfactory reporters under PQRS, successful e-prescribers under eRx Incentive Program, and participants in the EHR Incentive Program. Include an indicator for EPs who earn a PQRS Maintenance of Certification Incentive and EPs who report the PQRS Cardiovascular Prevention measures group in support of Million Hearts.
2013	December 2014	WI	3 DM and 1 CAD measures collected via the WI for groups of 25 or more EPs with a minimum sample size of 20 patients.
2013	December 2014	Survey Vendor	6 CAHPS for ACO summary survey measures for Shared Savings Program ACOs.
2014	Expected to be 2015	WI, EHR, Registry, Claims.	Include an indicator for satisfactory reporters under PQRS and participants in the EHR Incentive Program. Include an indicator for EPs who earn a PQRS Maintenance of Certification Incentive and EPs who report the PQRS Cardiovascular Prevention measures group in support of Million Hearts.
2014	Expected to be late 2015	WI, EHR, Registry	All measures reported via the WI, 13 EHR, and 16 registry measures for group practices of 2 or more EPs reporting under PQRS with a minimum sample size of 20 patients. Include composites for DM and CAD, if available.
2014	Expected to be late 2015	WI, Survey Vendor Administrative Claims.	All measures reported by Shared Savings Program ACOs, including CAHPS for ACO and claims based measures.
2014	Expected to be late 2015	WI, Certified Survey Vendor.	Up to 12 CAHPS for PQRS summary measures for groups of 100 or more EPs reporting via the WI and group practices of 25 to 99 EPs reporting via a CMS-approved certified survey vendor.
2014	Expected to be late 2015	Registry, EHR, or Claims	A sub-set of 20 PQRS measures submitted by individual EPs that align with those available for group reporting via the WI and that are collected through registry, EHR, or claims with a minimum sample size of 20 patients.
2014	Expected to be late 2015	Registry	Measures from the Cardiovascular Prevention measures group reported by individual EPs in support of Million Hearts with a minimum sample size of 20 patients.

TABLE 18—SUMMARY OF PREVIOUSLY FINALIZED POLICIES FOR PUBLIC REPORTING ON PHYSICIAN COMPARE—Continued

Data collection year	Public reporting year	Reporting mechanism(s)	Quality measures and data for public reporting
2015	Expected to be late 2016	WI, EHR, Registry, Claims.	Include an indicator for satisfactory reporters under PQRS and participants in the EHR Incentive Program. Include an indicator for EPs who report 4 individual PQRS measures in support of Million Hearts.
2015	Expected to be late 2016	WI, EHR, Registry	All PQRS measures for group practices of 2 or more EPs.
2015	Expected to be late 2016	WI, Survey Vendor Administrative Claims.	All measures reported by Shared Savings Program ACOs, including CAHPS for ACOs and claims based measures.
2015	Expected to be late 2016	Certified Survey Vendor	All CAHPS for PQRS measures reported for groups of 2 or more EPs who meet the specified sample size requirements and collect data via a CMS-specified certified CAHPS vendor.
2015	Expected to be late 2016	Registry, EHR, or Claims	All PQRS measures for individual EPs collected through a registry, EHR, or claims.
2015	Expected to be late 2016	Registry, EHR, or Claims	4 PQRS measures reported by individual EPs in support of Million Hearts with a minimum sample size of 20 patients.
2015	Expected to be late 2016	QCDR	All individual EP QCDR measures, including PQRS and non-PQRS measures.

3. Proposed Policies for Public Data Disclosure on Physician Compare

We are expanding public reporting on Physician Compare by continuing to make a broad set of quality measures available for publication on the Web site. We started the phased approach with a small number of possible PQRS GPRO Web Interface measures for 2012 and have been steadily building on this to provide Medicare consumers with more information to help them make informed health care decisions. As a result, we are now proposing to add new data elements to the individual EP and/or group practice profile pages and to continue to publicly report a broad set of quality measures on the Web site.

a. Value Modifier

We propose to expand the section on each individual EP and group practice profile page that indicates Medicare quality program participation with a green check mark to include the names of those individual EPs and group practices who received an upward adjustment for the Value Modifier (VM). We propose to include this on Physician Compare annually. For the 2018 VM, this information would be based on 2016 data and included on the site no earlier than late 2017. The VM upward adjustment indicates that a physician or group has achieved one of the following: higher quality care at a lower cost; higher quality care at an average cost; or average quality care at a lower cost. The first goal of the HHS Strategic Plan is to strengthen health care. One of the ways to do this is to reduce the growth of health care costs while promoting high-value, effective care (Objective D, Strategic Goal 1).[3] This VM indicator can help consumers identify higher quality care provided at a lower cost. This means this type of quality information may be very useful to consumers as they work to choose the best possible health care available to them. Including the check mark is a way to share what can be a very complex concept in a user-friend, easy-to-understand format. We believe this is a positive first step in making this important information available to the public in a way that is most likely to be accurately interpreted and beneficial. We solicit comments on this proposal.

b. Million Hearts

In support of the HHS-wide Million Hearts initiative, we include an indicator for individual EPs who choose to report on specific ''ABCS'' (Appropriate Aspirin Therapy for those who need it, Blood Pressure Control, Cholesterol Management, and Smoking Cessation) measures (79 FR 67764). Based on available measures the criteria for this indicator have evolved over time. In 2015, an indicator was included if EPs satisfactorily reported four individual PQRS Cardiovascular Prevention measures. In previous years, the indicator was based on satisfactory reporting of the Cardiovascular Prevention measures group, which was not available via PQRS for 2015. To further support this initiative, we now propose to include on Physician Compare annually in the year following the year of reporting (for example, 2016 data will be included on Physician Compare in 2017) an indicator for individual EPs who satisfactorily report the new Cardiovascular Prevention measures group being proposed under PQRS, should this measures group be finalized. The Million Hearts initiative's primary goal is to improve cardiovascular heart health, and therefore, we believe it is important to continue supporting the program and acknowledging those physicians and other health care professionals working to excel in performance on the ABCS. We solicit comments on this proposal.

c. PQRS GPRO and ACO Reporting

Understanding the importance of including quality data on Physician Compare to support the goals of section 10331(a) of the Affordable Care Act, we finalized in the CY 2015 PFS final rule with comment period (79 FR 67547) a decision to publicly report on Physician Compare all PQRS GPRO measures collected in 2015 via the Web Interface, registry, or EHR. We propose to continue to make available for public reporting on Physician Compare on an annual basis all PQRS GPRO measures across all PQRS group practice reporting mechanisms—Web Interface, registry, and EHR– for groups of 2 or more EPs available in the year following the year the measures are reported. Similarly, all measures reported by Shared Savings Program ACOs, including CAHPS for ACO measures, would be available for public reporting on Physician Compare annually in the year following the year the measures are reported. For group practice and ACO measures, the measure performance rate will be represented on the Web site. We solicit comments on this proposal.

d. Individual EP PQRS Reporting

Consumer testing indicates that consumers are looking for measures regarding individual doctors and other health care professionals. As a result, we plan to make available for public reporting on Physician Compare all 2015 PQRS measures for individual EPs collected through a registry, EHR, or claims (79 FR 67773). Through

[3] *http://www.hhs.gov/strategic-plan/goal1.html.*

stakeholder outreach and consumer testing we have learned that these PQRS quality data provide the public with useful information to help consumers make informed decisions about their health care. As a result, we propose to continue to make all PQRS measures across all individual EP reporting mechanisms available for public reporting on Physician Compare annually in the year following the year the measures are reported (for example, 2016 data will be included on Physician Compare in 2017). For individual EP measures, the measure performance rate will be represented on the Web site. We solicit comments on this proposal.

e. Individual EP and Group Practice QCDR Measure Reporting

Stakeholder outreach and consumer testing have repeatedly shown that consumers find individual EP quality measures valuable and helpful when making health care decisions. Consumers want to know more about the individual EPs they can make an appointment to see for their health care needs. And expanding group practice-level public reporting ensures that more quality data are available to assist consumers with their decision making. We do appreciate, however, that not all specialties have a full complement of available quality measures specific to the work they do currently available through PQRS. As a result, we decided to make individual EP level Qualified Clinical Data Registry (QCDR) measures–both PQRS and non-PQRS measures—available for public reporting starting with 2015 data (79 FR 67774 through 67775). To further support the availability of quality measure data most relevant for all specialties, we propose to continue to make available for public reporting on Physician Compare all individual EP level QCDR PQRS and non-PQRS measure data that have been collected for at least a full year. In addition, we are now proposing to also make group practice level QCDR PQRS and non-PQRS measure data that have been collected for at least a full year available for public reporting. Previously, the PQRS program only included QCDR data at the individual EP level. In this proposed rule, CMS is proposing, under the PQRS, to expand QCDR data to be available to group practices as well. In this case, group practice refers to a group of 2 or more EPs billing under the same Tax Identification Number (TIN). We propose to publicly report these data annually in the year following the year the measures are reported. For both EP and group level measures, the measure performance rate will be represented on the Web site. We solicit comments on these proposals.

The QCDR would be required to declare during its self-nomination if it plans to post data on its own Web site and allow Physician Compare to link to it or if the QDCR will provide data to us for public reporting on Physician Compare. After a QCDR declares a public reporting method, that decision is final for the reporting year. If a declaration is not made, the data would be considered available for public reporting on Physician Compare.

f. Benchmarking

We previously proposed (79 FR 40389) a benchmark that aligned with the Shared Savings Program ACO benchmark methodology finalized in the November 2011 Shared Savings Program final rule (76 FR 67898) and amended in the CY 2014 PFS final rule with comment period (78 FR 74759). Benchmarks are important to ensuring that the quality data published on Physician Compare are accurately understood. A benchmark will allow consumers to more easily evaluate the information published by providing a point of comparison between groups and between individuals. However, given shortcomings when trying to apply the Shared Savings Program methodology to the group practice or individual EP setting, this proposal was not finalized. We noted we would discuss more thoroughly potential benchmarking methodologies with our stakeholders and evaluate other programs' methodologies to identify the best possible option for a benchmark for Physician Compare (79 FR 67772). To accomplish this, we reached out to stakeholders, including specialty societies, consumer advocacy groups, physicians and other health care professionals, 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 (TEP), we propose to publicly report on Physician Compare an item or measure-level benchmark derived using the Achievable Benchmark of Care (ABC™) [4] methodology annually based on the PQRS performance rates most recently available. For instance, in 2017 we would publicly report a benchmark derived from the 2016 PQRS performance rates. The specific measures the benchmark would be derived for would be determined once the data are available and analyzed. The benchmark would only be applied to those measures deemed valid and reliable and that are reported by enough EPs or group practices to produce a valid result (see 79 FR 67764 through 79 FR 67765 for a more detailed discussion regarding the types of analysis done to ensure data are suitable for public reporting). We solicit comments on this proposal.

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 individual EPs 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 will derive the benchmark 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 produces a benchmark that represents the best care provided to the top 10 percent of patients.

An Example: A doctor reports which of her patients with diabetes have maintained their blood pressure at a healthy level. There are four steps to establishing the benchmark for this measure.

(1) We look at the total number of patients with diabetes for all doctors who reported this diabetes measure.

(2) We rank doctors that reported this diabetes measure from highest performance score to lowest performance score to identify the set of top doctors 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 doctors also had blood pressure at a healthy level.

(4) This number is divided by the total number of patients with diabetes

[4] 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.

who were treated by the top doctors, producing the ABC™ benchmark.

To account for low denominators, ABC™ calls for the calculation of an adjusted performance fraction (AFP), a Bayesian Estimator. The AFP is calculated by dividing the actual number of patients receiving the intervention or the desired level of care plus 1 by the total number of patients in the total sample plus 2. This ensures that very small sample sizes do not over influence the benchmark and allows all data to be included in the benchmark calculation. To ensure that a sufficient number of cases are included by mean performance percent, ABC™ provides a minimum sufficient denominator (MSD) for each performance level. Together this ensures that all cases are appropriately accounted for and adequately figured in to the benchmark.

The ABC™ methodology for a publicly reported benchmark on Physician Compare would be based on the current year's data, so the benchmark would be appropriate regardless of the unique circumstances of data collection or the measures available in a given reporting year. We also propose to use the ABC™ methodology to generate a benchmark which can be used to systematically assign stars for the Physician Compare 5 star rating. ABC™ has been historically well received by the health care professionals 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.[5 6 7]

To summarize, we propose to publicly report on Physician Compare an item or measure-level benchmark derived using the Achievable Benchmark of Care (ABC™) methodology annually based on the PQRS performance rates most recently available (that is, in 2017 we would publicly report a benchmark derived from the 2016 PQRS performance rates), and use this benchmark to systematically assign stars for the Physician Compare 5 star rating. We solicit comments on this proposal.

g. Patient Experience of Care Measures

In the CY 2015 PFS final rule with comment period (79 FR 67547), we adopted a policy to publicly report patient experience data for all group practices of two or more EPs. Consumer testing shows that other patients' assessments of their experience resonate with consumers because it is important to them to hear about positive and negative experiences others have with physicians and other health care professionals. As a result, consumers report these patient experience data help them make an informed health care decision. Understanding the value consumers place on patient experience data and our commitment to reporting these data on Physician Compare, we propose to continue to make available for public reporting all patient experience data for all group practices of two or more EPs, who meet the specified sample size requirements and collect data via a CMS-specified certified CAHPS vendor, annually in the year following the year the measures are reported (for example, 2016 PQRS reported data will be included on the Web site in 2017). The patient experience data available that we propose to make available for public reporting are the CAHPS for PQRS measures, which include the CG–CAHPS core measures. For group practices, we propose to annually make available for public reporting a representation of the top box performance rate[8] for these 12 summary survey measures:

- Getting Timely Care, Appointments, and Information.
- How Well Providers Communicate.
- Patient's Rating of Provider.
- Access to Specialists.
- Health Promotion & Education.
- Shared Decision Making.
- Health Status/Functional Status.
- Courteous and Helpful Office Staff.
- Care Coordination.
- Between Visit Communication.
- Helping You to Take Medication as Directed.
- Stewardship of Patient Resources.

We solicit comments on this proposal.

h. Downloadable Database

(a) Addition of VM Information

To further aid in transparency, we also propose to add new data elements to the Physician Compare downloadable database (*https://data.medicare.gov/data/physician-compare*). Currently, the downloadable database includes all quality information publicly reported on Physician Compare, including quality program participation, and all measures submitted and reviewed and found to be statistically valid and reliable. We propose to add to the Physician Compare downloadable database for group practices and individual EPs the 2018 VM quality tiers for cost and quality, based on the 2016 data, noting if the group practice or EP is high, low, or average on cost and quality per the VM. We also propose to include a notation of the payment adjustment received based on the cost and quality tiers, and an indication if the individual EP or group practice was eligible to but did not report quality measures to CMS. The profile pages on Physician Compare are meant to provide information to average Medicare consumers that can help them identify quality health care and choose a quality clinician, while this database is geared toward health care professionals, industry insiders, and researchers who are more able to accurately use more complex data. Therefore, adding this information to the downloadable database promotes transparency and provides useful data to the public while we conduct consumer testing to ensure VM data beyond the indication for an upward adjustment discussed above can be packaged and explained in such a way that it is accurately interpreted, understood, and useful to average consumers. We solicit comments on this proposal.

(b) Addition of Utilization Data

In addition, we propose to add utilization data to the Physician Compare downloadable database. Utilization data is information generated from Medicare Part B claims on services and procedures provided to Medicare beneficiaries by physicians and other health care professionals; and are 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*). It provides counts of services and procedures rendered by health care professionals by Healthcare Common Procedure Coding System (HCPCS) code. Under section 104(e) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), Pub. L. 114–10, § 104, signed into law April 16, 2015; beginning with 2016, the Secretary shall integrate utilization data information on Physician Compare. This

[5] 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.

[6] 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.

[7] 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.

[8] Top Box score refers to the most favorable response category for a given measure. If the measure has a scale of ''always,'' ''sometimes,'' ''never,'' the Top Box score is ''always'' if this represents the most favorable response. For the CAHPS for PQRS doctor rating, the Top Box score is a rating of 9 or 10.

section of the law discusses data that can help empower people enrolled in Medicare by providing access to information about physician services. These data are very useful to the health care industry and to health care researchers and other stakeholders who can accurately interpret these data and use them in meaningful analysis. These data are less immediately useable in their raw form by the average Medicare consumer. As a result, we propose that the data be added to the downloadable database versus the consumer-focused Web site profile pages. Including these data in the Physician Compare downloadable database provides transparency without taking away from the information of most use to consumers on the main Web site. We solicit comments on this proposal.

(i) 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 other health care professional by a board of specialists in the relevant field. We currently include American Board of Medical Specialties (ABMS) data as part of individual EP profiles on Physician Compare. We appreciate that there are additional, well respected boards that are not included in the ABMS data currently available on Physician Compare that represent EPs and specialties represented on the Web site. Such board certification information is of interest to consumers as it provides additional information to use to evaluate and distinguish between EPs 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. Specifically, we are now proposing to add to the Web site board certification information from the American Board of Optometry (ABO) and American Osteopathic Association (AOA). Please note we are not endorsing any particular boards. These two specific boards showed interest in being added to the Web site and have demonstrated that they have the data to facilitate inclusion of this information on the Web site. These two boards also fill a gap, as the ABMS does not certify Optometrists and only certain types of DOs are covered by AMBS Osteopathic certification. In general, we will review interest from boards as it is brought to our attention, and if the necessary data are available and appropriate arrangements and agreements can be made to share the needed information with Physician Compare, additional board information could be added to the Web site in future. At this time, however, we are specifically proposing to include ABO and AOA Board Certification information on Physician Compare. We solicit comments on this proposal.

We solicit comments on all proposals. Increasing the measures and data elements for public reporting on Physician Compare at both the individual and group level will help accomplish the Web site's twofold purpose:

- To provide more information for consumers to encourage informed patient choice.
- To create explicit incentives for physicians to maximize performance.

Table 19 summarizes the Physician Compare measure and participation data proposals detailed in this section.

TABLE 19—SUMMARY OF PROPOSED MEASURE AND PARTICIPATION DATA FOR PUBLIC REPORTING

Data collection year *	Publication year *	Data type	Reporting mechanism	Proposed quality measures and data for public reporting
2016	2017	PQRS, PQRS, GPRO, EHR, and Million Hearts.	Web Interface, EHR, Registry, Claims.	Include an indicator for satisfactory reporters under PQRS, participants in the EHR Incentive Program, and EPs who satisfactorily report the Cardiovascular Prevention measures group proposed under PQRS in support of Million Hearts.
2016	2018	PQRS, PQRS, GPRO.	Web Interface, EHR, Registry, Claims.	Include an indicator for individual EPs and group practices who receive an upward adjustment for the VM.
2016	2017	PQRS, GPRO	Web Interface, EHR, Registry.	All PQRS GPRO measures reported via the Web Interface, EHR, and registry that are available for public reporting for group practices of 2 or more EPs. Publicly report an item-level benchmark, as appropriate.
2016	2017	ACO	Web Interface, Survey Vendor Claims.	All measures reported by Shared Savings Program ACOs, including CAHPS for ACOs.
2016	2017	CAHPS for PQRS	CMS-Specified Certified CAHPS Vendor.	All CAHPS for PQRS measures for groups of 2 or more EPs who meet the specified sample size requirements and collect data via a CMS-specified certified CAHPS vendor.
2016	2017	PQRS	Registry, EHR, or Claims	All PQRS measures for individual EPs collected through a registry, EHR, or claims. Publicly report an item-level benchmark, as appropriate.
2016	2017	QCDR data	QCDR	All individual EP and group practice QCDR measures.
2016	2017	Utilization data	Claims	Utilization data for individual EPs in the downloadable database.
2016	2017	PQRS, PQRS, GPRO.	Web Interface, EHR, Registry, Claims.	The following data for group practices and individual EPs in the downloadable database: • The VM quality tiers for cost and quality, noting if the group practice or EP is high, low, or neutral on cost and quality per the VM. • A notation of the payment adjustment received based on the cost and quality tiers. • An indication if the individual EP or group practice was eligible to but did not report quality measures to CMS.

* Note that these data are proposed to be reported annually. The table only provides the first year in which these proposals would begin on an annual basis, and such dates also serve to illustrate the data collection year in relation to the publication year. Therefore, after 2016, 2017 data would be publicly reported in 2018, 2018 data would be publicly reported in 2019, etc.

4. Seeking Public Comment for Possible Future Rulemaking

a. Quality Measures

In addition to these proposals, we seek comment on several new data elements for possible inclusion on the individual EP and group profile pages of Physician Compare. In future years, we will consider expanding public reporting to include additional quality measures. We know there are gaps in the measures currently available for public reporting on Physician Compare. Understanding this, we would like to hear from stakeholders about the types of quality measures that will help us fill these gaps and meet the needs of consumers and stakeholders. Therefore, we seek comment on potential measures that would benefit future public reporting on Physician Compare. We are working to identify possible data sources and we seek comment on the measure concepts, as well as potential specific measures of interest. The quality measures that would be considered for future posting on Physician Compare are those that have been comprehensively vetted and tested, and are trusted by the physician community.

b. Medicare Advantage

We also seek comment on adding Medicare Advantage information to Physician Compare individual EP and group practice profile pages. Specifically, we are seeking comment on adding information on the relevant EP and group practice profile pages about which Medicare Advantage health plans the EP or group accepts and making this information a link to more information about that plan on the Medicare.gov Plan Finder Web site. An increasing number of Medicare clinicians provide services via Medicare Advantage. Medicare Advantage quality data is reported via Plan Finder at the plan level. As a result, physicians and other health care professionals who participate in Medicare Advantage do not have quality measure data available for public reporting on Physician Compare. Adding a link between Physician Compare clinicians participating in Medicare Advantage plans and the associated quality data available for those plans on Plan Finder ensures that consumers have access to all of the quality data available to make an informed health care decision.

c. Value Modifier

We also seek comment on including additional VM cost and quality data on Physician Compare. Specifically, we seek comment on including in future years an indicator for a downward and neutral VM adjustment on group practice and individual EP profile pages. We also seek comment on including the VM quality composite or other VM quality performance data on Physician Compare group practice and individual EP profile pages and/or the Physician Compare downloadable database. Similarly, we seek comment on including the VM cost composite or other VM cost measure data on Physician Compare group practice and individual EP profile pages and/or the downloadable database. These VM quality and cost measures ultimately help determine the payment adjustment and are an indication of whether the individual or group is meeting the Affordable Care Act goals of improving quality while lowering cost. Specifically, including this cost data is consistent with the section 10331(a)(2) of the Affordable Care Act as it is an assessment of efficiency. However, these data are complex and we need time to establish the best method for public reporting and to ensure this information is accurately understood and interpreted by consumers. Therefore, we only seek comment at this time.

d. Open Payments Data

We currently make Open Payments data available at *http://www.cms.gov/openpayments/*. Consumer testing has indicated that these data are of great interest to consumers. Consumers have indicated that this level of transparency is important to them and access to this information on Physician Compare increases their ability to find and evaluate the information. We seek comment about including Open Payments data on individual EP profile pages. Although these data are already publicly available, consumer testing has also indicated that additional context, wording, and data display considerations can help consumers better understand the information. We are now seeking comment on adding these data to Physician Compare; to the extent it is feasible and appropriate. Prior to considering a formal proposal, we can continue to test these data with consumers to establish the context and framing needed to best ensure these data are accurately understood and presented in a way that assists decision making. Therefore, we only seek comment at this time.

e. Measure Stratification

Finally, we seek comment on including individual EP and group practice-level quality measure data stratified by race, ethnicity, and gender on Physician Compare, if feasible and appropriate (*i.e.* statistically appropriate, etc.). By stratification we mean that we will report quality measures for each group of a given category. For example, if we were to report a measure for blood pressure control stratified by sex, we would report a performance score for women and one for men. We also seek comment on potential quality measures, including composite measures, for future postings on Physician Compare that could help consumers and stakeholders monitor trends in health equity. Inclusion of data stratified by race and ethnicity and gender, as well as the inclusion of other measures of health equity would help ensure that HHS is beginning to work to fulfill one of the Affordable Care Act goals of reporting data on race, ethnicity, sex, primary language, and disability status through public postings on HHS Web sites and other dissemination strategies (see ACA Section 4302).

We are specifically seeking comment on these issues. Any data recommended in these areas for public disclosure on Physician Compare would be addressed through separate notice-and-comment rulemaking.

I. Physician Payment, Efficiency, and Quality Improvements—Physician Quality Reporting System

This section contains the proposed requirements for the Physician Quality Reporting System (PQRS). The PQRS, as set forth in sections 1848(a), (k), and (m) of the Act, is a quality reporting program that provides incentive payments (which ended in 2014) and payment adjustments (which began in 2015) to eligible professionals (EPs) and group practices based on whether they satisfactorily report data on quality measures for covered professional services furnished during a specified reporting period or to individual EPs based on whether they satisfactorily participate in a qualified clinical data registry (QCDR). Please note that section 101(b)(2)(A) of the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10, enacted on April 16, 2015) (MACRA) amends section 1848(a)(8)(A) by striking ''2015 or any subsequent year'' and inserting ''each of 2015 through 2018.'' This amendment authorizes the end of the PQRS in 2018 and beginning of a new program, which may incorporate aspects of the PQRS, the Merit-based Incentive Payment System (MIPS).

The proposed requirements primarily focus on our proposals related to the 2018 PQRS payment adjustment, which will be based on an EP's or a group practice's reporting of quality measures

data during the 12-month calendar year reporting period occurring in 2016 (that is, January 1 through December 31, 2016). Please note that, in developing these proposals, we focused on aligning our requirements, to the extent appropriate and feasible, with other quality reporting programs, such as the Medicare Electronic Health Record (EHR) Incentive Program for EPs, the Physician Value-Based Payment Modifier (VM), and the Medicare Shared Savings Program. In previous years, we have made various strides in our ongoing efforts to align the reporting requirements in CMS' quality reporting programs to reduce burden on the EPs and group practices that participate in these programs. We continue to focus on alignment as we develop our proposals for the 2018 PQRS payment adjustment below.

In addition, please note that, in our quality programs, we are beginning to emphasize the reporting of certain types of measures, such as outcome measures, as well as measures within certain NQS domains. Indeed, in its March 2015 report (available at *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=79068*) the Measure Applications Partnership (MAP) has suggested that CMS place an emphasis on higher quality measures, such as functional outcome measures. For example, in the PQRS, we have placed an emphasis on the reporting of the Consumer Assessment of Healthcare Providers and Systems (CAHPS) for PQRS survey and cross-cutting measures that promote the health of larger populations and that are applicable to a larger number of patients. As discussed further in this section, we are proposing to require the reporting of the CAHPS for PQRS survey for groups of 25 or more EPs who register to participate in the PQRS Group Practice Reporting Option (GPRO) and select the GPRO web interface as the reporting mechanism. In addition, we are proposing to continue to require the reporting of at least 1 applicable cross-cutting measure if an EP sees at least 1 Medicare patient. Furthermore, when reporting measures via a QCDR, we emphasize the reporting of outcome measures, as well as resource use, patient experience of care, efficiency/appropriate use, or patient safety measures.

The PQRS regulations are specified in § 414.90. The program requirements for the 2007 through 2014 PQRS incentives and the 2015 through 2017 PQRS payment adjustments that were previously established, as well as information on the PQRS, including related laws and established requirements, are available at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html.* In addition, the 2013 PQRS and eRx Experience Report, which provides information about EP participation in PQRS, is available for download at *http://cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2013_PQRS_eRx_Experience_Report_zip.zip.*

1. The Definition of EP for Purposes of Participating in the PQRS

CMS implemented the first PQRS payment adjustment on January 1, 2015. Specifically, EPs who did not satisfactorily report data on quality measures during the 12-month calendar year reporting period occurring in 2013 are receiving a 1.5 percent negative adjustment during CY 2015 on all of the EPs' Part B covered professional services under the Medicare Physician Fee Schedule (PFS). The 2015 PQRS payment adjustment applies to payments for all of the EPs' Part B covered professional services furnished under the PFS. We received many questions surrounding who must participate in the PQRS to avoid the PQRS payment adjustment. As such, we seek to clarify here who is required to participate in the PQRS for purposes of the payment adjustments in this rule.

Please note that there are no hardship or low volume exemptions for the PQRS payment adjustment. All EPs who furnish covered professional services must participate in the PQRS each year by meeting the criteria for satisfactory reporting—or, in lieu of satisfactory reporting, satisfactory participation in a QCDR—to avoid the PQRS payment adjustments.

The PQRS payment adjustment applies to EPs who furnish covered professional services. The definition of an EP for purposes of participating in the PQRS is specified in section 1848(k)(3)(B) of the Act. Specifically, the term ''eligible professional'' (EP) means any of the following: (i) A physician; (ii) a practitioner described in section 1842(b)(18)(C); (iii) a physical or occupational therapist or a qualified speech-language pathologist; or (iv) beginning with 2009, a qualified audiologist (as defined in section 1861(ll)(3)(B)). The term ''covered professional services'' is defined in section 1848(k)(3)(A) of the Act to mean services for which payment is made under, or is based on, the Medicare PFS established under section 1848 and which are furnished by an EP.

EPs in Critical Access Hospitals Billing under Method II (CAH–IIs): We note that EPs in critical access hospitals billing under Method II (CAH–IIs) were previously not able to participate in the PQRS. Due to a change we made in the manner in which EPs in CAH–IIs are reimbursed by Medicare, it is now feasible for EPs in CAH–IIs to participate in the PQRS. EPs in CAH–IIs may participate in the PQRS using ALL reporting mechanisms available, including the claims-based reporting mechanism.

EPs Who Practice in Rural Health Clinics (RHCs) and/or Federally Qualified Health Centers (FQHCs): Services furnished at RHCs and/or FQHCs for which payment is not made under, or based on, the Medicare PFS, or which are not furnished by an EP, are not subject to the PQRS negative payment adjustment. With respect to EPs who furnish covered professional services at RHCs and/or FQHCs that are paid under the Medicare PFS, we note that we are currently unable to assess PQRS participation for these EPs due to the way in which these EPs bill for services under the PFS. Therefore, EPs who practice in RHCs and/or FQHCs would not be subject to the PQRS payment adjustment.

EPs Who Practice in Independent Diagnostic Testing Facilities (IDTFs) and Independent Laboratories (ILs): We note that due to the way IDTF and IL suppliers and their employee EPs are enrolled with Medicare and claims are submitted for services furnished by these suppliers and billed by the IDTF or IL, we are unable to assess PQRS participation for these EPs. Therefore, claims submitted for services performed by EPs who perform services as employee of, or on a reassignment basis to, IDTFs or ILs would not be subject to the PQRS payment adjustment.

2. Requirements for the PQRS Reporting Mechanisms

The PQRS includes the following reporting mechanisms: Claims; qualified registry; EHR (including direct EHR products and EHR data submission vendor products); the GPRO web interface; certified survey vendors, for CAHPS for PQRS survey measures; and the QCDR. Under the existing PQRS regulation, § 414.90(h) through (k) govern which reporting mechanisms are available for use by individuals and group practices for the PQRS incentive and payment adjustment. This section contains our proposals to change the QCDR and qualified registry reporting mechanisms. Please note that we are not proposing to make changes to the other PQRS reporting mechanisms.

One of our goals, as indicated in the Affordable Care Act, is to report data on

race, ethnicity, sex, primary language, and disability status. A necessary step toward fulfilling this mission is the collection and reporting of quality data, stratified by race, ethnicity, sex, primary language, and disability status. The agency intends to require the collection of these data elements within each of the PQRS reporting mechanisms. Although we are not proposing in this proposed rule to require the collection of these data elements, we are seeking comments regarding the facilitators and obstacles providers and vendors may face in collecting and reporting these attributes. Additionally, we seek comments on preference for a phased-in approach, perhaps starting with a subset of measures versus a requirement across all possible measures and mechanisms with an adequate timeline for implementation.

a. Proposed Changes to the Requirements for the QCDR

We are required, under section 1848(m)(3)(E)(i) of the Act, to establish requirements for an entity to be considered a QCDR. Such requirements must include a requirement that the entity provide the Secretary with such information, at such times, and in such manner as the Secretary determines necessary to carry out this subsection. Section 1848(m)(3)(E)(iv) of the Act, as added by section 601(b)(1)(B) of the American Taxpayer Relief Act of 2012 (ATRA), requires CMS to consult with interested parties in carrying out this provision. Below, we seek to clarify issues related to QCDR self-nomination, as well as propose a change related to the requirements for an entity to become a QCDR.

Who May Apply to Self-Nominate to Become a QCDR: We have received many questions related to what entities may participate in the PQRS as a QCDR. We note that § 414.90(b) defines a QCDR as a CMS-approved entity that has self-nominated and successfully completed a qualification process showing that it collects medical and/or clinical data for the purpose of patient and disease tracking to foster improvement in the quality of care provided to patients. A QCDR must perform the following functions:

- Submit quality measures data or results to CMS for purposes of demonstrating that, for a reporting period, its EPs have satisfactorily participated in PQRS. A QCDR must have in place mechanisms for the transparency of data elements and specifications, risk models, and measures.
- Submit to CMS, for purposes of demonstrating satisfactory participation, quality measures data on multiple payers, not just Medicare patients.
- Provide timely feedback, at least four times a year, on the measures at the individual participant level for which the QCDR reports on the EP's behalf for purposes of the individual EP's satisfactory participation in the QCDR.
- Possess benchmarking capacity that compares the quality of care an EP provides with other EPs performing the same or similar functions.

We established further details regarding the requirements to become a QCDR in the CYs 2014 and 2015 PFS final rules (78 FR 74467 through 74473 and 79 FR 67779 through 67782). Please note that the requirements we established were not meant to prohibit entities that meet the basic definition of a QCDR outlined in § 414.90(b) from self-nominating to participate in the PQRS as a QCDR. As long as the entity meets the basic definition of a QCDR provided in § 414.90(b), we encourage the entity to self-nominate to become a QCDR.

Self-Nomination Period: We established a deadline for an entity becoming a QCDR to submit a self-nomination statement—specifically, self-nomination statements must be received by CMS by 5:00 p.m., eastern standard time (e.s.t.), on January 31 of the year in which the clinical data registry seeks to be qualified (78 FR 74473). However, we did not specify when the QCDR self-nomination period opens. We received feedback from entities that believed they needed more time to self-nominate. Typically, we open the self-nomination period on January 1 of the year in which the clinical data registry seeks to be qualified. While it is not technically feasible for us to extend the self-nomination deadline past January 31, we will open the QCDR self-nomination period on December 1 of the prior year to allow more time for entities to self-nominate. This would provide entities with an additional month to self-nominate.

Proposed Establishment of a QCDR Entity: In the CY 2014 PFS final rule (78 FR 74467), we established the requirement that, for an entity to become qualified for a given year, the entity must be in existence as of January 1 the year prior to the year for which the entity seeks to become a QCDR (for example, January 1, 2013, to be eligible to participate for purposes of data collected in 2014). We established this criterion to ensure that an entity seeking to become a QCDR is well-established prior to self-nomination. We have received feedback from entities that this requirement is overly burdensome, as it delays entities otherwise fully capable of becoming a QCDR from participating in the PQRS. To address these concerns while still ensuring that an entity seeking to become a QCDR is well-established, beginning in 2016, we propose to modify this requirement to require the following: For an entity to become qualified for a given year, the entity must be in existence as of January 1 the year for which the entity seeks to become a QCDR (for example, January 1, 2016, to be eligible to participate for purposes of data collected in 2016). We invite public comment on this proposal.

Attestation Statements for QCDRs Submitting Quality Measures Data during Submission: In the CY 2014 PFS final rule, to ensure that the data provided by the QCDR is correct, we established the requirement that QCDRs provide CMS a signed, written attestation statement via email which states that the quality measure results and any and all data, including numerator and denominator data, provided to CMS are accurate and complete (78 FR 74472). In lieu of submitting an attestation statement via email, beginning in 2016, we propose to allow QCDRs to attest during the data submission period that the quality measure results and any and all data including numerator and denominator data provided to CMS will be accurate and complete using a web-based check box mechanism available at *https://www.qualitynet.org/portal/server.pt/community/pqri_home/212.* We believe it is less burdensome for QCDRs to check a box acknowledging and attesting to the accuracy of the data they provide, rather than having to email a statement to CMS. Please note that, if this proposal is finalized, QCDRs will no longer be able to submit this attestation statement via email. We invite public comment on this proposal.

In addition, we noted in the CY 2015 PFS final rule (79 FR 67903) that entities wishing to become QCDRs would have until March 31 of the year in which it seeks to become a QCDR to submit measure information the entity intends to report for the year, which included submitting the measure specifications for non-PQRS measures the QCDR intends to report for the year. However, we have experienced issues related to the measures data we received during the 2013 reporting year. These issues prompt us to more closely analyze the measures for which an entity intends to report as a QCDR. Therefore, so that we may vet and analyze these vendors to determine whether they are fully ready to be qualified to participate in the PQRS as a QCDR, we propose to require that all

other documents that are necessary to analyze the vendor for qualification be provided to CMS at the time of self-nomination, that is, by no later than January 31 of the year in which the vendor intends to participate in the PQRS as a QCDR (that is, January 31, 2016 to participate as a QCDR for the reporting periods occurring in 2016). This includes, but is not limited to, submission of the vendor's data validation plan as well as the measure specifications for the non-PQRS measures the entity intends to report. In addition, please note that after the entity submits this information on January 31, it cannot later change any of the information it submitted to us for purposes of qualification. For example, once an entity submits measure specifications on non-PQRS measures, it cannot later modify the measures specifications the entity submitted. Please note that this does not prevent the entity from providing supplemental information if requested by CMS.

Data Validation Requirements: A validation strategy details how the qualified registry will determine whether EPs and GPRO group practices have submitted data accurately and satisfactorily on the minimum number of their eligible patients, visits, procedures, or episodes for a given measure. Acceptable validation strategies often include such provisions as the qualified registry being able to conduct random sampling of their participant's data, but may also be based on other credible means of verifying the accuracy of data content and completeness of reporting or adherence to a required sampling method. The current guidance on validation strategy is available at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2015_RegistryVendorCriteria.pdf.* In analyzing our requirements, we believe adding the following additional requirements will help mitigate issues that may occur when collecting, calculating, and submitting quality measures data to CMS. Therefore, we propose that, beginning in 2016, a QCDR must provide the following information to CMS at the time of self-nomination to ensure that QCDR data is valid:

- Organization Name (Specify Sponsoring Organization name and qualified registry name if the two are different).
- Program Year.
- Vendor Type (for example, qualified registry).
- Provide the method(s) by which the entity obtains data from its customers: claims, web-based tool, practice management system, EHR, other (please explain). If a combination of methods (Claims, Web Based Tool, Practice Management System, EHR, and/or other) is utilized, please state which method(s) the entity utilizes to collect reporting numerator and denominator data.
- Indicate the method the entity will use to verify the accuracy of each Tax Identification Number (TIN) and National Provider Identifier's (NPI) it is intending to submit (that is, National Plan and Provider Enumeration System (NPPES), CMS claims, tax documentation).
- Describe the method that the entity will use to accurately calculate both reporting rates and performance rates for measures and measures groups based on the appropriate measure type and specification. For composite measures or measures with multiple performance rates, the entity must provide us with the methodology the entity uses for these composite measures and measures with multiple performance rates.
- Describe the process that the entity will use for completion of a randomized audit of a subset of data prior to the submission to CMS. Periodic examinations may be completed to compare patient record data with submitted data and/or ensure PQRS measures were accurately reported based on the appropriate Measure Specifications (that is, accuracy of numerator, denominator, and exclusion criteria).
- If applicable, provide information on the entity's sampling methodology. For example, it is encouraged that 3 percent of the TIN/NPIs be sampled with a minimum sample of 10 TIN/NPIs or a maximum sample of 50 TIN/NPIs. For each TIN/NPI sampled, it is encouraged that 25 percent of the TIN/NPI's patients (with a minimum sample of 5 patients or a maximum sample of 50 patients) should be reviewed for all measures applicable to the patient.
- Define a process for completing a detailed audit if the qualified registry's validation reveals inaccuracy and describe how this information will be conveyed to CMS.

QCDRs must perform the validation outlined in the validation strategy and send evidence of successful results to CMS for data collected in the reporting periods occurring in 2016. The Data Validation Execution Report must be sent via email to the QualityNet Help Desk at *Qnetsupport@sdps.org* by 5:00 p.m. ET on June 30, 2016. The email subject should be ''PY2015 Qualified Registry Data Validation Execution Report.''

Submission of Quality Measures Data for Group Practices: Section 101(d)(1)(B) of the MACRA amends section 1848(m)(3)(D) of the Act by inserting ''and, for 2016 and subsequent years, subparagraph (A) or (C)'' after ''subparagraph (A)''. This change authorizes CMS to create an option for EPs participating in the GPRO to report quality measures via a QCDR. As such, in addition to being able to submit quality measures data for individual EPs, we propose that QCDRs also have the ability to submit quality measures data for group practices.

b. Proposed Changes to the Requirements for Qualified Registries

Attestation Statements for Registries Submitting Quality Measures Data: In the CY 2013 PFS final rule, we finalized the following requirement to ensure that the data provided by a registry is correct: We required that the registry provide CMS a signed, written attestation statement via mail or email which states that the quality measure results and any and all data including numerator and denominator data provided to CMS are accurate and complete for each year the registry submits quality measures data to CMS (77 FR 69180). In lieu of submitting an attestation statement via email or mail, beginning in 2016, we propose to allow registries to attest during the submission period that the quality measure results and any and all data including numerator and denominator data provided to CMS will be accurate and complete using a web-based check box mechanism available at *https://www.qualitynet.org/portal/server.pt/community/pqri_home/212.* We believe it is less burdensome for registries to check a box acknowledging and attesting to the accuracy of the data they provide, rather than having to email a statement to CMS. Please note that, if this proposal is finalized, qualified registries will no longer be able to submit this attestation statement via email or mail. We invite public comment on this proposal.

In addition, so that we may vet and analyze these vendors to determine whether they are fully ready to be qualified to participate in the PQRS as a qualified registry, we propose to require that all other documents that are necessary to analyze the vendor for qualification be provided to CMS at the time of self-nomination, that is, by no later than January 31 of the year in which the vendor intends to participate in the PQRS as a qualified registry (that is, January 31, 2016 to participate as a qualified registry for the reporting periods occurring in 2016). This

includes, but is not limited to, submission of the vendor's data validation plan. Please note that this does not prevent the entity from providing supplemental information if requested by CMS.

Data Validation Requirements: A validation strategy details how the qualified registry will determine whether EPs and GPRO group practices have submitted accurately and satisfactorily on the minimum number of their eligible patients, visits, procedures, or episodes for a given measure. Acceptable validation strategies often include such provisions as the qualified registry being able to conduct random sampling of their participant's data, but may also be based on other credible means of verifying the accuracy of data content and completeness of reporting or adherence to a required sampling method. The current guidance on validation strategy is available at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2015_RegistryVendorCriteria.pdf.* In analyzing our requirements, we believe adding the following additional requirements will help mitigate issues that may occur when collecting, calculating, and submitting quality measures data to CMS. Therefore, we propose that, beginning in 2016, a QCDR must provide the following information to CMS at the time of self-nomination to ensure that data submitted by a qualified registry is valid:

- Organization Name (specify the sponsoring entity name and qualified registry name if the two are different).
- Program Year.
- Vendor Type (for example, qualified registry).
- Provide the method(s) by which the entity obtains data from its customers: claims, web-based tool, practice management system, EHR, other (please explain). If a combination of methods (Claims, Web Based Tool, Practice Management System, EHR, and/or other) is utilized, please state which method(s) the entity utilizes to collect its reporting numerator and denominator data.
- Indicate the method the entity will use to verify the accuracy of each TIN and NPI it is intending to submit (that is, NPPES, CMS claims, tax documentation).
- Describe how the entity will verify that EPs or group practices report on at least 1 measure contained in the cross-cutting measure set if the EP or group practice sees at least 1 Medicare patient in a face-to-face encounter. Describe how the entity will verify that the data provided is complete and contains the entire cohort of data.
- Describe the method that the entity will use to accurately calculate both reporting rates and performance rates for measures and measures groups based on the appropriate measure type and specification.
- Describe the method the entity will use to verify that only the measures in the applicable PQRS Claims and Registry Individual Measure Specifications (that is, the 2016 PQRS Claims and Registry Individual Measure Specifications for data submitted for reporting periods occurring in 2016) and applicable PQRS Claims and Registry Measures Groups Specifications (that is, the 2016 PQRS Claims and Registry Measures Groups Specifications for data submitted for reporting periods occurring in 2016) are utilized for submission.
- Describe the process that the entity will use for completion of a randomized audit of a subset of data prior to the submission to CMS. Periodic examinations may be completed to compare patient record data with submitted data and/or ensure PQRS measures were accurately reported based on the appropriate Measure Specifications (that is, accuracy of numerator, denominator, and exclusion criteria).
- If applicable, provide information on the entity's sampling methodology. For example, it is encouraged that 3 percent of the TIN/NPIs be sampled with a minimum sample of 10 TIN/NPIs or a maximum sample of 50 TIN/NPIs. For each TIN/NPI sampled, it is encouraged that 25 percent of the TIN/NPI's patients (with a minimum sample of 5 patients or a maximum sample of 50 patients) should be reviewed for all measures applicable to the patient.
- Define a process for completing a detailed audit if the qualified registry's validation reveals inaccuracy and describe how this information will be conveyed to CMS.
- Registries must maintain the ability to randomly request and receive documentation from providers to verify accuracy of data. Registries must also provide CMS access to review the Medicare beneficiary data on which the applicable PQRS registry-based submissions are based or provide to CMS a copy of the actual data (if requested for validation purposes).

Qualified registries must perform the validation outlined in the validation strategy and send evidence of successful results to CMS for data collected for the applicable reporting periods. The Data Validation Execution Report must be sent via email to the QualityNet Help Desk at *Qnetsupport@sdps.org* by 5:00 p.m. ET on June 30 of the year in which the reporting period occurs (that is, June 30, 2016 for reporting periods occurring in 2016). The email subject should be ''PY2015 Qualified Registry Data Validation Execution Report.''

c. Auditing of Entities Submitting PQRS Quality Measures Data

We are in the process of auditing PQRS participants, including vendors who submit quality measures data. We believe it is essential for vendors to corporate with this audit process. In order to ensure that CMS has adequate information to perform an audit of a vendor, we are proposing that, beginning in 2016, any vendor submitting quality measures data for the PQRS (for example, entities participating the PQRS as a qualified registry, QCDR, direct EHR, or DSV) comply with the following requirements:

- The vendor make available to CMS the contact information of each EP on behalf of whom it submits data. The contact information will include, at a minimum, the EP practice's phone number, address, and, if applicable email.
- The vendor must retain all data submitted to CMS for the PQRS program for a minimum of seven years.

We invite public comment on these proposals.

3. Proposed Criteria for the Satisfactory Reporting for Individual EPs for the 2018 PQRS Payment Adjustment

Section 1848(a)(8) of the Act, as added by section 3002(b) of the Affordable Care Act, provides that for covered professional services furnished by an EP during 2015 or any subsequent year, if the EP does not satisfactorily report data on quality measures for covered professional services for the quality reporting period for the year, the fee schedule amount for services furnished by such professional during the year (including the fee schedule amount for purposes of determining a payment based on such amount) shall be equal to the applicable percent of the fee schedule amount that would otherwise apply to such services. For 2016 and subsequent years, the applicable percent is 98.0 percent.

a. Proposed Criterion for the Satisfactory Reporting of Individual Quality Measures via Claims and Registry for Individual EPs for the 2018 PQRS Payment Adjustment

We finalized the following criteria for satisfactory reporting for the submission of individual quality measures via

claims and registry for 2017 PQRS payment adjustment (see Table 50 at 79 FR 67796): For the applicable 12-month reporting period, the EP would report at least 9 measures, covering at least 3 of the NQS domains, OR, if less than 9 measures apply to the EP, report on each measure that is applicable, AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted. For an EP who reports fewer than 9 measures covering less than 3 NQS domains via the claims- or registry-based reporting mechanism, the EP would be subject to the measure application validity (MAV) process, which would allow us to determine whether the EP should have reported quality data codes for additional measures. To meet the criteria for the 2017 PQRS payment adjustment, we added the following requirement: Of the measures reported, if the EP sees at least 1 Medicare patient in a face-to-face encounter, as we propose to define that term below, the EP would report on at least 1 measure contained in the PQRS cross-cutting measure set.

To be consistent with the satisfactory reporting criterion we finalized for the 2017 PQRS payment adjustment, we are proposing to amend § 414.90(j) to specify the same criterion for individual EPs reporting via claims and registry for the 2018 PQRS payment adjustment. Specifically, for the 12-month reporting period for the 2018 PQRS payment adjustment, the EP would report at least 9 measures, covering at least 3 of the NQS domains AND report each measure for at least 50 percent of the EP's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Of the measures reported, if the EP sees at least 1 Medicare patient in a face-to-face encounter, as we propose to define that term below, the EP would report on at least 1 measure contained in the PQRS cross-cutting measure set. If less than 9 measures apply to the EP, the EP would report on each measure that is applicable, AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.

For what defines a ''face-to-face'' encounter, for purposes of proposing to require reporting of at least 1 cross-cutting measure, we propose to determine whether an EP had a ''face-to-face'' encounter by assessing whether the EP billed for services under the PFS that are associated with face-to-face encounters, such as whether an EP billed general office visit codes, outpatient visits, and surgical procedures. We would not include telehealth visits as face-to-face encounters for purposes of the proposal requiring reporting of at least 1 cross-cutting measure. For our current list of face-to-face encounter codes for the requirement to report a cross-cutting measure, please see *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/FacetoFace_Encounter_CodeList_01302015.zip.*

In addition, we understand that there may be instances where an EP may not have at least 9 measures applicable to an EP's practice. In this instance, like the criterion we finalized for the 2017 payment adjustment (*see* Table 50 at 79 FR 67796), an EP reporting on less than 9 measures would still be able to meet the satisfactory reporting criterion via claims and registry if the EP reports on each measure that is applicable to the EP's practice. If an EP reports on less than 9 measures, the EP would be subject to the MAV process, which would allow us to determine whether an EP should have reported quality data codes for additional measures. In addition, the MAV process will also allow us to determine whether an EP should have reported on any of the PQRS cross-cutting measures. The MAV process we are proposing to implement for claims and registry is the same process that was established for reporting periods occurring in 2015 for the 2017 PQRS payment adjustment. For more information on the claims and registry MAV process, please visit the measures section of the PQRS Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/MeasuresCodes.html.*

We seek public comment on our proposed satisfactory reporting criteria for individual EPs reporting via claims or registry for the 2018 PQRS payment adjustment.

b. Proposed Criterion for Satisfactory Reporting of Individual Quality Measures via EHR for Individual EPs for the 2018 PQRS Payment Adjustment

We finalized the following criterion for the satisfactory reporting for individual EPs reporting individual measures via a direct EHR product or an EHR data submission vendor product for the 2017 PQRS payment adjustment (*see* Table 50 at 79 FR 67796): For the applicable 12-month reporting period, report at least 9 measures covering at least 3 of the NQS domains. If an EP's direct EHR product or EHR data submission vendor product does not contain patient data for at least 9 measures covering at least 3 domains, then the EP must report all of the measures for which there is Medicare patient data. Although all-payer data may be included in the file, an EP must report on at least 1 measure for which there is Medicare patient data for their submission to be considered for PQRS.

To be consistent with the criterion we finalized for the 2017 PQRS payment adjustment, as well as to continue to align with the final criterion for meeting the clinical quality measure (CQM) component of achieving meaningful use under the Medicare EHR Incentive Program, we are proposing to amend § 414.90(j) to specify the criterion for the satisfactory reporting for individual EPs to report individual measures via a direct EHR product or an EHR data submission vendor product for the 2018 PQRS payment adjustment. Specifically, the EP would report at least 9 measures covering at least 3 of the NQS domains. If an EP's direct EHR product or EHR data submission vendor product does not contain patient data for at least 9 measures covering at least 3 domains, then the EP would be required to report all of the measures for which there is Medicare patient data. An EP would be required to report on at least 1 measure for which there is Medicare patient data.

We seek public comment on this proposal.

c. Proposed Criterion for Satisfactory Reporting of Measures Groups via Registry for Individual EPs for the 2018 PQRS Payment Adjustment

We finalized the following criterion for the satisfactory reporting for individual EPs to report measures groups via registry for the 2017 PQRS payment adjustment (see Table 50 at 79 FR 67796): For the applicable 12-month reporting period, report at least 1 measures group AND report each measures group for at least 20 patients, the majority (11 patients) of which must be Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted.

To be consistent with the criterion we finalized for the 2017 PQRS payment adjustment, we are proposing to amend § 414.90(j) to specify the same criterion for the satisfactory reporting for individual EPs to report measures groups via registry for the 2018 PQRS payment adjustment. Specifically, for the 12-month reporting period for the 2018 PQRS payment adjustment, the EP would report at least 1 measures group AND report each measures group for at

least 20 patients, the majority (11 patients) of which would be required to be Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate would not be counted.

We seek public comment on our proposed satisfactory reporting criterion for individual EPs reporting measures groups via registry for the 2018 PQRS payment adjustment.

4. Satisfactory Participation in a QCDR by Individual EPs

Section 601(b) of the ATRA amended section 1848(m)(3) of the Act, by redesignating subparagraph (D) as subparagraph (F) and adding new subparagraphs (D) and (E), to provide for a new standard for individual EPs to satisfy the PQRS beginning in 2014, based on satisfactory participation in a QCDR.

a. Proposed Criterion for the Satisfactory Participation for Individual EPs in a QCDR for the 2018 PQRS Payment Adjustment

Section 1848(a)(8) of the Act provides that for covered professional services furnished by an EP during 2015 or any subsequent year, if the EP does not satisfactorily report data on quality measures for covered professional services for the quality reporting period for the year, the fee schedule amount for services furnished by such professional during the year shall be equal to the applicable percent of the fee schedule amount that would otherwise apply to such services. For 2016 and subsequent years, the applicable percent is 98.0 percent.

Section 1848(m)(3)(D) of the Act, as added by section 601(b) of the ATRA, authorizes the Secretary to treat an individual EP as satisfactorily submitting data on quality measures under section 1848(m)(3)(A) of the Act if, in lieu of reporting measures under section 1848(k)(2)(C) of the Act, the EP is satisfactorily participating in a QCDR for the year. ''Satisfactory participation'' is a relatively new standard under the PQRS and is an analogous standard to the standard of ''satisfactory reporting'' data on covered professional services that EPs who report through other mechanisms must meet to avoid the PQRS payment adjustment. Currently, § 414.90(e)(2) states that individual EPs must be treated as satisfactorily reporting data on quality measures if the individual EP satisfactorily participates in a QCDR.

To be consistent with the number of measures reported for the satisfactory participation criterion we finalized for the 2017 PQRS payment adjustment (*see* Table 50 at 79 FR 67796), for purposes of the 2018 PQRS payment adjustment (which would be based on data reported during the 12-month period that falls in CY 2016), we propose to revise § 414.90(k) to use the same criterion for individual EPs to satisfactorily participate in a QCDR for the 2018 PQRS payment adjustment. Specifically, for the 12-month reporting period for the 2018 PQRS payment adjustment, the EP would report at least 9 measures available for reporting under a QCDR covering at least 3 of the NQS domains, AND report each measure for at least 50 percent of the EP's patients. Of these measures, the EP would report on at least 2 outcome measures, OR, if 2 outcomes measures are not available, report on at least 1 outcome measures and at least 1 of the following types of measures—resource use, patient experience of care, efficiency/appropriate use, or patient safety.

We seek public comment on this proposal.

5. Proposed Criteria for Satisfactory Reporting for Group Practices Participating in the GPRO

In lieu of reporting measures under section 1848(k)(2)(C) of the Act, section 1848(m)(3)(C) of the Act provides the Secretary with the authority to establish and have in place a process under which EPs in a group practice (as defined by the Secretary) shall be treated as satisfactorily submitting data on quality measures. Accordingly, this section III.K.4 contains our proposed satisfactory reporting criteria for group practices participating in the GPRO. Please note that, for a group practice to participate in the PQRS GPRO in lieu of participating as individual EPs, a group practice is required to register to participate in the PQRS GPRO. For more information on GPRO participation, please visit *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Group_Practice_Reporting_Option.html.* For more information on registration, please visit *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Self-Nomination-Registration.html.*

a. The CAHPS for PQRS Survey

In the CY 2015 PFS final rule, we required group practices of 100 or more EPs that register to participate in the GPRO for 2015 reporting to select a CMS-certified survey vendor to report the CAHPS for PQRS survey, regardless of the reporting mechanism the group practice chooses (79 FR 67794). We also stated that group practices would bear the cost of administering the CAHPS for PQRS survey. To collect CAHPS for PQRS data from smaller groups, for purposes of the 2018 PQRS payment adjustment (which would be based on data reported during the 12-month period that falls in CY 2016), we propose to require group practices of 25 or more EPs that register to participate in the GPRO and select the GPRO web interface as the reporting mechanism to select a CMS-certified survey vendor to report CAHPS for PQRS. We believe this proposal is consistent with our effort to collect CAHPS for PQRS data whenever possible. However, we are excluding from this proposal group practices that report measures using the qualified registry, EHR, and QCDR reporting mechanisms, because we have discovered that certain group practices reporting through these mechanisms may be highly specialized or otherwise unable to report CAHPS for PQRS. Please note that we are still proposing to keep CAHPS for PQRS reporting as an option for all group practices. We note that all group practices that would be required to report or voluntarily elect to report CAHPS for PQRS would need to continue to select and pay for a CMS-certified survey vendor to administer the CAHPS for PQRS survey on their behalf. We invite public comment on this proposal.

We understand that this proposed requirement may cause concern for smaller group practices who choose to participate in the PQRS via the GPRO web interface, particularly those who have not yet administered the CAHPS for PQRS survey (as we introduced reporting of the CAHPS for PQRS survey in 2014) or those group practices who do not believe the CAHPS for PQRS survey applies to their practice. Since the introduction of the CAHPS for PQRS survey, we have received questions as on when the CAHPS for PQRS survey applies to a group practice. In this section below, we seek to clarify questions we have received regarding the administration of the CAHPS for PQRS survey. We note that this proposed requirement would only apply to group practices of 25 or more EPs for whom CAHPS for PQRS applies.

In addition, we note that we finalized a 12-month reporting period for the administration of the CAHPS for PQRS survey. However, as group practice s have until June of the applicable reporting period (that is, June 30, 2016 for the 12-month reporting period occurring January 1, 2016–December 31, 2016) to elect to participate in the PQRS as a GPRO and administer CAHPS for PQRS, it is not technically feasible for us to collect data for purposes of CAHPS for PQRS until the close of the GPRO

registration period. As such, the administration of the CAHPS for PQRS survey only contains 6-months of data. We do not believe this significantly alters the administration of CAHPS for PQRS, as we believe that 6-months of data provides an adequate sample of the 12-month reporting period.

The CAHPS for PQRS survey consists of the core CAHPS Clinician & Group Survey developed by AHRQ, plus additional survey questions to meet CMS' information and program needs. The survey questions are aggregated into 12 content domains called Summary Survey Measures (SSMs). SSMs contain one or more survey questions. The CAHPS for PQRS survey consists of the following survey measures: (1) Getting timely care, appointments, & information; (2) How well your providers communicate; (3) Patient's rating of provider; (4) Access to specialists; (5) Health promotion and education; (6) Shared decision making; (7) Health status & functional status; (8) Courteous & helpful office staff; (9) Care coordination; (10) Between visit communication; (11) Helping you take medications as directed; and (12) Stewardship of patient resources. For the CAHPS for PQRS survey to apply to a group practice, the group practice must have an applicable focal provider as well as meet the minimum beneficiary sample for the CAHPS for PQRS survey.

Identifying Focal Providers: Which provider does the survey ask about? The provider named in the survey provided the beneficiary with the plurality of the beneficiary's primary care services delivered by the group practice. Plurality of care is based on the number of primary care service visits to a provider. The provider named in the survey can be a physician (primary care provider or specialist), nurse practitioner (NP), physician's assistant (PA), or clinical nurse specialist (CNS).

Exclusion Criteria for Focal Providers: Several specialty types are excluded from selection as focal provider such as anesthesiology, pathology, psychiatry optometry, diagnostic radiology, chiropractic, podiatry, audiology, physical therapy, occupational therapy, clinical psychology, diet/nutrition, emergency medicine, addiction medicine, critical care, and clinical social work. Hospitalists are also excluded from selection as a focal provider.

Beneficiary Sample Selection: CMS retrospectively assigns Medicare beneficiaries to your group practice based on whether the group provided a wide range of primary care services. Assigned beneficiaries must have a plurality of their primary care claims delivered by the group practice. Assigned beneficiaries have at least one month of both Part A and Part B enrollment and no months of Part A only enrollment or Part B only enrollment. Assigned beneficiaries cannot have any months of enrollment in a Medicare Advantage plan. Regardless of the number of EPs, some group practices may not have a sufficient number of assigned beneficiaries to participate in the CAHPS for PQRS survey.

We draw a sample of Medicare beneficiaries assigned to a practice. For practices with 100 or more eligible providers, the desired sample is 860, and the minimum sample is 416. For practices with 25 to 99 eligible providers, the desired sample is 860, and the minimum sample is 255. For practices with 2 to 24 eligible providers, the desired sample is 860, and the minimum sample is 125. The following beneficiaries are excluded in the practice's patient sample: Beneficiaries under age 18 at the time of the sample draw; beneficiaries known to be institutionalized at the time of the sample draw; and beneficiaries with no eligible focal provider. For more information on CAHPS for PQRS, please visit the PQRS Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/CMS-Certified-Survey-Vendor.html*.

b. Proposed Criteria for Satisfactory Reporting on PQRS Quality Measures via the GPRO Web Interface for the 2018 PQRS Payment Adjustment

Under our authority specified for the group practice reporting requirements under section 1848(m)(3)(C) of the Act—to be consistent with the criterion we finalized for the satisfactory reporting of PQRS quality measures for group practices registered to participate in the GPRO for the 2017 PQRS payment adjustment using the GPRO web interface (see Table 51 at 79 FR 67797)—we propose to amend § 414.90(j) to specify criteria for the satisfactory reporting of PQRS quality measures for group practices registered to participate in the GPRO for the 12-month reporting period for the 2018 PQRS payment adjustment using the GPRO web interface for groups practices of 25 or more EPs for which the CAHPS for PQRS survey does not apply. Specifically, the group practice would report on all measures included in the web interface; AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice would report on 100 percent of assigned beneficiaries. In other words, we understand that, in some instances, the sampling methodology CMS provides will not be able to assign at least 248 patients on which a group practice may report, particularly those group practices on the smaller end of the range of 25–99 EPs. If the group practice is assigned less than 248 Medicare beneficiaries, then the group practice would report on 100 percent of its assigned beneficiaries. A group practice would be required to report on at least 1 measure in the GPRO web interface. Although the criteria proposed above are specified for groups practices of 25 or more EPs, please note that, given our proposal below to require that group practices of 25 or more EPs report the CAHPS for PQRS survey, the criteria proposed above would apply to a group practices of 25 or more EPs only if the CAHPS for PQRS survey does not apply to the group practice.

Furthermore, similar to the criteria we established for the 2017 PQRS payment adjustment (*see* Table 51 at 79 FR 67797), as we specified in section III.K.4.a., we propose to require that group practices of 25 or more EPs who elect to report quality measures via the GPRO web interface report the CAHPS for PQRS survey, if applicable. Therefore, similar to the criteria we established for the 2017 PQRS payment adjustment in accordance with section 1848(m)(3)(C) of the Act (see Table 51 at 79 FR 67797), we propose to amend § 414.90(j) to specify criteria for the satisfactory reporting of PQRS quality measures for group practices of 25 or more EPs that registered to participate in the GPRO for the 12-month reporting period for the 2018 PQRS payment adjustment using the GPRO web interface and for which the CAHPS for PQRS survey applies. Specifically, if a group practice chooses to use the GPRO web interface in conjunction with reporting the CAHPS for PQRS survey measures, we propose to specify the criterion for satisfactory reporting for the 2018 PQRS payment adjustment. For the 12-month reporting period for the 2018 PQRS payment adjustment, the group practice would report all CAHPS for PQRS survey measures via a certified survey vendor. In addition, the group practice would report on all measures included in the GPRO web interface; AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each

module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice would report on 100 percent of assigned beneficiaries. A group practice would be required to report on at least 1 measure for which there is Medicare patient data.

For assignment of patients for group practices reporting via the GPRO web interface, in previous years, we have aligned with the Medicare Shared Savings Program methodology of beneficiary assignment (see 77 FR 69195). However, for the 2017 PQRS payment adjustment, we used a beneficiary attribution methodology utilized within the VM for the claims-based quality measures and cost measures that is slightly different from the Medicare Shared Savings Program assignment methodology that applied in 2015, namely (1) eliminating the primary care service pre-step that is statutorily required for the Shared Savings Program and (2) including NPs, PAs, and CNSs in step 1 rather than in step 2 of the attribution process. We believe that aligning with the VM's method of attribution is appropriate, as the VM is directly tied to participation in the PQRS (79 FR 67790). Therefore, to be consistent with the sampling methodology we used for the 2017 PQRS payment adjustment, we propose to continue using the attribution methodology used for the VM for the GPRO web interface beneficiary assignment methodology for the 2018 PQRS payment adjustment and future years.

As we clarified in the CY 2015 PFS final rule with comment period (79 FR 67790), if a group practice has no Medicare patients for which any of the GPRO measures are applicable, the group practice will not meet the criteria for satisfactory reporting using the GPRO web interface. Therefore, to meet the criteria for satisfactory reporting using the GPRO web interface, a group practice must be assigned and have sampled at least 1 Medicare patient for any of the applicable GPRO web interface measures. If a group practice does not typically see Medicare patients for which the GPRO web interface measures are applicable, or if the group practice does not have adequate billing history for Medicare patients to be used for assignment and sampling of Medicare patients into the GPRO web interface, we advise the group practice to participate in the PQRS via another reporting mechanism.

We invite public comment on these proposals.

c. Proposed Criteria for Satisfactory Reporting on Individual PQRS Quality Measures for Group Practices Registered To Participate in the GPRO via *Registry* for the 2018 PQRS Payment Adjustment

We finalized the following satisfactory reporting criteria for the submission of individual quality measures via registry for group practices of 2–99 EPs in the GPRO for the 2017 PQRS payment adjustment (see Table 51 at 79 FR 67797): Report at least 9 measures, covering at least 3 of the NQS domains, OR, if less than 9 measures covering at least 3 NQS domains apply to the group practice, report up to 8 measures covering 1–3 NQS domains for which there is Medicare patient data, AND report each measure for at least 50 percent of the group practice's Medicare Part B FFS patients seen during the reporting period to which the measure applies.

Consistent with the group practice reporting criteria we finalized for the 2017 PQRS payment adjustment in accordance with section 1848(m)(3)(C) of the Act, for those group practices that choose to report using a qualified registry, we propose to amend § 414.90(j) to specify satisfactory reporting criteria via qualified registry for group practices of 2+ EPs who select to participate in the GPRO for the 2018 PQRS payment adjustment. Specifically, for the 12-month 2018 PQRS payment adjustment reporting period, the group practice would report at least 9 measures, covering at least 3 of the NQS domains. Of these measures, if a group practice has an EP that sees at least 1 Medicare patient in a face-to-face encounter, the group practice would report on at least 1 measure in the PQRS cross-cutting measure set. If the group practice reports on less than 9 measures covering at least 3 NQS domains, the group practice would report on each measure that is applicable to the group practice, AND report each measure for at least 50 percent of the EP's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.

In addition, if a group practice of 2+ EPs chooses instead to use a qualified registry in conjunction with reporting the CAHPS for PQRS survey measures, for the 12-month reporting period for the 2018 PQRS payment adjustment, the group practice would report all CAHPS for PQRS survey measures via a certified survey vendor, and report at least 6 additional measures, outside of the CAHPS for PQRS survey, covering at least 2 of the NQS domains using the qualified registry. If less than 6 measures apply to the group practice, the group practice must report on each measure that is applicable to the group practice. Of the non-CAHPS for PQRS measures, if any EP in the group practice sees at least 1 Medicare patient in a face-to-face encounter, the group practice would be required to report on at least 1 measure in the PQRS cross-cutting measure set. We note that this proposed option to report 6 additional measures, including at least 1 cross-cutting measure if a group practice sees at least 1 Medicare patient in a face-to-face encounter, is consistent with the proposed criterion for satisfactory reporting for the 2018 PQRS payment adjustment via qualified registry.

As with individual reporting, we understand that there may be instances where a group practice may not have at least 9 measures applicable to a group practice's practice. In this instance, like the criterion we finalized for the 2017 PQRS payment adjustment (*see* Table 51 at 79 FR 67797), a group practice reporting on less than 9 measures would still be able to meet the satisfactory reporting criterion via registry if the group practice reports on each measure that is applicable to the group practice's practice. If a group practice reports on less than 9 measures, the group practice would be subject to the MAV process, which would allow us to determine whether a group practice should have reported quality data codes for additional measures and/or measures covering additional NQS domains. In addition, if a group practice does not report on at least 1 cross-cutting measure and the group practice has at least 1 EP who sees at least 1 Medicare patient in a face-to-face encounter, the MAV will also allow us to determine whether a group practice should have reported on any of the PQRS cross-cutting measures. The MAV process we are proposing to implement for registry reporting is a similar process that was established for reporting periods occurring in 2015 for the 2017 PQRS payment adjustment. However, please note that the MAV process for the 2018 PQRS payment adjustment will now allow us to determine whether a group practice should have reported on at least 1 cross-cutting measure. For more information on the registry MAV process, please visit *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2014_PQRS_Registry_MeasureApplicabilityValidation_12132013.zip.*

We invite public comment on these proposals.

d. Proposed Criteria for Satisfactory Reporting on Individual PQRS Quality Measures for Group Practices Registered To Participate in the GPRO via *EHR* for the 2018 PQRS Payment Adjustment

For EHR reporting, consistent with the criterion finalized for the 2017 PQRS payment adjustment (*see* Table 51 at 79 FR 67797) that aligns with the criteria established for meeting the CQM component of meaningful use under the Medicare EHR Incentive Program and in accordance with the group practice reporting requirements under section 1848(m)(3)(C) of the Act, for those group practices that choose to report using an EHR, we propose to amend § 414.90(j) to specify satisfactory reporting criteria via a direct EHR product or an EHR data submission vendor product for group practices of 2+ EPs who select to participate in the GPRO for the 2018 PQRS payment adjustment. Specifically, for the 12-month reporting period for the 2018 PQRS payment adjustment, the group practice would report 9 measures covering at least 3 domains. If the group practice's direct EHR product or EHR data submission vendor product does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report all of the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

In addition, if a group practice of 2+ EPs chooses instead to use a direct EHR product or EHR data submission vendor in conjunction with reporting the CAHPS for PQRS survey measures, for the 12-month reporting period for the 2018 PQRS payment adjustment, the group practice would report all CAHPS for PQRS survey measures via a certified survey vendor, and report at least 6 additional measures, outside of the CAHPS for PQRS survey, covering at least 2 of the NQS domains using the direct EHR product or EHR data submission vendor product. If less than 6 measures apply to the group practice, the group practice must report all applicable measures. Of the non-CAHPS for PQRS measures that must be reported in conjunction with reporting the CAHPS for PQRS survey measures, a group practice would be required to report on at least 1 measure for which there is Medicare patient data. We note that this proposed option to report 6 additional measures is consistent with the proposed criterion for satisfactory reporting for the 2018 PQRS payment adjustment via EHR without CAHPS for PQRS, since both criteria assess a total of 3 domains.

We invite public comment on these proposals.

e. Satisfactory Participation in a QCDR for Group Practices Registered To Participate in the GPRO via a *QCDR* for the 2018 PQRS Payment Adjustment

Section 101(d)(1)(B) of the MACRA amends section 1848(m)(3)(D) of the Act by inserting ''and, for 2016 and subsequent years, subparagraph (A) or (C)'' after ''subparagraph (A)''. This change authorizes CMS to create an option for EPs participating in the GPRO to report quality measures via a QCDR.

As such, please note that we are modifying § 414.90(k) to indicate that group practices may also use a QCDR to participate in the PQRS.

f. Proposed Reporting Period for the Satisfactory Participation by Individual EPs in a QCDR for the 2018 PQRS Payment Adjustment

Section 1848(m)(3)(D) of the Act, as redesignated and added by section 601(b) of the America Taxpayer Relief Act of 2012 and further amended by MACRA, authorizes the Secretary to treat a group practice as satisfactorily submitting data on quality measures under section 1848(m)(3)(A) of the Act if the group practice is satisfactorily participating in a QCDR for the year. Given that satisfactory participation is with regard to the year, and to provide consistency with the reporting period applicable to individual EPs who participate in the PQRS via a QCDR, we propose to revise § 414.90(k) to specify a 12-month, CY reporting period from January 1, 2016 through December 31, 2016 for group practices participating in the GPRO to satisfactorily participate in a QCDR for purposes of the 2018 PQRS payment adjustment. We are proposing a 12-month reporting period. Based on our experience with the 12 and 6-month reporting periods for the PQRS incentives, we believe that data on quality measures collected based on 12-months provides a more accurate assessment of actions performed in a clinical setting than data collected based on shorter reporting periods. In addition, we believe a 12-month reporting period is appropriate given that the full calendar year would be utilized with regard to the participation by the group practice in the QCDR. We invite public comment on the proposed 12-month, CY 2016 reporting period for the satisfactory participation of group practices in a QCDR for the 2018 PQRS payment adjustment.

g. Proposed Criteria for Satisfactory Participation in a QCDR for Group Practices Registered To Participate in the GPRO via a *QCDR* for the 2018 PQRS Payment Adjustment

To be consistent with individual reporting criteria that we finalized for the 2017 PQRS payment adjustment (*see* Table 50 at 79 FR 67796) as well as our proposed individual reporting criteria for the 2018 PQRS payment adjustment, for purposes of the 2018 PQRS payment adjustment (which would be based on data reported during the 12-month period that falls in CY 2016), we propose to amend § 414.90(j) to use the same criterion for group practices as individual EPs to satisfactorily participate in a QCDR for the 2018 PQRS payment adjustment. Specifically, for the 12-month reporting period for the 2018 PQRS payment adjustment, the group practice would report at least 9 measures available for reporting under a QCDR covering at least 3 of the NQS domains, AND report each measure for at least 50 percent of the group practice's patients. Of these measures, the group practice would report on at least 2 outcome measures, OR, if 2 outcomes measures are not available, report on at least 1 outcome measures and at least 1 of the following types of measures—resource use, patient experience of care, efficiency/appropriate use, or patient safety.

Tables 20 and 21 reflect our proposed criteria for satisfactory reporting—or, in lieu of satisfactory reporting, satisfactory participation in a QCDR—for the 2018 PQRS payment adjustment:

TABLE 20—SUMMARY OF PROPOSED REQUIREMENTS FOR THE 2018 PQRS PAYMENT ADJUSTMENT: INDIVIDUAL REPORTING CRITERIA FOR THE SATISFACTORY REPORTING OF QUALITY MEASURES DATA VIA CLAIMS, QUALIFIED REGISTRY, AND EHRS AND SATISFACTORY PARTICIPATION CRITERION IN QCDRS

Reporting period	Measure type	Reporting mechanism	Satisfactory reporting/satisfactory participation criteria
12-month (Jan 1–Dec 31, 2016).	Individual Measures.	Claims	Report at least 9 measures, covering at least 3 of the NQS domains AND report each measure for at least 50 percent of the EP's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Of the measures reported, if the EP sees at least 1 Medicare patient in a face-to-face encounter, the EP will report on at least 1 measure contained in the PQRS cross-cutting measure set. If less than 9 measures apply to the EP, the EP would report on each measure that is applicable), AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.
12-month (Jan 1–Dec 31, 2016).	Individual Measures.	Qualified Registry	Report at least 9 measures, covering at least 3 of the NQS domains AND report each measure for at least 50 percent of the EP's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Of the measures reported, if the EP sees at least 1 Medicare patient in a face-to-face encounter, the EP will report on at least 1 measure contained in the PQRS cross-cutting measure set. If less than 9 measures apply to the EP, the EP would report on each measure that is applicable, AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.
12-month (Jan 1–Dec 31, 2016).	Individual Measures.	Direct EHR Product or EHR Data Submission Vendor Product.	Report 9 measures covering at least 3 of the NQS domains. If an EP's direct EHR product or EHR data submission vendor product does not contain patient data for at least 9 measures covering at least 3 domains, then the EP would be required to report all of the measures for which there is Medicare patient data. An EP would be required to report on at least 1 measure for which there is Medicare patient data.
12-month (Jan 1–Dec 31, 2016).	Measures Groups	Qualified Registry	Report at least 1 measures group AND report each measures group for at least 20 patients, the majority (11 patients) of which are required to be Medicare Part B FFS patients. Measures groups containing a measure with a 0 percent performance rate will not be counted.
12-month (Jan 1–Dec 31, 2016).	Individual PQRS measures and/or non-PQRS measures reportable via a QCDR.	Qualified Clinical Data Registry (QCDR).	Report at least 9 measures available for reporting under a QCDR covering at least 3 of the NQS domains, AND report each measure for at least 50 percent of the EP's patients. Of these measures, the EP would report on at least 2 outcome measures, OR, if 2 outcomes measures are not available, report on at least 1 outcome measures and at least 1 of the following types of measures—resource use, patient experience of care, efficiency/appropriate use, or patient safety.

TABLE 21—SUMMARY OF PROPOSED REQUIREMENTS FOR THE 2018 PQRS PAYMENT ADJUSTMENT: GROUP PRACTICE REPORTING CRITERIA FOR SATISFACTORY REPORTING OF QUALITY MEASURES DATA VIA THE GPRO

Reporting period	Group practice size	Measure type	Reporting mechanism	Satisfactory reporting criteria
12-month (Jan 1–Dec 31, 2016).	25+ EPs (if CAHPS for PQRS does not apply).	Individual GPRO Measures in the GPRO Web Interface.	GPRO Web Interface.	Report on all measures included in the web interface; AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice must report on 100 percent of assigned beneficiaries. In other words, we understand that, in some instances, the sampling methodology we provide will not be able to assign at least 248 patients on which a group practice may report, particularly those group practices on the smaller end of the range of 25–99 EPs. If the group practice is assigned less than 248 Medicare beneficiaries, then the group practice must report on 100 percent of its assigned beneficiaries. A group practice must report on at least 1 measure for which there is Medicare patient data.

TABLE 21—SUMMARY OF PROPOSED REQUIREMENTS FOR THE 2018 PQRS PAYMENT ADJUSTMENT: GROUP PRACTICE REPORTING CRITERIA FOR SATISFACTORY REPORTING OF QUALITY MEASURES DATA VIA THE GPRO—Continued

Reporting period	Group practice size	Measure type	Reporting mechanism	Satisfactory reporting criteria
12-month (Jan 1–Dec 31, 2016).	25+ EPs (if CAHPS for PQRS applies).	Individual GPRO Measures in the GPRO Web Interface + CAHPS for PQRS.	GPRO Web Interface + CMS-Certified Survey Vendor.	The group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor. In addition, the group practice must report on all measures included in the GPRO web interface; AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice must report on 100 percent of assigned beneficiaries. A group practice will be required to report on at least 1 measure for which there is Medicare patient data. Please note that, if the CAHPS for PQRS survey is applicable to a group practice who reports quality measures via the GPRO web interface, the group practice must administer the CAHPS for PQRS survey in addition to reporting the GPRO web interface measures.
12-month (Jan 1–Dec 31, 2016).	2+ EPs	Individual Measures.	Qualified Registry	Report at least 9 measures, covering at least 3 of the NQS domains. Of these measures, if a group practice sees at least 1 Medicare patient in a face-to-face encounter, the group practice would report on at least 1 measure in the PQRS cross-cutting measure set. If less than 9 measures covering at least 3 NQS domains apply to the group practice, the group practice would report on each measure that is applicable to the group practice, AND report each measure for at least 50 percent of the group's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.
12-month (Jan 1–Dec 31, 2016).	2+ EPs that elect CAHPS for PQRS.	Individual Measures + CAHPS for PQRS.	Qualified Registry + CMS-Certified Survey Vendor.	The group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor, and report at least 6 additional measures, outside of the CAHPS for PQRS survey, covering at least 2 of the NQS domains using the qualified registry. If less than 6 measures apply to the group practice, the group practice must report on each measure that is applicable to the group practice. Of the additional measures that must be reported in conjunction with reporting the CAHPS for PQRS survey measures, if any EP in the group practice sees at least 1 Medicare patient in a face-to-face encounter, the group practice must report on at least 1 measure in the PQRS cross-cutting measure set.
12-month (Jan 1–Dec 31, 2016).	2+ EPs	Individual Measures.	Direct EHR Product or EHR Data Submission Vendor Product.	Report 9 measures covering at least 3 domains. If the group practice's direct EHR product or EHR data submission vendor product does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report all of the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.
12-month (Jan 1–Dec 31, 2016).	2+ EPs that elect CAHPS for PQRS.	Individual Measures + CAHPS for PQRS.	Direct EHR Product or EHR Data Submission Vendor Product + CMS-Certified Survey Vendor.	The group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor, and report at least 6 additional measures, outside of CAHPS for PQRS, covering at least 2 of the NQS domains using the direct EHR product or EHR data submission vendor product. If less than 6 measures apply to the group practice, the group practice must report all of the measures for which there is Medicare patient data. Of the additional 6 measures that must be reported in conjunction with reporting the CAHPS for PQRS survey measures, a group practice would be required to report on at least 1 measure for which there is Medicare patient data.

TABLE 21—SUMMARY OF PROPOSED REQUIREMENTS FOR THE 2018 PQRS PAYMENT ADJUSTMENT: GROUP PRACTICE REPORTING CRITERIA FOR SATISFACTORY REPORTING OF QUALITY MEASURES DATA VIA THE GPRO—Continued

Reporting period	Group practice size	Measure type	Reporting mechanism	Satisfactory reporting criteria
12-month (Jan 1–Dec 31, 2016).	2+ EPs	Individual PQRS measures and/or non-PQRS measures reportable via a QCDR.	Qualified Clinical Data Registry (QCDR).	Report at least 9 measures available for reporting under a QCDR covering at least 3 of the NQS domains, AND report each measure for at least 50 percent of the group practice's patients. Of these measures, the group practice would report on at least 2 outcome measures, OR, if 2 outcomes measures are not available, report on at least 1 outcome measures and at least 1 of the following types of measures—resource use, patient experience of care, efficiency/appropriate use, or patient safety.

6. Statutory Requirements and Other Considerations for the Selection of PQRS Quality Measures for Meeting the Criteria for Satisfactory Reporting for 2016 and Beyond for Individual EPs and Group Practices

Annually, we solicit or ''Call for Measures'' from the public for possible inclusion in the PQRS. During the Call for Measures, we request measures for inclusion in PQRS that meet the following statutory and other criteria.

Sections 1848(k)(2)(C) and 1848(m)(3)(C)(i) of the Act, respectively, govern the quality measures reported by individual EPs and group practices under the PQRS. Under section 1848(k)(2)(C)(i) of the Act, the PQRS quality measures shall be such measures selected by the Secretary from measures that have been endorsed by the entity with a contract with the Secretary under section 1890(a) of the Act, which is currently the National Quality Forum (NQF). However, in the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the NQF, section 1848(k)(2)(C)(ii) of the Act authorizes the Secretary to specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. In light of these statutory requirements, we believe that, except in the circumstances specified in the statute, each PQRS quality measure must be endorsed by the NQF. Additionally, section 1848(k)(2)(D) of the Act requires that for each PQRS quality measure, the Secretary shall ensure that EPs have the opportunity to provide input during the development, endorsement, or selection of measures applicable to services they furnish. The statutory requirements under section 1848(k)(2)(C) of the Act, subject to the exception noted previously, require only that the measures be selected from measures that have been endorsed by the entity with a contract with the Secretary under section 1890(a) of the Act (that is, the NQF) and are silent as to how the measures that are submitted to the NQF for endorsement are developed.

The steps for developing measures applicable to physicians and other EPs prior to submission of the measures for endorsement may be carried out by a variety of different organizations. We do not believe there needs to be special restrictions on the type or make-up of the organizations carrying out this process of development of physician measures, such as restricting the initial development to physician-controlled organizations. Any such restriction would unduly limit the development of quality measures and the scope and utility of measures that may be considered for endorsement as voluntary consensus standards for purposes of the PQRS.

In addition to section 1848(k)(2)(C) of the Act, section 1890A of the Act, which was added by section 3014(b) of the Affordable Care Act, requires that the Secretary establish a pre-rulemaking process under which certain steps occur for the selection of certain categories of quality and efficiency measures, one of which is that the entity with a contract with the Secretary under section 1890(a) of the Act (that is, the NQF) convene multi-stakeholder groups to provide input to the Secretary on the selection of such measures. These categories are described in section 1890(b)(7)(B) of the Act, and include such measures as the quality measures selected for reporting under the PQRS. In accordance with section 1890A(a)(1) of the Act, the NQF convened multi-stakeholder groups by creating the MAP. Section 1890A(a)(2) of the Act requires that the Secretary must make publicly available by December 1st of each year a list of the quality and efficiency measures that the Secretary is considering for selection through rulemaking for use in the Medicare program. The NQF must provide CMS with the MAP's input on the selection of measures by February 1st of each year. The lists of measures under consideration for selection through rulemaking in 2015 are available at *http://www.qualityforum.org/map/.*

As we noted above, section 1848(k)(2)(C)(ii) of the Act provides an exception to the requirement that the Secretary select measures that have been endorsed by the entity with a contract under section 1890(a) of the Act (that is, the NQF). We may select measures under this exception if there is a specified area or medical topic for which a feasible and practical measure has not been endorsed by the entity, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Under this exception, aside from NQF endorsement, we requested that stakeholders apply the following considerations when submitting measures for possible inclusion in the PQRS measure set:

- Measures that are not duplicative of another existing or proposed measure.
- Measures that are further along in development than a measure concept.
- We are not accepting claims-based-only reporting measures in this process.
- 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 include the NQS domain for care coordination and communication.
- Measures that include the NQS domain for patient experience and patient-reported outcomes.
- Measures that address efficiency, cost and resource use.

a. Proposed PQRS Quality Measures

Taking into consideration the statutory and non-statutory criteria we described previously, this section contains our proposals for the inclusion or removal of measures in PQRS for 2016 and beyond. We are classifying all proposed measures against six domains based on the NQS's six priorities, as follows:

(1) Patient Safety. These are measures that reflect the safe delivery of clinical services in all healthcare settings. These measures may address a structure or process that is designed to reduce risk in the delivery of healthcare or measure the occurrence of an untoward outcome such as adverse events and complications of procedures or other interventions.

(2) Person and Caregiver-Centered Experience and Outcomes. These are measures that reflect the potential to improve patient-centered care and the quality of care delivered to patients. They emphasize the importance of collecting patient-reported data and the ability to impact care at the individual patient level, as well as the population level. These are measures of organizational structures or processes that foster both the inclusion of persons and family members as active members of the health care team and collaborative partnerships with providers and provider organizations or can be measures of patient-reported experiences and outcomes that reflect greater involvement of patients and families in decision making, self-care, activation, and understanding of their health condition and its effective management.

(3) Communication and Care Coordination. These are measures that demonstrate appropriate and timely sharing of information and coordination of clinical and preventive services among health professionals in the care team and with patients, caregivers, and families to improve appropriate and timely patient and care team communication. They may also be measures that reflect outcomes of successful coordination of care.

(4) Effective Clinical Care. These are measures that reflect clinical care processes closely linked to outcomes based on evidence and practice guidelines or measures of patient-centered outcomes of disease states.

(5) Community/Population Health. These are measures that reflect the use of clinical and preventive services and achieve improvements in the health of the population served. They may be measures of processes focused on primary prevention of disease or general screening for early detection of disease unrelated to a current or prior condition.

(6) Efficiency and Cost Reduction. These are measures that reflect efforts to lower costs and to significantly improve outcomes and reduce errors. These are measures of cost, resource use and appropriate use of healthcare resources or inefficiencies in healthcare delivery.

Please note that the PQRS quality measure specifications for any given proposed PQRS individual quality measure may differ from specifications for the same quality measure used in prior years. For example, for the proposed PQRS quality measures that were selected for reporting in 2016 and beyond, please note that detailed measure specifications, including the measure's title, for the proposed individual PQRS quality measures for 2016 and beyond may have been updated or modified during the NQF endorsement process or for other reasons.

In addition, due to our desire to align measure titles with the measure titles that have been finalized for 2013, 2014, 2015 reporting, and potentially subsequent years of the Medicare EHR Incentive Program, we note that the measure titles for measures available for reporting via EHR-based reporting mechanisms may change. To the extent that the Medicare EHR Incentive Program updates its measure titles to include version numbers (see 77 FR 13744), we will use these version numbers to describe the PQRS EHR measures that will also be available for reporting for the EHR Incentive Program. We will continue to work toward complete alignment of measure specifications across programs whenever possible.

Through NQF's measure maintenance process, NQF-endorsed measures are sometimes updated to incorporate changes that we believe do not substantively change the nature of the measure. Examples of such changes may include updated diagnosis or procedure codes or changes to exclusions to the patient population or definitions. While we address such changes on a case-by-case basis, we generally believe these types of maintenance changes are distinct from substantive changes to measures that result in what are considered new or different measures. Further, we believe that non-substantive maintenance changes of this type do not trigger the same agency obligations under the Administrative Procedure Act.

In the CY 2013 PFS final rule with comment period, we finalized our proposal providing that if the NQF updates an endorsed measure that we have adopted for the PQRS in a manner that we consider to not substantively change the nature of the measure, we would use a subregulatory process to incorporate those updates to the measure specifications that apply to the program (77 FR 69207). We believe this adequately balances our need to incorporate non-substantive NQF updates to NQF-endorsed measures in the most expeditious manner possible, while preserving the public's ability to comment on updates that change an endorsed measure such that it is no longer the same measure that we originally adopted. We also note that the NQF process incorporates an opportunity for public comment and engagement in the measure maintenance process. We will revise the Specifications Manual and post notices to clearly identify the updates and provide links to where additional information on the updates can be found. Updates will also be available on the CMS PQRS Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html*.

We are not the measure steward for most of the measures available for reporting under the PQRS. We rely on outside measure stewards and developers to maintain these measures. In Table 25, we are proposing that certain measures be removed from the PQRS measure set due to the measure steward indicating that it will not be able to maintain the measure. We note that this proposal is contingent upon the measure steward not being able to maintain the measure. Should we learn that a certain measure steward is able to maintain the measure, or that another entity is able to maintain the measure in a manner that allows the measure to be available for reporting under the PQRS for the CY 2018 PQRS payment adjustment, we propose to keep the measure available for reporting under the PQRS and therefore not finalize our proposal to remove the measure. In addition, if, after the display of this proposed rule and before the display of the CY 2016 PFS final rule, we discover additional measures within the current PQRS measure set that a measure steward can no longer maintain, we propose to remove these measures from reporting for the PQRS beginning in 2016. We will discuss any such instances in the CY 2016 PFS final rule with comment period.

In addition, we note that we have received feedback from stakeholders, particularly first-time participants who find it difficult to understand which measures are applicable to their

particular practice. In an effort to aide EPs and group practices to determine what measures best fit their practice, and in collaboration with specialty societies, we are beginning to group our final measures available for reporting according to specialty. The current listing of our measures by specialty can be found on our Web site at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/index.html*. Please note that these groups of measures are meant to provide guidance to those EPs seeking to determine what measures to report. EPs are not required to report measures according to these suggested groups of measures. As measures are adopted or revised, we will continue to update these groups to reflect the measures available under the PQRS, as well as add more specialties.

In Tables 22 through 30, we propose changes to the PQRS measures set. The current PQRS measures list is available at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/PQRS_2015_Measure-List_111014.zip*.

b. Proposed Cross-Cutting Measures for 2016 Reporting and Beyond

In the CY 2015 PFS final rule with comment period, we finalized a set of 19 cross-cutting measures for reporting in the PQRS for 2015 and beyond (see Table 52 at 79 FR 67801). The current PQRS cross-cutting measure set is available at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2015_PQRS_Crosscutting Measures_12172014.pdf*. In Table 22, we propose the following measures to be added to the current PQRS cross-cutting measure set. Please note that our rationale for proposing each of these measures is found below the measure description.

TABLE 22: Proposed Individual Quality Cross-Cutting Measures for the PQRS to be Available for Satisfactory Reporting via Claims, Registry, and HER beginning in 2016

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description[¥]	Measure Steward	Other Quality Reporting Programs
2152/ N/A	N/A	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling:** Percentage of patients aged 18 years and older who were screened at least once within the last 24 months for unhealthy alcohol use using a systematic screening method AND who received brief counseling if identified as an unhealthy alcohol user. **Rationale**: This measure has been proposed as a cross-cutting measure for PQRS for CY 2016 as it represents a screening assessment for unhealthy alcohol use that most EPs may perform, assess, and document to ensure maintenance for this risk, and is applicable to most Medicare adult patients.	American Medical Association – Physician Consortium for Performance Improvement	
2372/ 112	125v3	Effective Clinical Care	**Breast Cancer Screening:** Percentage of women 50 through 74 years of age who had a mammogram to screen for breast cancer within 27 months. **Rationale**: This measure has been reportable through PQRS for 8 years and was finalized for reporting through claims, registry, EHR, GPRO and measures group in the PQRS in the CY 2013 PFS final rule (77 FR 69227). This measure has been proposed as a cross-cutting measure for PQRS for CY 2016 as it represents a screening assessment for breast cancer that most EPs may perform, assess, and document to ensure maintenance for this risk, and is applicable to most Medicare female adult patients.	National Committee for Quality Assurance	ACO/ MU2
0101/ 154	N/A	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. **Rationale**: This measure has been reportable through PQRS for 7 years and was finalized for reporting through claims and registry in the PQRS in the CY 2013 PFS final rule (77 FR 69232). In the CY 2015 PFS final rule, this measure was finalized for the addition of measures group reporting. This measure has been proposed as a cross-cutting measure for PQRS for CY 2016 PFS as it is applicable to a variety of physican specialties and should be integrated into the standard of care for providers who serve patients with a history of falls.	National Committee for Quality Assurance/ American Medical Association – Physician Consortium for Performance Improvement	
0101/ 155	N/A	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. **Rationale**: This measure has been reportable through PQRS for 7 years and was finalized for reporting through claims and registry in the PQRS in the CY 2013 PFS final rule (77 FR 69232). In the CY 2015 PFS final rule, this measure was finalized for the addition of measures group reporting. This measure has been proposed as a cross-cutting measure for PQRS for CY 2016 as it is applicable to a variety of physican specialties and should be integrated into the standard of care for providers who serve patients with a history of falls.	National Committee for Quality Assurance/ American Medical Association – Physician Consortium for Performance Improvement	

[¥] Measure details including titles, descriptions and measure owner information may vary during a particular program year. This is due to the timing of measure specification preparation and the measure versions used by the various reporting options/methods. Please refer to the measure specifications that apply for each of the reporting options/methods for specific measure details.

c. Proposed New PQRS Measures Available for Reporting for 2016 and Beyond and Proposed Changes to Existing PQRS Measures

Table 23 contains additional measures we propose to include in the PQRS measure set for CY 2016 and beyond. We have also indicated the PQRS reporting mechanism or mechanisms through which each measure could be submitted, as well as the MAP recommendations. Additional comments and measure information from the MAP review can be found at *http://www.qualityforum.org/WorkArea/linkit.aspx?LinkIdentifier=id&ItemID=78711*.

Please note that, in some cases specified below, we propose adding a measure to the PQRS measure set that the MAP believes requires further development prior to inclusion or does not support a measure for inclusion in the PQRS measure set. Please note that, while CMS takes these recommendations into consideration, in these instances, CMS believes the rationale provided for proposing the addition of a measure outweighs the MAP's recommendation.

TABLE 23: New Individual Quality Measures and those Included in Measures Groups for the PQRS to be Available for Satisfactory Reporting Beginning in 2016

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
N/A/ N/A	N/A	Patient and Caregiver-Centered Experience and Outcomes	**Adult Kidney Disease: Referral to Hospice:** Percentage of patients aged 18 years and older with a diagnosis of end-stage renal disease (ESRD) who withdraw from hemodialysis peritoneal dialysis who are referred to hospice care.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure supports interdisciplinary communication between EPs providing palliative care to Medicare patients. This measure fills a clinical gap in the program, as it addresses palliative care.	Renal Physicians Association/ American Medical Association – Physician Consortium for Performance Improvement			X			
N/A/ N/A	N/A	Community/ Population Health	**Amblyopia Screening in Children:** The percentage of children who were screened for the presence of amblyopia at least once by their 6th birthday; and if necessary, were referred appropriately.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure fills a clinical gap in the program, as it addresses screening for amblyopia within the pediatric population. This measure is also clinically robust, not duplicative of any measures in the PQRS, and	The Office of the National Coordinator for Health Information Technology / Centers for Medicare & Medicaid Services			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
					reportable by EPs that provide care to pediatric patients.							
N/A/ N/A	N/A	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.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure clinically supports positive outcomes for patients undergoing anesthesia. This measure supports a gap in reporting for EPs who practice in anesthesia.	American Society of Anesthesiologists			X			
N/A/ N/A	N/A	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	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure supports EPs within the profession of radiology. This process measure is clinically sound and addresses a clinical concept gap within radiology. This measure also addresses the important issue of assessing the overutilization of resources.	American College of Radiology	X		X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
N/A/ N/A	N/A	Effective Clinical Care	**Appropriate Follow-Up Imaging for Incidental Thyroid Nodules in Patients:** Percentage of final reports for computed tomography (CT) or magnetic resonance imaging (MRI) 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.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure targets imaging specialists and radiologists, who are currently underrepresented in the PQRS. This measure also fills a clinical gap in the PQRS, as it addresses preventing the overuse of imaging for incidental diagnoses.	American College of Radiology	X		X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
N/A/ N/A	N/A	Effective Clinical Care	**Appropriate Treatment of MSSA - For MSSA Bacteremia, a β-lactam Antibiotic is the Drug of Choice in the Hospitalized Patient in the Absence of a Documented Allergy or Drug Intolerance:** Percentage of patients with MSSA bacteremia who received beta-lactam antibiotic (e.g., nafcillin or cefazolin) as definitive therapy.	2013 MAP stated there was "Insufficient Information" and provided no further comments.	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure represents a PQRS program gap and targets EPs who provide care within the inpatient care setting. This measure addresses a strong clinical need, as Beta-lactam use in patients with MSSA bacteremia is associated with improved outcomes for both hospital-acquired and community-acquired infections.	Infectious Diseases Society of America	X		X			
N/A/ N/A	N/A	Effective Clinical Care	**Chronic Opioid Therapy (COT) 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 COT documented in the medical record.	Conditional Support	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure is an analytically robust, and clinically-sound measure that identifies the importance of patient safety and evaluating patients on chronic opioid therapy. This	American Academy of Neurology			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
					measure promotes patient safety within PQRS.							
N/A/ N/A	N/A	Effective Clinical Care	**Clinical Outcome Post-Endovascular Stroke Treatment:** Patients with 90 day mRs score of 0 to 2 post-endovascular stroke intervention.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure fills a clinical concept gap in the PQRS, as it addresses clinical outcomes for post-endovascular stroke treatment.	Society of Interventional Radiologists			X			
N/A/ N/A	N/A	Person and Caregiver-Centered Experience and Outcomes	**Clinical Response to Oral Systemic or Biologic Medications:** This measure evaluates the proportion of psoriasis patients receiving 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.	Conditional Support	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This outcome measure represents an NQS domain gap, "Person and Caregiver Centered Experience and Outcomes," and targets a dermatology clinician group underrepresented in current PQRS measures.	American Academy of Dermatology	X		X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
N/A/ N/A	N/A	Community/ Population Health	**Cognitive Impairment Assessment Among At-Risk Older Adults:** Percentage of patients age 80 years or older at the start of the measurement period with documentation in the electronic health record at least once during the measurement period of (1) results from a standardized cognitive impairment assessment tool or (2) a patient or informant interview.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure is clinically sound, analytically feasible, and fills a clinical concept gap in PQRS for a high-risk elderly patients with cognitive impairment. This measure supports a variety of EPs that support this high-risk Medicare patient population.	Centers for Medicare & Medicaid Services			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
N/A/ N/A	N/A	Communication and Care Coordination	**Coordinating Care - Emergency Department Referrals:** Percentage of patients (1) of any age with asthma or (2) ages 18 and over with chest pain who had a visit to the emergency department (not resulting in an inpatient admission), whose emergency department provider attempted to communicate with the patient's primary care provider or their specialist about the patient's visit to the emergency department.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure supports interdisciplinary communication between EPs providing palliative care to Medicare patients. This measure covers a gap in reporting for palliative care and promotes the clinical concept of interdisciplinary communication within the PQRS.	Centers for Medicare & Medicaid Services			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
0711/ N/A	N/A	Communication and Care Coordination	**Depression Remission at Six Months:** Adult patients age 18 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. The Patient Health Questionnaire (PHQ-9) tool is a widely accepted, standardized tool [Copyright © 2005 Pfizer, Inc. All rights reserved] that is completed by the patient, ideally at each visit, and utilized by the provider to monitor treatment progress. 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.	2013 MAP Report Recommendation was "Supports"	This is an outcomes measure that supports patients who struggle with the diagnosis of depression. This measure also supports EPs within the mental health profession.	Minnesota Community Measurement			X			
N/A/ N/A	N/A	Effective Clinical Care	**Documentation of a Health Care Proxy for Patients with Cognitive Impairment:** The percentage of patients with a diagnosis of dementia or a positive result on a standardized tool for assessment of cognitive impairment, with documentation of a designated health	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application	Centers for Medicare & Medicaid Services			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
			care proxy during the measurement period.		partnership. This measure supports interdisciplinary communication between EPs providing cognitive impairment care to Medicare patients. This measure promotes the clinical concept of interdisciplinary communication within the PQRS as a whole.							
N/A/ N/A	N/A	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 COT documented in the medical record.	Conditional Support	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure fills a clinical gap in the program, as it addresses educating patients on opiate use. This measure is also clinically robust and not duplicative of any measures in the PQRS.	American Academy of Neurology			X			
N/A/ N/A	N/A	Effective Clinical Care	**Door to Puncture Time for Endovascular Stroke Treatment:** Door to puncture time less than 2 hours for patients undergoing endovascular stroke treatment.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure fills a clinical gap in the	Society of Interventional Radiologists			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
					program, as it addresses the concept of capturing how much delay occurs in a facility for patients undergoing endovascular stroke treatment. This outcomes measure is clinically robust, clinically sound, and reportable by a variety of EPs who practice within the profession of endovascular stroke treatment.							
N/A/ N/A	N/A	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 COT in the medical record.	Conditional Support	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure fills a clinical gap in the program, as it addresses the importance of patient safety and compliance. This measure is clinically robust and reportable by a variety of specialties.	American Academy of Neurology			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
N/A/ N/A	N/A	Patient Safety	**Extravasation of Contrast Following Contrast-Enhanced Computed Tomography (CT):** Percentage of final reports for patients aged 18 years and older who received intravenous iodinated contrast for a computed tomography (CT) examination who had an extravasation of contrast.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure evaluates contrast extravasation which is a patient safety issue not currently represented within the PQRS. This measure is applicable in both inpatient and outpatient settings and can be reported by radiologists, who currently have a limited number of measures to report within the PQRS.	American College of Radiology	X		X			
N/A/ N/A	N/A	Efficiency and Cost Reduction	**Frequency of Inadequate Bowel Preparation:** Percentage of outpatient examinations with "inadequate" bowel preparation that require repeat colonoscopy in one year or less.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure determines inadequate bowel preparation and would compliment the existing colonoscopy measure within the PQRS program and is reportable by gastroenterologists.	American Society for Gastrointestinal Endoscopy	X		X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
N/A/ N/A	N/A	Effective Clinical Care	**HIV Screening of STI patients:** Percentage of patients diagnosed with an acute STI who were tested for HIV.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure fulfills an important clinical concept not represented in the PQRS. PQRS #205 "HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis" is related but not duplicative of this new measure. This measure is reportable by a variety of specialists, including primary care physicians, family practice doctors, OB-GYNs, urologists, and internal medicine physicians.	Centers for Disease Control and Prevention	X		X			
N/A/ N/A	N/A	Community/ Population Health	**HIV: Ever Screened for HIV:** Percentage of persons 15-65 ever screened for HIV.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure is clinically-sound and represents an	Centers for Disease Control and Prevention	X		X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
					important screening concept. This measure is reportable by a variety of specialists, including infectious disease physicians, OB-GYNs, internal medicine physicians, urologists, family practice doctors, and primary care providers.							
N/A/ N/A	N/A	Efficiency and Cost Reduction	**Imaging in Adult Emergency Department (ED) Patients with Minor Head Injury:** Percent of adult patients who presented within 24 hours of a non-penetrating head injury with a Glasgow coma score (GCS)<=15 and underwent head CT for trauma in the ED who have a documented indication consistent with guidelines prior to imaging.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure fills a clinical gap in the program, as it addresses the appropriate use of imaging in the Emergency Department. Inappropriate use of imaging results in increased healthcare expenditures, unnecessary patient radiation exposure, and possible prolonged evaluation times. This measure is reportable by Emergency Department physicians.	American College of Emergency Physicians	X		X			
N/A/ N/A	N/A	Efficiency and Cost Reduction	**Imaging in Pediatric ED Patients Aged 2 through 17 years with Minor Head Injury:** Percent of pediatric patients who presented within 24 hours of a non-penetrating head injury with a	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and	American College of Emergency Physicians	X		X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
			Glasgow coma score (GCS) of 14 or 15 and underwent head CT for trauma in the ED who have a documented indication consistent with guidelines (PECARN) prior to imaging.		practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure is clinically robust, analytically feasible, and fills a clinical gap in the program, as it addresses the importance of radiation safety within the adolescent population. This measure is also reportable by radiologists, emergency department physicians, neurologists, and pediatricians.							
N/A/ N/A	N/A	Patient Safety	**In-Hospital Mortality Following Elective Open Repair of AAAs:** Percentage of aymptomatic patients undergoing open repair of abdominal aortic aneurysms (AAA) who die while in hospital. This measure is proposed for both hospitals and individual providers.	Support	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This outcomes measure fills a clinical gap in the program, as it assesses mortality rate in AAA repair. This measure is clinically sound, analytically feasible, and is reportable by both general surgeons and vascular surgeons.	Society for Vascular Surgeons			X			
0053 /N/A	N/A	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a	2013 MAP Report Recommendation was "Supports"	CMS proposes adding NQF 0053: Osteoporosis Management in Women Who Had a Fracture as a new measure to replace	National Committee for Quality Assurance/ American Medical Association-Physician Consortium for	X		X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
			fracture and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis.		the existing NQF 0048 (PQRS #40): Osteoporosis: Management Following Fracture of Hip, Spine or Distal Radius for Men and Women Aged 50 Years and Older for CY 2016 PFS. NQF 0053 was harmonized with NQF 0048 which is being retired as a separate NQF endorsed measure. NQF 0053 represents a more harmonized and up-to-date measure than its predecessor.	Performance Improvement						
N/A/ N/A	N/A	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 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.	Conditional Support	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure fills a clinical gap in the PQRS, as it addresses the overuse of neuroimaging, which further addresses both patient safety and efficient health care. This measure is reportable by neurologists and radiologists.	American Academy of Neurology	X		X			
N/A/ N/A	N/A	Effective Clinical Care	**Percentage of Patients Treated for Varicose Veins who are Treated with Saphenous Ablation and Receive an Outcomes Survey Before and after**	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because	Society of Interventional Radiologists			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
			Treatment: Percentage of patients treated for varicose veins (CEAP C2) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that receive a disease specific patient reported outcome survey before and after treatment.		a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure provides a measurement tool of successful varicose vein therapy, and is reportable by general and vascular surgeons providing surgical treatment.							
N/A/ N/A	N/A	Effective Clinical Care	**Percentage of Patients with a Retrievable Inferior Vena Cava (IVC) Filter who are Appropriately Assessed for Continued Filtration or Device Removal:** Proportion 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.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure fills a clinical gap in the program, as it encourages patient safety and fosters patient follow-up for IVC filter removal. This measure is reportable by interventional radiologists who are currently underrepresented in the PQRS.	Society of Interventional Radiologists			X			
N/A/ N/A	N/A	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	Support	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the	American Urogynecologic Society	X		X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
			hysterectomy for pelvic organ prolapse.		NQF that has been submitted to the measures application partnership. This measure fills a clinical concept gap in the PQRS, as it addresses injury during hysterectomies. This measure is reportable by surgeons, OB-GYNs, urogynecologists, and urologists.							
N/A/ N/A	N/A	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 (aspirin or clopidogrel or equivalent such as aggrenox/tiglacor, etc.) within 48 hours prior to surgery and are prescribed this medication at hospital discharge following surgery.	Conditional Support	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure fills a clinical concept gap in the program, as it promotes secondary prevention of vascular disease beyond the timeframe of surgery. This measure is reportable by vascular surgeons, cardiovascular surgeons, and interventional radiologists.	Society for Vascular Surgeons	X		X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
N/A/ N/A	N/A	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.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure supports a gap in reporting for EPs that practice in anesthesia. This measure is an updated version of the current PQRS Measure #193: Perioperative Temperature, which is proposed for removal; however, this measure clinically supports positive outcomes for patients undergoing anesthesia.	American Society of Anesthesiologists			X			
N/A/ N/A	N/A	Effective Clinical Care	**Photodocumentation of Cecal Intubation:** The rate of screening and surveillance colonoscopies for which photodocumentation of landmarks of cecal intubation is performed to establish a complete examination.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure fills a clinical gap in the program, as photodocumentation of cecal intubation allows a complete assessment of the cecum area that can aid in the prevention	American Society for Gastrointestinal Endoscopy	X		X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
					of colon cancer. Additionally, this measure would be applicable for gastroenterology specialists to report.							
N/A/ N/A	N/A	Communication and Care Coordination	**Post-Anesthetic Transfer of Care Measure: Procedure Room to a Post-Anesthesia Care Unit (PACU):** Percentage of patients 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.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure clinically supports positive outcomes for patients undergoing anesthesia. Additionally, this measure supports a gap in reporting for EPs who practice in anesthesia.	American Society of Anesthesiologists			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
N/A/ N/A	N/A	Communication and Care Coordination	**Post-Anesthetic Transfer of Care Measure: 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.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure identifies a process of documentation that supports positive outcomes for patients undergoing anesthesia. Additionally, this measure supports a gap in reporting for EPs that practice in anesthesia.	American Society of Anesthesiologists			X			
N/A/ N/A	N/A	Effective Clinical Care	**Preoperative Assessment of Occult Stress Urinary Incontinence Prior to any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing appropriate preoperative evaluation for the indication of stress urinary incontinence per ACOG/AUGS/AUA guidelines.	Conditional Support	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure fills a clinical concept gap in the program, as it addresses patients who do not receive preoperative assessment of occult stress urinary incontinence prior to pelvic organ prolapse repair. This measure is reportable by surgeons.	American Urogynecologic Society			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
N/A/ N/A	N/A	Patient Safety	**Preoperative Exclusion of Uterine Malignancy Prior to any Pelvic Organ Prolapse Repair:** Percentage of patients having documented assessment of abnormal uterine or postmenopausal bleeding prior to surgery for pelvic organ prolapse.	Conditional Support	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure fills a clinical gap in the program, as it addresses patients who receive preoperative exclusion of uterine malignancy prior to any pelvic organ prolapse repair. This measure is reportable by gynecologists and urologists.	American Urogynecologic Society	X		X			
N/A/ N/A	N/A	Patient Safety	**Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination:** 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.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure clinically supports positive outcomes for patients undergoing anesthesia. Additionally, this measure supports a gap in reporting for EPs who practice in anesthesia.	American Society of Anesthesiologists			X			
2152/ N/A	N/A	Community/ Population Health	**Preventive Care and Screening: Unhealthy Alcohol**	Encourage Continued Development	This measure will replace PQRS #173 "Preventive Care and	American Medical Association – Physician			X			X

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
			Use: Screening & Brief Counseling: Percentage of patients aged 18 years and older who were screened at least once within the last 24 months for unhealthy alcohol use using a systematic screening method AND who received brief counseling if identified as an unhealthy alcohol user.		Screening: Unhealthy Alcohol Use-Screening," as it represents a more clinically robust measure for unhealthy alcohol use. Additionally, this measure is broadly applicable to many specialties.	Consortium for Performance Improvement						
N/A/ N/A	N/A	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.	Conditional Support	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure fills a clinical concept gap in the PQRS, as it address an outcome regarding injury while performing pelvic organ prolapse surgeries. This outcomes measure is reportable by surgeons.	American Urogynecologic Society	X		X			
N/A/ N/A	N/A	Patient Safety	**Proportion of Patients Sustaining a Major Viscus Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing surgical repair of pelvic organ prolapse that is complicated by perforation of a major viscus at the	Conditional Support	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been	American Urogynecologic Society	X		X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
			time of index surgery that is recognized intraoperative or within 1 month after surgery.		submitted to the measures application partnership. This measure fills a clinical gap in the program, as it address injury while performing pelvic organ prolapse surgeries. This outcomes measure is reportable by surgeons.							
N/A/ N/A	N/A	Patient Safety	**Proportion of Patients Sustaining A Ureter Injury at the Time of any Pelvic Organ Prolapse Repair:** Percentage of patients undergoing a pelvic organ prolapse repair who sustain an injury to the ureter recognized either during or within 1 month after surgery.	Conditional Support	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure fills a clinical gap in the program, as it address injury while performing pelvic organ prolapse surgeries. This outcomes measure is reportable by surgeons.	American Urogynecologic Society	X		X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
N/A/ N/A	N/A	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.	Conditional Support	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This outcomes measure fills a clinical concept gap in the PQRS, as it addresses quality of life in patients with headaches.	American Academy of Neurology	X		X			
N/A/ N/A	N/A	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	Not on this year's MUC list and thus not reviewed by MAP this year. Was on prior year MUC list and reviewed by MAP in prior year.	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure targets a provider group currently under represented in the program, radiologists. This measure also fills a current gap within the program for inpatient care.	American College of Radiology/ American Medical Association – Physician Consortium for Performance Improvement / National Committee for Quality Assurance	X		X			
N/A/ N/A	N/A	Patient Safety	**Rate of Surgical Conversion from Lower Extremity Endovascular Revascularization Procedure:** In patients assigned to endovascular treatment for obstructive arterial	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and	Society of Interventional Radiology	X		X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
			disease, the percent of patients who undergo unplanned major amputation or surgical bypass within 48 hours of the index procedure.		practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure fills a clinical concept gap in PQRS, as it addresses the concept of capturing unplanned complications (major amputation or surgical bypass), which are increasingly common for patients undergoing endovascular lower extremity revascularization. This measure is reportable by surgeons.							
N/A/ N/A	N/A	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of high-risk adult patients aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR adult patients aged ≥21 years with a fasting or direct Low-Density Lipoprotein Cholesterol (LDL-C) level ≥ 190 mg/dL; OR patients aged 40-75 years with a diagnosis of diabetes with a fasting or direct Low-Density Lipoprotein Cholesterol (LDL-C) level of 70-189 mg/dL who were prescribed or are	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure addresses statin therapy, which is an important treatment option for patients with cardiovascular disease, which includes up-to-date clinical guidelines. This measure is reportable by cardiologists and cardiology specialists, cardiovascular physicians, and primary care physicians.	Centers for Medicare & Medicaid Services/Quality Insights of Pennsylvania/ Mathematica	X		X		X	X

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation	Rationale	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO (Web Interface)	Measures Groups
			already on statin medication therapy during the measurement period.									
N/A/ N/A	N/A	Efficiency and Cost Reduction	**Unnecessary Screening Colonoscopy in Older Adults:** Percentage of patients age 86 or older who received an unnecessary screening colonoscopy.	Encourage Continued Development	Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This measure fills a clinical concept gap in the PQRS, as it addresses the overuse of colonoscopy which further addresses efficiency and cost aspects of health care.	American Gastroenterological Association			X			

¥ Measure details including titles, descriptions and measure owner information may vary during a particular program year. This is due to the timing of measure specification preparation and the measure versions used by the various reporting options/methods. Please refer to the measure specifications that apply for each of the reporting options/methods for specific measure details.

In Table 24, we provide our proposals for a NQS domain change for measures that are currently available for reporting under the PQRS.

TABLE 24: Proposed NQS Domain Changes for Individual Quality Measures and those Included in Measures Groups for the PQRS beginning in 2016

NQF/ PQRS	CMS E-Measure ID	Previously Finalized NQS Domain	Proposed New NQS Domain	Measure Title and Description
0089/ 019	142v3	Effective Clinical Care (PFS 2015 final rule)	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 **Rationale**: This measure has been reportable through PQRS for 9 years and was finalized for reporting through claims, registry, and EHR in the PQRS in the CY 2013 PFS final rule (77 FR 69217). CMS is proposing to recategorize this measure from the effective clinical care domain to the communication and care coordination domain in the CY 2016 PFS proposed rule in accordance with NQS priorities which follow the General Rules for Categorizing Measures in the HHS Decision Rule for Categorizing Measures. According to the HHS guidelines for categorizing measures, this measure constitutes the deliberate organization of patient care activities to facilitate appropriate delivery of health care services and outcomes that primarily reflect successful care coordination.
0420/ 131	N/A	Community/Population Health (PFS 2013 final rule)	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. **Rationale**: This measure has been reportable through PQRS for 8 years and was finalized for reporting through claims and registy in the PQRS in the CY 2013 PFS final rule. In the CY 2015 PFS final rule this measure was finalized for the addition of measures group reporting and finalized for designation as a cross-cutting measure (77 FR 69230). CMS is proposing to recategorize this measure from the community/population health domain to the communication and care coordination domain in the CY 2016 PFS proposed rule in accordance with NQS priorities which follow the General Rules for Categorizing Measures in the HHS Decision Rule for Categorizing Measures. According to the HHS guidelines for categorizing measures, this measure constitutes the deliberate organization of patient care activities to facilitate appropriate delivery of health care services and outcomes that primarily reflect successful care coordination.
0643/ 243	N/A	Effective Clinical Care (PFS 2015 final rule)	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 **Rationale**: This measure has been reportable through PQRS for 4 years and was finalized for reporting through registy in the PQRS in the CY 2013 PFS final rule (77 FR 69245). CMS is proposing to recategorize this measure from the effective clinical care domain to the communication and care coordination domain in the CY 2016 PFS proposed rule in accordance with NQS priorities which follow the General Rules for Categorizing Measures in the HHS Decision Rule for Categorizing Measures. According to the HHS guidelines for categorizing measures, this measure constitutes the deliberate organization of patient care activities to facilitate appropriate delivery of health care services and outcomes that primarily reflect successful care coordination.
N/A/ 330	N/A	Effective Clinical Care (PFS 2015 final rule)	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 **Rationale**: This measure has been reportable through PQRS for 2 years and was finalized

NQF/ PQRS	CMS E-Measure ID	Previously Finalized NQS Domain	Proposed New NQS Domain	Measure Title and Description
				for reporting through registryin the PQRS in the CY 2014 PFS final rule (78 FR 74638). CMS is proposing to recategorize this measure from the effective clinical care domain to the patient safety domain in the CY 2016 PFS proposed rule in accordance with NQS priorities which follow the General Rules for Categorizing Measures in the HHS Decision Rule for Categorizing Measures. According to the HHS guidelines for categorizing measures, this measure reflects an effort to reduce risk in the delivery of health care to patients and the occurance of a health outcome that results from the absence of appropriate structures or processed.
N/A/ 378	75v3	Effective Clinical Care (PFS 2015 final rule)	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 **Rationale**: This measure has been reportable through PQRS for 2 years and was finalized for reporting through EHR in the PQRS in the CY 2014 PFS final rule (78 FR 74678). CMS is proposing to recategorize this measure from the effective clinical care domain to the community/ population health domain in the CY 2016 PFS proposed rule in accordance with NQS priorities which follow the General Rules for Categorizing Measures in the HHS Decision Rule for Categorizing Measures. According to the HHS guidelines for categorizing measures, this measure is a measurement of process focused on the prevention of and screening for disease.

¥ Measure details including titles, descriptions and measure owner information may vary during a particular program year. This is due to the timing of measure specification preparation and the measure versions used by the various reporting options/methods. Please refer to the measure specifications that apply for each of the reporting options/methods for specific measure details.

In Table 25, we propose to remove the following measures from reporting under the PQRS.

TABLE 25: Measures Proposed for Removal from the Existing PQRS Measure Set Beginning in 2016

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0241/ 033	Effective Clinical Care	**Stroke and Stroke Rehabilitation: Anticoagulant Therapy Prescribed for Atrial Fibrillation (AF) at Discharge:** Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or transient ischemic attack (TIA) with documented permanent, persistent, or paroxysmal atrial fibrillation who were prescribed an anticoagulant at discharge. **Rationale**: This measure has been reportable through PQRS for 9 years and was finalized for reporting through registry in the PQRS in the CY 2013 PFS final rule (77 FR 69219). CMS proposes removal in the CY 2016 PFS proposed rule as this measure is duplicated within the PQRS with current measure, Stroke and Stroke Rehabiliation: Discharged on Antithrombotic Therapy (PQRS#32).	American Academy of Neurology			X				
0048/ 040	Effective Clinical Care	**Osteoporosis: Management Following Fracture of Hip, Spine or Distal Radius for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older with fracture of the hip, spine, or distal radius who had a central dual-energy X-ray absorptiometry (DXA) measurement ordered or performed or pharmacologic therapy prescribed. **Rationale**: This measure has been reportable through PQRS for 9 years and was finalized for reporting through claims and registry in the PQRS in the CY 2013 final rule (77 FR 69220). CMS proposes removal in the CY 2016 PFS proposed rule as this measure (PQRS 40/NQF 0048) was combined within NQF 0053: Osteoporosis Management in Women Who Had a Fracture, to encompass	National Committee for Quality Assurance/American Medical Association-Physician Consortium for Performance Improvement	X		X				

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		both the physician and health plan levels in one measure. NQF 0048: Osteoporosis: Management Following Fracture of Hip, Spine or Distal Radius for Men and Women Aged 50 Years and Older is being retired and both measures will now be represented as one measure under the proposed new measure, Osteoporosis Management in Women Who Had a Fracture (NQF 0053).								
0323/ 081	Communication and Care Coordination	**Adult Kidney Disease: Hemodialysis Adequacy: Solute:** Percentage of calendar months within a 12 month period during which patients aged 18 years and older with a diagnosis of End Stage Renal Disease (ESRD) receiving hemodialysis three times a week for ≥ 90 days who have a spKt/V ≥ 1.2. **Rationale**: This measure has been reportable through PQRS for 8 years and was finalized for reporting through registry in the PQRS in the CY 2013 PFS final rule (77 FR 69224). CMS proposes removal in the CY 2016 PFS proposed rule due to this measure representing a clinical concept that does not add clinical value to PQRS, and because EPs consistently meet performance on this measure with performance rates close to 100%, suggesting there is no gap in care.	Renal Physicians Association			X				
0321/ 082	Effective Clinical Care	**Adult Kidney Disease: Peritoneal Dialysis Adequacy: Solute:** Percentage of patients aged 18 years and older with a diagnosis of End Stage Renal Disease (ESRD) receiving peritoneal dialysis who have a total Kt/V ≥ 1.7 per week measured once every 4 months. **Rationale**: This measure has been reportable through PQRS for 8 years and was finalized for reporting through registry in the PQRS in the CY 2013 PFS final rule (77 FR 69244).	Renal Physicians Association			X				

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		CMS proposes removal in the CY 2016 PFS proposed rule due to this measure representing a clinical concept that does not add clinical value to PQRS, and because EPs consistently meet performance on this measure with performance rates close to 100%, suggesting there is no gap in care.								
N/A/ 172	Effective Clinical Care	**Hemodialysis Vascular Access Decision-Making by Surgeon to Maximize Placement of Autogenous Arterial Venous (AV) Fistula:** Percentage of patients aged 18 years and older with a diagnosis of advanced Chronic Kidney Disease (CKD) (stage 3, 4 or 5) or End Stage Renal Disease (ESRD) requiring hemodialysis vascular access documented by surgeon to have received autogenous AV fistula. **Rationale**: This measure has been reportable through PQRS for 7 years and was finalized for reporting through claims and registry in the PQRS in the CY 2013 PFS final rule (77 FR 69235). CMS proposes removal in the CY 2016 PFS proposed rule due to EPs consistently meeting performance on this measure with performance rates close to 100%, suggesting there is no gap in care.	Society for Vascular Surgeons	X		X				
AQA Endorsed /173	Community/Population Health	**Preventive Care and Screening: Unhealthy Alcohol Use – Screening:** Percentage of patients aged 18 years and older who were screened for unhealthy alcohol use at least once within 24 months using a systematic screening method. **Rationale**: This measure has been reportable through PQRS for 7 years and was finalized for reporting through claims, registry, EHR, and the Preventive Care Measures Group in the PQRS in the CY 2013 PFS final rule (77 FR 69235). In the CY 2014 PFS final rule, this measure was finalized for removal of claims and EHR	American Medical Association-Physician Consortium for Performance Improvement			X			X	

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		reporting methods. CMS proposes removal of this measure in the CY 2016 PFS proposed rule and replacing it with NQF 2152: Preventive Care and Screening: Unhealthy Alcohol Use: Screening and Brief Counseling. NQF 2152 includes counseling in addition to screening.								
N/A/ 193	Patient Safety	**Perioperative Temperature Management:** Percentage of patients, regardless of age, undergoing surgical or therapeutic procedures under general or neuraxial anesthesia of 60 minutes duration or longer, except patients undergoing cardiopulmonary bypass, for whom either active warming was used intraoperatively for the purpose of maintaining normothermia, OR at least one body temperature equal to or greater than 36 degrees Centigrade (or 96.8 degrees Fahrenheit) was recorded within the 30 minutes immediately before or the 15 minutes immediately after anesthesia end time. **Rationale**: This measure has been reportable through PQRS for 6 years and was finalized for reporting through claims and registry in the PQRS in the CY 2013 PFS final rule (77 FR 69238). CMS proposes removal in the CY 2016 PFS proposed rule due to this measure representing a clinical concept that does not add clinical value to PQRS. Literature indicates that the adverse outcomes result in prolonged hospital stays and increased health care costs. CMS also recommends removal due to EPs consistently meeting performance on this measure with performance rates close to 100%, suggesting there is no gap in care.	American Society for Anesthesiologists	X		X				

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0386/ 194	Effective Clinical Care	**Oncology: Cancer Stage Documented:** Percentage of patients, regardless of age, with a diagnosis of cancer who are seen in the ambulatory setting who have a baseline American Joint Committee on Cancer (AJCC) cancer stage or documentation that the cancer is metastatic in the medical record at least once during the 12 month reporting period. **Rationale**: This measure has been reportable through PQRS for 6 years and was finalized for reporting through claims, registry, and measure groups in the PQRS in the CY 2013 PFS final rule (77 FR 69238). In the CY 2015 PFS final rule, this measure was finalized for a removal of claims and measures group reporting methods. CMS proposes removal in the CY 2016 PFS proposed rule due to this measure representing a clinical concept that does not add clinical value to PQRS because documenting cancer stage is a basic standard of care for oncology. Cancer stage is standard of care that is documented early in the patient's care before treatment options are discussed.	American Medical Association-Physician Consortium for Performance Improvement/American Society of Clinical Oncology			X				
N/A/ 285	Effective Clinical Care	**Dementia: Screening for Depressive Symptoms:** Percentage of patients, regardless of age, with a diagnosis of dementia who were screened for depressive symptoms within a 12 month period. **Rationale**: This measure has been reportable through PQRS for 4 years and was finalized for reporting through the Dementia Measures Group in the PQRS in the CY 2013 PFS final rule (77 FR 69251). CMS proposes removal in the CY 2016 PFS proposed rule as this measure is duplicated within PQRS with current measure, Preventive Care and Screening: Screening for Clinical Depression and Follow-up (PQRS#134), which includes a	American Academy of Neurology Institute/American Psychological Association						X	

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		follow-up concept.								
N/A/335	Patient Safety	**Maternity Care: Elective Delivery or Early Induction Without Medical Indication at ≥ 37 and < 39 Weeks:** Percentage of patients, regardless of age, who gave birth during a 12-month period who delivered a live singleton at ≥ 37 and < 39 weeks of gestation completed who had elective deliveries or early inductions without medical indication. **Rationale**: This measure has been reportable through PQRS for 2 years and was finalized for reporting through registry in the PQRS in the CY 2014 PFS final rule. CMS proposes removal in the CY 2016 PFS proposed rule due to measure steward indicating they will no longer maintain this measure.	American Medical Association-Physician Consortium for Performance Improvement			X				
N/A/336	Communication and Care Coordination	**Maternity Care: Post-Partum Follow-Up and Care Coordination:** Percentage of patients, regardless of age, who gave birth during a 12-month period who were seen for post-partum care within 8 weeks of giving birth who received a breast feeding evaluation and education, post-partum depression screening, post-partum glucose screening for gestational diabetes patients, and family and contraceptive planning. **Rationale**: This measure has been reportable through PQRS for 2 years and was finalized for reporting through registry in the PQRS in the CY 2014 PFS final rule. CMS proposes removal in the CY 2016 PFS proposed rule due to measure steward indicating they will no longer maintain this measure.	American Medical Association-Physician Consortium for Performance Improvement			X				

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
0076/349	Effective Clinical Care	**Optimal Vascular Composite:** Percent of patients aged 18 to 75 with ischemic vascular disease (IVD) who have optimally managed modifiable risk factors demonstrated by meeting all of the numerator targets of this patient level all-or-none composite measure: blood pressure less than 140/90, tobacco-free status, and daily aspirin use. **Rationale**: This measure has been reportable through PQRS for 2 years and was finalized for reporting through registry in the PQRS in the CY 2014 PFS final rule (78 FR 74659). CMS proposes removal in the CY 2016 PFS proposed rule as parts of this composite measure are duplicative of Million Hearts measures.	Minnesota Community Measurement			X				

¥ Measure details including titles, descriptions and measure owner information may vary during a particular program year. This is due to the timing of measure specification preparation and the measure versions used by the various reporting options/methods. Please refer to the measure specifications that apply for each of the reporting options/methods for specific measure details.

In Table 26, we propose to change the mechanism(s) by which an EP or group practice may report a respective PQRS measure beginning in 2016.

TABLE 26: Existing Individual Quality Measures and those Included in Measures Groups for the PQRS for Which Measure Reporting Updates will be Effective beginning in 2016

NQF/ PQRS	CMS E-Measure ID	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups
0088/ 018	167v 3	**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 **Rationale**: This measure has been reportable through PQRS for 9 years and was finalized for reporting through claims, registry, and EHR in the PQRS in the CY 2013 PFS final rule (77 FR 69216). In the CY 2015 PFS final rule (79 FR 67855), this measure was finalized for removal of claims and registry reporting methods. CMS proposes to add this measure to the Diabetes Retinopathy Measures Group in the CY 2016 PFS proposed rule. Several level 1 RCT studies demonstrate the ability of timely treatment to reduce the rate and severity of vision loss from diabetes (Diabetic Retinopathy Study – DRS, Early Treatment Diabetic Retinopathy Study – ETDRS). Necessary examination prerequisites to applying the study results are that the presence and severity of both peripheral diabetic retinopathy and macular edema be accurately documented. In the RAND chronic disease quality project, while administrative data indicated that roughly half of the patients had an eye exam in the recommended time period, chart review data indicated that only 19% had documented evidence of a dilated examination. (McGlynn, 2003). Thus, ensuring timely treatment that could prevent 95% of the blindness due to diabetes requires the performance and documentation of key examination parameters. The documented level of severity of retinopathy and the documented presence or absence of macular edema assists with the on-going plan of care for the patient with diabetic retinopathy. This measure is the only measure in this proposed measures group that evaluates such documentation.	American Medical Association – Physician Consortium for Performance Improvement / National Committee for Quality Assurance				X		X
0089/ 019	142v 3	**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 **Rationale**: This measure has been reportable through PQRS for 9 years and was finalized for reporting through claims, registry, and EHR in the PQRS in the CY 2013 PFS final rule (77 FR 69217). CMS proposes to add this measure to the Diabetes Retinopathy Measures Group in the CY 2016 PFS proposed rule. The physician that manages the ongoing care of the patient with diabetes should be aware of the patient's dilated eye examination and severity of retinopathy to manage the ongoing diabetes care. Such communication is important in assisting the physician to better manage the diabetes. Several studies have shown that better management of diabetes is directly related to lower rates of development of diabetic eye disease (Diabetes Control and Complications Trial – DCCT, UK Prospective Diabetes Study –	American Medical Association – Physician Consortium for Performance Improvement / National Committee for Quality Assurance	X		X	X		X

NQF/ PQRS	CMS E-Measure ID	Measure Title and Description¥	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups
		UKPDS).							
0236/ 044	N/A	**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 **Rationale**: This measure has been reportable through PQRS for 9 years and was finalized for reporting through claims, registry, and measures groups in the PQRS in the CY 2013 PFS final rule (77 FR 69220). CMS proposes to remove the claims reporting option in the CY 2016 PFS proposed rule for this measure as CMS seeks to move the PQRS program away from claims reporting.	Centers for Medicare & Medicare Services/Quality Insights of Pennsylvania			X			X
0062/ 119	134v 3	**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 **Rationale**: This measure has been reportable through PQRS for 8 years and was finalized for reporting through claims, registry, EHR, and measures groups in the PQRS in the CY 2013 PFS final rule (77 FR 69228). CMS proposes to remove the claims reporting option in the CY 2016 PFS proposed rule for this measure as CMS seeks to move the PQRS program away from claims reporting.	National Committee for Quality Assurance			X	X		X
0417/ 126	N/A	**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 **Rationale**: This measure has been reportable through PQRS for 8 years and was finalized for reporting through claims and registry in the PQRS in the CY 2013 PFS final rule (77 FR 69229). CMS proposes to replace PQRS 163 "Diabetes: Foot Exam" with PQRS 126 "Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation" in the Diabetes Measures Group in the CY 2016 PFS proposed rule. PQRS 126 targets an at-risk patient population, is clinically significant, and is in alignment with current clinical guidelines for neurological evaluation of diabetic neuropathy.	American Podiatric Medical Association			X			X
0056/ 163	123v 3	**Diabetes: Foot Exam:** Percentage of patients aged 18-75 years of age with diabetes who had a foot exam during the measurement period **Rationale**: This measure has been reportable through PQRS for 7 years and was finalized for reporting through claims, registry, EHR, and measures groups in the PQRS in the CY 2013 PFS final rule (77 FR 69233). CMS proposes to make this measure reportable via EHR only in the CY 2016 PFS proposed rule. CMS initially wanted to propose removal of this measure as it is a process measure that is low bar. However, to maintain alignment with the EHR Incentive	National Committee for Quality Assurance				X		

NQF/ PQRS	CMS E-Measure ID	Measure Title and Description¥	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups
		Program, under which this measure is also available for reporting in 2016, CMS proposes to maintain this measure in PQRS for EHR reporting only, removing all other reporting options.							
0130/ 165	N/A	**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 **Rationale**: This measure has been reportable through PQRS for 7 years and was finalized for reporting through registry and measures groups in the PQRS in the CY 2013 PFS final rule (77 FR 69234). CMS proposes to make this individual measure reportable via measures group only in the CY 2016 PFS proposed rule to help mitigate the burden of EPs reporting individual measures based on the current requirement of 9 measures over 3 domains. Additionally, the clinical topic of this measure contained within the Coronary Artery Bypass Graft measures group allows CMS to evaluate patients who undergo Coronary Artery Bypass Graft surgery to be assessed in a more comprehensive manner.	Society of Thoracic Surgeons						X
0131/ 166	N/A	**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 **Rationale**: This measure has been reportable through PQRS for 7 years and was finalized for reporting through registry and measures groups in the PQRS in the CY 2013 PFS final rule (77 FR 69234). CMS proposes to make this individual measure reportable via measures group only in the CY 2016 PFS proposed rule to help mitigate the burden of EPs reporting individual measures based on the current requirement of 9 measures over 3 domains. Additionally, the clinical topic of this measure contained within the Coronary Artery Bypass Graft measures group allows CMS to evaluate patients who undergo Coronary Artery Bypass Graft surgery to be assessed in a more comprehensive manner.	Society of Thoracic Surgeons						X
0114/ 167	N/A	**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 **Rationale**: This measure has been reportable through PQRS for 7 years and was finalized for reporting through registry and measures groups in the PQRS in the CY 2013 PFS final rule (77 FR 69234). CMS proposes to make this individual measure reportable via measures group only in the CY 2016 PFS proposed rule to help mitigate the burden of EPs reporting individual measures based on the current requirement of 9 measures over 3 domains. Additionally, the clinical topic of this measure contained within the Coronary Artery Bypass Graft measures group allows CMS to evaluate patients who undergo Coronary Artery Bypass Graft surgery to be assessed in a more comprehensive manner.	Society of Thoracic Surgeons						X

NQF/ PQRS	CMS E-Measure ID	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups
0115 /168	N/A	**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 **Rationale**: This measure has been reportable through PQRS for 7 years and was finalized for reporting through registry and measures groups in the PQRS in the CY 2013 PFS final rule (77 FR 69234). CMS proposes to make this individual measure reportable via measures group only in the CY 2016 proposed rule to help mitigate the burden of EPs reporting individual measures based on the current requirement of 9 measures over 3 domains. Additionally, the clinical topic of this measure contained within the Coronary Artery Bypass Graft measures group allows CMS to evaluate patients who undergo Coronary Artery Bypass Graft surgery to be assessed in a more comprehensive manner.	Society of Thoracic Surgeons						X
0068/ 204	164v 3	**Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic:** Percentage of patients 18 years of age and older who were discharged alive for 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 antithrombotic during the measurement period **Rationale**: This measure has been reportable through PQRS for 6 years and was finalized for reporting through claims, registry, EHR, GPRO, and measures groups in the PQRS in the CY 2013 PFS final rule (77 FR 69239). CMS proposes to add this measure to the proposed Cardiovascular Prevention measures group in the CY 2016 proposed rule, as the Cardiovascular Prevention measures group supports the Million Hearts initiative with overall cardiovascular health.	National Committee for Quality Assurance	X		X	X	X	X
0018/ 236	165v 3	**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 **Rationale**: This measure has been reportable through PQRS for 5 years and was finalized for reporting through claims, registry, EHR, GPRO, and measures groups in the PQRS in the CY 2013 PFS final rule (77 FR 69243). In the CY 2015 PFS final rule (79 FR 67805), this measure was finalized for designation as a cross-cutting measure. CMS proposes to add this measure to the proposed Cardiovascular Prevention measures group in the CY 2016 proposed rule, as the Cardiovascular Prevention measures group supports the Million Hearts initiative with overall cardiovascular health.	National Committee for Quality Assurance	X		X	X	X	X

NQF/ PQRS	CMS E-Measure ID	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups
0022/ 238	156v 3	**Use of High-Risk Medications in the Elderly:** 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. **Rationale**: This measure has been reportable through PQRS for 4 years and was finalized for reporting through EHR in the PQRS in the CY 2013 PFS final rule (77 FR 69244). In the CY 2015 PFS final rule (79 FR 67865), this measure was finalized for the addition of registry reporting method. CMS proposes to add this measure to the proposed Multiple Chronic Conditions Measures Group in the CY 2016 proposed rule, as the Multiple Chronic Conditions measures group offers broadly applicable measures which should be addressed in the management of patients with multiple chronic conditions.	National Committee for Quality Assurance			X	X		X
N/A/ 242	N/A	**Coronary Artery Disease (CAD): Symptom Management:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12 month period with results of an evaluation of level of activity and an assessment of whether anginal symptoms are present or absent with appropriate management of anginal symptoms within a 12 month period **Rationale**: This measure has been reportable through PQRS for 4 years and was finalized for reporting through registry and measures groups in the PQRS in the CY 2013 PFS final rule (77 FR 69244). CMS proposes to make this individual measure reportable via measures group only in the CY 2016 proposed rule to help mitigate the burden of EPs reporting individual measures based on the current requirement of 9 measures over 3 domains. Additionally, the clinical topic of this measure contained within the Coronary Artery Disease measures group allows CMS to evaluate patients diagnosed with Coronary Artery Disease.	American Medical Association – Physician Consortium for Performance Improvement /American College of Cardiology Foundation/American Heart Association						X
N/A/ 262	N/A	**Image Confirmation of Successful Excision of Image–Localized Breast Lesion:** Image confirmation of lesion(s) targeted for image guided excisional biopsy or image guided partial mastectomy in patients with nonpalpable, image-detected breast lesion(s). Lesions may include: microcalcifications, mammographic or sonographic mass or architectural distortion, focal suspicious abnormalities on magnetic resonance imaging (MRI) or other breast imaging amenable to localization such as positron emission tomography (PET) mammography, or a biopsy marker demarcating site of confirmed pathology as established by previous core biopsy **Rationale**: This measure has been reportable through PQRS for 4 years and was finalized for reporting through claims and registry in the PQRS in the CY 2013 PFS final rule (77 FR 69248). CMS proposes to remove the claims reporting option in the CY 2016 PFS proposed rule for this measure as CMS seeks to move the PQRS program away from claims reporting.	American Society of Breast Surgeons			X			
N/A/ 263	N/A	**Preoperative Diagnosis of Breast Cancer:** The percent of patients undergoing breast cancer operations who obtained the diagnosis of breast cancer preoperatively by a minimally invasive biopsy method	American Society of Breast Surgeons			X			

NQF/ PQRS	CMS E-Measure ID	Measure Title and Description¥	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups
		Rationale: This measure has been reportable through PQRS for 4 years and was finalized for reporting through claims and registry in the PQRS in the CY 2013 PFS final rule (77 FR 69248). CMS proposes to remove the claims reporting option in the CY 2016 PFS proposed rule for this measure as CMS seeks to move the PQRS program away from claims reporting.							
N/A/ 337	N/A	**Tuberculosis 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 **Rationale**: This measure has been reportable through PQRS for 2 years and was finalized for reporting through registry in the PQRS in the CY 2014 PFS final rule (78 FR 74648). CMS proposes to add this measure to the Rheumatoid Arthritis Measures Group in the CY 2016 PFS proposed rule. This measure targets an at-risk patient population, is clinically significant, and is in alignment with current clinical guidelines for neurological evaluation of diabetic neuropathy.	American Academy of Dermatology			X			X
0710/ 370	159v 3	**Depression Remission at Twelve Months:** Adult patients age 18 and older with major depression or dysthymia and an initial PHQ-9 score > 9 who demonstrate remission at twelve months defined as 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 **Rationale**: This measure has been reportable through PQRS for 2 years and was finalized for reporting through EHR in the PQRS in the CY 2014 PFS final rule (77 FR 69265). In the CY 2015 PFS final rule (79 FR 67867), this measure was finalized for reporting with the addition of the GPRO Web Interface reporting method. CMS proposes to adjust the reporting methods for this measure by adding registry for the CY 2016 proposed rule. CMS had intended to make this measure reportable via registry in the 2015 Program Year, however this was mistakenly never proposed on the 2015 NPRM.	Minnesota Community Measurement			X	X	X	

¥ Measure details including titles, descriptions and measure owner information may vary during a particular program year. This is due to the timing of measure specification preparation and the measure versions used by the various reporting options/methods. Please refer to the measure specifications that apply for each of the reporting options/methods for specific measure details.

d. PQRS Measures Groups

Section 414.90(b) defines a measures group as a subset of six or more PQRS measures that have a particular clinical condition or focus in common. The denominator definition and coding of the measures group identifies the condition or focus that is shared across the measures within a particular measures group.

We propose to add the following 3 new measures groups as shown in Tables 27, 28 and 29 that will be available for reporting in the PQRS beginning in 2016. Please note that, in these tables, we provide the PQRS measure numbers for the measures within these proposed measures groups that were previously finalized in the PQRS. New measures within these proposed measures groups that are proposed to be added, as indicated in Table 23 above, do not have a PQRS number. Therefore, in lieu of a PQRS number, an ''NA'' is indicated.

- Multiple Chronic Conditions Measures Group: We propose to add the Multiple Chronic Conditions Measures Group in the CY 2016 proposed rule. A large proportion of the Medicare population are impacted by Multiple Chronic Conditions, and providers that treat this population are often not recognized for the complexity of treatment for a patient with multiple chronic conditions. The addition of this measures group would specifically identify those providers that address the exponential complexity of treating the combination of these conditions rather than a sum of the individual conditions. This measures group addresses the

complexity of care that is required for patients that may have multiple disease processes that require clinical management and treatment.

• Cardiovascular Prevention Measures Group (Millions Hearts): We propose to add the Cardiovascular Prevention Measures Group in the CY 2016 proposed rule. Prior to 2015, the PQRS included a Cardiovascular Prevention Measures Group (Measures 2, 204, 226, 236, 241 and 317 in 2014 (78 FR 74741)). The measures group was removed for 2015 PQRS reporting due to clinical guideline changes that affected many of the measures. Given the efficacy of cardiovascular prevention on cardiovascular health, this measures group is being re-considered with an adjustment to align with current clinical guidelines. This measures group is also fully supported by the Million Hearts Initiative.

• Diabetic Retinopathy Measures Group: We propose to add the Diabetic Retinopathy Measures Group in the CY 2016 proposed rule. An increase in the frequency of Type 2 diabetes in the pediatric age group is associated with increased childhood obesity. The implications are significantly increased burdens of disability and complications associated with diabetes, including diabetic retinopathy, which has a projected prevalence of 6 million individuals with diabetic retinopathy by the year 2020 in the United States, and a prevalence rate of 28.5% in all adults with diabetes aged 40 and older. The addition of the Diabetic Retinopathy Measures Group would help to address this significant public health problem by allowing for the comprehensive evaluation of provider performance and patient outcomes related to a disease that threatens the eyesight of a very large population, and by supporting improvements in quality of care and outcomes related to diabetic retinopathy.

TABLE 27—CARDIOVASCULAR PREVENTION MEASURES GROUP FOR 2016 AND BEYOND

[Millions Hearts]

NQF/PQRS	Measure title and description	Measure developer
0419/130	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the EP 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/Quality Insights of Pennsylvania.
0028/226	Preventive Care and Screening: Tobacco use: Screening and 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.	American Medical Association—Physician Consortium for Performance Improvement.
0068/204	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic: Percentage of patients 18 years of age and older who were discharged alive for 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 antithrombotic during the measurement period.	National Committee for Quality Assurance.
0018/236	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
N/A/317	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/Quality Insights of Pennsylvania.
N/A/N/A	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease: Percentage of high-risk adult patients aged ≥21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR adult patients aged ≥21 years with a fasting or direct Low-Density Lipoprotein Cholesterol (LDL–C) level ≥190 mg/dL; OR patients aged 40–75 years with a diagnosis of diabetes with a fasting or direct Low-Density Lipoprotein Cholesterol (LDL–C) level of 70–189 mg/dL who were prescribed or are already on statin medication therapy during the measurement period.	Centers for Medicare & Medicaid Services/Quality Insights of Pennsylvania/Mathematica.
	This is a new measure described in Table 23 above	

TABLE 28—DIABETIC RETINOPATHY MEASURES GROUP FOR 2016 AND BEYOND

NQF/PQRS	Measure title and description	Measure developer
0059/001	Diabetes: Hemoglobin A1c Poor Control: 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.
0088/018	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.	American Medical Association-Physician Consortium for Performance Improvement/National Committee for Quality Assurance.

TABLE 28—DIABETIC RETINOPATHY MEASURES GROUP FOR 2016 AND BEYOND—Continued

NQF/PQRS	Measure title and description	Measure developer
0089/019	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.	American Medical Association-Physician Consortium for Performance Improvement/National Committee for Quality Assurance.
0055/117	Diabetes: Eye Exam: Percentage of patients 18 through 75 years of age with a diagnosis of diabetes (type 1 and type 2) who had a retinal or dilated eye exam by an eye care professional in the measurement period or a negative retinal or dilated eye exam (negative for retinopathy) in the year prior to the measurement period.	National Committee for Quality Assurance.
0419/130	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the EP 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/Quality Insights of Pennsylvania.
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients 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.	American Medical Association-Physician Consortium for Performance Improvement.
N/A/317	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/Quality Insights of Pennsylvania.

TABLE 29—MULTIPLE CHRONIC CONDITIONS MEASURES GROUP FOR 2016 AND BEYOND

NQF/PQRS	Measure title and description	Measure developer
0326/047	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/American Medical Association-Physician Consortium for Performance Improvement.
0041/110	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.	American Medical Association-Physician Consortium for Performance Improvement.
0421/128	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 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 65 years and older BMI ≥23 and <30 kg/m2; Age 18–64 years BMI ≥18.5 and <25 kg/m2.	Centers for Medicare & Medicaid Services/Quality Insights of Pennsylvania.
0419/130	Documentation of Current Medications in the Medical Record: Percentage of visits for patients aged 18 years and older for which the EP 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/Quality Insights of Pennsylvania.
0420/131	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/Quality Insights of Pennsylvania.
0418/134	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/Quality Insights of Pennsylvania.
0101/154	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/American Medical Association-Physician Consortium for Performance Improvement.

TABLE 29—MULTIPLE CHRONIC CONDITIONS MEASURES GROUP FOR 2016 AND BEYOND—Continued

NQF/PQRS	Measure title and description	Measure developer
0101/155	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/American Medical Association-Physician Consortium for Performance Improvement.
0022/238	Use of High-Risk Medications in the Elderly: 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.

We propose to amend the following previously finalized measures groups for reporting in the PQRS beginning in 2016. Please note that, in these tables, we provide the PQRS measure numbers for the measures within these proposed measures groups that were previously finalized in the PQRS. New measures within these proposed measures groups that are proposed to be added, as indicated in Table 23 above, do not have a PQRS number. Therefore, in lieu of a PQRS number, an ''NA'' is indicated.

TABLE 29A—CORONARY ARTERY BYPASS GRAFT (CABG) MEASURES GROUP FOR 2016 AND BEYOND

NQF/PQRS	Measure title and description	Measure developer
0134/043	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 Coronary Artery Bypass Graft surgery who received an Internal Mammary Artery graft.	Society of Thoracic Surgeons.
0236/044	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.	Center for Medicare & Medicaid Services/Quality Insights of Pennsylvania.
0129/164	Coronary Artery Bypass Graft (CABG): Prolonged Intubation: Percentage of patients aged 18 years and older undergoing isolated Coronary Artery Bypass Graft (CABG) surgery who require postoperative intubation >24 hours.	Society of Thoracic Surgeons.
0130/165	Coronary Artery Bypass Graft (CABG): Deep Sternal Wound Infection Rate: Percentage of patients aged 18 years and older undergoing isolated Coronary Artery Bypass Graft surgery who, within 30 days postoperatively, develop deep sternal wound infection involving muscle, bone, and/or mediastinum requiring operative intervention.	Society of Thoracic Surgeons.
0131/166	Coronary Artery Bypass Graft (CABG): Stroke: Percentage of patients aged 18 years and older undergoing isolated Coronary Artery Bypass Graft 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.	Society of Thoracic Surgeons.
0114/167	Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure: Percentage of patients aged 18 years and older undergoing isolated Coronary Artery Bypass Graft surgery (without pre-existing renal failure) who develop postoperative renal failure or require dialysis.	Society of Thoracic Surgeons.
0115/168	Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration: Percentage of patients aged 18 years and older undergoing isolated Coronary Artery Bypass Graft 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.

We propose to amend the following measures groups for reporting in the PQRS beginning in 2016.

TABLE 29B—DEMENTIA MEASURES GROUP FOR 2016 AND BEYOND

[CMS proposes to add PQRS #134 preventive care and screening and delete PQRS #285 dementia: Screening for depressive symptoms from this measures group]

NQF/PQRS	Measure title and description	Measure developer
0326/047	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/American Medical Association-Physician Consortium for Performance Improvement.

TABLE 29B—DEMENTIA MEASURES GROUP FOR 2016 AND BEYOND—Continued

[CMS proposes to add PQRS #134 preventive care and screening and delete PQRS #285 dementia: Screening for depressive symptoms from this measures group]

NQF/PQRS	Measure title and description	Measure developer
0418/134	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.	Center for Medicare & Medicaid Services/Quality Insights of Pennsylvania.
N.A/280	Dementia: Staging of Dementia: Percentage of patients, regardless of age, with a diagnosis of dementia whose severity of dementia was classified as mild, moderate or severe at least once within a 12 month period.	American Academy of Neurology/American Psychological Association.
N/A/281	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.	American Medical Association-Physician Consortium for Performance Improvement.
N/A/282	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/American Psychological Association.
N/A/283	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/American Psychological Association.
N/A/284	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/American Psychological Association.
N/A/286	Dementia: Counseling Regarding Safety Concerns: 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.	American Academy of Neurology/American Psychological Association.
N/A/287	Dementia: Counseling Regarding Risks of Driving: Percentage of patients, regardless of age, with a diagnosis of dementia or their caregiver(s) who were counseled regarding the risks of driving and the alternatives to driving at least once within a 12 month period.	American Academy of Neurology/American Psychological Association.
N/A/288	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/American Psychological Association.

TABLE 29C—DIABETES MEASURES GROUP FOR 2016 AND BEYOND

[CMS Proposes to Add PQRS #126 Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy and Delete PQRS #163 Diabetes: Foot Exam From This Measures Group]

NQF/PQRS	Measure title and description	Measure developer
0059/001	Diabetes: Hemoglobin A1c Poor Control: 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.
0041/110	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.	American Medical Association-Physician Consortium for Performance Improvement.
0055/117	Diabetes: Eye Exam: Percentage of patients 18 through 75 years of age with a diagnosis of diabetes (type 1 and type 2) who had a retinal or dilated eye exam in the measurement period or a negative retinal or dilated eye exam (negative for retinopathy) in the year prior to the measurement period.	National Committee for Quality Assurance.
0062/119	Diabetes: Medical Attention for Neuropathy: 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	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.
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients 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.	American Medical Association-Physician Consortium for Performance Improvement.

TABLE 29D—PREVENTIVE CARE MEASURES GROUP FOR 2016 AND BEYOND

[CMS Proposes to Add NQF #2152 Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling and Delete PQRS #173 Preventive Care and Screening: Unhealthy Alcohol Use—Screening From This Measures Group]

NQF/PQRS	Measure title and description	Measure developer
0046/039	Screening or Therapy for Osteoporosis for Women Aged 65 Years and Older: Percentage of female patients aged 65 years and older who have a central dual-energy X-ray absorptiometry (DXA) measurement ordered or performed at least once since age 60 or pharmacologic therapy prescribed within 12 months.	National Committee for Quality Assurance/American Medical Association-Physician Consortium for Performance Improvement.
N/A/048	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/American Medical Association-Physician Consortium for Performance Improvement.
0041/110	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.	American Medical Association-Physician Consortium for Performance Improvement.
0043/111	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	Breast Cancer Screening: Percentage of women 50 through 74 years of age who had a mammogram to screen for breast cancer within 27 months.	National Committee for Quality Assurance.
0034/113	Colorectal Cancer Screening: Percentage of patients 50 through 75 years of age who had appropriate screening for colorectal cancer.	National Committee for Quality Assurance.
0421/128	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 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 encounter Normal Parameters: Age 65 years and older BMI ≥23 and <30 kg/m2; Age 18–64 years BMI ≥18.5 and <25 kg/m2.	Center for Medicare & Medicaid Services/Quality Insights of Pennsylvania.
0418/134	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.	Center for Medicare & Medicaid Services/Quality Insights of Pennsylvania.
0028/226	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention: Percentage of patients 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.	American Medical Association-Physician Consortium for Performance Improvement.
2152/N/A	Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling: Percentage of patients aged 18 years and older who were screened at least once within the last 24 months for unhealthy alcohol use using a systematic screening method AND who received brief counseling if identified as an unhealthy alcohol user. This is a new measure described in Table 23 above.	American Medical Association-Physician Consortium for Performance Improvement.

TABLE 29E—RHEUMATOID ARTHRITIS MEASURES GROUP FOR 2016 AND BEYOND

[CMS Proposes to Add PQRS 337 Tuberculosis Prevention for Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis Patients on a Biological Immune Response Modifier to This Measures Group]

NQF/PQRS	Measure title and description	Measure developer
0054/108	Rheumatoid Arthritis (RA): Disease Modifying Anti-Rheumatic Drug (DMARD) Therapy: Percentage of patients aged 18 years and older who were diagnosed with RA and were prescribed, dispensed, or administered at least one ambulatory prescription for a disease-modifying anti-rheumatic drug (DMARD).	National Committee for Quality Assurance.
0421/128	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 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 encounter Normal Parameters: Age 65 years and older BMI ≥23 and <30 kg/m2; Age 18–64 years BMI ≥18.5 and <25 kg/m2.	Center for Medicare & Medicaid Services/Quality Insights of Pennsylvania.
0420/131	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.	Center for Medicare & Medicaid Services/Quality Insights of Pennsylvania.
N/A/176	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	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.

TABLE 29E—RHEUMATOID ARTHRITIS MEASURES GROUP FOR 2016 AND BEYOND—Continued

[CMS Proposes to Add PQRS 337 Tuberculosis Prevention for Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis Patients on a Biological Immune Response Modifier to This Measures Group]

NQF/PQRS	Measure title and description	Measure developer
N/A/178	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	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	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.
N/A/337	Tuberculosis 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 College of Rheumatology.

e. Measures Available for Reporting in the GPRO Web Interface

We finalized the measures that are available for reporting in the GPRO web interface for 2015 and beyond in the CY 2015 PFS final rule (79 FR 67893 through 67902). The current measures available for reporting under the GPRO web interface are available at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2014_GPROWebInterface_MeasuresList_NarrativeSpecs_ReleaseNotes_12132013.zip.* We are proposing to adopt the following measure in Table 30 for reporting via the GPRO web interface beginning in 2016:

TABLE 30—MEASURE FOR ADDITION TO THE GROUP PRACTICE REPORTING OPTION WEB INTERFACE BEGINNING IN 2016 AND BEYOND

NQF/PQRS	GPRO Module	Measure and title description ¥	Measure steward	Other quality reporting programs
		Additions		
N/A/N/A	STAT–1 (Statin)	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease: Percentage of high-risk adult patients aged ≥21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR adult patients aged ≥21 years with a fasting or direct Low-Density Lipoprotein Cholesterol (LDL–C) level ≥190 mg/dL; OR patients aged 40–75 years with a diagnosis of diabetes with a fasting or direct Low-Density Lipoprotein Cholesterol (LDL–C) level of 70–189 mg/dL who were prescribed or are already on statin medication therapy during the measurement period. Rationale: Although this measure is not NQF-endorsed, we are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to propose this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. This is a new measure that is proposed for the GPRO Web Interface in the PQRS for the CY 2016 PFS proposed rule. This measure addresses statin therapy, which is an important treatment option for patients with cardiovascular disease, which includes up-to-date clinical guidelines.	Centers for Medicare & Medicaid Services/Quality Insights of Pennsylvania/Mathematica.	MSSP.

7. Request for Input on the Provisions Included in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)

The primary purpose of the Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10, enacted on April 16, 2015) (MACRA) was to repeal the Medicare sustainable growth rate (SGR) and strengthen Medicare access by improving physician payments and making other improvements, as well as to reauthorize the Children's Health Insurance Program. In this section of the proposed rule, we are seeking public input on the following provisions of MACRA:

- Section 101(b): Consolidation of Certain Current Law Performance Programs with New Merit-based Incentive Payment System (hereinafter MIPS)
- Section 101(c): Merit-based Incentive Payment System
- Section 101(e): Promoting Alternative Payment Models

a. The Merit-Based Incentive Payment System (MIPS)

Section 1848(q) of the Act, added by section 101(c) of the MACRA, requires creation of the MIPS, applicable beginning with payments for items and services furnished on or after January 1, 2019, under which the Secretary shall: (1) Develop a methodology for assessing the total performance of each MIPS eligible professional according to performance standards for a performance period for a year; (2) using the methodology, provide for a composite performance score for each eligible professional for each performance period; and (3) use the composite performance score of the MIPS eligible professional for a performance period for a year to determine and apply a MIPS adjustment factor (and, as applicable, an additional MIPS adjustment factor) to the professional for the year. To aid in the planning and implementation of the MIPS, we are seeking public input on provisions related to the MIPS, including, but not limited to:

- *Low-volume threshold:* Section 1848(q)(1)(C)(iv) of the Act requires the Secretary to select a low-volume threshold to apply for purposes of excluding certain eligible professionals (as defined in section 1848(k)(3)(B) of the Act) from the definition of a MIPS eligible professional. The low-volume threshold may include one or more or a combination of the following: (1) The minimum number (as determined by the Secretary) of individuals enrolled under Medicare Part B who are treated by the eligible professional for the performance period involved; (2) the minimum number (as determined by the Secretary) of items and services furnished to individuals enrolled under Medicare Part B by such professional for such performance period; and (3) the minimum amount (as determined by the Secretary) of allowed charges billed by such professional under Medicare Part B for such performance period. We seek comment as to what would be an appropriate low-volume threshold for purposes of excluding certain eligible professionals (as defined in section 1848(k)(3)(B) of the Act) from the definition of a MIPS eligible professional. We also seek comment as to whether CMS should consider establishing a low-volume threshold using more than one or a combination of factors or, alternatively, whether CMS should focus on establishing a low-volume threshold based on one factor. We invite comments on which factors to include, individually or in combination, in determining a low-volume threshold.

Low-volume thresholds are currently used in other CMS reporting programs. For example, as required by section 1903(t)(2) of the Act, eligible professionals and acute care hospitals must meet certain Medicaid patient volume thresholds (in general, 30 percent for eligible professionals and 10 percent for acute care hospitals) to be eligble for the Medicaid EHR Incentive Program. We would consider proposing similar thresholds, such as to exclude eligible professionals that do not have at least 10 percent of their patient volume derived from Medicare Part B encounters from participating in the MIPs. We seek comment as to whether this would be an appropriate low-volume threshold for the MIPS. In addition, we invite comments on the applicability of existing low-volume thresholds used in other CMS reporting programs toward MIPs.

- *Clinical practice improvement activities:* Section 1848(q)(2)(A)(iii) of the Act provides for clinical practice improvement activities as one of the performance categories used in determining the composite performance score under the MIPS. In section 1848(q)(2)(C)(v)(III) of the Act, clinical practice improvement activities are defined as activities that relevant eligible professional organizations and other relevant stakeholders identify as improving clinical practice or care delivery and that the Secretary determines, when effectively executed, are likely to result in improved outcomes. Section 1848(q)(2)(B)(iii) of the Act provides that the clinical practice improvement activities under subcategories specified by the Secretary for a performance period for a year must include at least the following subcategories:

(1) Expanded practice access, such as same day appointments for urgent needs and after-hours access to clinician advice.

(2) Population management, such as monitoring health conditions of individuals to provide timely health care interventions or participation in a qualified clinical data registry.

(3) Care coordination, such as timely communication of test results, timely exchange of clinical information to patients and other providers, and use of remote monitoring or telehealth.

(4) Beneficiary engagement, such as the establishment of care plans for individuals with complex care needs, beneficiary self-management assessment and training, and using shared decision-making mechanisms.

(5) Patient safety and practice assessment, such as through use of clinical or surgical checklists and practice assessments related to maintaining certification.

(6) Participation in an alternative payment model (as defined in section 1833(z)(3)(C) of the Act).

We seek comment on what activities could be classified as clinical practice improvement activities according to this definition.

b. Alternative Payment Models

Section 101(e) of MACRA, Promoting Alternative Payment Models, introduces a framework for promoting and developing alternative payment models (APMs) and providing incentive payments for eligible professionals who participate in APMs. The statutory amendments made by this section have payment implications for eligible professionals beginning in 2019. We are broadly seeking public comment on the topics in this section through this proposed rule.

In preparation to implement the changes introduced by section 101(e) of MACRA, we intend to publish questions for public comment on these amendments through a forthcoming Request for Information (RFI). Section 101(e) of MACRA includes the following provisions: Increasing Transparency of Physician-Focused Payment Models and Criteria and Process for Submission and Review of Physician-focused Payment Models (section 101(e)(1) of MACRA adds new section 1868(c) of the Act), Incentive Payments for Participation in Eligible Alternative Payment Models (section 101(e)(2) of MACRA adds new section 1833(z) of the Act), Encouraging

Development and Testing of Certain Models (section 101(e)(4) of MACRA amends section 1115A(b)(2) of the Act), a study on Integrating Medicare Alternative Payment Models in the Medicare Advantage payment system (section 101(e)(6) of MACRA), and Study and Report on Fraud Related to Alternative Payment Models under the Medicare Program (section 101(e)(7) of MACRA).

We intend to publish specific questions in the forthcoming RFI on topics within these provisions, including the following: The criteria for assessing physician-focused payment models; the criteria and process for the submission of physician-focused payment models eligible APMS, qualifying APM participants; the Medicare payment threshold option and the combination all-payer and Medicare payment threshold option for qualifying and partial-qualifying APM participants; the time period to use to calculate eligibility for qualifying and partial-qualifying APM participants, eligible APM entities, quality measures and EHR use requirements; and the definition of nominal financial risk for eligible APM entities. In anticipation of the future RFI and subsequent notice and comment rulemaking, we welcome comments on approaches to implementing any of the topics listed in this section, including in provisions not enumerated above, and any other related concerns.

J. Electronic Clinical Quality Measures (eCQM) and Certification Criteria; and Electronic Health Record (EHR) Incentive Program-Comprehensive Primary Care (CPC) Initiative and Medicare Meaningful Use Aligned Reporting

1. Background

The Health Information Technology for Economic and Clinical Health (HITECH) Act (Title IV of Division B of the ARRA, together with Title XIII of Division A of the ARRA) authorizes incentive payments under Medicare and Medicaid for the adoption and meaningful use of certified EHR technology (CEHRT). Section 1848(o)(2)(B)(iii) of the Act requires that in selecting clinical quality measures (CQMs) for eligible professionals (EPs) to report under the EHR Incentive Program, and in establishing the form and manner of reporting, the Secretary shall seek to avoid redundant or duplicative reporting otherwise required. As such, we have taken steps to establish alignments among various quality reporting and payment programs that include the submission of CQMs.

Under section 1848(o)(2)(A)(iii) of the Act and the definition of ''meaningful EHR user'' under § 495.4, EPs must report on CQMs selected by CMS using CEHRT, as part of being a meaningful EHR user under the Medicare EHR Incentive Program. For CY 2012 and subsequent years, § 495.8(a)(2)(ii) requires an EP to successfully report the CQMs selected by CMS to CMS or the states, as applicable, in the form and manner specified by CMS or the states, as applicable.

In the CY 2014 PFS final rule with comment period (78 FR 74756), we finalized our proposal to require EPs who seek to report CQMs electronically under the Medicare EHR Incentive Program to use the most recent version of the electronic specifications for the CQMs and have CEHRT that is tested and certified to the most recent version of the electronic specifications for the CQMs. We stated that we believe it is important for EPs to electronically report the most recent versions of the electronic specifications for the CQMs as updated measure versions to correct minor inaccuracies found in prior measure versions. We stated that to ensure that CEHRT products can successfully transmit CQM data using the most recent version of the electronic specifications for the CQMs, it is important that the product be tested and certified to the most recent version of the electronic specifications for the CQMs.

2. Certification Requirements for Reporting Electronic Clinical Quality Measures (eCQMs) in the EHR Incentive Program and PQRS

In the CY 2015 PFS final rule with comment period (79 FR 67906), we finalized our proposal for the Medicare EHR Incentive Program that, beginning in CY 2015, EPs are not required to ensure that their CEHRT products are recertified to the most recent version of the electronic specifications for the CQMs. Although we are not requiring recertification, EPs must still report the most recent version of the electronic specifications for the CQMs if they choose to report CQMs electronically for the Medicare EHR Incentive Program.

In the FY 2016 IPPS proposed rule (80 FR 24611 through 24615), HHS' Office of the National Coordinator for Health Information Technology (ONC) proposed a certification criterion for ''CQMs—report'' at 45 CFR 170.315(c)(3). This proposal would require that health information technology enable users to electronically create a data file for transmission of clinical quality measurement data in accordance with the Quality Reporting Document Architecture (QRDA) Category I (individual patient-level report) and Category III (aggregate report) standards, at a minimum. As part of the ''CQMs—report'' criterion, ONC also proposed to offer optional certification for EHRs according to the ''form and manner'' that CMS requires for electronic submission to participate in the EHR Incentive Programs and PQRS. These requirements are published annually as the ''CMS QRDA Implementation Guide'' and posted on CMS' Web site at *http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/eCQM_Library.html*. The latest set of requirements (2015 CMS QRDA Implementation Guide for Eligible Professional Programs and Hospital Quality Reporting) combines the requirements for EPs, eligible hospitals, and CAHs. For a complete discussion of these proposals, we refer readers to 80 FR 24611 through 24615.

In the FY 2016 IPPS proposed rule (80 FR 24323 through 24629), we stated that we anticipate proposing to require EPs, eligible hospitals, and CAHs seeking to report CQMs electronically as part of meaningful use under the EHR Incentive Programs for 2016 to adhere to the additional standards and constraints on the QRDA standards for electronic reporting as described in the CMS QRDA Implementation Guide. We stated that we anticipate proposing to revise the definition of ''certified electronic health record technology'' at § 495.4 to require certification to the optional portion of the 2015 Edition CQM reporting criterion (proposed at 45 CFR 170.315(c)(3)) in the CY 2016 Medicare PFS proposed rule later this year.

Accordingly, to allow providers to upgrade to 2015 Edition CEHRT before 2018, we propose to revise the CEHRT definition for 2015 through 2017 to require that EHR technology is certified to report CQMs, in accordance with the optional certification, in the format that CMS can electronically accept (CMS' ''form and manner'' requirements) if certifying to the 2015 Edition ''CQMs—report'' certification criterion at § 170.315(c)(3). Specifically, this would require technology to be certified to § 170.315(c)(3)(i) (the QRDA Category I and III standards) and § 170.315(c)(3)(ii) (the optional CMS ''form and manner''). We note that the proposed CEHRT definition for 2015 through 2017 included in the Stage 3 proposed rule published on March 30, 2014 (80 FR 16732 through 16804) allows providers to use 2014 Edition or 2015 Edition certified EHR technology. These

proposed revisions would apply for EPs, eligible hospitals, and CAHs.

We also propose to revise the CEHRT definition for 2018 and subsequent years to require that EHR technology is certified to report CQMs, in accordance with the optional certification, in the format that CMS can electronically accept. Specifically, this would require technology to be certified to § 170.315(c)(3)(i) (the QRDA Category I and III standards) and § 170.315(c)(3)(ii) (the optional CMS ''form and manner''). These proposed revisions would apply for EPs, eligible hospitals, and CAHs.

We are proposing these amendments at § 495.4 to ensure that providers participating in PQRS and the EHR Incentive Programs under the 2015 Edition possess EHRs that have been certified to report CQMs according to the format that CMS requires for submission. We invite comment on our proposals.

3. Electronic Health Record (EHR) Incentive Program-Comprehensive Primary Care (CPC) Initiative Aligned Reporting

The Comprehensive Primary Care (CPC) initiative, under the authority of section 3021 of the Affordable Care Act, is a multi-payer initiative fostering collaboration between public and private health care payers to strengthen primary care. Under this initiative, we pay participating primary care practices a care management fee to support enhanced, coordinated services. Simultaneously, participating commercial, state, and other federal insurance plans are also offering enhanced support to primary care practices that provide high-quality primary care. There are approximately 480 CPC practice sites across seven health care markets in the U.S.

Under the CPC initiative, CPC practice sites are required to report to CMS a subset of the CQMs that were selected in the EHR Incentive Program Stage 2 final rule for EPs to report under the EHR Incentive Program beginning in CY 2014 (for a list of CQMs that were selected in the EHR Incentive Program Stage 2 final rule for EPs to report under the EHR Incentive Program beginning in CY 2014, see 77 FR 54069 through 54075).

In the CY 2015 PFS final rule with comment period (79 FR 67906 through 67907), we finalized a group reporting option for CQMs for the Medicare EHR Incentive Program under which EPs who are part of a CPC practice site that successfully reports at least nine electronically specified CQMs across two domains for the relevant reporting period in accordance with the requirements established for the CPC Initiative and using CEHRT would satisfy the CQM reporting component of meaningful use for the Medicare EHR Incentive Program. If a CPC practice site is not successful in reporting, EPs who are part of the site would still have the opportunity to report CQMs in accordance with the requirements established for the Medicare EHR Incentive Program in the Stage 2 final rule. Additionally, only those EPs who are beyond their first year of demonstrating meaningful use may use this CPC group reporting option. The CPC practice sites must submit the CQM data in the form and manner required by the CPC Initiative. Therefore, whether CPC required electronic submission or attestation of CQMs, the CPC practice site must submit the CQM data in the form and manner required by the CPC Initiative.

We propose to retain the group reporting option for CPC practice sites as finalized in the CY 2015 PFS final rule, but for CY 2016, to require CPC practice sites to submit at least 9 CPC CQMs that cover 3 domains. In CY 2015, the CPC CQM subset was increased from a total of 11 to 13 measures, of which 8 measures fall in the clinical process/effectiveness domain, 3 in the population health domain, and 2 in the safety domain. Additionally, the CPC practice sites have had ample time to obtain measures from the CPC eCQM subset of meaningful use measures. Given the increased number of measures in the CPC eCQM set the addition of one measure to the safety domain, and the sufficient time that CPC practice sites have had to upgrade their EHR systems, it is reasonable to expect that CPC practice sites would have enough measures to report across the three domains as required for the Medicare EHR Incentive Program CQM reporting requirement. If a CPC practice site is not successful in reporting, EPs who are part of the site would still have the opportunity to report CQMs in accordance with the current requirements established for the Medicare EHR Incentive Program. As proposed in the Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Modifications to Meaningful Use in 2015 through 2017 proposed rule (80 FR 20375), EPs in any year of participation may electronically report clinical quality measures for a reporting period in 2016. Therefore, we are proposing that for CY 2016, EPs who are part of CPC practice site and are in their first year of demonstrating meaningful use may also use this CPC group reporting option to report their CQMs electronically instead of reporting CQMs by attestation through the EHR Incentive Program's Registration and Attestation System. However, we note that EPs who choose this CPC group reporting option must use a reporting period for CQMs of one full year (not 90 days), and that the data must be submitted during the submission period from January 1, 2017 through February 28, 2017. This means that EPs who elect to electronically report through the CPC practice site cannot successfully attest to meaningful use prior to October 1, 2016 (the deadline established for EPs who are first-time meaningful users in CY 2016) and therefore will receive reduced payments under the PFS in CY 2017 for failing to demonstrate meaningful use, if they have not applied and been approved for a significant hardship exception under the EHR Incentive Program. We invite public comment on these proposals.

K. Potential Expansion of the Comprehensive Primary Care (CPC) Initiative

1. Background

As we discussed in the CY 2013 PFS final rule (77 FR 68978) and the CY 2014 PFS proposed rule (78 FR 43337), we are committed to supporting advanced primary care, including the recognition of care management as one of the critical components of primary care that contributes to better health for individuals and reduced expenditure growth. In January 2015, the Secretary announced the vision of ''Better Care; Smarter Spending; Healthier People,'' with emphases on incentives (''promote value based payment systems; bring proven models to scale''); care delivery (''encourage the integration and coordination of clinical care services; improve population health; promote patient engagement through shared decision making''); and information (''create transparency on cost and quality information; bring electronic health information to the point of care for meaningful use''). More information on the Secretary's January 2015 announcement is available at *http://www.hhs.gov/news/press/2015pres/01/20150126a.html.* Accordingly, we are continuing to prioritize the development and implementation of initiatives designed to improve payment for, and encourage long-term investment in, primary care and care management services. These initiatives include the following payment policies, programs, and demonstrations:

- The Comprehensive Primary Care (CPC) initiative (described in this section of this proposed rule).

• Separate payment under the Medicare PFS beginning January 1, 2015, for new CPT code 99490. Under this CPT code, the fee-for-service program now pays separately for non-face-to-face care coordination services furnished to Medicare beneficiaries with multiple chronic conditions, as provided in the CY 2014 and 2015 PFS final rules with comment period (78 FR 74414–74427, and 79 FR 67715–67730 and 80 FR 14853, respectively).

• Medicare participation in multi-payer reform initiatives conducted by states in the Multi-payer Advanced Primary Care Practice (MAPCP) Demonstration (described on CMS' Center for Medicare and Medicaid Innovation's (Innovation Center's) Web site at *http://innovation.cms.gov/initiatives/Multi-Payer-Advanced-Primary-Care-Practice/*).

• The Medicare Shared Savings Program (described in the ''Medicare Program; Medicare Shared Savings Program; Accountable Care Organizations; Final Rule'' that appeared in the November 2, 2011 **Federal Register** (76 FR 67802) and the subsequent final rule that addressed changes to the program, that appeared in the June 9, 2015 **Federal Register** (80 FR 32692).

• The testing of the Pioneer ACO Model, designed for experienced health care organizations (described on the Innovation Center's Web site at *http://innovation.cms.gov/initiatives/Pioneer-ACO-Model/*).

• The testing of the ACO Investment Model, designed to support organizations participating in the Medicare Shared Savings Program (described on the Innovation Center's Web site at *http://innovation.cms.gov/initiatives/ACO-Investment-Model/*).

The CPC initiative is a multi-payer initiative fostering collaboration between public and private health care payers to strengthen primary care. It is being conducted under the authority of section 1115A of the Act (added by section 3021 of the Affordable Care Act) (42 U.S.C. 1315a). The Act authorizes the Innovation Center to test innovative health care payment and service delivery models that have the potential to reduce Medicare, Medicaid, and Children's Health Insurance Program (CHIP) expenditures while preserving or enhancing the quality of patient care. The CPC initiative began on October 1, 2012, and is scheduled to end on December 31, 2016. The initiative is being implemented in seven U.S. regions: statewide in Arkansas, Colorado, New Jersey, and Oregon; and regionally in Capital District-Hudson Valley, New York; Cincinnati-Dayton Region, Ohio/Kentucky; and Greater Tulsa, Oklahoma. There are approximately 480 participating practices spread across the regions, and 38 participating payers.

In the CPC initiative, we are collaborating with commercial payers and state Medicaid offices to test a payment model consisting of non-visit based per beneficiary per month care management payments and shared savings opportunities. Practices receive a monthly non-visit based care management fee for each Medicare FFS beneficiary and, in cases where the state Medicaid agency is participating, for each Medicaid FFS beneficiary. The monthly payment for each Medicare beneficiary averaged $20 per beneficiary per month during years 1 and 2 of the initiative (CY 2013–14), and averages $15 per beneficiary per month in years 3 and 4 (CY 2015 and CY 2016). The per beneficiary per month care management fee is in addition to the usual FFS payments that practitioners at the practice receive for furnishing services to their Medicare patients. Practices also receive non-visit based care management payments from other participating CPC payers and are expected to combine CPC revenues across payers to support a whole-practice care delivery transformation strategy. Additionally, we are offering each CPC practice the opportunity to share net savings generated from improved care to Medicare beneficiaries attributable to the practice. For each of three separate performance periods (that is, CY 2014, CY 2015, and CY 2016), we will calculate savings to the Medicare program generated by all CPC practices within each region, taken as a group. A portion of any savings accomplished at the level of each region will be distributed to practices in that region according to each practice's performance on quality metrics (patient experience measures, claims-based measures and electronic CQMs). Practices have similar shared savings opportunities with other CPC payers in their region.

The payment model is designed to support the provision by practices of the following five comprehensive primary care functions:

(1) *Risk Stratified Care Management:* The provision of intensive care management of appropriate intensity for high-risk, high-need, high-cost patients.

(2) *Access and Continuity:* 24/7 access to the care team; use of asynchronous communication; designation of a provider or care team for patients to build continuity of care.

(3) *Planned Care for Chronic Conditions and Preventive Care:* Proactive, appropriate care based on systematic assessment of patients' needs and personalized care plans.

(4) *Patient and Caregiver Engagement:* Active support of patients in managing their health care to meet their personal health goals; establishment of systems of care that include engagement of patients and caregivers in goal-setting and decision making, creating opportunities for patient and caregiver engagement throughout the care delivery process.

(5) *Coordination of Care across the Medical Neighborhood:* Management by the primary care practice of communication and information flow in support of referrals, transitions of care, and when care is received in other settings.

The CPC initiative is testing whether provision of these five comprehensive primary care functions by each practice site—supported by multi-payer payment reform, the continuous use of data to guide improvement, and meaningful use of health information technology—can achieve improved care, better health for populations, and lower costs, and can inform Medicare and Medicaid policy. Participating practices must demonstrate progress towards the provision of the five comprehensive primary care functions by meeting nine annual Milestones. These Milestones are: (1) Budget; (2) care management for high risk patients; (3) access and continuity; (4) patient experience; (5) quality improvement; (6) care coordination across the medical neighborhood; (7) shared decision making; (8) participate in learning collaborative; (9) health information technology. Full requirements of each Milestone are available at *http://innovation.cms.gov/Files/x/CPCI-Implementation-GuidePY2015.pdf*.

Practices must also report at least 9 of 13 specified electronic clinical quality measures (eCQMs) at the level of the practice site population as a method of measuring the quality of care delivered to all patients served by the practice, regardless of payer. We have aimed to align CPC clinical quality measures and reporting with other CMS programs to reduce burden on providers from having to report the same measures to multiple CMS programs through various reporting mechanisms. Under the CPC initiative, EPs participating in the CPC initiative who would otherwise need to report PQRS measures individually, or who are part of TINs that are participating as a whole in CPC, are able to satisfy their PQRS reporting requirements by successfully reporting data in accordance with the requirements for the CPC initiative. The decision to elect this waiver must be

made at the level of the CPC practice site (that is, all EPs at the site must elect the waiver). Additionally, completion of eCQM reporting in accordance with CPC requirements allows practices to satisfy the CQM reporting component of meaningful use for the Medicare EHR Incentive Program. This alignment between CPC and the Medicare EHR Incentive Program is described in section III.L. of this proposed rule.

We provide resources to help practices address the five comprehensive primary care functions through the CPC learning system, which includes regular webinars (regional and national), two in-person regional learning collaborative meetings per year, opportunities for moderated online collaboration with CPC practices across the country on specific issues, and access to providers of technical assistance (Regional Learning Faculty) in each region. Additionally, we support regular, professionally moderated collaborative meetings in each region between participating payers, practices and other interested parties (for example, hospital systems), to monitor the progress of the initiative at the regional level and ensure regional support to help participating practices succeed in the CPC initiative.

The first independent evaluation report of the CPC initiative was released on January 23, 2015, and covered impacts in the first four payment quarters of the initiative. The evaluator's report concluded that in these first four payment quarters, the initiative appears to have reduced total monthly Medicare Parts A and B expenditures per beneficiary (compared to what they would have been absent the CPC initiative) by $14, or 2 percent (not including care management fees paid). Results from this first year suggest that CPC has generated nearly enough savings in Medicare health care expenditures to offset care management fees paid by CMS. There were also statistically significant declines in hospitalizations and emergency department utilization. However, the report found that expenditure and service use impact estimates differed significantly across regions. No statistically significant impacts were seen in early measurements of quality. Further information about the CPC initiative, including the first independent evaluation report, is available on the Innovation Center's Web site at *http://innovation.cms.gov/initiatives/comprehensive-primary-care-initiative/*.

2. Interaction With the Chronic Care Management Code

The CPC initiative includes per beneficiary per month payments for care management services that closely overlap with the scope of service for the new chronic care management (CCM) services code under the PFS. To avoid duplicative payment for substantially the same services, practitioners participating in the CPC initiative may not bill Medicare for CCM services furnished to patients attributed to the practice for purposes of the practice's participation in the CPC initiative, as the payment for CCM services would be a duplicative payment for substantially the same services for which payment is made through the per beneficiary per month payment under CPC. Practitioners may bill Medicare for CCM services furnished to eligible beneficiaries who are not attributed to the practice for the purpose of the practice's participation as part of the CPC initiative.

3. Considerations for Potential Model Expansion

Section 1115A(c) of the Act provides the Secretary with the authority to expand (including implementation on a nationwide basis) through rulemaking the duration and scope of a model that is being tested under section 1115A(b) of the Act if the following findings are made, taking into account the evaluation of the model under section 1115A(b)(4): (1) The Secretary determines that the expansion is expected to either reduce Medicare spending without reducing quality of care or improve the quality of patient care without increasing spending; (2) the CMS Chief Actuary certifies that the expansion would reduce (or would not result in any increase in) net Medicare program spending; and (3) the Secretary determines that the expansion would not deny or limit the coverage or provision of Medicare benefits. We are not proposing to expand the CPC initiative at this time. The decision of whether or not to expand the CPC initiative will be made by the Secretary in coordination with CMS and the Office of the Chief Actuary based on whether findings about the initiative meet the statutory criteria for expansion under section 1115A(c) of the Act. The primary goal for this solicitation of public comments is to receive information about issues surrounding a potential expansion of the CPC initiative. Furthermore, consistent with our ongoing commitment to developing new models and refining existing models based on additional information and experience, CMS may modify existing models or test additional models under its testing authority under section 1115A of the Act. We may possibly do so, taking into consideration stakeholder input, including feedback received through public comments submitted in response to the discussion in this section.

The following list is not an exhaustive list of issues on which we are requesting public comments, and the inclusion of the list of issues is not, in any way, meant to imply that all of these issues would be addressed in any expanded model. The solicitation of public comments is for planning purposes, and we would use additional rulemaking if we decide to expand the initiative. We are soliciting input from the public on the following considerations for any potential expansion of the CPC initiative:

- *Practice readiness:* CPC practices currently are asked to reorganize their work flows to accomplish the five comprehensive primary care functions. Practices must use the most recent edition of Office of the National Coordinator Certified Electronic Health Records Technology (CEHRT), to perform and deliver comprehensive primary care and to monitor and report practice level electronic clinical quality measures (eCQMs) (full details of these requirements are available at *http://innovation.cms.gov/Files/x/CPCI-Implementation-GuidePY2015.pdf*). We are interested in understanding the proportion of primary care practices ready for these transformation expectations and whether readiness varies systematically for differently structured practices (for example, small primary care practices, multi-specialty practices, and employed primary care practices within integrated health systems).
- *Practice standards and reporting:* We seek input on the value and operational burden of the current CPC Milestones approach, including the current system of quarterly reporting via a web portal (full details of these requirements are available at *http://innovation.cms.gov/Files/x/CPCI-Implementation-GuidePY2015.pdf*).
- *Practice groupings:* We seek input as to whether any potential expansion should be limited to existing CPC regions, or include new geographic regions. We are also interested in whether multi-site group practices would be willing to involve all their primary care sites in a potential expansion of the CPC initiative (practice sites currently participating in the CPC initiative were selected for the model individually), and how practices could

best be grouped for the purposes of calculating shared savings.

• *Interaction with state primary care transformation initiatives:* Though many primary care transformation efforts predated the start of the CPC initiative, the number of such efforts has grown significantly during the existence of this initiative. Various states are leading their own efforts to transform primary care practices. Although these efforts may have processes and goals that are similar to those in the CPC initiative, requirements and outcomes can differ in important ways. We are interested in whether a potential expansion of the CPC initiative could and should exist in parallel in a state with a separate state-led primary care transformation effort, especially if Medicare is participating in that effort.

• *Learning activities:* The CPC initiative currently offers a range of live, telephone, and online support through national and regional ''learning communities.'' In the first 2 years of the model these efforts have been focused on building practices' capability to deliver comprehensive primary care through fulfilment of the CPC Milestones. In the remaining period of the model, these learning activities are aimed at adapting and optimizing clinical services within the five CPC comprehensive primary care functions to achieve the aims of the CPC initiative. We are interested in what support practices would require to provide the five comprehensive primary care CPC functions in a potential expansion of the CPC initiative, and the readiness of the private sector to respond to the need for this support. We are also interested in the willingness and ability of existing state and regional primary care or patient centered medical home learning collaboratives to support practices in an a potential expansion of the CPC initiative.

• *Payer and self-insured employer readiness:* We seek input on the readiness of currently participating payers in the CPC initiative to expand their current investment in CPC; and the readiness of new payers, including self-insured employers, to enter the initiative under a potential expansion. We are interested in thresholds for payer participation, for example, whether there should be a minimum threshold of payer participation for a region, or at the level of an individual practice, in order for a payer to be eligible for participation in a potential expansion of the CPC initiative. We also seek input about the best methods for payers to engage with one another, participating practices, and CMS under a potential expansion.

• *Medicaid:* The CPC initiative is a multi-payer initiative that seeks to include as many payers as possible to provide practices with sufficient resources for a practice-level transformation that benefits their entire patient population. A number of state Medicaid agencies currently participate as payers in the CPC initiative for their fee-for-service enrollees. We are interested in whether state Medicaid agencies would be willing to participate in a potential expanded CPC initiative for their fee-for-service enrollees. We are also interested in whether Medicaid managed care plans would be willing to participate in a potential expanded CPC initiative.

• *Quality reporting:* We are interested in comment on practice readiness to report eCQMs, and payer interest in using practice site level data rather than their own enrollees' information for performance based payments, including shared savings, in a potential expansion of the CPC initiative.

• *Interaction with the CCM fee:* The CY 2015 PFS final rule with comment period (79 FR 67729) discussed the policy for the billing of CCM services when a practitioner is participating in the CPC initiative, as described earlier in this proposed rule. We seek input on how payment for CCM services might interact with a potential expansion of the CPC initiative and affect practice interest in participation.

• *Provision of data feedback to practices:* We currently send quarterly feedback reports to practices including cost and utilization information for the Medicare FFS attributed population of that practice. We seek comment about how we can best provide actionable data to support quality improvement and promote attention to total cost of care under a potential expansion.

L. Medicare Shared Savings Program

Under section 1899 of the Act, we established the Medicare Shared Savings Program (Shared Savings Program) to facilitate coordination and cooperation among providers to improve the quality of care for Medicare Fee-For-Service (FFS) beneficiaries and reduce the rate of growth in health care costs. Eligible groups of providers and suppliers, including physicians, hospitals, and other health care providers, may participate in the Shared Savings Program by forming or participating in an Accountable Care Organization (ACO). The final rule establishing the Shared Savings Program appeared in the November 2, 2011 **Federal Register** (Medicare Shared Savings Program: Accountable Care Organizations Final Rule (76 FR 67802)).

We identified the following policies under the Shared Savings Program that we are addressing in this proposed rule.

1. Quality Measures and Performance Standard

Section 1899(b)(3)(A) of the Act requires the Secretary to determine appropriate measures to assess the quality of care furnished by ACOs, such as measures of clinical processes and outcomes; patient, and, wherever practicable, caregiver experience of care; and utilization such as rates of hospital admission for ambulatory sensitive conditions. Section 1899(b)(3)(B) of the Act requires ACOs to submit data in a form and manner specified by the Secretary on measures that the Secretary determines necessary for ACOs to report to evaluate the quality of care furnished by ACOs. Section 1899(b)(3)(C) of the Act requires the Secretary to establish quality performance standards to assess the quality of care furnished by ACOs, and to seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both for the purposes of assessing the quality of care. Additionally, section 1899(b)(3)(D) of the Act gives the Secretary authority to incorporate reporting requirements and incentive payments related to the PQRS, EHR Incentive Program and other similar initiatives under section 1848 of the Act. Finally, section 1899(d)(1)(A) of the Act states that an ACO is eligible to receive payment for shared savings, if they are generated, only after meeting the quality performance standards established by the Secretary.

In the November 2011 final rule establishing the Shared Savings Program and recent CY PFS final rules with comment period (77 FR 69301 through 69304; 78 FR 74757 through 74764; and 79 FR 67907 through 67931), we established the quality performance standards that ACOs must meet to be eligible to share in savings that are generated. In the CY 2015 PFS final rule with comment period, we made a number of updates to the quality requirements within the program, such as updates to the quality measure set, the addition of a quality improvement reward, and the establishment of benchmarks that will apply for 2 years. Through these previous rulemakings, we worked to improve the alignment of quality performance measures, submission methods, and incentives under the Shared Savings Program and PQRS. Currently, eligible professionals participating in an ACO may qualify for the PQRS incentive payment under the

Shared Savings Program or avoid the downward PQRS payment adjustment when the ACO satisfactorily reports the ACO GPRO measures on their behalf using the GPRO web interface.

We identified a few policies related to the quality measures and quality performance standard that we are proposing in this rule. Specifically, we are proposing to add a new quality measure to be reported through the CMS web interface and to adopt a policy for addressing quality measures that no longer align with updated clinical guidelines or where the application of the measure may result in patient harm.

a. Existing Quality Measures and Performance Standard

Section 1899(b)(3)(C) of the Act states that the Secretary shall establish quality performance standards to assess the quality of care furnished by ACOs and ''seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both . . . .'' In the November 2011 Shared Savings Program Final Rule, we established a quality performance standard consisting of 33 measures across four domains, including patient experience of care, care coordination/patient safety, preventive health, and at-risk population. In the CY 2015 PFS final rule with comment period, we made a number of updates to the quality performance standard, including adding new measures that ACOs must report, retiring measures that no longer aligned with updated clinical guidelines, reducing the sample size for measures reported through the CMS web interface, establishing a schedule for the phase in of new quality measures, and establishing an additional reward for quality improvement. In the CY 2015 PFS final rule with comment period, we finalized an updated measure set of 33 measures.

Quality measures are submitted by the ACO through the GPRO web interface, calculated by CMS from administrative and claims data, and collected via a patient experience of care survey based on the Clinician and Group Consumer Assessment of Healthcare Providers and Systems (CG–CAHPS) survey. The CAHPS for ACOs patient experience of care survey used for the Shared Savings Program includes the core CG–CAHPS modules, as well as some additional modules. The measures collected through the GPRO web interface are also used to determine whether eligible professionals participating in an ACO avoid the PQRS and automatic Value Modifier payment adjustments for 2015 and subsequent years. Eligible professionals in an ACO may avoid the downward PQRS payment adjustment when the ACO satisfactorily reports all of the ACO GPRO measures on their behalf using the GPRO web interface. Beginning with the 2017 Value Modifier, performance on the ACO GPRO web interface measures and all cause readmission measure will be used in calculating the quality component of the Value Modifier for eligible professionals participating within an ACO (79 FR 67941 through 67947).

As we previously stated (76 FR 67872), our principal goal in selecting quality measures for ACOs has been to identify measures of success in the delivery of high-quality health care at the individual and population levels with a focus on outcomes. We believe endorsed measures have been tested, validated, and clinically accepted, and therefore, when selecting the original 33 measures, we had a preference for NQF-endorsed measures. However, the statute does not limit us to using endorsed measures in the Shared Savings Program. As a result, we also exercised our discretion to include certain measures that we believe to be high impact but that are not currently endorsed, including for example, ACO#11, Percent of PCPs Who Successfully Qualify for an EHR Incentive Program Payment.

In selecting the 33 measure set, we balanced a wide variety of important considerations. Our measure selection emphasized prevention and management of chronic diseases that have a high impact on Medicare FFS beneficiaries, such as heart disease, diabetes mellitus, and chronic obstructive pulmonary disease. We believed that the quality measures used in the Shared Savings Program should be tested, evidence-based, target conditions of high cost and high prevalence in the Medicare FFS population, reflect priorities of the National Quality Strategy, address the continuum of care to reflect the requirement that ACOs accept accountability for their patient populations, and align with existing quality programs and value-based purchasing initiatives.

In selecting the set of 33 measures finalized in the CY 2015 PFS final rule with comment period, we sought to include both process and outcome measures, including patient experience of care (79 FR 67907 through 67931). We believe it is important to retain a combination of both process and outcomes measures, because ACOs are charged with improving and coordinating care and delivering high quality care, but also need time to form, acquire infrastructure and develop clinical care processes. We noted, however, that as other CMS quality reporting programs, such as PQRS, move to more outcomes-based measures and fewer process measures over time, we might also revise the quality performance standard for the Shared Savings Program to incorporate more outcomes-based measures and fewer process measures over time.

In the CY 2015 PFS final rule with comment period, we finalized a number of changes to the quality measures used in establishing the quality performance standard to better align with PQRS, retire measures that no longer align with updated clinical practice, and add new outcome measures that support the CMS Quality Strategy and National Quality Strategy goals. We are continuing to work with the measures community to ensure that the specifications for the measures used under the Shared Savings Program are up-to-date. We believe that it is important to balance the timing of the release of specifications so they are as up-to-date as possible, while also giving ACOs sufficient time to review specifications. Our intention is to issue the specifications annually, prior to the start of the reporting period for which they will apply.

b. Proposed New Measure To Be Used in Establishing Quality Standards That ACOs Must Meet To Be Eligible for Shared Savings

Since the November 2011 Shared Savings Program final rule, we have continued to review the quality measures used for the Shared Savings Program to ensure that they are up to date with current clinical practice and are aligned with the GPRO web interface reporting for PQRS. Based on these reviews, in the CY 2015 PFS final rule with comment period, we retired several measures that no longer aligned with updated clinical guidelines regarding cholesterol targets. As a result of retiring measures that did not align with updated clinical practice, we identified a gap in the Shared Savings Program measure set for measures that address treatment for patients at high risk of cardiovascular disease due to high cholesterol. Cardiovascular disease affects a high volume of Medicare beneficiaries and the prevention of cardiovascular disease as well as its treatment is important. Following further analysis and coordination with agencies such as the Centers for Disease Control and Prevention and the Agency for Healthcare Research & Quality, we are proposing to add a new statin therapy measure for the Shared Savings

Program that has been developed to align with the updated clinical guidelines and PQRS reporting. We are proposing to add one new measure to the Preventive Health domain, which would increase our current total number of measures from 33 to 34 measures. Data collection for the new measure would occur through the CMS web interface. Table 31 lists the Shared Savings Program quality measure set, including the one measure we are proposing to add, that would be used to assess ACO quality starting in 2016.

- Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

We propose to add the Statin Therapy for the Prevention and Treatment of Cardiovascular Disease to the Preventive Health domain. The measure was developed by CMS in collaboration with other federal agencies and the Million Hearts® Initiative and is intended to support the prevention and treatment of cardiovascular disease by measuring the use of statin therapies according to the updated clinical guidelines for patients with high cholesterol. The measure reports the percentage of beneficiaries who were prescribed or were already on statin medication therapy during the measurement year and who fall into any of the following three categories:

1. High-risk adult patients aged greater than or equal to 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD);
2. Adult patients aged greater than or equal to 21 years with any fasting or direct Low-Density Lipoprotein Cholesterol (LDL–C) level that is greater than or equal to 190 mg/dL; or
3. Patients aged 40 to 75 years with a diagnosis of diabetes with a fasting or direct LDL–C level of 70 to 189 mg/dL who were prescribed or were already on statin medication therapy during the measurement year.

The measure contains multiple denominators to align with the updated clinical guidelines for cholesterol targets and would replace the low-density lipid control measures previously retired from the measure set. We are proposing this measure to continue Shared Savings Program alignment with the PQRS program (Table 30) and Million Hearts Initiative. We propose that the multiple denominators will be equally weighted when calculating the performance rate. The measure was reviewed by the NQF Measure Applications Partnership (MAP) and the MAP encouraged further development (Measures Under Consideration (MUC) ID: X3729).

As a result, we are seeking public comment on the implementation of the measure for the Shared Savings Program. We are seeking comment on whether the measure should be considered a single measure with weighted denominators or three measures given the multiple denominators were developed to adhere to the updated clinical guidelines. In addition, the use of multiple denominators raises questions on how the measure should be benchmarked for the Shared Savings Program. Therefore, we are seeking public feedback on the benchmarking approach for the measure, such as whether the measure should be benchmarked as a single measure or three measures. The measure specifications that were submitted to the NQF MAP include multiple denominators, which may require larger sample sizes to accommodate exclusions when identifying relevant beneficiaries for each of the denominators used for CMS web interface reporting. Due to the multiple denominators, there may be a large number of beneficiaries who may not meet each denominator for reporting and would result in a low number of beneficiaries meeting the measure denominators. Hence, we are proposing to increase the size of the oversample for this measure from the normal 616 beneficiaries for CMS web interface reporting to an oversample of 750 or more beneficiaries. We are proposing such an oversample size for this measure to account for reporting on the multiple denominators and to ensure a sufficient number of beneficiaries meet the measure denominators for reporting. The consecutive reporting requirement for measures reported through the CMS web interface would remain at 248 beneficiaries. We are proposing that the measure will be pay for reporting for 2 years and then phase into pay for performance in the third year of the agreement period, as seen in Table 31. Previously, we finalized that new measures will have a 2-year transition period before being phased in as pay for performance (79 FR 67910). However, we are also seeking comment on whether stakeholders believe the measure should be pay for reporting for the entire agreement period due to the application of multiple denominators for a single measure. In summary, we seek comment on our proposal to include this measure in the Preventive Health domain, whether it should be treated as a single or multiple measures for reporting and benchmarking, the transition of the measure into pay for performance or if they measure should remain pay for reporting for the entire agreement period, and the size of the oversample to ensure sufficient identification of beneficiaries for reporting.

TABLE 31—MEASURES FOR USE IN ESTABLISHING QUALITY PERFORMANCE STANDARDS THAT ACOS MUST MEET FOR SHARED SAVINGS

Domain	ACO Measure No.	Measure title	New measure	NQF #/measure steward	Method of data submission	Pay for performance phase-in R—Reporting P—Performance		
						PY1	PY2	PY3
AIM: Better Care for Individuals								
Patient/ Caregiver Experience	ACO–1	CAHPS: Getting Timely Care, Appointments, and Information.		NQF #0005, AHRQ.	Survey	R	P	P
	ACO–2	CAHPS: How Well Your Doctors Communicate.		NQF #0005, AHRQ.	Survey	R	P	P
	ACO–3	CAHPS: Patients' Rating of Doctor.		NQF #0005, AHRQ.	Survey	R	P	P
	ACO–4	CAHPS: Access to Specialists		NQF #N/A, CMS/AHRQ.	Survey	R	P	P
	ACO–5	CAHPS: Health Promotion and Education.		NQF #N/A, CMS/AHRQ.	Survey	R	P	P

TABLE 31—MEASURES FOR USE IN ESTABLISHING QUALITY PERFORMANCE STANDARDS THAT ACOS MUST MEET FOR SHARED SAVINGS—Continued

Domain	ACO Measure No.	Measure title	New measure	NQF #/measure steward	Method of data submission	Pay for performance phase-in R—Reporting P—Performance		
						PY1	PY2	PY3
	ACO–6	CAHPS: Shared Decision Making.	.....	NQF #N/A, CMS/AHRQ.	Survey	R	P	P
	ACO–7	CAHPS: Health Status/Functional Status.	.....	NQF #N/A, CMS/AHRQ.	Survey	R	R	R
	ACO–34	CAHPS: Stewardship of Patient Resources.	.....	NQF #N/A, CMS/AHRQ.	Survey	R	P	P
Care Coordination/Safety.	ACO–8	Risk-Standardized, All Condition Readmission.	.....	Adapted NQF #1789, CMS.	Claims	R	R	P
	ACO–35	Skilled Nursing Facility 30-Day All-Cause Readmission Measure (SNFRM).	.....	NQF #TBD, CMS.	Claims	R	R	P
	ACO–36	All-Cause Unplanned Admissions for Patients with Diabetes.	.....	NQF#TBD, CMS.	Claims	R	R	P
	ACO–37	All-Cause Unplanned Admissions for Patients with Heart Failure.	.....	NQF#TBD, CMS.	Claims	R	R	P
	ACO–38	All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions.	.....	NQF#TBD, CMS.	Claims	R	R	P
	ACO–9	Ambulatory Sensitive Conditions Admissions: Chronic Obstructive Pulmonary Disease or Asthma in Older Adults (AHRQ Prevention Quality Indicator (PQI) #5).	.....	Adapted NQF #0275, AHRQ.	Claims	R	P	P
	ACO–10	Ambulatory Sensitive Conditions Admissions: Heart Failure (AHRQ Prevention Quality Indicator (PQI) #8).	.....	Adapted NQF #0277, AHRQ.	Claims	R	P	P
	ACO–11	Percent of PCPs who Successfully Meet Meaningful Use Requirements.	.....	NQF #N/A, CMS.	EHR Incentive Program Reporting.	R	P	P
	ACO–39	Documentation of Current Medications in the Medical Record.	.....	NQF #0419, CMS.	CMS Web Interface.	R	P	P
	ACO–13	Falls: Screening for Future Fall Risk.	.....	NQF #0101, NCQA.	CMS Web Interface.	R	P	P
AIM: Better Health for Populations								
Preventive Health.	ACO–14	Preventive Care and Screening: Influenza Immunization.	.....	NQF #0041, AMA–PCPI.	CMS Web Interface.	R	P	P
	ACO–15	Pneumonia Vaccination Status for Older Adults.	.....	NQF #0043, NCQA.	CMS Web Interface.	R	P	P
	ACO–16	Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow Up.	.....	NQF #0421, CMS.	CMS Web Interface.	R	P	P
	ACO–17	Preventive Care and Screening: Tobacco Use: Screening and Cessation Intervention.	.....	NQF #0028, AMA–PCPI.	CMS Web Interface.	R	P	P
	ACO–18	Preventive Care and Screening: Screening for Clinical Depression and Follow-up Plan.	.....	NQF #0418, CMS.	CMS Web Interface.	R	P	P
	ACO–19	Colorectal Cancer Screening ...	.....	NQF #0034, NCQA.	CMS Web Interface.	R	R	P
	ACO–20	Breast Cancer Screening	.....	NQF #NA, NCQA.	CMS Web Interface.	R	R	P
	ACO–21	Preventive Care and Screening: Screening for High Blood Pressure and Follow-up Documented.	.....	CMS	CMS Web Interface.	R	R	P
	ACO–42	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease.	X	NQF #TBD, MUC ID: X3729, CMS.	CMS Web Interface.	R	R	P

TABLE 31—MEASURES FOR USE IN ESTABLISHING QUALITY PERFORMANCE STANDARDS THAT ACOS MUST MEET FOR SHARED SAVINGS—Continued

Domain	ACO Measure No.	Measure title	New measure	NQF #/measure steward	Method of data submission	Pay for performance phase-in R—Reporting P—Performance		
						PY1	PY2	PY3
Clinical Care for At Risk Population—Depression.	ACO–40	Depression Remission at Twelve Months.	.....	NQF #0710, MNCM.	CMS Web Interface.	R	R	R
Clinical Care for At Risk Population—Diabetes.	ACO–27	Diabetes Composite (All or Nothing Scoring): ACO–27: Diabetes Mellitus: Hemoglobin A1c Poor Control.	.....	NQF #0059, NCQA (individual component).	CMS Web Interface.	R	P	P
	ACO–41	ACO–41: Diabetes: Eye Exam	.....	NQF #0055, NCQA (individual component).	CMS Web Interface.	R	P	P
Clinical Care for At Risk Population—Hypertension.	ACO–28	Hypertension (HTN): Controlling High Blood Pressure.	.....	NQF #0018, NCQA.	CMS Web Interface.	R	P	P
Clinical Care for At Risk Population—Ischemic Vascular Disease.	ACO–30	Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antithrombotic.	.....	NQF #0068, NCQA.	CMS Web Interface.	R	P	P
Clinical Care for At Risk Population —Heart Failure.	ACO–31	Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD).	.....	NQF #0083, AMA–PCPI.	CMS Web Interface.	R	R	P
Clinical Care for At Risk Population—Coronary Artery Disease.	ACO–33	Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy—for patients with CAD and Diabetes or Left Ventricular Systolic Dysfunction (LVEF<40%).	.....	NQF # 0066, ACC.	CMS Web Interface.	R	R	P

The quality scoring methodology is explained in the regulations at § 425.502 and in the preamble to the November 2011 final rule with comment period (76 FR 67895 through 67900). As a result of this proposed addition, each of the four domains will include the following number of quality measures (See Table 32 for details.):

- Patient/Caregiver Experience of Care—8 measures
- Care Coordination/Patient Safety—10 measures
- Preventive Health—9 measures
- At Risk Population—7 measures (including 6 individual measures and a 2-component diabetes composite measure)

Table 32 provides a summary of the number of measures by domain and the total points and domain weights that will be used for scoring purposes with the proposed additional measure in the At-Risk Population domain. The total possible points for the Preventive Health domain would increase from 16 points to 18 points. Otherwise, the current methodology for calculating an ACO's overall quality performance score would continue to apply. We are also seeking comment on whether the proposed Statin Therapy measure, with multiple denominators, should be scored at more than 2 points if commenters believe this measure should be treated as multiple measures within the Preventive Health domain instead of a single measure. For instance, the measure could be scored as 3 points, 1 point for each of the three denominators, due to the clinical importance of prevention and treatment of cardiovascular disease and the complexity of the measure. The EHR measure is currently the only measure scored more than 2 points in the current measure set, but given the multiple denominators that exist within the Statin Therapy measure, it could be scored greater than 2 points as well.

TABLE 32—NUMBER OF MEASURES AND TOTAL POINTS FOR EACH DOMAIN WITHIN THE QUALITY PERFORMANCE STANDARD

Domain	Number of individual measures	Total measures for scoring purposes	Total possible points	Domain weight (%)
Patient/Caregiver Experience	8	8 individual survey module measures	16	25
Care Coordination/Patient Safety	10	10 measures. Note that the EHR measure is double-weighted (4 points).	22	25
Preventive Health	9	9 measures	18	25

TABLE 32—NUMBER OF MEASURES AND TOTAL POINTS FOR EACH DOMAIN WITHIN THE QUALITY PERFORMANCE STANDARD—Continued

Domain	Number of individual measures	Total measures for scoring purposes	Total possible points	Domain weight (%)
At-Risk Population	7	6 individual measures, plus a 2-component diabetes composite measure, scored as one.	12	25
Total in all Domains	34	33	68	100

We believe that the proposed addition of the Statin Therapy quality measure to the quality measure set for the Shared Savings Program would further enhance the quality of care patients receive from ACO participants and ACO providers/suppliers, better reflect clinical practice guidelines and high quality care, enhance alignment with PQRS and the Million Hearts ® Initiative, and focus on important preventive care and effective treatments for high prevalence conditions.

c. Proposed Policy for Measures No Longer Aligning With Clinical Guidelines, High Quality Care or Outdated Measure May Cause Patient Harm

We have encountered circumstances where changes in clinical guidelines result in quality measures within the Shared Savings Program quality measure set no longer aligning with best clinical practice. For instance, in the CY 2015 PFS final rule with comment period we retired measures that were no longer consistent with updated clinical guidelines for cholesterol targets, but we were unable to finalize retirement of the measures for the 2014 reporting year due to the timing of the guideline updates and rulemaking cycle. We issued an update in the 2014 Shared Savings Program benchmark guidance document that maintained these measures as pay-for-reporting for the 2014 reporting year due to the measures not aligning with updated clinical evidence.

However, given the frequency of changes that occur in scientific evidence and clinical practice, we are proposing to adopt a general policy under which we will maintain measures as pay-for-reporting, or revert pay-for-performance measures to pay-for-reporting measures, if the measure owner determines the measure no longer meets best clinical practices due to clinical guideline updates or when clinical evidence suggests that continued measure compliance and collection of the data may result in harm to patients. This flexibility will enable us to respond more quickly to clinical guideline updates that affect measures without waiting until a future rulemaking cycle to retire a measure or revert to pay for reporting. We expect that we will continue to retire measures through the annual PFS final rule with comment period as clinical guidelines change; however, the timing of clinical guideline updates may not always correspond with the rulemaking cycle. Under this proposal, if a guideline update is published during a reporting year and the measure owner determines the measure specifications do not align with the updated clinical practice, we would have the authority to maintain a measure as pay for reporting or revert a pay-for-performance measure to pay for reporting and finalize changes in the subsequent PFS final rule with comment period. Therefore, we are proposing to add a new provision at § 425.502(a)(5) to reserve the right to maintain a measure as pay for reporting, or revert a pay-for-performance measure to pay for reporting, if a measure owner determines the measure no longer meets best clinical practices due to clinical guideline updates or clinical evidence suggests that continued application of the measure may result in harm to patients. The measure owner will inform CMS if a measure's specification does not align with updated guidelines or if continued application of the measure may result in patient harm. We would then implement any necessary change to the measure in the next PFS rulemaking cycle by either retiring the measure or maintaining it as pay for reporting. We seek comment on this proposal and whether there may be additional criteria we should consider in deciding when it may be appropriate to maintain a measure as pay-for-reporting or revert from pay-for-performance back to pay-for-reporting.

d. Request for Comment Related to Use of Health Information Technology

In the November 2011 final rule, we included a measure related to the use of health information technology under the Care Coordination/Patient Safety domain: the percent of PCPs within an ACO who successfully qualify for an EHR Incentive Program incentive (76 FR 67878). In finalizing this measure, we included eligible professionals that qualified for payments to adopt, implement, or upgrade EHR technology, in addition to those receiving a payment for meeting Meaningful use Requirements. We selected this measure as opposed to other proposed measures in order to focus on EHR adoption among the primary care physicians within an ACO. Finally, we chose to focus on this measure because it represented a structural measure of EHR program participation that is not duplicative of measures within the EHR Incentive program for which providers may already qualify for incentive payments or face penalties. Although this was the only measure we finalized related to use of health information technology, we chose to double weight this measure for scoring purposes in order to signal the importance of health information technology for ACOs (76 FR 67895).

In the CY 2015 PFS final rule with comment period, we finalized a proposal to change the name and specification of this measure to ''Percent of PCPs who Successfully Meet Meaningful Use Requirements'' in order to reflect the transition from incentive payments to downward payment adjustments in 2015 (79 FR 67912). We believe this name will more accurately depict successful use and adoption of EHR technology.

We continue to believe that measures which encourage the effective adoption and use of health information technology among participants in accountable care initiatives are an important way to signal the importance of technology infrastructure in supporting successful ACOs, especially as they mature and assume additional risk. Since the initial EHR quality measure was finalized in 2011, the EHR Incentive Program and Meaningful Use requirements have shifted from an initial focus on technology adoption and data capture to interoperable exchange of data across systems and the use of more advanced health IT functions to support care coordination and quality

improvement. A notice of proposed rulemaking for ''Stage 3'' of the EHR Incentive program, was released in March 2015 (80 FR 16731), along with a related proposed 2015 Edition of ONC certification criteria (80 FR 16804), which aim to support providers' ability to exchange a common clinical dataset across the continuum of care. In addition, ONC has released a document entitled ''Connecting Health and Care for the Nation: A Shared Nationwide Interoperability Roadmap (available at *http://www.healthit.gov/sites/default/files/nationwide-interoperability-roadmap-draft-version-1.0.pdf*) which focuses on actions that will enable a majority of individuals and providers across the care continuum to send, receive, find and use a common set of electronic clinical information at the nationwide level by the end of 2017.

We believe that the widespread inclusion of these capabilities within health IT systems, and their adoption and effective use by providers, will greatly enhance ACOs' ability to coordinate care for beneficiaries with practitioners both within and outside their ACO and more effectively manage the total cost of care for attributed patients. While we are not proposing any changes to the current measure ''Percent of PCPs who Successfully Meet Meaningful Use Requirements'' (ACO–11) at this time, we are seeking comment on how this measure might evolve in the future to ensure we are incentivizing and rewarding providers for continuing to adopt and use more advanced health IT functionality as described above, and broadening the set of providers across the care continuum that have adopted these tools. We welcome comments on the following questions:

- Although the current measure focuses only on primary care physicians, should this measure be expanded in the future to include all eligible professionals, including specialists?
- How could the current measure be updated to reward providers who have achieved higher levels of health IT adoption?
- Should we substitute or add another measure that would focus specifically on the use of health information technology, rather than meeting overall Meaningful Use requirements, for instance, the transitions of care measure required for the EHR Incentives Program?
- What other measures of IT-enabled processes would be most relevant to participants within ACOs? How could we seek to minimize the administrative burden on providers in collecting these measures?

e. Conforming Changes To Align With PQRS

Under the Shared Savings Program rules at § 425.504, ACOs, on behalf of their ACO providers/suppliers who are eligible professionals, must submit quality measures using a CMS web interface (currently the CMS Group Practice Reporting Option Web Interface) to satisfactorily report on behalf of their eligible professionals for purposes of the PQRS payment adjustment under the Shared Savings Program. Under § 425.118(a)(4), all Medicare enrolled individuals and entities that have reassigned their right to receive Medicare payment to the TIN of the ACO participant must be included on the ACO provider/supplier list and must agree to participate in the ACO and comply with the requirements of the Shared Savings Program, including the quality reporting requirements. Thus, each eligible professional that bills under the TIN of an ACO participant must be included on the ACO provider/supplier list in accordance with the requirements in § 425.118.

The methodology for applying the PQRS adjustment to group practices takes into account the services billed by all eligible professionals through the TIN of the group practice, however, the references to ''ACO providers/suppliers who are eligible professionals'' in § 425.504 indicate that the ACO provider/supplier list should be used to determine the eligible professionals. Our intent and current practice is to treat the ACO and its ACO participants the same as any other physician group electing to report for purposes of PQRS through the GPRO Web Interface. We therefore have determined that it is necessary to modify the language in § 425.504 for clarity and to bring it into alignment with the methodology used to determine the applicability of the payment adjustment under the PQRS GPRO methodology so that it is consistently applied to eligible professionals billing through an ACO participant TIN. We propose to revise § 425.504(a) to replace the phrase ''ACO providers/suppliers who are eligible professionals'' and ''ACO providers/suppliers that are eligible professionals'' with the phrase ''eligible professionals who bill under the TIN of an ACO participant'' along with conforming changes anywhere the term ACO providers/suppliers appears in § 425.504. We believe these changes are necessary to clarify that the requirement that the ACO report on behalf of these eligible professionals applies in a way that is consistent with the PQRS GPRO policies and also addresses mid-year updates to and deletions from the ACO provider/supplier list. For example, this change clarifies that an ACO must still report quality data for services billed under the TIN of an ACO participant by an eligible professional that was an ACO provider/supplier for a portion of the performance year, but was removed from the ACO provider/supplier list mid-year when he or she started a new job and ceased billing under the TIN of the ACO participant.

2. Assignment of Beneficiaries to ACOs

Section 1899(c) of the Act requires the Secretary to ''determine an appropriate method to assign Medicare fee-for-service beneficiaries to an ACO based on their utilization of primary care services provided under this title by an ACO professional described in paragraph (h)(1)(A).'' As we have explained in detail elsewhere (79 FR 72792), we established the current list of codes that constitute primary care services under the Shared Savings Program at § 425.20 because we believed the listed codes represented a reasonable approximation of the kinds of services that are described by the statutory language which refers to assignment of ''Medicare fee for service beneficiaries to an ACO based on their utilization of primary care services'' furnished by physicians. We propose the following revisions to the assignment of beneficiaries to ACOs under the Shared Savings Program.

a. Assignment of Beneficiaries Based on Certain Evaluation and Management Services in SNFs

As discussed in detail in the November 2014 proposed rule for the Shared Savings Program (79 FR 72792 through 72793), we welcomed comment from stakeholders on the implications of retaining certain evaluation and management codes used for physician services furnished in SNFs and other nursing facility settings (CPT codes 99304 through 99318) in the definition of primary care services. As we noted in the proposed rule, in some cases, hospitalists that perform evaluation and management services in SNFs have requested that these codes be excluded from the definition of primary care services so that their ACO participant TIN need not be exclusive to only one ACO based on the exclusivity policy established in the November 2011 final rule (76 FR 67810 through 67811). The requirement under § 425.306(b) that an ACO participant TIN be exclusive to a single ACO applies when the ACO

participant TIN submits claims for primary care services that are considered in the assignment process. However, ACO participant TINs upon which beneficiary assignment is not dependent (that is, ACO participant TINs that do not submit claims for primary care services that are considered in the assignment process) are not required to be exclusive to a single ACO.

In response to the discussion in the Shared Savings Program proposed rule of our policy of including the codes for SNF visits, CPT codes 99304 through 99318, in the definition of primary care services, some commenters objected to inclusion of SNF visit codes, believing a SNF is more of an extension of the inpatient setting rather than a component of the community based primary care setting. As a result, these commenters believe that ACOs are often inappropriately assigned patients who have had long SNF stays but would not otherwise be aligned to the ACO and with whom the ACO has no clinical contact after their SNF stay. Some commenters draw a distinction between such services provided in two different places of service, POS 31 (SNF) and POS 32 (NF). Although the same CPT visit codes are used to describe these services in SNFs (POS 31) and NFs (POS 32), the patient population is arguably quite different. These commenters suggest excluding SNF visit codes furnished in POS 31 to potentially relieve hospitalists from the requirement that these ACO professionals must be exclusive to a single ACO if their services are considered in assignment. Patients in SNFs (POS 31) are shorter stay patients who are receiving continued acute medical care and rehabilitative services. While their care may be coordinated during their time in the SNF, they are then transitioned back in the community. Patients in a SNF (POS 31) require more frequent practitioner visits—often from 1 to 3 times a week. In contrast, patients in NFs (POS 32) are almost always permanent residents and generally receive their primary care services in the facility for the duration of their life. Patients in the NF (POS 32) are usually seen every 30 to 60 days unless medical necessity dictates otherwise.

We agree that it would be feasible to use POS 31 to identify claims for services furnished in a SNF. Therefore, we are proposing to amend our definition of primary care services at § 425.20, for purposes of the Shared Savings Program, to exclude services billed under CPT codes 99304 through 99318 when the claim includes the POS 31 modifier. We recognize that SNF patients are shorter stay patients who are generally receiving continued acute medical care and rehabilitative services. While their care may be coordinated during their time in the SNF, they are then transitioned back in the community to the primary care professionals who are typically responsible for providing care to meet their true primary needs. If we finalize this proposal, we anticipate applying this revised definition of primary care services for purposes of determining ACO eligibility during the application cycle for the 2017 performance year, which occurs during 2016, and the revision would be then be applicable for all ACOs starting with the 2017 performance year. This would align the assignment algorithms for both new ACOs entering the program and existing ACOs ensuring that beneficiaries are being assigned to the most appropriate ACO and that assigned beneficiary populations are determined using consistent assignment algorithms for all ACOs, as well as aligning our program operations with the application cycle. We propose to make a conforming change to the definition of primary care services in paragraph (2) by indicating that the current definition will be in use for the 2016 performance year and to add a new definition of primary care services in paragraph (4), which excludes SNFs from the definition of primary care services effective starting with the 2017 performance year. We believe that excluding services furnished in SNFs from the definition of primary care services will complement our goal to assign beneficiaries to an ACO based on their utilization of primary care services. Further, based on preliminary analysis, we do not expect removal of these claims from the assignment process would result in a significant reduction in the number of beneficiaries assigned to ACOs, although we recognize that assignment to some ACOs may be more affected than others, depending on the practice patterns of their ACO professionals. We invite comments on these issues.

b. Assignment of Beneficiaries to ACOs That Include ETA Hospitals

We have developed special operational instructions and processes (79 FR 72801 through 72802) that enable us to include primary care services performed by physicians at ETA hospitals in the assignment of beneficiaries to ACOs under § 425.402. ETA hospitals are hospitals that, under section 1861(b)(7) of the Act and § 415.160, have voluntarily elected to receive payment on a reasonable cost basis for the direct medical and surgical services of their physicians in lieu of Medicare PFS payments that might otherwise be made for these services. We use institutional claims submitted by ETA hospitals in the assignment process under the Shared Savings Program because ETA hospitals are paid for physician professional services on a reasonable cost basis through their cost reports and no other claim is submitted for such services. However, ETA hospitals bill us for their separate facility services when physicians and other practitioners provide services in the ETA hospital and the institutional claims submitted by ETA hospitals include the HCPCS code for the services provided. To determine the rendering physician for ETA institutional claims, we use the NPI listed in the ''other provider'' NPI field on the institutional claim. Then we use PECOS to obtain the CMS specialty for the NPI listed on the ETA institutional claim.

These institutional claims do not include allowed charges, which are necessary to determine where a beneficiary received the plurality of primary care services as part of the assignment process. Accordingly, we use the amount that would otherwise be payable under the PFS for the applicable HCPCS code, in the applicable geographic area as a proxy for the allowed charges for the service.

The definition of primary care services at § 425.20 includes CPT codes in the range 99201 through 99205 and 99211 through 99215, and certain other codes. For services furnished prior to January 1, 2014, we use the HCPCS code included on this institutional claim to identify whether the primary care service was rendered to a beneficiary in the same way as for any other claim. However, we implemented a change in coding policy under the Outpatient Hospital Prospective Payment System (OPPS) that inadvertently affects the assignment of beneficiaries to an ACO when the beneficiary receives care at an ETA hospital. Effective for services furnished on or after January 1, 2014, outpatient hospitals, including ETA hospitals, were instructed to use the single HCPCS code G0463 and to no longer use CPT codes in the ranges of 99201 through 99205 and 99211 through 99215. (For example, see our Web site at *http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/MM8572.pdf,* page 3). In other words, for ETA hospitals, G0463 is a replacement code for CPT codes in the ranges of 99201 through 99205 and 99211 through 99215.

We continue to believe that it is appropriate to use ETA institutional claims for purposes of identifying primary care services furnished by physicians in ETA hospitals and to allow these services to be included in the stepwise methodology for assigning beneficiaries to ACOs. We believe including these claims increases the accuracy of the assignment process by helping ensure that beneficiaries are assigned to the ACO or other entity that is actually managing the beneficiary's care. ETA hospitals are often located in underserved areas and serve as providers of primary care for the beneficiaries they serve. Therefore, we are proposing to consider HCPCS code G0463 when submitted by ETA hospitals as a code designated by us as a primary care service for purposes of the Shared Savings Program. We recently updated our existing operational guidance on this issue so that we can continue to consider services furnished in ETA hospitals for beneficiary assignment purposes using the new G code until we codify a change to our definition of primary care services. This approach will allow us to continue to accurately assign Medicare FFS beneficiaries based on their utilization of primary care services furnished by ACO professionals, including those ACOs that may include ETA hospitals.

We would note that in order to promote flexibility for the Shared Savings Program and to allow the definition of primary care services used in the Shared Savings Program to respond more quickly to HCPCS/CPT coding changes made in the annual PFS rulemaking process, we recently adopted a policy of making revisions to the definition of primary care service codes for the Shared Savings Program through the annual PFS rulemaking process, and we amended the definition of primary care services at § 425.20 to include additional codes designated by CMS as primary care services for purposes of the Shared Savings Program, including new HCPCS/CPT codes or revenue codes and any subsequently modified or replacement codes. Therefore, we propose to amend the definition of primary care services at § 425.20 by adding HCPCS code G0463 for services furnished in an ETA hospital to the definition of primary care services that will be applicable for performance year 2016 and subsequent performance years.

We also propose to revise § 425.402 by adding a new paragraph (d) to provide that when considering services furnished by physicians in ETA hospitals in the assignment methodology, we would use an estimated amount based on the amounts payable under the PFS for similar services in the geographic location in which the ETA hospital is located as a proxy for the amount of the allowed charges for the service. In this case, because G0463 is not payable under the PFS, we are proposing to use the weighted mean amount payable under the PFS for CPT codes in the range 99201 through 99205 and 99211 through 99215 as a proxy for the amount of the allowed charges for HCPCS code G0463 when submitted by ETA hospitals. The weights needed to impute the weighted mean PFS payment rate for HCPCS code G0463 would be derived from the relative number of services furnished at the national level for CPT codes 99201 through 99205 and 99211 through 99215. This is consistent with our current practice and guidance and would continue to allow for beneficiaries to be attributed to the ACO responsible for their care. Additional details regarding computation of the proxy amount for G0463 would be provided through sub-regulatory guidance.

In addition, because we are able to consider claims submitted by ETA hospitals as part of the assignment process, we also propose to amend § 425.102(a) to add ETA hospitals to the list of ACO participants that are eligible to form an ACO that may apply to participate in the Shared Savings Program.

M. Value-Based Payment Modifier and Physician Feedback Program

1. Overview

Section 1848(p) of the Act requires that we establish a value-based payment modifier (VM) and apply it to specific physicians and groups of physicians the Secretary determines appropriate starting January 1, 2015, and to all physicians and groups of physicians by January 1, 2017. On or after January 1, 2017, section 1848(p)(7) of the Act provides the Secretary discretion to apply the VM to eligible professionals (EPs) as defined in section 1848(k)(3)(B) of the Act. Section 1848(p)(4)(C) of the Act requires the VM to be budget neutral. The VM program continues CMS's initiative to increase the transparency of health care quality information and to assist providers and beneficiaries in improving medical decision-making and health care delivery.[9]

2. Governing Principles for VM Implementation.

In the CY 2013 PFS final rule with comment period, we discussed the goals of the VM and also established that specific principles should govern the implementation of the VM (77 FR 69307). We refer readers to that rule for a detailed discussion and list those principles here for reference.

- *A focus on measurement and alignment.* Measures for the VM should consistently reflect differences in performance among groups or solo practitioners, reflect the diversity of services furnished, and should be consistent with the National and CMS Quality Strategies and other CMS quality initiatives, including PQRS, the Medicare Shared Savings Program (Shared Savings Program), and the Medicare EHR Incentive Program.
- *A focus on physician and eligible professional choice.* Physicians and other nonphysician EPs should be able to choose the level (individual or group) at which their quality performance will be assessed, reflecting EPs' choice over their practice configurations. The choice of level should align with the requirements of other physician quality reporting programs.
- *A focus on shared accountability.* The VM can facilitate shared accountability by assessing performance at the group level and by focusing on the total costs of care, not just the costs of care furnished by an individual professional.
- *A focus on actionable information.* The Quality and Resource Use Reports (QRURs) should provide meaningful and actionable information to help groups and solo practitioners identify clinical, efficiency and effectiveness areas where they are doing well, as well as areas in which performance could be improved by providing groups and solo practitioners with QRURs on the quality and cost of care they furnish to their patients.
- *A focus on a gradual implementation.* The VM should focus initially on identifying high and low performing groups and solo practitioners. As we gain more experience with physician measurement tools and methodologies, we can broaden the scope of measures assessed, refine physician peer groups, create finer payment distinctions, and provide greater payment incentives for high performance.

[9] Kate Goodrich, et al. ''A History and a Vision for CMS Quality Measurement Programs''. Joint Comm'n J. Quality & Patient Safety. 2012. 38,465, *available at http://www.ingentaconnect.com/content/jcaho/jcjqs/2012/00000038/00000010/art00006.*

3. Overview of Existing Policies for the Physician VM.

In the CY 2013 PFS final rule with comment period (77 FR 69310), we finalized policies to phase-in the VM by applying it beginning January 1, 2015, to Medicare PFS payments to physicians in groups of 100 or more EPs. A summary of the existing policies that we finalized for the CY 2015 VM can be found in the CY 2014 PFS proposed rule (78 FR 43486 through 43488). Subsequently, in the CY 2014 PFS final rule with comment period (78 FR 74765 through 74787), we finalized policies to continue the phase-in of the VM by applying it starting January 1, 2016, to payments under the Medicare PFS for physicians in groups of 10 or more EPs. Then, in the CY 2015 PFS final rule with comment period (79 FR 67931 through 67966), we finalized policies to complete the phase-in of the VM by applying it starting January 1, 2017, to payments under the Medicare PFS for physicians in groups of 2 or more EPs and to physician solo practitioners. We also finalized that beginning in January 1, 2018, the VM will apply to nonphysician EPs in groups with 2 or more EPs and to nonphysician EPs who are solo practitioners.

4. Provisions of This Proposed Rule

As a general summary, we are proposing the following VM policies:

- Beginning with the CY 2016 payment adjustment period, a TIN's size would be determined based on the lower of the number of EPs indicated by the Medicare Provider Enrollment, Chain, and Ownership System (PECOS)-generated list or our analysis of the claims data for purposes of determining the payment adjustment amount under the VM.
- For the CY 2018 payment adjustment period, to apply the VM to nonphysician EPs who are physician assistants (PAs), nurse practitioners (NPs), clinical nurse specialists (CNSs), and certified registered nurse anesthetists (CRNAs) in groups and those who are solo practitioners, and not to other types of professionals who are nonphysician EPs.
- For the CY 2018 payment adjustment period, to identify TINs as those that consist of nonphysician EPs if either the PECOS-generated list or our analysis of the claims data shows that the TIN consists of nonphysician EPs and no physicians.
- For the CY 2018 payment adjustment period, to not apply the VM to groups and solo practitioners if either the PECOS-generated list or claims analysis shows that the groups and solo practitioners consist only of nonphysician EPs who are not PAs, NPs, CNSs, and CRNAs.
- To continue apply a two-category approach for the CY 2018 VM based on participation in the PQRS by groups and solo practitioners.
- For the CY 2018 payment adjustment period, to apply the quality-tiering methodology to all groups and solo practitioners in Category 1. Groups and solo practitioners would be subject to upward, neutral, or downward adjustments derived under the quality-tiering methodology, with the exception finalized in the CY 2015 PFS final rule with comments period (79 FR 67937), that groups consisting only of nonphysician EPs and solo practitioners who are nonphysician EPs will be held harmless from downward adjustments under the quality-tiering methodology in CY 2018.
- Beginning with the CY 2017 payment adjustment period, to apply the VM adjustment percentage for groups and solo practitioners that participate in two or more ACOs during the applicable performance period based on the performance of the ACO with the highest quality composite score.
- For the CY 2018 payment adjustment period, to apply the VM for groups and solo practitioners that participate in an ACO under the Shared Savings Program during the applicable performance period as described under § 414.1210(b)(2), regardless of whether any EPs in the group or the solo practitioner also participated in an Innovation Center model during the performance period.
- For the CY 2018 payment adjustment period, if the ACO does not successfully report quality data as required by the Shared Savings Program, all groups and solo practitioners participating in the ACO will fall in Category 2 for the VM and will be subject to a downward payment adjustment.
- Beginning in the CY 2017 payment adjustment period, to apply an additional upward payment adjustment of +1.0x to Shared Savings ACO Program participant TINs that are classified as ''high quality'' under the quality-tiering methodology, if the ACOs in which the TINs participated during the performance period have an attributed patient population that has an average beneficiary risk score that is in the top 25 percent of all beneficiary risk scores nationwide as determined under the VM methodology.
- Beginning with the CY 2017 payment adjustment period, to waive application of the VM for groups and solo practitioners, as identified by TIN, if at least one EP who billed for PFS items and services under the TIN during the applicable performance period for the VM participated in the Pioneer ACO Model, CPC Initiative, or other similar Innovation Center models during the performance period.
- To set the maximum upward adjustment under the quality-tiering methdology for the CY 2018 VM to +4.0 times an upward payment adjustment factor (to be determined after the performance period has ended) for groups with 10 or more EPs; +2.0 times an adjustment factor for groups with between 2 to 9 EPs and physician solo practitioners; and +2.0 times an adjustment factor for groups and solo practitioners that consist of nonphysician EPs who are PAs, NPs, CNSs, and CRNAs.
- To set the amount of payment at risk under the CY 2018 VM to 4.0 percent for groups with 10 or more EPs, 2 percent for groups with between 2 to 9 EPs and physician solo practitioners, and 2 percent for groups and solo practitioners that consist of nonphysician EPs who are PAs, NPs, CNSs, and CRNAs.
- To not recalculate the VM upward payment adjustment factor after it is made public unless there was a significant error made in the calculation of the adjustment factor.
- To use CY 2016 as the performance period for the CY 2018 VM.
- To align the quality measures and quality reporting mechanisms for the CY 2018 VM with those available to groups and individuals under the PQRS during the CY 2016 performance period.
- To separately benchmark the PQRS electronic clinical quality measures (eCQMs) beginning with the CY 2018 VM.
- To include Consumer Assessment of Healthcare Providers and Systems (CAHPS) Surveys in the VM for Shared Savings Program ACOs beginning with the CY 2018 VM.
- To apply the VM to groups for which the PQRS program removes individual EPs from that program's unsuccessful participants list beginning with the 2016 VM.
- Beginning with the CY 2017 payment adjustment period, to increase the minimum number of episodes for inclusion of the MSPB measure in the cost composite to 100 episodes.
- Beginning with the 2018 VM, to include hospitalizations at Maryland hospitals as an index admission for the MSPB measure for the purposes of the VM program.
- Beginning in the CY 2016 payment adjustment period, a group or solo

practitioner subject to the VM would receive a quality composite score that is classified as average under the quality-tiering methodology if the group or solo practitioner does not have at least one quality measure that meets the minimum number of cases required for the measure to be included in the calculation of the quality composite.

- To make technical changes to § 414.1255 and § 414.1235.

We also seek comment on, but make no proposals regarding stratifying cost measure benchmarks by beneficiary risk score.

a. Group Size

The policies to identify groups and solo practitioners that are subject to the VM during a specific payment adjustment period are described in § 414.1210(c). Beginning with the CY 2016 payment adjustment period, the list of groups and solo practitioners subject to the VM is based on a query of the PECOS that occurs within 10 days of the close of the PQRS group registration process during the applicable performance period described at § 414.1215. Groups are removed from the PECOS-generated list if, based on our analysis of claims, the group did not have the required number of EPs that submitted claims during the performance period for the applicable calendar year payment adjustment period. Solo practitioners are removed from the PECOS-generated list if, based on a claims analysis, the solo practitioner did not submit claims during the performance period for the applicable CY payment adjustment period. In the CY 2013 PFS final rule with comment period, we stated that for the CY 2015 payment adjustment period, we will not add groups to the PECOS-generated list based on the analysis of claims (77 FR 69309 through 69310). In the CY 2014 PFS final rule with comment period, we finalized that we will continue to follow this procedure for the CY 2016 payment adjustment period and subsequent adjustment period (78 FR 74767).

In the CY 2014 PFS final rule with comment period (78 FR 74767 to 74771), we established different payment adjustment amounts under the 2016 VM for (1) groups with between 10 to 99 EPs, and (2) groups with 100 or more EPs. Similarly, in the CY 2015 PFS final rule with comment period (79 FR 67938 to 67941 and 67951 to 67954), we established different payment adjustment amounts under the 2017 VM for: (1) Groups with between 2 to 9 EPs and physician solo practitioners; and (2) groups with 10 or more EPs. However, we have not addressed how we would handle scenarios where the size of a TIN as indicated on the PECOS-generated list is not consistent with the size of the TIN based on our analysis of the claims data. Therefore, we propose that, beginning with the CY 2016 payment adjustment period, the TIN's size would be determined based on the lower of the number of EPs indicated by the PECOS-generated list or by our analysis of the claims data for purposes of determining the payment adjustment amount under the VM. In the event that our analysis of the claims data indicates that a TIN had fewer EPs during the performance period than indicated by the PECOS-generated list, and the TIN is still subject to the VM based on its size, then we would apply the payment adjustment amount under the VM that is applicable to the size of the TIN as indicated by our analysis of the claims data. In the event that our analysis of the claims data indicates that a TIN had more EPs during the performance period than indicated by the PECOS-generated list, then we would apply the payment adjustment amount under the VM that is applicable to the size of the TIN as indicated by the PECOS-generated list.

For example, for the CY 2016 payment adjustment period, if the PECOS list indicates that a TIN had 100 EPs in the CY 2014 performance period, but our analysis of claims shows that the TIN had 90 EPs based in CY 2014, then we would apply the payment policies to the TIN that are applicable to groups with between 10 to 99 EPs, instead of the policies applicable to groups with 100 or more EPs. Alternatively, if the PECOS list indicates that a TIN had 90 EPs in the CY 2014 performance period, but our analysis of claims shows that the TIN had 100 EPs based in CY 2014, then we would apply the payment policies to the TIN that are applicable to groups with between 10 to 99 EPs, instead of the policies applicable to groups with 100 or more EPs. We propose to update § 414.1210(c) accordingly.

In section III.M.4.b. of this proposed rule, we propose to apply the VM in the CY 2018 payment adjustment period to nonphysician EPs who are PAs, NPs, CNSs, and CRNAs in groups with two or more EPs and to those who are solo practitioners. In section III.M.4.f. of this proposed rule, we propose to apply different payment adjustment amounts under the CY 2018 VM based on the composition of a group. Specifically, in that section we propose that the PAs, NPs, CNSs, and CRNAs in groups that consist of nonphysician EPs (in other words, groups that do not include any physicians) and those who are solo practitioners would be subject to different payment adjustment amounts under the CY 2018 VM than would groups composed of physicians and nonphysician EPs and physician solo practitioners. We propose to identify TINs that consist of nonphysician EPs as those TINs for which either the PECOS-generated list or our analysis of the claims data shows that the TIN consists of nonphysician EPs and no physicians. We note that under our proposal the VM would only apply to the PAs, NPs, CNSs, and CRNAs who bill under these TINs, and not to the other types of nonphysician EPs who may also bill under these TINs. We propose that the VM would not apply to a TIN if either the PECOS-generated list or our analysis of the claims data shows that the TIN consists of only nonphysician EPs who are *not* PAs, NPs, CNSs, and CRNAs. The following examples illustrate these proposals. If the PECOS-generated list shows that a TIN consists of physicians and NPs and the claims data show that only NPs billed under the TIN, then we would apply the payment adjustments proposed in section III.M.4.f. of this proposed rule that are applicable to PAs, NPs, CNSs, and CRNAs in TINs that consist of nonphysician EPs. If the PECOS-generated list shows that a TIN consists of PAs, NPs, CNSs, or CRNAs, and no physicians, and the claims data show that the TIN also consists of physicians, then we would apply the payment adjustments applicable to PAs, NPs, CNSs, and CRNAs in TINs that consist of nonphysician EPs. This would be consistent with our policy to apply the payment adjustments applicable to the lower group size when there is a discrepancy in the group size between PECOS and claims analysis, in that it would result in the group being subject to the lower amount at risk and lower possible upward payment adjustment, when there is a difference between the PECOS and claims analyses.

If the PECOS-generated list shows that a TIN consists of physicians and the claims data shows, for example, that PAs and physicians billed under the TIN, then we would apply the payment adjustments proposed in section III.M.4.f. of this proposed rule for TINs with physicians and nonphysician EPs depending on the size of the TIN. If the PECOS-generated list shows, for example, that a TIN consists of PAs and the claims data shows that only physical therapists billed under the group, then the TIN would not be subject to the VM in CY 2018. Conversely, if the PECOS-generated list shows, for example, that a TIN consists of physical therapists and the claims data shows that only PAs

billed under the group, then the TIN would not be subject to the VM in CY 2018. We welcome public comment on these proposals. We propose to revise § 414.1210(c) accordingly.

b. Application of the VM to Nonphysician EPs Who Are PAs, NPs, CNSs, and CRNAs

Section 1848(p)(7) of the Act provides the Secretary discretion to apply the VM on or after January 1, 2017 to EPs as defined in section 1848(k)(3)(B) of the Act. In the CY 2015 PFS final rule with comment period (79 FR 67937), we finalized that we will apply the VM beginning in the CY 2018 payment adjustment period to nonphysician EPs in groups with two or more EPs and to nonphysician EPs who are solo practitioners. We added § 414.1210(a)(4) to reflect this policy. Under this policy, we will apply the VM beginning in CY 2018 to the items and services billed under the PFS by all of the physicians and nonphysician EPs who bill under a group's TIN. Beginning in CY 2018, the VM will apply to all of the EPs, as specified in section 1848(k)(3)(B) of the Act, that bill under a group's TIN based on the TIN's performance during the applicable performance period. During the payment adjustment period, all of the nonphysician EPs who bill under a group's TIN will be subject to the same VM that will apply to the physicians who bill under that TIN. We finalized the modification to the definition of ''group of physicians'' under § 414.1205 to also include the term ''group'' to reflect these policies. Additionally, we finalized that beginning in CY 2018, physicians and nonphysician EPs will be subject to the same VM policies established in earlier rulemakings and under subpart N. For example, nonphysician EPs will be subject to the same amount of payment at risk and quality-tiering policies as physicians. We finalized modifications to the regulations under subpart N accordingly.

Under section 1848(p)(4)(B)(iii) of the Act, as amended by section 101(b)(3) of MACRA, the VM shall not be applied to payments for items and services furnished on or after January 1, 2019. Section 1848(q) of the Act, as added by section 101(c) of MACRA, establishes the Merit-based Incentive Payment System (MIPS) that shall apply to payments for items and services furnished on or after January 1, 2019. Under section 1848(q)(1)(C)(i)(I) of the Act, with regard to payments for items and services furnished in 2019 and 2020, the MIPS will only apply to:

- A physician (as defined in section 1861(r) of the Act);
- A PA, NP, and CNS (as defined in section 1861(aa)(5) of the Act);
- A CRNA (as defined in section 1861(bb)(2) of the Act); and
- A group that includes such professionals.

Then, under section 1848(q)(1)(C)(i)(II) of the Act, beginning with payments for items and services furnished in 2021, the MIPS will apply to such other EPs as defined in section 1848(k)(3)(B) of the Act as specified by the Secretary. As noted above, section 1848(p)(7) of the Act provides the Secretary discretion to apply the VM on or after January 1, 2017 to EPs as defined in section 1848(k)(3)(B) of the Act. In the CY 2015 PFS final rule with comment period (79 FR 67937), we finalized that we will apply the VM beginning in the CY 2018 payment adjustment period to all nonphysician EPs in groups with two or more EPs and to nonphysician EPs who are solo practitioners. However, after the enactment of MACRA in April 2015, we believe it would not be appropriate to apply the VM in CY 2018 to any nonphysician EP who is not a PA, NP, CNS, or CRNA since payment adjustments under the MIPS would not apply to them until 2021. Therefore, we propose to apply the VM in the CY 2018 payment adjustment period to nonphysician EPs who are PAs, NPs, CNSs, and CRNAs in groups with two or more EPs and to PAs, NPs, CNSs, and CRNAs who are solo practitioners. We propose to revise § 414.1210(a)(4) to reflect this proposed policy. We propose to define PAs, NPs, and CNSs as defined in section 1861(aa)(5) of the Act and to define CRNAs as defined in section 1861(bb)(2) of the Act. We propose to add these definitions under § 414.1205.

Under our proposal, we would apply the VM in CY 2018 to the items and services billed under the PFS by all of the PAs, NPs, CNSs, and CRNAs who bill under a group's TIN based on the TIN's performance during the applicable performance period. We note that the VM would not apply to other types of nonphysician EPs (that is, nonphysician EPs who are not PAs, NPs, CNSs, or CRNAs) who may also bill under the TIN.

As noted above, we finalized in the CY 2015 PFS final rule with comment period (79 FR 67937) that beginning in CY 2018, all of the nonphysician EPs who bill under a group's TIN will be subject to the same VM that will apply to the physicians who bill under that TIN, and physicians and nonphysician EPs will be subject to the same VM policies established in earlier rulemakings and under subpart N. For example, nonphysician EPs who are in groups containing one or more physicians will be subject to the same amount of payment at risk and quality-tiering policies as physicians. We are not proposing to revise these policies; however, we note that if a group is composed of physicians and nonphysician EPs, only the physicians and the nonphysician EPs who are PAs, NPs, CNSs, and CRNAs would be subject to the VM in CY 2018.

In the CY 2015 PFS final rule with comment period (79 FR 67937), we also finalized that we will apply the VM beginning in CY 2018 to groups that consist only of nonphysician EPs (for example, groups with only NPs or PAs) and to nonphysician EPs who are solo practitioners. However, since CY 2018 will be the first year that groups that consist only of nonphysician EPs and solo practitioners who are nonphysician EPs will be subject to the VM, we finalized a policy to hold these groups and solo practitioners harmless from downward adjustments under the quality-tiering methodology in CY 2018. We stated that we will add regulation text under § 414.1270 to reflect this policy when we establish the policies for the VM for the CY 2018 payment adjustment period in future rulemaking. Accordingly, we propose to add § 414.1270(d) to codify that PAs, NPs, CNSs, and CRNAs in groups that consist of nonphysician EPs and PAs, NPs, CNSs, and CRNAs who are solo practitioners will be held harmless from downward adjustments under the quality-tiering methodology in CY 2018. In section III.M.4.f. of this proposed rule, we discuss the proposed CY 2018 payment adjustment amounts for groups that consist of nonphysician EPs and solo practitioners who are nonphysician EPs that fall in Category 1 and Category 2 for the CY 2018 VM. As discussed above, we are proposing to apply the VM in CY 2018 only to nonphysician EPs who are PAs, NPs, CNSs, and CRNAs.

c. Approach to Setting the VM Adjustment Based on PQRS Participation

Section 1848(p)(4)(B)(iii)(II) of the Act requires the Secretary to apply the VM to items and services furnished under the PFS beginning not later than January 1, 2017, for all physicians and groups of physicians. Therefore, in the CY 2015 PFS final rule with comment period (79 FR 67936), we established that, beginning with the CY 2017 payment adjustment period, the VM will apply to physicians in groups with two or more EPs and to physicians who are solo practitioners based on the applicable performance period. In the CY 2015 PFS

final rule with comment period (79 FR 67938 to 67939), we adopted a two-category approach for the CY 2017 VM based on participation in the PQRS by groups and solo practitioners. For purposes of the CY 2017 VM, we finalized that Category 1 includes those groups that meet the criteria for satisfactory reporting of data on PQRS quality measures via the GPRO (through use of the web-interface, EHR, or registry reporting mechanism) for the CY 2017 PQRS payment adjustment. We finalized that Category 1 also includes groups that do not register to participate in the PQRS as a group practice participating in the PQRS GPRO in CY 2015 and that have at least 50 percent of the group's EPs meet the criteria for satisfactory reporting of data on PQRS quality measures as individuals (through the use of claims, EHR, or registry reporting mechanism) for the CY 2017 PQRS payment adjustment, or in lieu of satisfactory reporting, satisfactorily participate in a PQRS-qualified clinical data registry (QCDR) for the CY 2017 PQRS payment adjustment. Lastly, we finalized that Category 1 includes those solo practitioners that meet the criteria for satisfactory reporting of data on PQRS quality measures as individuals (through the use of claims, registry, or EHR reporting mechanism) for the CY 2017 PQRS payment adjustment, or in lieu of satisfactory reporting, satisfactorily participate in a PQRS QCDR for the CY 2017 PQRS payment adjustment. We finalized that Category 2 includes those groups and solo practitioners that are subject to the CY 2017 VM and do not fall within Category 1. The CY 2017 VM payment adjustment amount for groups and solo practitioners in Category 2 is −4.0 percent for groups with 10 or more EPs and −2.0 percent for groups with between 2 to 9 EPs and solo practitioners.

We propose to use a similar two-category approach for the CY 2018 VM based on participation in the PQRS by groups and solo practitioners. However, we note that during the 2014 PQRS submission period, we received feedback from groups who experienced difficulty reporting through the reporting mechanism they had chosen at the time of 2014 PQRS GPRO registration. For example, some groups registered for the group EHR reporting mechanism and were subsequently informed that their EHR vendor could not support submission of group data for the group EHR reporting mechanism. To address these concerns and continue to accommodate the various ways in which EPs and groups can participate in the PQRS, for purposes of the CY 2018 VM, we propose that Category 1 would include those groups that meet the criteria to avoid the PQRS payment adjustment for CY 2018 as a group practice participating in the PQRS GPRO, as proposed in table 21 of this proposed rule. We also propose to include in Category 1 groups that have at least 50 percent of the group's EPs meet the criteria to avoid the PQRS payment adjustment for CY 2018 as individuals, as proposed in table 20 of this proposed rule. We propose to add corresponding regulation text to § 414.1270(d)(1).

We note that the proposed criteria for groups to be included in Category 1 for the CY 2018 VM differ from the criteria we finalized for the CY 2017 VM in the CY 2015 PFS final rule with comment period. Under the policy for the CY 2017 VM, we would only consider whether at least 50 percent of a group's EPs met the criteria to avoid the PQRS payment adjustment as individuals if the group did not register to participate in a PQRS GPRO. In contrast, under our proposal for the CY 2018 VM, in determining whether a group would be included in Category 1, we would consider whether the 50 percent threshold has been met regardless of whether the group registers for a PQRS GPRO. We believe this proposal would allow groups that register for a PQRS GPRO but fail as a group to meet the criteria to avoid the PQRS payment adjustment an additional opportunity for the quality data reported by individual EPs in the group to be taken into account for purposes of applying the CY 2018 VM.

We also propose to revise the criteria for groups to be included in Category 1 for the CY 2017 VM, if it is operationally feasible for our systems to utilize data reported through a mechanism other than the one through which a group registered to report under PQRS GPRO. At this time, it is unclear whether CMS systems can support this type of assessment as soon as the CY 2017 VM, and thus our proposal is contingent upon operational feasibility. For the CY 2017 VM, we propose that Category 1 would include those groups that meet the criteria to avoid the PQRS payment adjustment for CY 2017 as a group practice participating in the PQRS GPRO in CY 2015. We also propose to include in Category 1 groups that have at least 50 percent of the group's EPs meet the criteria to avoid the PQRS payment adjustment for CY 2017 as individuals. We propose that if operationally feasible, we would apply these criteria to identify which groups would fall in Category 1 for the CY 2017 VM regardless of whether or how the group registered to participate in the PQRS as a group practice in CY 2015. If our systems are not able to accomplish this, then we will apply our existing policy for the CY 2017 VM, as finalized in the CY 2015 PFS final rule with comment period (79 FR 67938 through 67939), to consider whether at least 50 percent of a group's EPs meet the criteria to avoid the PQRS payment adjustment for CY 2017 as individuals only in the event that the group did not register to report as a group under the PQRS GPRO. We seek comments on these proposals.

Lastly, we propose to include in Category 1 for the CY 2018 VM those solo practitioners that meet the criteria to avoid the CY 2018 PQRS payment adjustment as individuals, as proposed in table 20 of this proposed rule.

Category 2 would include those groups and solo practitioners that are subject to the CY 2018 VM and do not fall within Category 1. As discussed in section III.M.4.f. of this proposed rule, we are proposing to apply the following VM adjustment to payments for groups and solo practitioners that fall in Category 2 for the CY 2018 VM: A −4.0 percent VM to physicians, PAs, NPs, CNSs, and CRNAs in groups with 10 or more EPs; a −2.0 percent VM to physicians, PAs, NPs, CNSs, and CRNAs in groups with between 2 to 9 EPs and to physician solo practitioners; and a −2.0 percent VM to PAs, NPs, CNSs, and CRNAs in groups that consist of nonphysician EPs and solo practitioners who are PAs, NPs, CNSs, and CRNAs. As discussed in section III.M.4.b. of this proposed rule, we propose to apply the VM in CY 2018 to the nonphysician EPs who are PAs, NPs, CNSs, and CRNAs. We seek comment on these proposals.

For a group or solo practitioner that would be subject to the CY 2018 VM to be included in Category 1, the criteria for satisfactory reporting (or the criteria for satisfactory participation, in the case of solo practitioners and the 50 percent option described above for groups) would need to be met during the reporting periods occurring in CY 2016 for the CY 2018 PQRS payment adjustment. In section III.M.4.h. of this proposed rule, we propose to use CY 2016 as the performance period for the VM adjustments that will apply during CY 2018. In the event that the criteria that are finalized for the CY 2018 PQRS payment adjustment differ from what is proposed for the PQRS in this proposed rule, our intention is to align the criteria for inclusion in Category 1 to the extent possible with the criteria that are

ultimately established for the CY 2018 PQRS payment adjustment.

In the CY 2015 PFS final rule with comment period (79 FR 67939 to 67941), we finalized that the quality-tiering methodology will apply to all groups and solo practitioners in Category 1 for the VM for CY 2017, except that groups with between 2 to 9 EPs and solo practitioners would be subject only to upward or neutral adjustments derived under the quality-tiering methodology, while groups with 10 or more EPs would be subject to upward, neutral, or downward adjustments derived under the quality-tiering methodology. In other words, groups with between 2 to 9 EPs and solo practitioners in Category 1 would be held harmless from any downward adjustments derived from the quality-tiering methodology for the CY 2017 VM.

As stated earlier in this proposed rule, in CY 2018, the same VM would apply to all of the physicians, PAs, NPs, CNSs, and CRNAs who bill under a TIN. The VM would not apply to other types of nonphysician EPs who may also bill under the TIN. For the CY 2018 VM, we propose to continue to apply the quality-tiering methodology to all groups and solo practitioners in Category 1. We propose that groups and solo practitioners would be subject to upward, neutral, or downward adjustments derived under the quality-tiering methodology, with the exception finalized in the CY 2015 PFS final rule with comments period (79 FR 67937), that groups consisting only of nonphysician EPs and solo practitioners who are nonphysician EPs will be held harmless from downward adjustments under the quality-tiering methodology in CY 2018. Based on our proposal to apply the CY 2018 VM only to certain types of nonphysician EPs, only the PAs, NPs, CNSs, and CRNAs in groups consisting of nonphysician EPs and those who are solo practitioners will be held harmless from downward adjustments under the quality-tiering methodology in CY 2018. We propose to revise § 414.1270 to reflect these proposals. We seek comments on these proposals. In section III.M.4.f. of this proposed rule, we discuss the proposed CY 2018 payment adjustment amounts for groups and solo practitioners that fall in Category 1 and Category 2 for the CY 2018 VM.

For groups with between 2 to 9 EPs and physician solo practitioners, we believe it is appropriate to begin both the upward and downward payment adjustments under the quality-tiering methodology for the CY 2018 VM. As stated in the CY 2015 PFS final rule with comment period (79 FR 67935), in September 2014, we made available QRURs based on CY 2013 data to all groups of physicians and physicians who are solo practitioners. These QRURs contain performance information on the quality and cost measures used to calculate the quality and cost composites of the VM and show how all TINs fare under the policies established for the VM for the CY 2015 payment adjustment period. As discussed in section III.M.5.a. of this proposed rule, in April 2015, we made available 2014 Mid-Year QRURs to groups of physicians and physician solo practitioners nationwide. The Mid-Year QRURs provide interim information about performance on the claims-based quality outcome measures and cost measures that are a subset of the measures that will be used to calculate the CY 2016 VM and are based on performance from July 1, 2013 through June 30, 2014. Then, during the Fall of 2015, we intend to disseminate QRURs based on CY 2014 data to all groups and solo practitioners, and the reports would show all TINs their performance during CY 2014 on all of the quality and cost measures that will be used to calculate the CY 2016 VM. Thus, we believe groups with between 2 to 9 EPs and physician solo practitioners will have adequate data to improve performance on the quality and cost measures that will be used to calculate the VM in CY 2018. We note that the quality and cost measures in the QRURs that these groups will receive are similar to the measures that will be used to calculate the CY 2018 VM. In addition, we believe that these groups and solo practitioners have had sufficient time to understand how the VM works and how to participate in the PQRS. As a result, we believe it is appropriate to apply both upward and downward adjustments under the quality-tiering methodology to groups with between 2 to 9 EPs and physician solo practitioners in CY 2018.

We will continue to monitor the VM program and continue to examine in the VM Experience Report the characteristics of those groups and solo practitioners that would be subject to an upward or downward payment adjustment under our quality-tiering methodology to determine whether our policies create anomalous effects in ways that do not reflect consistent differences in performance among physicians and physician groups.

d. Application of the VM to Physicians and Nonphysician EPs Who Participate in ACOs Under the Shared Savings Program

In the CY 2015 PFS final rule with comment period, we finalized a policy to apply the VM, beginning with the CY 2017 payment adjustment period, to physicians in groups with two or more EPs and physicians who are solo practitioners that participate in an ACO under the Shared Savings Program, and beginning with the CY 2018 payment adjustment period, to nonphysician EPs in groups with two or more EPs and nonphysician EPs who are solo practitioners that participate in an ACO under the Shared Savings Program. We finalized that the determination of whether a group or solo practitioner is considered to be in an ACO under the Shared Savings Program would be based on whether that group or solo practitioner, as identified by TIN, was an ACO participant in the performance period for the applicable payment adjustment period for the VM. For groups and solo practitioners determined to be ACO participants, we finalized a policy that we would classify the group or solo practitioner's cost composite as ''average'' and calculate its quality composite based on the quality-tiering methodology using quality data submitted by the Shared Savings Program ACO for the performance period and apply the same quality composite to all of the groups and solo practitioners, as identified by TIN, under that ACO. For further explanation of the final policies for applying the VM to ACO participants in Shared Savings Program ACOs, we refer readers to 79 FR 67941 through 67947 and 67956 through 67957.

(1) Application of the VM to Groups and Solo Practitioners Who Participate in Multiple Shared Savings Program ACOs

Under the Shared Savings Program regulations (§ 425.306(b)), an ACO participant TIN upon which beneficiary assignment is dependent may only participate in one Shared Savings Program ACO. ACO participant TINs that do not bill for primary care services, however, are not required to be exclusive to one Shared Savings Program ACO. As a result, there are a small number of TINs that are ACO participants in multiple Shared Savings Program ACOs. We did not previously address how the VM will be applied to these TINs.

Beginning with the CY 2017 payment adjustment period, we propose that TINs that participate in multiple Shared Savings Program ACOs in the applicable

performance period would receive the quality composite score of the ACO that has the highest numerical quality composite score. For this determination, we will only consider the quality data of an ACO that completes quality reporting under the Shared Savings Program. We propose to apply this policy in situations where the VM is determined based on quality-tiering or the ACO's failure to successfully report quality data as required by the Shared Savings Program. Below are several examples to illustrate the proposal:

Example A: TIN A participates in ACO 1 and ACO 2 in the 2015 performance period. ACO 1 fails to complete quality reporting under the Shared Savings Program as required under § 425.504(a)(1), and therefore, the ACO 1 participants would be classified as Category 2 and subject to the automatic downward adjustment under the VM. ACO 2 completes quality reporting as required under § 425.504(a)(1), and applying the quality-tiering methodology as described at § 414.1210(b)(2)(i)(B) using ACO 2's quality data, the TIN would be classified as average quality. Under our proposal, TIN A would receive a neutral (0 percent) VM in 2017 based on a quality composite determined using ACO 2's quality reporting and a cost composite of average.

Example B: TIN B participates in ACO 2 and ACO 3 in the 2015 performance period. ACO 2 and ACO 3 complete quality reporting under the Shared Savings Program, and ACO 3 has a higher numerical quality composite score than ACO 2. Under our proposal, TIN B would receive a VM in 2017 based on a quality composite determined using ACO 3's quality reporting and a cost composite of average.

Example C: TIN C participates in ACO 1 and ACO 4 in the 2015 performance period. Both ACO 1 and ACO 4 fail to complete quality reporting under the Shared Savings Program. TIN C would still be classified as Category 2 and would receive an automatic downward adjustment because both ACOs failed to report. This scenario is not affected by our proposal.

Under the VM, any TIN's quality composite score must be at least one standard deviation away from and statistically significantly different from the mean, for it to be classified as other than average quality (77 FR 69325). Because of this requirement, it is possible for any TIN's quality composite to be categorized as ''average,'' due to its being either within one standard deviation of the mean or not statistically significant from it. Similarly, it is possible that including performance data for the ACO with the higher quality composite score in a given TIN's VM calculation would not result in a higher VM adjustment percentage than would inclusion of data from another ACO with a lower quality composite score that is also at least 1 standard deviation away from the mean. Given the requirement that a Shared Savings Program ACO must have at least 5,000 assigned beneficiaries, we do not expect that this situation is likely to occur, though it is possible. The following example illustrates how this situation could occur:

Example D: TIN B participates in ACO 2 and ACO 3 in the 2015 performance period. ACO 2 completes quality reporting and the quality composite score using ACO 2's quality data is two standard deviations below the mean but is not statistically below the mean, in the sense of being both below the mean and statistically significantly different from the mean. Under § 414.1275(b)(1), the quality composite score would be classified as average because it is not statistically below the mean. ACO 3 completes quality reporting and the quality composite score using ACO 3's quality data is one and a half standard deviations below the mean and, is statistically significantly below the mean. Under § 414.1275(b)(1), the quality composite score would be classified as low. The quality composite score that is one and a half standard deviations below the mean is numerically higher than the quality composite score that is two standard deviations below the mean, so under our proposal, TIN B would receive a negative VM in 2017 based on a quality composite determined using ACO 3's quality reporting and a cost composite of average.

We believe our proposed approach is appropriate because it is straightforward for TINs participating in multiple Shared Savings Program ACOs to understand. The proposed policy is transparent and would allow Shared Savings Program ACO participant TINs the ability to compare the performance of the highest-performing ACO in which they participate to national benchmarks. Given that we did not make proposals for applying the VM to these TINs prior to the start of the 2015 performance period for the 2017 VM, we do not believe it would be fair to give ACO participants in multiple Shared Savings Program ACOs the lower of the quality composite scores for which they may have been eligible. We propose to make corresponding changes to § 414.1210(b)(2). We are seeking comment on this proposal.

In developing this proposed policy, we considered several alternative options. We considered proposing that the above policy would apply as long as all ACOs in which the TIN participates complete reporting under the Shared Savings Program. If one of the ACOs failed to report, the TIN would be categorized as Category 2 even though it participated in another ACO that successfully reported. We believe this would create unnecessary complexity and would not be fair to TINs that were not made aware of this policy prior to the start of the CY 2015 performance period for the 2017 payment adjustment period. We also considered proposing a policy under which the TIN would be required to indicate which ACO it wanted to be associated with for purposes of the VM. We did not make this proposal because we believed it created additional operational complexity for the TINs and us, and would put the TIN in a position of having to predict which ACO would perform better under the VM, which we do not believe would be appropriate. We welcome feedback on these alternatives we considered.

(2) Application of VM to Participant TINs in Shared Savings Program ACOs That Also Include EPs Who Participate in Innovation Center Models

Under the Shared Savings Program statute and regulations, ACO participants may not participate in another Medicare initiative that involves shared savings payments (§ 425.114(b)). However, there are Medicare initiatives, including models authorized by the Innovation Center, that do not involve shared savings payments, and in some cases a TIN that is a Shared Savings Program participant may also include EPs who participate in an Innovation Center model. Because the Shared Savings Program identifies participants by a TIN and many Innovation Center models allow some EPs under a TIN to participate in the model while other EPs under that TIN do not, we believe it is more appropriate to apply the VM policies finalized for Shared Savings Program participants to these TINs than to apply the policies for Innovation Center models proposed in section III.M.4.e. of this proposed rule. We are proposing that, beginning with the 2017 payment adjustment period for the VM, we would determine the VM for groups and solo practitioners (as identified by TIN) who participated in a Shared Savings Program ACO in the performance period in accordance with the VM policies for Shared Savings Program participants under § 414.1210(b)(2), regardless of whether any EPs under the TIN also participated in an Innovation Center model during the performance period. We propose to make corresponding changes to § 414.1210(b)(2)(i)(E). We are seeking comment on this proposal.

(3) Application of VM to Participant TINs in Shared Savings Program ACOs That Do Not Complete Quality Reporting

In the CY 2015 PFS proposed rule, we did not specifically address the scenario in which a Shared Savings Program ACO does not successfully report on

quality as required under the Shared Savings Program during the performance period for the VM. We clarified in the CY 2015 PFS final rule with comment period that we intended to adopt for groups and solo practitioners that participate in a Shared Savings Program ACO the same policy that is generally applicable to groups and solo practitioners that fail to satisfactorily report or participate under PQRS and thus fall in Category 2 and are subject to an automatic downward adjustment under the VM in CY 2017 (79 FR 67946). We stated that, consistent with the application of the VM to other groups and solo practitioners that report under PQRS, if the ACO does not successfully report quality data as required by the Shared Savings Program under § 425.504, all groups and solo practitioners participating in the ACO will fall in Category 2 for the VM, and therefore, will be subject to a downward payment adjustment. We finalized this policy for the 2017 payment adjustment period for the VM at § 414.1210(b)(2)(i)(C). We propose to continue this policy in the CY 2018 payment adjustment period for all groups and solo practitioners subject to the VM, including groups composed of nonphysician EPs and solo practitioners who are nonphysician EPs. We propose corresponding revisions to § 414.1210(b)(2)(i)(D). This policy is consistent with our policy for groups and solo practitioners who are subject to the VM and do not participate in the Shared Savings Program, and we believe it would further encourage quality reporting. We are seeking comment on this proposal.

(4) Application of an Additional Upward Payment Adjustment to High Quality Participant TINs in Shared Savings Program ACOs for Treating High-Risk Beneficiaries

In the CY 2015 PFS final rule with comment period, we finalized in the regulation text at § 414.1275(d)(2) that groups and solo practitioners that are classified as high quality/low cost, high quality/average cost, or average quality/low cost under the quality-tiering methodology for the CY 2017 payment adjustment period would receive an additional upward payment adjustment of +1.0x, if their attributed patient population has an average beneficiary risk score that is in the top 25 percent of all beneficiary risk scores nationwide. We are proposing a similar policy for the CY 2018 payment adjustment period as discussed in section III.M.4.f. of this proposed rule.

Beginning in the CY 2017 payment adjustment period, we propose to apply a similar additional upward adjustment to groups and solo practitioners that participated in high performing Shared Savings Program ACOs that cared for high-risk beneficiaries (as evidenced by the average HCC risk score of the ACO's attributed beneficiary population as determined under the VM methodology) during the performance period. We finalized in the CY 2015 PFS final rule with comment period that the quality composite score for TINs that participated in Shared Savings Program ACOs during the performance period will be calculated using the quality data reported by the ACO through the ACO GPRO Web Interface and the ACO all-cause hospital readmission measure, and the cost composite will be classified as ''average'' (79 FR 67941 through 67947). We believe this policy would be appropriate because attribution on the quality measures used in the VM calculation for Shared Savings Program ACO TINs is done at the ACO level. Further, under the Shared Savings Program ACO participants are responsible for coordinating the care of beneficiaries assigned to the ACO, so it is appropriate to determine whether those beneficiaries are in the highest risk category, at the ACO level. Therefore, beginning in the CY 2017 payment adjustment period, we propose to apply an additional upward payment adjustment of +1.0x to Shared Savings Program ACO participant TINs that are classified as ''high quality'' under the quality-tiering methodology, if the attributed patient population of the ACO in which the TINs participated during the performance period has an average beneficiary risk score that is in the top 25 percent of all beneficiary risk scores nationwide as determined under the VM methodology. We propose corresponding revisions to the regulation text at § 414.1210(b)(2). We are seeking comment on this proposal.

In the CY 2015 PFS proposed rule (79 FR 40500), we proposed that groups and solo practitioners participating in ACOs under the Shared Savings Program would be eligible for the additional upward payment adjustment +1.0x for caring for high-risk beneficiaries; however, the proposal was not finalized in the CY 2015 PFS final rule with comment period. We note that our proposal above is based on using the ACO's assigned beneficiary population; whereas, our proposal in the CY 2015 PFS Proposed Rule was based on using the group or solo practitioner's attributed beneficiary population.

e. Application of the VM to Physicians and Nonphysician EPs That Participate in the Pioneer ACO Model, the CPC Initiative, or Other Similar Innovation Center Models or CMS Initiatives

We established a policy in the CY 2013 PFS final rule with comment period (77 FR 69313) to not apply the VM in the CY 2015 and CY 2016 payment adjustment periods to groups of physicians that participate in Shared Savings Program ACOs, the Pioneer ACO Model, the Comprehensive Primary Care (CPC) initiative, or other similar Innovation Center models or CMS initiatives. We stated in the CY 2014 PFS final rule with comment period (78 FR 74766) that from an operational perspective, we will apply this policy to any group of physicians that otherwise would be subject to the VM, if one or more physician(s) in the group participate(s) in one of these programs or initiatives during the relevant performance period (CY 2013 for the CY 2015 payment adjustment period, and CY 2014 for the CY 2016 payment adjustment period). In the CY 2015 PFS final rule with comment period (79 FR 67949), we finalized a policy that for solo practitioners and groups subject to the VM with at least one EP participating in the Pioneer ACO Model or CPC Initiative during the performance period, we will classify the cost composite as ''average cost'' and the quality composite as ''average quality'' for the CY 2017 payment adjustment period. We did not finalize a policy for any payment adjustment period after CY 2017. We believed this policy was appropriate because it would enable groups and solo practitioners participating in these Innovation Center models to focus on the goals of the models and would minimize the risk of potentially creating conflicting incentives with regard to the evaluation of the quality and cost of care furnished for the VM and evaluation of cost and quality under these models. In addition, given that these models include groups in which some EPs participate in the model and others do not participate, it is challenging to meaningfully evaluate the quality of care furnished by these groups.

(1) Application of the VM to Solo Practitioners and Groups With EPs Who Participate in the Pioneer ACO Model and CPC Initiative

We received many comments on the proposals made in the CY 2015 PFS proposed rule indicating that we should exempt Pioneer ACO Model and CPC Initiative participants from the VM. As we noted in response to comments in

the CY 2015 final rule with comment period (79 FR 67947), a few commenters also suggested that the application of the VM to Innovation Center initiatives should be waived under section 1115A of the Act. In considering potential policy options to include in this proposed rule, we agree with the commenters that it would be appropriate to use the waiver authority with regard to the Pioneer ACO Model and CPC Initiative. Accordingly, under section 1115A(d)(1) of the Act, we are proposing to waive application of the VM as required by section 1848(p) of the Act for groups and solo practitioners, as identified by TIN, if at least one EP who billed for PFS items and services under the TIN during the applicable performance period for the VM participated in the Pioneer ACO Model or CPC Initiative during the performance period. This policy, as well as the use of the waiver authority under section 1115A(d)(1) for this purpose, will no longer apply in CY 2019 when the Value Modifier program is incorporated into the new Merit-based Incentive Payment System. We believe a waiver is necessary to test these models because their effectiveness would be impossible to isolate from the confounding variables of quality and cost metrics and contrasting payment incentives utilized under the VM.

- CPC Initiative: CPC practice sites are assessed on and have the opportunity to receive shared savings based on their quality and cost performance. CPC practice sites are assessed on quality measures at the practice site level and, for utilization measures, at the regional level (all practice sites within a CPC region), rather than at the TIN level as for the VM. The cost evaluation methodology used by the CPC Initiative is significantly different from the cost measures and benchmarks used to calculate the cost composite for the VM. In addition, it is difficult to evaluate the quality of care furnished by groups that participate in the CPC Initiative in order to calculate a quality composite for the VM because the CPC Initiative includes ''split TINs'' (groups where some eligible professionals in the group participate in the model while others do not participate), whereas the VM is applied to an entire TIN. As we noted in the CY 2015 PFS proposed rule (79 FR 40501), we do not believe that we can reasonably use the quality data submitted under the CPC Initiative for purposes of calculating a quality composite score under the VM. For these reasons, we believe it is necessary to waive the VM for purposes of testing the CPC Initiative. We believe a waiver would allow CPC model participants to focus on the aims of and measures assessed in the model, diminish the potential for methodological differences between the model and the VM, and would avoid the potential for inequitable comparisons of cost and quality that could arise as a result of differences between VM and CPC.
- *Pioneer ACO Model:* The Pioneer ACO Model combines two-sided financial risk with quality outcomes. Participants in the Pioneer ACO Model are required to report quality, and their savings or loss determination is affected by their quality score. Similar to the CPC Initiative, the Pioneer ACO Model includes split TINs, and we do not believe that we can reasonably use the quality data reported under the Pioneer ACO Model for purposes of calculating a quality composite score for the VM. The Pioneer ACO Model's methodology for evaluating costs is also significantly different from the VM methodology, which could create conflicting incentives for model participants. We believe a waiver of the VM is necessary to test the Pioneer ACO Model for these reasons. We also note that Pioneer ACOs are in their final performance years of the Model. Changing the quality component of the Model at this stage would confound multiple variables of quality and cost metrics within the model.

We believe we could have waived application of the VM for these models with regard to the CY 2017 payment adjustment period, and we are proposing the waiver would apply beginning with the CY 2017 payment adjustment period. We note that in practice, this proposal would not affect a TIN's payments differently as compared with the current policy for the CY 2017 payment adjustment period. A TIN that is classified as ''average cost'' and ''average quality'' would receive a neutral (0 percent) adjustment, and thus its payments during the CY would not increase or decrease as a result of the application of the VM. We also note that we have established a policy to apply the VM at the TIN level (77 FR 69308–69310), and as a result, this proposed waiver would affect the payments for items and services billed under the PFS for the CY 2017 and 2018 payment adjustment periods for the EPs who participate in the Pioneer ACO Model and the CPC Initiative during the performance period, as well as the EPs who do not participate in one of these models but bill under the same TIN as the EPs who do participate. We are proposing to revise § 414.1210(b)(3) to reflect these proposals. We are seeking comment on these proposals. We continue to explore how to address practices that only have some physicians participating in a model and plan to seek stakeholder input on these 'split TIN' practices and related issues in an upcoming Request for Information.

(2) Application of the VM to Solo Practitioners and Groups With EPs Who Participate in Similar Innovation Center Models

In the CY 2015 PFS final rule with comment period (79 FR 67949–67950), we finalized criteria that we will use to determine if future Innovation Center models or CMS initiatives are ''similar'' to the Pioneer ACO Model and CPC Initiative. We finalized that we will apply the same VM policies adopted for participants in the Pioneer ACO Model and CPC Initiative to groups and solo practitioners who participate in similar Innovation Center models and CMS initiatives. The criteria are: (1) The model or initiative evaluates the quality of care and/or requires reporting on quality measures; (2) the model or initiative evaluates the cost of care and/or requires reporting on cost measures; (3) participants in the model or initiative receive payment based at least in part on their performance on quality measures and/or cost measures; (4) potential for conflict between the methodologies used for the VM and the methodologies used for the model or initiative; or (5) other relevant factors specific to a model or initiative. We noted that a model or initiative would not have to satisfy or address all of these criteria to be considered a similar model or initiative.

We are proposing that in the event we finalize our proposal to waive application of the VM under section 1115A(d)(1) of the Act for the Pioneer ACO Model and CPC Initiative as discussed in the preceding section, we would also waive application of the VM for Innovation Center models that we determine are similar models based on the criteria above and for which we determine such a waiver is necessary for purposes of testing the model in accordance with section 1115A(d)(1) of the Act. For models that we determine are similar and require a waiver, we would waive application of the VM as required by section 1848(p) of the Act for groups and solo practitioners, as identified by TIN, if at least one EP who billed for PFS items and services under the TIN during the applicable performance period for the VM participated in the model during the performance period. We again note that this policy and use of the waiver

authority under section 1115A(d)(1) would sunset prior to CY 2019 when the VM is replaced by MIPS. We would publish a notice of the waiver in the **Federal Register** and also provide notice to participants in the model through the methods of communication that are typically used for the model. We are proposing to revise § 414.1210(b)(4) to reflect this proposal. We are seeking comment on this proposal.

(a) Application of the VM to Solo Practitioners and Groups With EPs Who Participate in the Comprehensive ESRD Care Initiative, Oncology Care Model, and the Next Generation ACO Model

There are several new Innovation Center models starting in 2015 or 2016, including the Comprehensive ESRD Care Initiative, Oncology Care Model, and the Next Generation ACO Model. We have evaluated these models based on the criteria for ''similar'' models and initiatives described in the preceding section and determined that they are similar to the Pioneer ACO Model and CPC Initiative. We believe a waiver of the VM under section 1115A(d)(1) of the Act is necessary to test these models. These new models may include groups in which some EPs participate in the model and others do not, which will make it challenging to meaningfully calculate the quality and cost composite for these TINs needed for the application of the VM. The following bullets describe these models, including ways in which these models are similar to the Pioneer ACO Model and the CPC Initiative, and provide a brief explanation of our belief that a waiver is necessary to test the models:

- *The Next Generation ACO Model:* The Next Generation ACO Model builds upon CMS ACO initiatives with ACOs taking on even greater financial risk than they have in the Pioneer ACO Model. Next Generation ACOs may receive waivers related to coverage for telehealth services, post-discharge home visits, and skilled nursing without prior hospitalization. The first performance period for this model is 2016, and we want to minimize conflicting incentives with regard to the evaluation of the quality and cost of care furnished for the VM and evaluation of cost and quality under this model.
- *The Oncology Care Model:* The Oncology Care Model (OCM) is an episode-based model that provides an incentive for participating practices to reduce the total cost of care for 6-month episodes triggered by either an initial chemotherapy administration claim or initial Part D chemotherapy claim. The first performance period of this model will start in 2016. OCM will use a set of measures that are specific to oncology and may not be included in existing federal quality reporting programs, such as the PQRS. Additionally, OCM will use a quarterly reporting period that is different than the calendar year performance period for the VM. Due to the specialty-specific measure set and alternative reporting period, we believe that waiving the VM would minimize conflicting incentives between programs with regard to the evaluation of quality of cost and care.
- *The Comprehensive ESRD Care Initiative:* The Comprehensive ESRD Care (CEC) Initiative is planning to start an 18-month performance period in August 2015 and is seeking to use the authority under section 1899(b)(3)(D) of the Act to utilize alternative measures, namely the CEC Initiative quality measure set, to serve as satisfactory reporting for the PQRS program beginning in CY 2016. The use of the alternative CEC measure set would result in insufficient PQRS quality data to reliably calculate a quality composite score for the VM. While the CEC Initiative may have TINs that include non-participants that choose to report separately to the PQRS program, their PQRS data may not be representative of the TIN, and therefore we believe it would be inappropriate for calculating the VM. As with other CMMI models, we believe waiving the application of the VM would minimize conflicting incentives with regard to the evaluation of the quality and cost of care.

We are proposing that in the event we finalize our proposal to waive application of the VM as required by section 1848(p) of the Act under section 1115A(d)(1) of the Act for the Pioneer ACO Model and CPC Initiative, we would also waive application of the VM for the Next Generation ACO Model, the Oncology Care Model, and the Comprehensive ESRD Care Initiative as similar models. Specifically, we would waive application of the VM for the CY 2018 payment adjustment period for groups and solo practitioners, as identified by TIN, if at least one EP who billed for PFS items and services under the TIN during the CY 2016 performance period for the VM participated in the Next Generation ACO Model, the Oncology Care Model, or the Comprehensive ESRD Care Initiative during the CY 2016 performance period. We are seeking comment on this proposal.

(b) Application of VM to Similar CMS Initiatives That Are Not Innovation Center Models

In the CY 2015 PFS final rule with comment period (79 FR 67949–67950), we finalized criteria that we will use to determine if future Innovation Center models or CMS initiatives are ''similar'' to the Pioneer ACO Model and CPC Initiative. We finalized that we will apply the same VM policies adopted for participants in the Pioneer ACO Model and CPC Initiative to groups and solo practitioners who participate in similar Innovation Center models and CMS initiatives. We are proposing in section III.M.4.e.1. of this proposed rule to waive the VM for solo practitioners and groups with at least one EP participating in the Pioneer ACO Model or CPC Initiative under section 1115A(d)(1) of the Act. The waiver authority under section 1115A(d)(1) of the Act does not apply to CMS initiatives that are not Innovation Center models. Therefore, in the event that we finalize the waiver, we propose to remove the references to ''CMS initiatives'' from § 414.1210(b)(4). To the extent that any CMS initiatives that are not Innovation Center models would require alternative policies for application of the VM, we would address those policies through future rulemaking. We are seeking comment on this proposal.

f. Payment Adjustment Amount

Section 1848(p) of the Act does not specify the amount of payment that should be subject to the adjustment for the VM; however, section 1848(p)(4)(C) of the Act requires the VM be implemented in a budget neutral manner. Budget neutrality means that payments will increase for some groups and solo practitioners based on high performance and decrease for others based on low performance, but the aggregate expected amount of Medicare spending in any given year for physician and nonphysician EP services paid under the Medicare PFS will not change as a result of application of the VM.

In the CY 2015 PFS final rule with comment period (79 FR 67952 to 67954), we finalized that we will apply a −2.0 percent VM to groups with between 2 to 9 EPs and physician solo practitioners that fall in Category 2 for the CY 2017 VM. We also finalized that the maximum upward adjustment under the quality-tiering methodology in CY 2017 for groups with between 2 to 9 EPs and physician solo practitioners that fall in Category 1 will be +2.0x if a group or solo practitioner is classified as high quality/low cost and +1.0x if a group or solo practitioner is classified as either average quality/low cost or high quality/average cost. These groups and solo practitioners will be held harmless from any downward adjustments under the quality-tiering methodology in CY 2017,

if classified as low quality/high cost, low quality/average cost, or average quality/high cost.

For groups with 10 or more EPs, we finalized for CY 2017 that we will apply a −4.0 percent VM to a group that falls in Category 2. In addition, we finalized that we will set the maximum downward adjustment under the quality-tiering methodology in CY 2017 to −4.0 percent for groups with 10 or more EPs classified as low quality/high cost and set the adjustment to −2.0 percent for groups classified as either low quality/average cost or average quality/high cost. We finalized that we will also set the maximum upward adjustment under the quality-tiering methodology in CY 2017 to +4.0x for groups with 10 or more EPs classified as high quality/low cost and set the adjustment to +2.0x for groups classified as either average quality/low cost or high quality/average cost. We also finalized that we will continue to provide an additional upward payment adjustment of +1.0x to groups with two or more EPs and solo practitioners that care for high-risk beneficiaries (as evidenced by the average HCC risk score of the attributed beneficiary population).

As noted in section III.M.4.b. of this proposed rule, under section 1848(p)(4)(B)(iii) of the Act, as amended by section 101(b)(3) of MACRA, the VM shall not be applied to payments for items and services furnished on or after January 1, 2019. Section 1848(q) of the Act, as added by section 101(c) of MACRA, establishes the Merit-based Incentive Payment System (MIPS) that shall apply to payments for items and services furnished on or after January 1, 2019. To maintain stability in the payment adjustment amounts applicable under the VM as we transition to the MIPS in 2019, we propose to maintain the payment adjustment amounts in CY 2018 that we finalized for the CY 2017 VM in the CY 2015 PFS final rule with comment period for groups with 2 or more EPs and physician solo practitioners, with the exception discussed in section III.M.4.c. of this proposed rule that in CY 2018 we propose to apply both the upward and downward adjustments under the quality-tiering methodology to groups with 2 to 9 EPs and physician solo practitioners that are in Category 1.

For CY 2018, we propose to apply a −4.0 percent VM to physicians, PAs, NPs, CNSs, and CRNAs in groups with 10 or more EPs that fall in Category 2. In addition, we propose to set the maximum downward adjustment under the quality-tiering methodology in CY 2018 to −4.0 percent for physicians, PAs, NPs, CNSs, and CRNAs in groups with 10 or more EPs classified as low quality/high cost and to set the adjustment to −2.0 percent for groups classified as either low quality/average cost or average quality/high cost. We also propose to set the maximum upward adjustment under the quality-tiering methodology in CY 2018 to +4.0x for physicians, PAs, NPs, CNSs, and CRNAs in groups with 10 or more EPs classified as high quality/low cost and to set the adjustment to +2.0x for groups classified as either average quality/low cost or high quality/average cost. Table 33 shows the proposed quality-tiering payment adjustment amounts for CY 2018 for physicians, PAs, NPs, CNSs, and CRNAs in groups with 10 or more EPs. These proposed payment amounts would be applicable to all of the physicians, NPs, PAs, CNSs, and CRNAs who bill under a group's TIN in CY 2018.

For CY 2018, we propose to apply a −2.0 percent VM to physicians, PAs, NPs, CNSs, and CRNAs in groups with between 2 to 9 EPs and physician solo practitioners that fall in Category 2. In addition, we propose to set the maximum downward adjustment under the quality-tiering methodology in CY 2018 to −2.0 percent for physicians, PAs, NPs, CNSs, and CRNAs in groups with between 2 to 9 EPs and physician solo practitioners classified as low quality/high cost and to set the adjustment to −1.0 percent for groups and physciain solo practitioners classified as either low quality/average cost or average quality/high cost. We also propose to set the maximum upward adjustment under the quality-tiering methodology in CY 2018 to +2.0x for physicians, PAs, NPs, CNSs, and CRNAs in groups with between 2 to 9 EPs and physician solo practitioners classified as high quality/low cost and to set the adjustment to +1.0x for groups and physician solo practitioners classified as either average quality/low cost or high quality/average cost. Table 34 shows the proposed quality-tiering payment adjustment amounts for CY 2018 for physicians, PAs, NPs, CNSs, and CRNAs in groups with between 2 to 9 EPs and physician solo practitioners. These proposed payment adjustment amounts would be applicable to all of the physicians, NPs, PAs, CNSs, and CRNAs who bill under a group's TIN and to physician solo practitioners in CY 2018.

For CY 2018, we propose to apply a −2.0 percent VM to PAs, NPs, CNSs, and CRNAs in groups that consist of nonphysician EPs and solo practitioners who are PAs, NPs, CNSs, and CRNAs that fall in Category 2 for the CY 2018 VM. As proposed in section III.M.4.b. of this proposed rule, the nonphysician EPs to which the CY 2018 VM payment adjustments would apply are PAs, NPs, CNSs, and CRNAs. We also propose that the maximum upward adjustment under the quality-tiering methodology in CY 2018 for PAs, NPs, CNSs, and CRNAs in groups that consist of nonphysician EPs and solo practitioners who are PAs, NPs, CNSs, and CRNAs that fall in Category 1 would be +2.0x if a group or solo practitioner is classified as high quality/low cost and +1.0x if a group or solo practitioner is classified as either average quality/low cost or high quality/average cost. As established in the CY 2015 PFS final rule with comment period (79 FR 67937), these groups and solo practitioners will be held harmless from any downward adjustments under the quality-tiering methodology in CY 2018, if classified as low quality/high cost, low quality/average cost, or average quality/high cost. Table 35 shows the proposed quality-tiering payment adjustment amounts for CY 2018 for PAs, NPs, CNSs, and CRNAs in groups that consist of nonphysician EPs and PAs, NPs, CNSs, and CRNAs who are solo practitioners. These groups and solo practitioners will have had less time to become familiar with the QRURs since they will receive QRURs for the first time in the Fall of 2015; whereas, groups consisting of both physicians and nonphysician EPs and physician solo practitioners received QRURs in the Fall of 2014 or in previous years, which enable them to understand and improve performance on the measures used in the VM. We believe our proposed approach would reward groups and solo practitioners that provide high-quality/low-cost care. In addition, a smaller increase in the maximum amount of payment at risk would be consistent with our stated focus on gradual implementation of the VM.

We also propose to continue to provide an additional upward payment adjustment of +1.0x to groups and solo practitioners that are eligible for upward adjustments under the quality-tiering methodology and have average beneficiary risk score that is in the top 25 percent of all beneficiary risk scores. Lastly, we propose to revise § 414.1270, and § 414.1275(c)(4) and (d)(3) to reflect the proposed changes to the payment adjustments under the VM for the CY 2018 payment adjustment period. We seek comments on all of these proposals.

TABLE 33—CY 2018 VM AMOUNTS FOR THE QUALITY-TIERING APPROACH FOR PHYSICIANS, PAS, NPS, CNSS, AND CRNAS IN GROUPS WITH TEN OR MORE EPS

Cost/quality	Low quality	Average quality	High quality
Low cost	+0.0%	*+2.0x	*+4.0x
Average cost	−2.0%	+0.0%	*+2.0x
High cost	−4.0%	−2.0%	+0.0%

*Groups eligible for an additional +1.0x if reporting PQRS quality measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.

TABLE 34—CY 2018 VM AMOUNTS FOR THE QUALITY-TIERING APPROACH FOR PHYSICIANS, PAS, NPS, CNSS, AND CRNAS IN GROUPS WITH 2 TO 9 EPS AND PHYSICIAN SOLO PRACTITIONERS

Cost/quality	Low quality	Average quality	High quality
Low cost	+0.0%	*+1.0x	*+2.0x
Average cost	−1.0%	+0.0%	*+1.0x
High cost	−2.0%	−1.0%	+0.0%

*Groups and solo practitioners eligible for an additional +1.0x if reporting PQRS quality measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.

TABLE 35—CY 2018 VM AMOUNTS FOR THE QUALITY-TIERING APPROACH FOR PAS, NPS, CNSS, AND CRNAS IN GROUPS CONSISTING OF NONPHYSICIAN EPS AND PAS, NPS, CNSS, AND CRNAS WHO ARE SOLO PRACTITIONERS

Cost/quality	Low quality	Average quality	High quality
Low cost	+0.0%	*+1.0x	*+2.0x
Average cost	+0.0%	+0.0%	*+1.0x
High cost	+0.0%	+0.0%	+0.0%

*Groups and solo practitioners are eligible for an additional +1.0x if reporting PQRS quality measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.

Consistent with the policy adopted in the CY 2013 PFS final rule with comment period (77 FR 69324 through 69325), we note that the estimated funds derived from the application of the downward adjustments to groups and solo practitioners in Category 1 and Category 2 would be available to all groups and solo practitioners eligible for upward adjustments under the VM. Consequently, the upward payment adjustment factor (''x'' in Tables 33, 34, and 34) would be determined after the performance period has ended based on the aggregate amount of downward payment adjustments.

g. Finality of the VM Upward Payment Adjustment Factor

Beginning with the CY 2015 VM (77 FR 69324 through 69325), we established that the upward payment adjustment factor (''x'') would be determined after the performance period has ended based on the aggregate amount of downward payment adjustments. We are also proposing a similar policy for the CY 2018 VM as discussed in section III.M.4.h. of this proposed rule. In the interest of providing EPs that are eligible for an upward payment adjustment under the VM with finality, and to minimize the cost of reprocessing claims, we propose that we would not recalculate the upward payment adjustment factor for an applicable payment adjustment period after the adjustment factor is made public, unless CMS determines that a significant error was made in the calculation of the adjustment factor. We seek public comment on this proposal.

h. Performance Period

In the CY 2014 PFS final rule with comment period (78 FR 74772), we adopted a policy that we will use performance on quality and cost measures during CY 2015 to calculate the VM that would apply to items and services for which payment is made under the PFS during CY 2017. Likewise, we propose to use CY 2016 as the performance period for the VM adjustments that will apply during CY 2018. Accordingly, we propose to add § 414.1215(d) to indicate that the performance period is CY 2016 for VM adjustments made in the CY 2018 payment adjustment period. We seek comment on this proposal.

i. Quality Measures

In the CY 2015 PFS final rule with comment period (79 FR 67956), we aligned our policies for the VM for CY 2017 with the PQRS group reporting mechanisms available to groups in CY 2015 and the PQRS reporting mechanisms available to individual EPs in CY 2015, such that data that groups submit for quality reporting purposes through any of the PQRS group reporting mechanisms in CY 2015 and the data that individual EPs submit through any of the individual PQRS reporting mechanisms in CY 2015 will be used for calculating the quality composite under the quality-tiering approach for the VM for CY 2017. Moreover, we finalized the use of all of the quality measures that are available to be reported under these various PQRS reporting mechanisms to calculate a group or solo practitioner's VM in CY 2017, to the extent that a group (or individual EPs in the group, in the case of the ''50 percent option'') or solo practitioner submits data on these measures (79 FR 67956). We also noted that, groups with two or more EPs can elect to include the patient experience of care measures collected through the PQRS CAHPS survey for CY 2015 in their VM for CY 2017. We finalized our policy to continue to include the three outcome measures in § 414.1230 in the quality measures used for the VM in CY 2017. These measures are: (1) a composite of rates of potentially preventable hospital admissions for heart failure, chronic obstructive pulmonary disease, and diabetes; (2) a composite rate of potentially preventable hospital admissions for dehydration, urinary tract infections, and bacterial pneumonia; and (3) rates of an all-cause hospital readmissions measure (77 FR 69315).

In § 414.1270(c)(4), we finalized that for groups that are assessed under the ''50 percent option'' for the CY 2017 VM, where all of the EPs in the group who report as individuals under PQRS do so by satisfactorily participating in a PQRS QCDR in CY 2015, and we are unable to receive quality performance data for those EPs, then we will classify the group's quality composite score as ''average'' under the quality-tiering methodology. Because this is the same policy as for the CY 2016 payment adjustment period, we also made a conforming revision to § 414.1270(b)(4) (79 FR 67956). Moreover, we finalized a policy that, for groups that are assessed under the ''50 percent option'' where some EPs in the group report data using a QCDR and we are unable to obtain the data, but other EPs in the group report data using the other PQRS reporting mechanisms for individuals, then we will calculate the group's score based on the reported performance data that we obtain through those other PQRS reporting mechanisms. We finalized a policy that, beginning with the CY 2014 performance period, measures reported through a PQRS QCDR that are new to PQRS will not be included in the quality composite for the VM until such time as we have historical data to calculate benchmarks for them. Once we have historical data from measures submitted via QCDRs, the benchmark for quality of care measures will be the national mean for the measure's performance rate during the year prior

to the performance period (79 FR 67956). We finalized a policy, beginning with the CY 2017 payment adjustment period, to increase the case minimum from 20 cases to 200 cases for the all-cause hospital readmissions measure as described in § 414.1230(c) to be included in the quality composite for the VM. We finalized that we will exclude the measure from the VM calculation for a group or solo practitioner if the group or solo practitioner has fewer than 200 cases for the measure during the relevant performance period, and all remaining measures in the domain will be given equal weight. We codified this change in the case minimum at § 414.1265.

(1) PQRS Reporting Mechanisms

It is important to continue to align the VM for CY 2018 with the requirements of the PQRS, because quality reporting is a necessary component of quality improvement. We also seek to avoid placing an undue burden on EPs to report such data. Accordingly, for purposes of the VM for CY 2018, we propose to continue to include in the VM all of the PQRS GPRO reporting mechanisms available to groups for the PQRS reporting periods in CY 2016 and all of the PQRS reporting mechanisms available to individual EPs for the PQRS reporting periods in CY 2016. These reporting mechanisms are described in Tables 20 and 21 of this proposed rule.

(2) PQRS Quality Measures

We propose to continue to use all of the quality measures that are available to be reported under these various PQRS reporting mechanisms to calculate a group or solo practitioner's VM in CY 2018 to the extent that a group (or individual EPs in the group, in the case of the ''50 percent option'') or solo practitioner submits data on these measures. These PQRS quality measures are described in Tables 22 through 30 of this proposed rule.

(3) Benchmarks for eCQMs

Currently, the VM program utilizes quality of care measure benchmarks for a given performance year that are calculated as the case-weighted mean of the prior year's performance rates, inclusive of all available PQRS reporting mechanisms for that measure (claims, registries, Electronic Health Record (EHR), or Web Interface (WI)). We finalized this policy in CY 2013 and stated we would consider the effects of our policy as we implemented the VM and that we may consider changes and refinements in the future (77 FR 69322).

From experience in utilizing PQRS measures in the VM, we have become aware that a given measure may be calculated differently when it is collected through an EHR, and are making a proposal to address this issue. We refer to quality measures collected through EHRs as ''eCQMs.'' We note several variances with eCQMs compared to equivalent measures reported via a different reporting mechanism. First, the inclusion of all-payer data for the eCQMs differentiates them sufficiently from their equivalent measures reported via the other PQRS reporting mechanisms, which utilize Medicare FFS data. The inclusion of all-payer data may increase the cohort size and incorporate a pool of beneficiaries with different characteristics than those captured with Medicare FFS data. As our goal is to focus on how groups of EPs or individual EPs' performance differs from the benchmark on a measure-by-measure basis, we recognize the need to utilize separate eCQM benchmarks that allow us to compare eCQM measure performance rates to a benchmark that better reflects the measures' specifications. Second, eCQMs follow a different annual update cycle than do other versions of measures, and consequently, they are not always consistent with the current version of a measure as it is reported via claims, registries, or Web Interface. For example, during a given performance period, an eCQM's specifications might require data collection on a different age range than the specifications of the same measure reported via other reporting mechanisms. This means that the eCQM version of a measure may differ from the specifications of the all-mechanism benchmark, to which it is currently compared. Because of these differences, we propose to change our benchmark policy to indicate that eCQMs, as identified by their CMS eMeasure IDs, which are distinct from the CMS/PQRS measure numbers for other reporting mechanisms, will be recognized as distinct measures under the VM. As such, we would exclude eCQM measures from the overall benchmark for a given measure and create separate eCQM benchmarks, based on the CMS eMeasure ID. We propose to make this change beginning with the CY 2016 performance period, for which the eCQM benchmarks would be calculated based on CY 2015 performance data.

We seek comment on this proposal.

(4) CAHPS Reporting

In our efforts to maintain alignment with the PQRS quality reporting requirements, we note that the criteria for administration of the CAHPS for PQRS survey for the CY 2016 performance period will contain 6 months of data as proposed in Section III.I.5.a of this proposed rule. We believe that the CAHPS for PQRS data administered during this 6-month period would be sufficiently reliable so that we could meaningfully include it in a group's quality composite score under the Value Modifier, should they elect to have CAHPS for PQRS included in their VM calculation. In order for us to use the data to calculate the score, we would require data for each summary survey measure on at least 20 beneficiaries which is the reliability standard for the value-based payment modifier (77 FR 69322–69323). We note that we took a similar approach in the CY 2014 PFS Final Rule (78 FR 74772) with regard to the 6-month reporting period for individual eligible professionals reporting via qualified registries under PQRS for the CY 2014 PQRS incentive and CY 2016 payment adjustment. Additionally, in the CY 2015 PFS Final Rule (79 FR 67956), we noted that groups with two or more EPs could elect to include the patient experience of care measures collected through the PQRS CAHPS survey for CY 2015 in their VM for CY 2017. We propose to continue this policy for the CY 2016 performance period for the CY 2018 VM.

(5) Quality Measures for the Shared Savings Program

In the CY 2015 PFS final rule with comment period (79 FR 67957), we finalized a policy to use the ACO GPRO Web Interface measures and the Shared Savings Program ACO all-cause readmission measure to calculate a quality composite score for groups and solo practitioners who participate in an ACO under the Shared Savings Program. Also, we finalized a policy to apply the benchmark for quality measures for the VM as described under § 414.1250 to determine the standardized score for quality measures for groups and solo practitioners participating in ACOs under the Shared Savings Program.

We believe patient surveys are important tools for assessing beneficiary experience of care and outcomes. Accordingly, we are proposing that starting with the CY 2018 payment adjustment period, the ACO CAHPS survey will be required as an additional component of the VM quality composite for TINs participating in the Shared Savings Program. CAHPS surveys for Shared Savings Program ACOs have been collected since 2013, for the 2012 reporting period. In the 2014 reporting period, we provided two versions of the CAHPS for ACOs survey to assess patient experience ACO–8 and ACO–12, with Shared Savings Program ACOs

having the option to use either survey. We note that under the VM CAHPS for PQRS is optional for groups that report it and these groups must elect to have their CAHPS performance used in their VM quality composite calculations. As both PQRS and Shared Savings Program ACOs report on CAHPS for their Medicare FFS populations, there is an overlap between the CAHPS survey data collected for both programs and we have calculated 2014 performance period prior year benchmarks on 11 of the 12 ACO CAHPS summary survey measures for the VM. We believe that by the CY 2016 performance period, we will have sufficient data and experience with calculating these survey measures in the VM, to require the ACO CAHPS measures in conjunction with the GPRO WI measures and the all-cause readmission measure in the calculation of a quality composite score for groups and solo practitioners participating in an ACO under Shared Savings Program. We propose to include the CAHPS for ACOs survey in the quality composite of the VM for TINs participating in ACOs in the Shared Savings Program, beginning with the CY 2016 performance period and the CY 2018 payment adjustment period. We propose that whichever version of the CAHPS for ACOs survey the ACO chooses to administer will be included in the TIN's quality composite for the VM. We propose to make corresponding changes to § 414.1210(b)(2)(i)(B). We seek comment on this proposal.

j. Expansion of the Informal Inquiry Process To Allow Corrections for the Value-Based Payment Modifier

Section 1848(p)(10) of the Act provides that there shall be no administrative or judicial review under section 1869 of the Act, section 1878 of the Act, or otherwise of the following:

- The establishment of the VM.
- The evaluation of the quality of care composite, including the establishment of appropriate measures of the quality of care.
- The evaluation of the cost composite, including the establishment of appropriate measures of costs.
- The dates of implementation of the VM.
- The specification of the initial performance period and any other performance period.
- The application of the VM.
- The determination of costs.

These statutory requirements regarding limitations of review are reflected in § 414.1280. We previously indicated in the CY 2013 PFS final rule with comment period (77 FR 69326) that we believed an informal review mechanism is appropriate for groups of physicians to review and to identify any possible errors prior to application of the VM, and we established an informal inquiry process at § 414.1285. We stated that we intend to disseminate reports containing CY 2013 data in Fall 2014 to groups of physicians subject to the VM in 2015 and that we will make a help desk available to address questions related to the reports, and we have since followed through on those actions.

In the CY 2015 final rule with comment period (79 FR 67960), for the CY 2015 payment adjustment period, we finalized: (1) A February 28, 2015, deadline for a group to request correction of a perceived error made by CMS in the determination of its VM; and (2) finalized a policy to classify a TIN as ''average quality'' in the event we determined that we have made an error in the calculation of the quality composite. Beginning with the CY 2016 payment adjustment period, (1) we finalized a deadline of 60 days that would start after the release of the QRURs for the applicable performance period for a group or solo practitioner to request a correction of a perceived error related to the VM calculation, and (2) we stated we would take steps to establish a process for accepting requests from providers to correct certain errors made by CMS or a third-party vendor (for example, PQRS-qualified registry). Our intent was to design this process as a means to recompute a TIN's quality composite and/or cost composite in the event we determine that we initially made an erroneous calculation. We noted that if the operational infrastructure was not available to allow this recomputation, we would continue the approach for the CY 2015 payment adjustment period to classify a TIN as ''average quality'' in the event we determine that we have made an error in the calculation of the quality composite. We finalized that we would recalculate the cost composite in the event that an error was made in the cost composite calculation. We noted that we would provide additional operational details as necessary in subregulatory guidance.

Moreover, for both the CY 2015 payment adjustment period and future adjustment periods, we finalized a policy to adjust a TIN's quality-tier if we make a correction to a TIN's quality and/or cost composites because of this correction process.

We further noted that there is no administrative or judicial review of the determinations resulting from this expanded informal inquiry process under section 1848(p)(10) of the Act. In the CY 2015 final rule for the CY 2016 payment adjustment period we noted that if the operational infrastructure is not available to allow the recomputation of quality measure data we would continue the approach of the initial corrections process to classify a TIN as ''average quality'' in the event we determine CMS or a third-party vendor made an error in the calculation of the quality composite. We propose to continue this policy for the CY 2017 payment adjustment and future adjustment periods or until such a time that the operational infrastructure is in place to allow the recomputation of data. We seek comment on this proposal.

Our overall approach to the VM is based on participation in the PQRS. Beginning with the CY 2016 payment adjustment period for the VM, groups of physicians (or individual EPs in the group, in the case of the 50 percent option) must meet the criteria to avoid the CY 2016 PQRS payment adjustment, to be classified as Category 1 for the VM and avoid an automatic downward adjustment under the VM. The payment adjustment for the VM is applied at the TIN level whereas the PQRS payment adjustment is applied at the TIN/NPI level. We believe that we need a policy to address the circumstance in which a group is initially determined not to have met the criteria to avoid the PQRS payment adjustment and subsequently, through the informal review process, at least 50 percent of its EPs are determined to have met the criteria to avoid the PQRS payment adjustment as individuals. We note that the informal review submission period will occur during the 60 days following release of the QRURs for the 2016 VM and subsequent years. We believe that this will allow us sufficient time to process the majority of the requests before finalizing the adjustment factor. We propose to reclassify a TIN as Category 1 when PQRS determines on informal review that at least 50 percent of the TIN's EPs meet the criteria for satisfactory reporting of data on PQRS quality measures as individuals for the relevant CY PQRS payment adjustment, or in lieu of satisfactory reporting, satisfactorily participate in a PQRS QCDR for the relevant CY PQRS payment adjustment. Moreover, we note that if the group was initially classified as Category 2, then we do not expect to have data for calculating their quality composite, in which case they'd be classified as ''average quality'', however, if the data is available in a timely manner, then we would recalculate the quality composite. We seek comments on this proposal.

k. Minimum Episode Count for the Medicare Spending Per Beneficiary (MSPB) Measure

In the CY 2014 PFS final rule with comment period (78 FR 74780), we finalized inclusion of the MSPB measure as proposed in the cost composite beginning with the CY 2016 VM, with a CY 2014 performance period. We finalized a minimum of 20 MSPB episodes for inclusion of the MSPB measure in a TIN's cost composite. We stated that the nonspecialty-adjusted version of the measure using 2011 data had high reliability with a 20 episode minimum (79 FR 74779).

The reliability results presented in the CY 2014 PFS final rule with comment period (79 FR 74779), which supported the 20 episode case minimum, were based on the non-specialty-adjusted measure instead of the specialty-adjusted measure. We refined the methodology to account for the change in measure specifications and the results showed that the specialty-adjusted measure was more reliable at higher episode case minimums. Using a more appropriate methodology for calculating reliability, we have found that the specialty-adjusted measure does not have moderate or high reliability with a 20 episode minimum for many groups. Table 36 shows the reliability of the measure for different group sizes as the case minimum increases.

TABLE 36—SPECIALTY-ADJUSTED MSPB AMOUNT, PERCENT ABOVE 0.4 RELIABILITY THRESHOLD

Specialty-adjusted MSPB amount	All solo practitioners and groups	Solo practitioners	Groups with 2–9 EPs	Groups with 10–24 EPs	Groups with 25–99 EPs	Groups with 100+ EPs
Groups and Solo Practitioners with 20+ Episodes						
Percent above 0.4	40.1%	18.1%	41.7%	60.9%	66.5%	89.7%
Number of groups	29,190	10,639	10,505	3,664	3,229	1,153
Groups and Solo Practitioners with 50+ Episodes						
Percent above 0.4	80.2%	60.8%	79.0%	90.3%	91.6%	97.0%
Number of groups	15,881	3,406	6,194	2,699	2,499	1,083
Groups and Solo Practitioners with 60+ Episodes						
Percent above 0.4	86.8%	71.9%	84.6%	93.8%	94.7%	98.3%
Number of groups	13,614	2,416	5,279	2,506	2,352	1,061
Groups and Solo Practitioners with 75+ Episodes						
Percent above 0.4	92.9%	82.4%	91.1%	96.6%	97.3%	98.8%
Number of groups	11,213	1,567	4,182	2,256	2,173	1,035
Groups and Solo Practitioners with 100+ Episodes						
Percent above 0.4	97.6%	93.8%	96.3%	98.6%	99.2%	99.5%
Number of groups	8,543	785	2,873	1,924	1,957	1,004

Given that the measure has moderate reliability (above 0.4) for only 40.1 percent of all groups and solo practitioners and is as low as 18.1 percent for solo practitioners with an episode minimum of 20, we propose to increase the episode minimum to 100 episodes beginning with the CY 2017 payment adjustment period and CY 2015 performance period. Although this reduces the number of groups and solo practitioners for whom we would be able to include an MSPB calculation in the cost composite (from 29,190 to 8,543 based on 2013 data), we do not believe we should use the measure in calculating the cost composite if it is not reliable at the 20 episode minimum. We note that this change in policy could create a situation in which a group that would have performed well on this measure would no longer have this measure included in its cost composite, which could negatively impact their cost composite, and ultimately their VM adjustment. However, we believe that it would not be appropriate to include this measure in the cost composite even for those groups that performed well. Rather, we believe that it is more important to ensure that only reliable measures are included in the VM, and we want to avoid a situation in which groups or solo practitioners who may have performed poorly on the measure using a 20 episode minimum may receive a downward adjustment to payments under the VM as a result of a measure that was not reliable. We propose to add § 414.1265(a)(2) to reflect a case minimum of 100 episodes for the MSPB measure. We are seeking comment on this proposal.

We also considered increasing the episode minimum to 75 instead of 100. This would allow us to include the MSPB measure in the cost composite for a larger number of groups but we believe that the reliability for solo practitioners with a minimum of 100 episodes was preferable to the reliability when using a 75 episode minimum. We welcome comment on this alternative we considered, as well as other potential minimum case thresholds for this measure.

We also considered revising the case minimum for the MSPB measure beginning with the CY 2016 payment adjustment period and CY 2014 performance period, but did not propose this policy, because this PFS rule will be finalized after the 2014 QRURs with the 2016 VM payment adjustment information are released. We note that, using an episode minimum of 20 for the 2016 VM, the MSPB measure has moderate reliability for majority of the groups that will be subject to the VM in 2016 (60.9 percent of groups with 10–24 EPs, 66.5 percent of groups with 25–99 EPs and 89.7 percent of groups with 100 or more EPs).

l. Inclusion of Maryland Hospital Stays in Definition of Index Admissions

In the CY 2014 PFS final rule with comment period (78 FR 74780), we finalized inclusion of the MSPB

measure as proposed in the cost composite beginning with the CY 2016 VM, with a CY 2014 performance period. We indicated in the 2014 proposed rule with comment period (78 FR 43494) that we would use the MSPB measure as specified for the Hospital Inpatient Quality Reporting (IQR) and Hospital Value Based Purchasing (VBP) Program with the exception of changes to the attribution methodology. The MSPB measure used for the Hospital IQR and Hospital VBP Programs does not include hospitalizations at Maryland hospitals as an index admission that would trigger an episode because Maryland hospitals are not paid under the Inpatient Prospective Payment System (IPPS) and do not participate in the Hospital VBP Program. The result is that groups and solo practitioners in Maryland would not have the MSPB measure included in their cost composite under the Value Modifier. We propose that, beginning with the 2018 VM, we change the definition of index admission used for the MSPB used in the VM program to include inpatient hospitalizations at Maryland hospitals. This change would allow CMS to include this measure in the calculation of the cost composite for groups and solo practitioners in Maryland, consistent with what is done for providers in others states. Under this proposal, we would continue to standardized all Medicare claims as described in the ''CMS Price Standardization'' document, which can be found in the ''Measure Methodology'' section at *http://qualitynet.org/dcs/ContentServer?c=Page&pagename=QnetPublic%2FPage%2FQnetTier3&cid=1228772053996*. The standardization methodology is currently used in the calculation of the MSPB measure and is continually being reviewed and updated to account payment policy changes and updates; any methodological changes made across years are documented in the Appendix of the ''CMS Price Standardization'' document. We are seeking comment on our proposal to, beginning with the 2018 VM, include hospitalizations at Maryland hospitals as an index admission for the MSPB measure for the purposes of the VM program.

m. Average Quality and Average Cost Designations in Certain Circumstances

In the CY 2015 PFS final rule with comment period (79 FR 67934), we clarified a policy that was finalized at § 414.1270, that beginning with the CY 2016 payment adjustment period, a group or solo practitioner subject to the VM would receive a cost composite score that is classified as average under the quality-tiering methodology if the group or solo practitioner does not have at least one cost measure with at least 20 cases. We observed that groups that do not provide primary care services are not attributed beneficiaries or are attributed fewer than 20 beneficiaries, and thus, we are unable to calculate reliable cost measures for those groups of physicians (77 FR 69323). We stated in the CY 2014 PFS final rule with comment period (78 FR 74780) that we believe this policy is reasonable because we would have insufficient information on which to classify the groups' costs as ''high'' or ''low'' under the quality-tiering methodology. Moreover, we believed that to the extent a group's quality composite is classified as high or low, the group's VM should reflect that classification. As discussed in section III.M.4.k. of this proposed rule, beginning with the CY 2017 payment adjustment period, we are proposing to increase the minimum number of episodes for inclusion of the MSPB measure in the cost composite to 100 episodes. Therefore, we propose to revise § 414.1265(b) to indicate that a group or solo practitioner subject to the VM would receive a cost composite score that is classified as average under the quality-tiering methodology if the group or solo practitioner does not have at least one cost measure that meets the minimum number of cases required for the measure to be included in the calculation of the cost composite, as required in § 414.1265. To improve the organization of the regulation text, we also propose to move the provisions at § 414.1270(b)(5) and (c)(5) to § 414.1265(b)(3).

The quality composite score calculated for each group and solo practitioner subject to the VM is based on the PQRS measures reported by the group or solo practitioner and three claims-based outcome measures, as described in § 414.1225 and § 414.1230, respectively. A quality measure must have 20 or more cases in order to be included in the calculation of the quality composite; however, beginning with the CY 2017 payment adjustment period, the all-cause hospital readmissions measure must have 200 or more cases in order to be included. Section 414.1265(a) describes the minimum number of cases required for the quality and cost measures to be included in the calculation of the quality and cost composites, respectively. We believe it is important to have a policy to determine the designation of the quality composite when a quality measure cannot be calculated reliably that is similar to the one established for the cost composite. Therefore, we propose that beginning in the CY 2016 payment adjustment period, a group or solo practitioner subject to the VM would receive a quality composite score that is classified as average under the quality-tiering methodology if the group or solo practitioner does not have at least one quality measure that meets the minimum number of cases required for the measure to be included in the calculation of the quality composite, as required at § 414.1265. Consequently, to the extent a group or solo practitioner's cost composite is classified as high, average, or low, the group or solo practitioner's VM would reflect that classification. We propose to incorporate this proposal at § 414.1265(b)(2).

Current § 414.1265(b) states that in a performance period, if a reliable quality of care composite or cost composite cannot be calculated, payments will not be adjusted under the VM. In light of our proposals discussed in this section of the proposed rule, we do not believe this policy is necessary beginning with the CY 2016 payment adjustment period. As proposed above, the cost composite for a group or solo practitioner would be classified as average if there is not at least one cost measure that can be calculated reliably. Furthermore, we are proposing that the quality composite for a group or solo practitioner would be classified as average if there is not at least one quality measure that can be calculated reliably. Therefore, we propose to specify in § 414.1265(b)(1) that this policy was applicable only for the CY 2015 payment adjustment period.

n. Technical Changes to the ''Benchmarks for Cost Measures'' Section of Regulation Text

In the CY 2014 PFS final rule with comment period (78 FR 74781 to 74784), we finalized a policy to use the specialty adjustment method to create the standardized score for each group's cost measure beginning with the CY 2016 VM that refines the peer group methodology to account for specialty mix. We also amended § 414.1255 to include this policy in the cost composite methodology. We propose to move § 414.1255(b) and (c) (describing specialty adjustment of cost measures and benchmarks for cost measures) to § 414.1235(c)(4) and (5) (Cost measure adjustments) and revise the regulation text to align with the specialty adjustment methodology finalized in the CY 2014 PFS final rule with comment period. This is a technical change to the

regulation text only and will not impact how the cost measures will be specialty-adjusted beginning with the CY 2016 VM.

For the CY 2015 VM, the peer group for calculating the benchmarks for cost measures was all groups of physician to which beneficiaries are attributed and that are subject to the VM (for example, for CY 2015, the cost measures of groups with 100 or more EPs was compared to the cost measures of other groups of 100 or more EPs). About the specialty adjustment method, we stated in the CY 2014 PFS final rule (78 FR 74783) that this methodology creates one national benchmark for each cost measure against which all groups (regardless of size) would be assessed in creating the group's standardized score. We did not codify this policy in the regulation text in the CY 2014 PFS final rule with comment period. We also note that the benchmark for a cost measure includes the performance data for groups and solo practitioners that meet the minimum number of cases for that measure as described under § 414.1265(a). We believe this policy ensures that only the data for measures that are considered statistically reliable are included in the benchmarks, in addition to being included in the calculation of the cost composite. Therefore, we propose to codify at § 414.1255(b) that beginning with the CY 2016 payment adjustment period, the benchmark for each cost measure is the national mean of the performance rates calculated for all groups and solo practitioners that meet the minimum number cases for that measure under § 414.1265(a). We note that we are not proposing any revisions to the specialty adjustment method finalized in the CY 2014 PFS final rule with comment period (78 FR 74781 through 74784).

o. Discussion of Stratification of Cost Measure Benchmarks by Beneficiary Risk Score

In response to our previously-finalized policies, stakeholders have suggested that the CMS-hierarchical condition categories (HCC) Risk Adjustment methodology used in the total per capita cost measures for the VM does not accurately capture the additional costs associated with treating the sickest beneficiaries. Some of these commenters stated that groups that work exclusively in post-acute and long-term care settings would be unable to perform well on cost measures under the current methodology. Another commenter stated that beneficiaries who receive care at home typically have high HCC scores and higher costs. We appreciate the concerns raised by commenters and agree that it is important to make adjustments for differences in beneficiary characteristics that impact health and cost outcomes and are outside of the control of the provider. We continue to believe that our current methodology of using HCC scores that include adjustments for Medicare and Medicaid eligibility status in addition to diagnoses, and replacing the highest 1 percent of costs with the cost of the 99th percentile for the highest cost beneficiaries, help address these concerns. To address concerns regarding specialties that might routinely treat more complex and consequently more costly beneficiaries, we finalized in the CY 2013 PFS final rule with comment period that we would apply a specialty adjustment to all cost measures used in the VM (78 FR 74776). This enables groups' costs to be compared to similarly-comprised groups, based on specialty.

We note that high costs within the post-acute and long-term care settings present a unique opportunity for these providers to improve performance on cost and quality measures. Although we continue to encourage providers to report quality measures for patients in these settings and to use the information contained in their QRUR to improve and achieve high levels of performance, we stated in the CY 2015 PFS final rule with comment period (79 FR 67932) that we would continue to monitor these groups and solo practitioners' performance under the VM and continue to explore potential risk adjustment refinements. One option we are considering would be to stratify the cost measure benchmarks so that groups and solo practitioners are compared to other groups and individual practitioners treating beneficiaries with similar risk profiles. In this way, within a given grouping (for example, a quartile or decile), there remains an opportunity to gain efficiencies in care and lower costs, while beneficiary severity of illness and practice characteristics may be more fully recognized at a smaller, and likely less-heterogeneous, attributed beneficiary level. We are not making any proposals on this matter at this time. We are seeking feedback on this potential approach as well as other approaches..

5. Physician Feedback Program

a. CY 2014 Quality and Resource Use Reports (QRURs) Based on CY 2014 Data and Disseminated in CY 2015

In Fall 2015, we plan to expand the Physician Feedback Program by making QRURs, containing data on cost and quality performance during calendar year 2014, available to all solo practitioner EPs and groups of EPs of all sizes, as identified by TIN, including nonphysician EP solo practitioners and groups comprised of nonphysician EPs. We also plan to make the 2014 QRURs available to Shared Savings Program ACO participant TINs and groups that include one or more EPs who participated in a Pioneer ACO or the CPC Initiative. The reports will contain valuable information about a TIN's actual performance during CY 2014 on the quality and cost measures that will be used to calculate the CY 2016 VM. For physicians in groups of 10 or more, the 2014 QRURs will provide information on how a group's quality and cost performance will affect their Medicare payments in 2016 through the application of the VM based on performance in 2014.

The report will provide data on a group's or solo practitioner's performance on quality measures they report under the PQRS, as well as the three claims-based outcome measures calculated for the VM and described at § 414.1230. The 2014 QRUR will accommodate new PQRS reporting options, including QCDRs and CAHPS for PQRS. In addition, the reports will present data assessing a group practice's or solo practitioner's performance on cost measures and information about the services and procedures that contributed most to costs. The cost measures in the 2014 QRUR are payment-standardized and risk-adjusted and are also specialty-adjusted to reflect the mix of physician specialties in a TIN. For the 2014 QRURs, we will provide more detailed per capita cost of service breakdowns for all six cost measures. The reports also will contain additional supplementary information on the individual PQRS measures for EPs reporting PQRS measures as individuals; enhanced drill down tables; and a dashboard with key performance measures.

In response to stakeholder feedback to provide more timely and actionable information on outcomes and cost measures, we provided for the first time a mid-year report, the 2014 Mid-Year QRUR (MYQRUR) in Spring 2015. The 2014 MYQRUR was provided to physician solo practitioners and groups of physicians nationwide who billed for Medicare-covered services under a single TIN over the period of July 1, 2013 through June 30, 2014. We disseminated Mid-Year QRURs in the spring of each year to provide interim information about performance only on those cost and quality outcomes measures that we calculate directly from Medicare administrative claims, based

on the most recent 12 months of data that are available. The MYQRURs are for informational purposes and do not estimate performance for the calculation of the VM. Beginning in Spring 2016, we intend to expand the distribution of MYQRURs to nonphysician EPs, solo practitioners, and groups composed of nonphysician EPs.

We will continue to refine the QRURs based on stakeholder feedback, and we invite comment on which aspects of the QRURs reports have been most useful and how we can improve access to and actionability of performance reports.

b. Episode Costs and the Supplemental QRURs

Section 1848(n)(9)(A) of the Act requires CMS to develop an episode grouper and include episode-based costs in the QRURs. An episode of care consists of medical and/or procedural services that address a specific medical condition or procedure that are delivered to a patient within a defined time period and are captured by claims data. An episode grouper organizes administrative claims data into episodes.

In Summer 2014, we distributed the Supplemental QRUR: Episodes of Care based on 2012 data to groups with 100 or more EPs. The 2012 Supplemental QRUR provided information on 20 episode subtypes and 6 clinical episode-based measures. In Fall 2015, we expect to provide the 2014 Supplemental QRURs to all groups and solo practitioners nationwide who billed for Medicare-covered services under a single TIN in 2014 and for whom we are able to calculate at least one episode measure. The supplemental QRURs are provided in addition to the Annual and Mid-Year QRURs. They provide information on performance on episode-based cost measures that are not included in the VM, in order to help groups and solo practitioners understand the cost of care they provide to beneficiaries and work toward the provision of more efficient care. The 2014 Supplemental QRURs will likely include the 6 episode-based measures included in the 2012 Supplemental QRURS in addition to other episode-based payment measures. We will continue to seek stakeholder input as we develop the episode framework.

Lastly, we would to direct readers to the Physician Compare proposals in this rule (section III.H.), which propose the addition of a green check mark to the profile page of the Physician Compare Web site for providers receiving an upward adjustment under the VM starting in CY 2018. CY 2018 is the first year the VM applies to not only all physicians, but also all nonphysician EPs as well. More information is available about Physician Compare on the CMS Web site at *http://www.medicare.gov/physiciancompare/search.html*.

N. Physician Self-Referral Updates

1. Background

a. Statutory and Regulatory History

Section 1877 of the Act, also known as the physician self-referral law: (1) Prohibits a physician from making referrals for certain designated health services (DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship (ownership or compensation), unless an exception applies; and (2) prohibits the entity from filing claims with Medicare (or billing another individual, entity, or third party payer) for those referred services. The statute establishes a number of specific exceptions, and grants the Secretary the authority to create regulatory exceptions for financial relationships that pose no risk of program or patient abuse. Section 13624 of the Omnibus Budget Reconciliation Act of 1993 (Pub. L. 103–66) (OBRA 1993), entitled ''Application of Medicare Rules Limiting Certain Physician Referrals,'' added a new paragraph (s) to section 1903 of the Act, to extend aspects of the physician self-referral prohibitions to Medicaid. For additional information about section 1903(s) of the Act, see 66 FR 857 through 858.

Several more recent statutory changes have also affected the physician self-referral law. Section 6001 of the Affordable Care Act amended section 1877 of the Act to impose additional requirements for physician-owned hospitals to qualify for the rural provider and hospital ownership exceptions. Section 6409 of the Affordable Care Act required the Secretary, in cooperation with the Inspector General of the Department of Health and Human Services, to establish a Medicare self-referral disclosure protocol (SRDP) that sets forth a process to enable providers of services and suppliers to self-disclose actual or potential violations of the physician self-referral law.

This rulemaking follows a history of rulemakings related to the physician self-referral law. The following discussion provides a chronology of our more significant and comprehensive rulemakings; it is not an exhaustive list of all rulemakings related to the physician self-referral law. After the passage of section 1877 of the Act, we proposed rulemakings in 1992 (related only to referrals for clinical laboratory services) (57 FR 8588) (the 1992 proposed rule) and 1998 (addressing referrals for all DHS) (63 FR 1659) (the 1998 proposed rule). We finalized the proposals from the 1992 proposed rule in 1995 (60 FR 41914) (the 1995 final rule), and issued final rules following the 1998 proposed rule in three stages. The first final rulemaking (Phase I) was published in the **Federal Register** on January 4, 2001 (66 FR 856) as a final rule with comment period. The second final rulemaking (Phase II) was published in the **Federal Register** on March 26, 2004 (69 FR 16054) as an interim final rule with comment period. Due to a printing error, a portion of the Phase II preamble was omitted from the March 26, 2004 **Federal Register** publication. That portion of the preamble, which addressed reporting requirements and sanctions, was published on April 6, 2004 (69 FR 17933). The third final rulemaking (Phase III) was published in the **Federal Register** on September 5, 2007 (72 FR 51012) as a final rule.

In addition to Phase I, Phase II, and Phase III, we issued final regulations on August 19, 2008 in the ''Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates'' final rule with comment period (72 FR 48434) (the FY 2009 IPPS final rule). That rulemaking made various revisions to the physician self-referral regulations, including: (1) Revisions to the ''stand in the shoes'' provisions; (2) establishment of provisions regarding the period of disallowance and temporary noncompliance with signature requirements; and (3) expansion of the definition of ''entity.''

After passage of the Affordable Care Act, we issued final regulations on November 29, 2010 in the CY 2011 PFS final rule with comment period (75 FR 73170) that codified a disclosure requirement established by the Affordable Care Act for the in-office ancillary services exception. We also issued final regulations on November 24, 2010 in the CY 2011 OPPS final rule with comment period (75 FR 71800), on November 30, 2011 in the CY 2012 OPPS final rule with comment period (76 FR 74122), and on November 10, 2014 in the CY 2015 OPPS final rule with comment period (79 FR 66770) that established or revised certain regulatory provisions concerning physician-owned hospitals in order to codify and interpret the Affordable Care Act's revisions to section 1877 of the Act.

b. Purpose of This Proposed Rule

This rule would update the physician self-referral regulations to accommodate

delivery and payment system reform, to reduce burden, and to facilitate compliance. We have learned from stakeholder inquiries, review of relevant literature, and self-disclosures submitted to the SRDP that additional clarification of certain provisions of the physician self-referral law would be helpful. In addition to clarifying the regulations, we are also interested in expanding access to needed health care services. In keeping with these goals, the proposed rule expands the regulations to establish two new exceptions and clarifies certain regulatory terminology and requirements.

2. Recruitment and Retention (§ 411.357(e) and § 411.357(t))

In this proposed rule, we are proposing to establish new policies and revise certain existing policies regarding recruitment assistance and retention payments. Specifically, we are proposing a new exception for assistance to physicians to employ nonphysician practitioners. In addition, we are proposing to clarify for federally qualified health centers (FQHCs) and rural health clinics (RHCs) how to determine the geographic areas that they serve for purposes of the exception at § 411.357(e) and to change the language at § 411.357(e)(1)(iii) to ensure the consistency we intend for the ''volume or value'' standard found throughout the statute and our regulations. We are also proposing to lengthen the required record retention period at § 411.357(e)(4)(iv) from 5 years to 6 years to ensure consistency with the proposed exception at § 411.357(x) and other CMS record retention policies. For the exception for retention payments to physicians in underserved areas, we are proposing to clarify how parties should calculate the maximum amount for permissible retention payments. We describe these proposals in detail below.

a. Assistance To Employ a Nonphysician Practitioner

(1) Background

Section 1877(e)(5) of the Act sets forth an exception for remuneration provided by a hospital to a physician to induce the physician to relocate to the geographic area served by the hospital in order to be a member of the hospital's medical staff, subject to certain requirements. This exception is codified at § 411.357(e). The regulatory exception permits recruitment payments by FQHCs and RHCs on the same basis as those permitted by hospitals, but like the statute, limits the applicability of the exception to the recruitment of physicians. In Phase III, we responded to requests by commenters that we expand § 411.357(e) to cover the recruitment of nonphysician practitioners into a hospital's service area, including into an existing group practice (72 FR 51049). We declined to establish a new exception at that time. Further, we indicated that ''[r]ecruitment payments made by a hospital directly to a nonphysician practitioner would not implicate the physician self-referral law, unless the nonphysician practitioner serves as a conduit for physician referrals or is an immediate family member of a referring physician. Payments made by a hospital to subsidize a physician practice's costs of recruiting and employing nonphysician practitioners would create a compensation arrangement between the hospital and the physician practice for which no exception would apply'' (72 FR 51049).

Significant changes in our health care delivery and payment systems, as well as alarming trends in the primary care workforce shortage projections, have occurred since the publication of Phase III. A primary care workforce shortage has been a concern for years. (See Advisory Committee on Training in Primary Care Medicine and Dentistry, ''Coming Home: the Patient-Centered Medical-Dental Home in Primary Care Training,'' 7th annual report to the Secretary of the U.S. Department of Health and Human Services and to Congress, December 2008, *http://www.hrsa.gov/advisorycommittees/bhpradvisory/actpcmd/Reports/seventhreport.pdf*.) The Affordable Care Act expanded access to health care coverage to those previously uninsured. As a result, the need for primary care providers (including nonphysician practitioners) has increased, particularly in remote and underserved areas. (See Ewing, Joshua, et al., ''Meeting the Primary Care Needs of Rural America: Examining the Role of Non-Physician Providers,'' National Conference of State Legislatures, The Rural Health Connection, April 2013, *http://www.ncsl.org/documents/health/RuralBrief313.pdf*.) The projected rise in the demand for primary care is due also to a growing and aging population, according to the Health Resources and Services Administration (HRSA). (See HHS, HRSA, National Center for Health Workforce Analysis, ''Projecting the Supply and Demand for Primary Care Practitioners Through 2020,'' November 2013, *http://bhpr.hrsa.gov/healthworkforce/supplydemand/usworkforce/primarycare/*.) HRSA found that ''the demand for primary care physicians will grow more rapidly than physician supply, resulting in a projected shortage of more than 20,000 full-time equivalent physicians.'' (Id.) Similarly, a study in the Annals of Family Medicine journal projected the country will need 52,000 more primary care physicians by 2025. (Peterson, Stephen M., et al, ''Projecting US Primary Care Physician Workforce Needs: 2010–2025,'' 29 10(6) Ann. Of Fam. Med. 503 (2012).) Nonphysician practitioners, the fastest growing segment of the primary care workforce (Schwartz, Mark D., ''Health Care Reform and the Primary Care Workforce Bottleneck,'' 27(4) J. Gen. Intern. Med. 469, 470 (2011)), may help to mitigate this shortage. Finally, new and evolving care delivery models, which feature an increased role for nonphysician practitioners (often as care coordination facilitators or in team-based care) have been shown to improve patient outcomes while reducing costs, both of which are important Department goals as we move further toward quality- and value-based purchasing of health care services in the Medicare program and the health care system as a whole.

(2) New Exception

In light of the changes in the health care delivery and payment systems since we last considered the issue of nonphysician practitioner recruitment assistance to physicians, using the authority granted to the Secretary in section 1877(b)(4) of the Act, we are proposing a limited exception for hospitals, FQHCs, and RHCs that wish to provide remuneration to a physician to assist with the employment of a nonphysician practitioner. We believe that this exception is timely, will promote beneficiary access to care, and will remove barriers that could frustrate certain goals of the Affordable Care Act. When structured with the safeguards described below, we do not believe that arrangements for assistance to physicians to employ nonphysician practitioners pose a risk of program or patient abuse.

We propose to establish a new exception at § 411.357(x) to permit remuneration from a hospital, FQHC, or RHC to a physician to assist the physician in employing a nonphysician practitioner in the geographic area served by the hospital, FQHC, or RHC providing the remuneration. Because the physician self-referral law applies to financial relationships between physicians and entities furnishing DHS, the proposed exception is not structured to apply to remuneration from a hospital, FQHC, or RHC to a group practice or other type of physician

practice (both of which qualify as a ''physician organization,'' as defined at § 411.351) . However, under our regulations at § 411.354(c), remuneration from an entity furnishing DHS to a physician organization would be deemed to be a direct compensation arrangement between each physician who stands in the shoes of the physician organization and the entity furnishing DHS. A ''deemed'' direct compensation arrangement must satisfy the requirements of an applicable exception if the physician makes referrals to the DHS entity and the DHS entity bills the Medicare program for DHS furnished as a result of the physician's referrals. The proposed exception would be available to protect a direct compensation arrangement between a hospital, FQHC, or RHC providing remuneration to an individual physician, as well as ''deemed'' direct compensation arrangements between a hospital, FQHC, or RHC and the physicians standing in the shoes of the physician organization to which the hospital, FQHC, or RHC provided the remuneration. Parties would also need to apply the rules regarding indirect compensation arrangements at § 411.354(c) to any chain of financial relationships that runs between the entity furnishing DHS and any physician who does not stand in the shoes of the physician organization in order to determine whether an indirect compensation arrangement exists. If an indirect compensation arrangement exists as a result of remuneration provided by the entity furnishing DHS, it must satisfy the requirements of the exception at § 411.357(p) for indirect compensation arrangements.

The proposed exception would apply only where the nonphysician practitioner is a *bona fide* employee of the physician receiving the remuneration from the hospital (or of the physician's practice) and the purpose of the employment is to provide primary care services to patients of the physician practice. We believe that employing a nonphysician practitioner (rather than merely contracting on an independent basis with a nonphysician practitioner) indicates a commitment by the physician to increase the availability of patient care services to his or her patients on an ongoing basis and, as such, is an important safeguard against program and patient abuse. However, we are soliciting comments regarding whether we should also permit remuneration to physicians to assist in attracting nonphysician practitioners to their medical practices in an independent contractor capacity, and, if so, what requirements we should include for such arrangements (for example, a requirement that the arrangement between the physician and the nonphysician practitioner have a minimum term, such as 1 year).

Because our goal in proposing the exception at § 411.357(x) is to promote the expansion of access to primary care services—which we consider to include general family practice, general internal medicine, pediatrics, geriatrics, and obstetrics and gynecology patient care services—we are proposing to define ''nonphysician practitioner,'' for purposes of this exception, to include only physician assistants, nurse practitioners, clinical nurse specialists, and certified nurse midwives. We believe that these are the types of nonphysician practitioners that furnish ''primary care services.'' We note that the exception would not protect arrangements for assistance to a physician to employ a certified registered nurse anesthetist. We solicit comments regarding whether there is a compelling need to expand the scope of the proposed exception to additional types of nonphysician practitioners who furnish primary care services.

We are also proposing at § 411.357(x)(1)(vi) a requirement that the nonphysician practitioner provide only primary care services to patients of the physician's practice. As noted, we consider general family practice, general internal medicine, pediatrics, geriatrics, and obstetrics and gynecology patient care services to be ''primary care services.'' Thus, the exception would not protect arrangements for assistance to a physician to employ a nonphysician practitioner who furnishes specialty care services, such as cardiology or surgical services, to the physician practice's patients. We solicit comments regarding whether we should consider other, more, or fewer types of services to be ''primary care services'' for purposes of proposed § 411.357(x), whether there is a compelling need to expand the scope of the proposed exception to nonphysician practitioners who provide services that are not considered ''primary care services'' and, if so, safeguards that could be included in a final exception to ensure no risk of program or patient abuse. We are proposing two alternatives for establishing the minimum amount of primary care services furnished to patients of the physician's practice by the nonphysician practitioner: (1) At least 90 percent of the patient care services furnished by the nonphysician practitioner must be primary care services; or (2) substantially all of the patient care services furnished by the nonphysician practitioner must be primary care services. We would define ''substantially all'' patient care services consistent with our regulations; that is, at least 75 percent of the nonphysician practitioner's services to patients of the physician's practice must be primary care services. (See § 411.352(d) and § 411.356(c)(1).) We are soliciting comments regarding which of these alternatives is most appropriate and the nature of the documentation necessary to measure the nonphysician practitioner's services.

We do not intend to permit remuneration to physicians through ongoing or permanent subsidies of their nonphysician practitioner employment and other practice costs. Therefore, we are proposing a cap on the amount of remuneration from the hospital to the physician and a requirement that the hospital may not provide assistance for a period longer than the first 2 consecutive years of the nonphysician practitioner's employment by the physician. Under proposed § 411.357(x)(1)(iii), the amount of remuneration from the hospital, FQHC, or RHC would be capped at the lower of: (1) 50 percent of the actual salary, signing bonus, and benefits paid by the physician to the nonphysician practitioner; or (2) an amount calculated by subtracting the receipts attributable to services furnished by the nonphysician practitioner from the actual salary, signing bonus, and benefits paid to the nonphysician practitioner by the physician. We propose to interpret ''benefits'' to include only health insurance, paid leave, and other routine non-cash benefits offered to similarly situated employees of the physician's practice. We believe that requiring a physician who receives assistance to employ a nonphysician practitioner to contribute to the costs of the nonphysician practitioner's salary and benefits would limit any windfall to the physician that could influence the physician's decision whether to refer patients to the hospital, FQHC, or RHC providing the assistance. Limiting the remuneration from the hospital, FQHC, or RHC to the ''actual'' amount paid to the nonphysician practitioner should ensure that the nonphysician practitioner is the true beneficiary of the arrangement between the physician the hospital, FQHC, or RHC providing the subsidy. We recognize that there may be income tax implications for the physician receiving the remuneration from the hospital, FQHC, or RHC. Because the proposed exception would protect only

remuneration to reimburse a physician for amounts actually paid to the nonphysician practitioner, the hospital, FQHC, or RHC providing the remuneration could not increase it to account for any tax implications to the physician. We seek comments regarding the cap on the amount of remuneration in the proposed exception, including whether the offset of receipts attributable to services furnished by the nonphysician practitioner should include all receipts for all services furnished by the nonphysician practitioner, regardless of payor and regardless of whether the services were primary care services. We also seek comments regarding whether we should structure the exception with additional or different safeguards to ensure that the remuneration from the hospital, FQHC, or RHC directly benefits the nonphysician practitioner and whether it is necessary to address the issue of the tax implications that could result from the use of the exception to provide remuneration to a physician to assist in the employment a nonphysician practitioner.

The proposed exception is intended to permit subsidies necessary to expand access to primary care services; however, we do not believe that hospitals, FQHCs, and RHCs should bear the full costs of employing nonphysician practitioners who work in private physician practices. The 2-year limit on the assistance is intended to prevent ongoing payment to the physician that could serve as a reward for past referrals or an inducement to continue making referrals to the hospital, FQHC, or RHC. We solicit comments specifically addressing the time limitations set forth in our proposal.

The proposed exception at § 411.357(x) closely tracks the structure and requirements of the exception for physician recruitment at § 411.357(e). Similar to the exception at § 411.357(e), the proposed exception for assistance to employ nonphysician practitioners would include requirements that reference hospitals, but would apply in the same manner to FQHCs and RHCs that wish to provide assistance to physicians to employ nonphysician practitioners.

We are proposing requirements to safeguard against program or patient abuse similar to the requirements found in most of our exceptions in § 411.357. Specifically, we propose that an arrangement covered by the exception must be set out in writing and signed by the hospital providing the remuneration, the physician receiving the remuneration, and the nonphysician practitioner. In addition, the arrangement may not be conditioned on the physician's or the nonphysician practitioner's referral of patients to the hospital providing the remuneration. Further, the proposed exception would require that the remuneration from the hospital is not determined (directly or indirectly) in a manner that takes into account the volume or value of any actual or anticipated referrals by the physician or the nonphysician practitioner (or any other physician or nonphysician practitioner in the physician's practice) or other business generated between the parties. We note that the definition of ''referral'' at § 411.351 relates to the request, ordering of, or certifying or recertifying the need for DHS by a physician. For this reason, for purposes of the requirements of the new exception, we have proposed at § 411.357(x)(3) to define the term ''referral'' as it relates to nonphysician practitioners as a request by a nonphysician practitioner that includes the provision of any DHS for which payment may be made under Medicare, the establishment of any plan of care by a nonphysician practitioner that includes the provision of such DHS, or the certifying or recertifying of the need for such DHS, but not including any DHS personally performed or provided by the nonphysician practitioner. The definition of ''referral'' at proposed § 411.357(x)(3) is modeled closely on the definition of ''referral'' at § 411.351. We are also proposing that the arrangement may not violate the federal anti-kickback statute or any federal or state law or regulation governing billing or claims submission. Finally, we are proposing that records of the actual amount of remuneration provided to the physician (and to the nonphysician practitioner) be maintained for a period of at least 6 years and be made available to the Secretary upon request. We believe that a 6-year record retention requirement is appropriate. The 6-year period is in line with the requirements of other laws and regulations that protect against program or patient abuse as well as other CMS record retention requirements. We seek comment regarding whether these ''general'' safeguards are sufficient to protect against program or patient abuse resulting from arrangements to assist with nonphysician practitioner employment, or if additional safeguards are necessary.

We are also proposing requirements for the employment arrangement between the physician receiving remuneration and the nonphysician practitioner that the remuneration assists the physician to employ. Specifically, we are proposing to require that the nonphysician practitioner be a *bona fide* employee of the physician or the physician's practice. In addition, we are proposing that the aggregate salary, signing bonus, and benefits paid by the physician to the nonphysician practitioner must be consistent with fair market value. We recognize that employment arrangements may change over time, for example, moving from full-time status to part-time status or changing a compensation methodology from hourly payments to a pre-determined flat, monthly salary. Because of the fair market value requirement and because we are proposing a limit on the amount that the hospital may provide to the physician, we do not believe that it is necessary to require that the nonphysician practitioner's salary, signing bonus, and benefits be set in advance. In addition, we are proposing a requirement that the physician may not impose practice restrictions on the nonphysician practitioner that unreasonably restrict the nonphysician practitioner's ability to provide patient care services in the geographic area served by the hospital, FQHC, or RHC, and we intend to interpret this provision in the same way that we interpret the requirement at § 411.357(e)(4)(vi) with respect to physician recruitment arrangements.

In addition, we are proposing to include requirements to prevent gaming by ''rotating'' or ''cycling'' nonphysician practitioners through multiple physician practices located in the geographic area served by the hospital, FQHC, or RHC, an abuse that would effectively shift the long-term costs of employing nonphysician practitioners to the hospital, FQHC, or RHC. We are also concerned that parties may misuse the exception to shift to a hospital, FQHC, or RHC the costs of a nonphysician practitioner who is currently employed by a physician but provides patient care services in a medical office of the physician that is located outside of the geographic area served by the hospital, FQHC, or RHC. To address these concerns, we are proposing that the hospital, FQHC, or RHC may not provide assistance to a physician to employ a nonphysician practitioner if: (1) the nonphysician practitioner has practiced in the geographic area served by the hospital, FQHC, or RHC within the 3 years prior to becoming employed by the physician; or (2) the nonphysician practitioner was employed or otherwise engaged by a physician with a medical office in the geographic area served by the hospital,

FQHC, or RHC within the 3 years prior to becoming employed by the physician, even if the nonphysician practitioner did not provide patient care services in that office. We believe that 3 years is a reasonable limit to protect the program and prevent abuse, but we solicit comments regarding the appropriateness of this timeframe. For consistency and to ease administrative burden, we propose to define ''geographic area served by the hospital'' to have the same meaning assigned to this term in the exception at § 411.357(e) for physician recruitment, and to define the term ''geographic area served'' by a FQHC or RHC to have the same meaning assigned to this term in proposed § 411.357(e)(6)(ii) described in this section II.N.2.b of this proposed rule.

Finally, we are soliciting comments regarding whether additional safeguards are necessary to protect against program or patient abuse that might result from arrangements that would be covered by proposed § 411.357(x). We are particularly interested in comments addressing whether we should limit the number of times a hospital, FQHC, or RHC may assist the same physician with the employment of nonphysician practitioners and, if so, during what time period that limitation should apply. For example, should we limit the use of the exception to no more than once every 3 years with respect to a particular physician or no more than three times in the aggregate (regardless of time period) with respect to a particular physician? Could this type of limitation potentially undermine the goal of increased access to primary care in the event the nonphysician practitioner(s) employed by the physician receiving the assistance from the hospital, FQHC, or RHC left such employment after only a short period of time or moved from the geographic area served by the hospital, FQHC, or RHC? We are also interested in comments addressing whether the exception should include a requirement that there be a documented, objective need for additional primary care services in the geographic area served by the hospital, FQHC, or RHC. We also solicit comments specifically from FQHCs and RHCs regarding whether this exception would be useful to such entities and any barriers to its use that they perceive.

b. Geographic Area Served by Federally Qualified Health Centers and Rural Health Clinics

Section 1877(e)(5) of the Act sets forth an exception for remuneration provided by a hospital to an individual physician to induce the physician to relocate his or her medical practice to the geographic area served by the hospital in order to become a member of the hospital's medical staff. This exception was codified in our regulations at § 411.357(e) in the 1995 final rule. In Phase II, using our authority in section 1877(b)(4) of the Act, we expanded the exception to permit FQHCs to make recruitment payments to physicians on the same basis as hospitals (69 FR 16094 through 16095). Also in Phase II, we revised the exception to define the geographic area served by the hospital providing the recruitment remuneration as the lowest number of contiguous postal zip codes from which the hospital draws at least 75 percent of its inpatients (69 FR 16094 through 16095). In Phase III, we made numerous amendments to the exception for physician recruitment, including permitting RHCs to utilize the exception in the same manner as hospitals and FQHCs (72 FR 51049). We also responded to commenters objecting to the Phase II definition of ''geographic area served by the hospital'' on the grounds that it ''hurts rural hospitals, and that it is very difficult for [FQHCs] to satisfy'' by revising the exception to permit a hospital located in a rural area to determine the geographic area served by the hospital using an alternative test that encompasses the lowest number of contiguous (or in some cases, noncontiguous) zip codes from which the hospital draws at least 90 percent of its inpatients (72 FR 51049 through 51050).

We intended for these definitions to apply to the recruitment of physicians by FQHCs and RHCs in the same manner as they apply to hospitals. However, the definitions of geographic area served by a hospital and rural hospital at § 411.357(e)(2)(i) and § 411.357(e)(2)(iii), respectively, are contingent on the volume of the hospital's inpatients. By definition, FQHCs and RHCs provide access to primary care services in rural areas or underserved areas and only treat patients as outpatients or ambulatory patients (CMS Pub. 100–02, Chap. 13, Sec. 10.1 and 10.2 (Rev. 201, Dec. 12, 2014)). Thus, although the regulatory exception for physician recruitment is available to FQHCs and RHCs, it provides no guidance as to the geographic area into which such an entity may recruit a physician, a concept critical for compliance with the exception's requirements. Therefore, we are proposing to revise § 411.357(e)(6) to add a new definition of the geographic area served by a FQHC or RHC. The purpose of this revision is to ensure that the definition of the geographic area served by FQHCs and RHCs appropriately captures the areas where their patients actually reside and to provide certainty to FQHCs and RHCs that their physician recruitment arrangements satisfy the requirements of the exception at § 411.357(e).

We are proposing two alternative approaches for this policy, which aligns closely with the special optional rule for rural hospitals in § 411.357(e)(2)(iii) in recognition that rural hospitals, FQHCs, and RHCs often serve patients who are dispersed in wider geographic areas and may need to recruit physicians into more remote areas in order to achieve their goals of providing needed services to the communities that they serve. The first proposed approach would closely mirror our current definition of a rural hospital's geographic service area. It would indicate that the geographic area served by a FQHC or RHC is the area composed of the lowest number of contiguous zip codes from which the FQHC or RHC draws at least 90 percent of its patients, as determined on an encounter basis. If the FQHC or RHC draws fewer than 90 percent of its patients from all of the contiguous zip codes from which it draws patients, the geographic area served by the FQHC or RHC may include noncontiguous zip codes, beginning with the noncontiguous zip code in which the highest percentage of its patients reside, and continuing to add noncontiguous zip codes in decreasing order of percentage of patients. The geographic area served by the FQHC or RHC may include one or more zip codes from which it draws no patients, provided that such zip codes are entirely surrounded by zip codes in the geographic area from which it draws at least 90 percent of its patients.

In the alternative, we propose to define the geographic area served by a FQHC or RHC as the area composed of the lowest number of contiguous or noncontiguous zip codes from which the FQHC or RHC draws at least 90 percent of its patients, as determined on an encounter basis. This would be determined by beginning with the zip code in which the highest percentage of the FQHC's or RHC's patients reside, and continuing to add zip codes in decreasing order of percentage of patients. Although this approach would potentially result in larger geographic service areas than in the first approach, we see no potential for program or patient abuse in selecting noncontiguous zip codes to identify 90 percent of the patient base as long as there are patients in those areas. We seek comments on each of these alternatives, including whether patient

encounters is the appropriate measure for determining the geographic area served by a FQHC or RHC. Finally, we are soliciting comments specifically from FQHCs and RHCs regarding whether the exception at § 411.357(e) for physician recruitment is useful to such entities and any barriers to its use that they perceive.

c. Conforming Terminology: ''Takes into Account''

Under section 1877(e)(5) of the Act, the amount of remuneration cannot be determined in a manner that takes into account (directly or indirectly) the volume or value of the recruited physician's referrals. Several other exceptions for compensation arrangements in section 1877(e) of the Act also contain provisions pertaining to the volume or value of a physician's referrals. In each case, the statutory language consistently states that compensation cannot be determined in a manner that ''takes into account'' the volume or value of a physician's referrals. (See sections 1877(e)(1)(A)(iv), (e)(1)(B)(iv), (e)(2)(B)(ii), (e)(3)(A)(v), (e)(3)(B)(i), (e)(5)(B), (e)(6)(A), and (e)(7)(A)(v).)

In Phase I, we developed a uniform interpretation of the volume or value standard that applies to all provisions under section 1877 of the Act and 42 CFR part 411, subpart J (66 FR 877). In Phase III, we revised the terminology at § 411.354(c)(2)(iii) pertaining to the volume or value of referrals in indirect compensation arrangements (72 FR 51027). The original language at § 411.354(c)(2)(iii) provided that an indirect compensation arrangement exists if the DHS entity has knowledge that a physician's aggregate compensation varies with, or otherwise reflects the volume or value of referrals. Phase III replaced the phrase ''otherwise reflects'' with ''takes into account.'' We explained that the phrases ''takes into account'' and ''otherwise reflects'' were not intended to have separate and different meanings, and that we were revising § 411.354(c)(2)(iii) for the sake of consistency (72 FR 51027). We made similar conforming changes to the regulations at § 411.354(c)(2)(ii), § 411.354 (c)(2)(iii), and § 411.354 (d)(1).

Despite the consistent use of the phrase ''takes into account'' in section 1877(e) of the Act and our uniform interpretation of the volume or value standard, not all the regulatory exceptions for compensation arrangements in § 411.357 use the phrase ''takes into account'' to describe the volume or value standard. In particular, the regulatory exception for the recruitment of physicians at § 411.357(e) has two provisions relating to the volume or value standard, and the provisions use different terms. Current § 411.357(e)(1)(iii) excepts payments to a recruited physician if the hospital does not determine the amount of compensation (directly or indirectly) ''based on'' the volume or value of referrals. Where the recruited physician joins a physician practice, § 411.357(e)(4)(v) provides that the amount of remuneration may not be determined in a manner that ''takes into account'' (directly or indirectly) the volume or value of any actual or anticipated referrals by the recruited physician or the physician practice (or any physician affiliated with the physician practice) receiving the direct payments from the hospital. Like the physician recruitment exception, the following exceptions do not use the phrase ''takes into account'' in reference to the volume or value standard: the exception for medical staff incidental benefits at § 411.357(m); the exception for obstetrical malpractice insurance subsidies at § 411.357(r); and the exception for professional courtesy at § 411.357(s). The exception for obstetrical malpractice insurance premiums at § 411.357(r) provides that the amount of payment cannot be ''based on'' the volume or value of actual or anticipated referrals. The exceptions at § 411.357(m)(1) and § 411.357(s)(1) require that medical staff incidental benefits and professional courtesies, respectively, are offered to physicians ''without regard to'' the volume or value of referrals.

We are concerned that the use of different phrases pertaining to the volume or value of referrals (''takes into account,'' ''based on,'' and ''without regard to'') may cause some to conclude incorrectly that there are different volume or value standards in the compensation exceptions. We interpret the phrase ''takes into account'' throughout section 1877(e) of the Act as requiring that compensation not be determined in a manner that takes into account the volume or value of a physician's referrals. Nothing in the regulatory history of the exceptions for physician recruitment, medical staff incidental benefits, obstetrical malpractice insurance premiums, or professional courtesy arrangements suggests that the phrases ''based on'' and ''without regard to'' were intended to have a different meaning than ''takes into account.'' Rather, in Phase I we stated that we were adopting a uniform interpretation of the volume or value standard (66 FR 877), and in Phase III we revised our regulations to replace the phrases ''reflects'' and ''otherwise reflects'' with the phrase ''takes into account.'' Likewise, we do not believe that the ''takes into account'' standard for recruiting a physician who joins a physician practice (§ 411.357(e)(4)) differs in meaning from the current ''based on'' standard that otherwise applies to recruited physicians (§ 411.357(e)(1)(iii)). In sum, we believe that the there is no substantive difference between the phrases ''takes into account,'' ''based on,'' and ''without regard to,'' and that the terms have previously been used interchangeably in the compensation exceptions.

To clarify the regulations, we propose to modify § 411.357(e)(1)(iii) to conform to the exact language in section 1877(e)(5)(B) of the Act. Specifically, we propose to amend § 411.357(e) to require that the compensation provided to a recruited physician may not take into account (directly or indirectly) the volume or value of the recruited physician's referrals to the hospital, FQHC, or RHC providing the recruitment remuneration. We also propose to amend § 411.357(r) to require that the amount of payment under the arrangement not may take into account the volume or value of any actual or anticipated referrals. Lastly, we propose to revise the language of § 411.357(m) and § 411.357(s) to provide that the offer of medical staff incidental benefits or professional courtesy, respectively, may not take into account the volume or value of a physician's referrals. Taken together, these revisions would make the use of the phrase ''takes into account'' consistent throughout the compensation exceptions in § 411.357. The consistent terminology would reflect our longstanding policy that the volume or value standard in the various compensation exceptions should be interpreted uniformly.

d. Retention Payments in Underserved Areas

Our regulation at § 411.357(t) permits certain retention payments made to a physician with a practice located in an underserved area. This exception was first established in Phase II, and covered only retention payments made to a physician who has a bona fide firm, written recruitment offer that would require the physician to move his or her medical practice at least 25 miles and outside of the geographic area served by the hospital or FQHC making the retention payment (69 FR 16142). In Phase III, we modified the exception to permit a hospital, RHC, or FQHC to retain a physician who does not have a bona fide written offer of recruitment or

employment if the physician certifies in writing that he or she has a bona fide opportunity for future employment that meets the requirements at § 411.357(t)(2) (72 FR 51066).

In Phase III, we explained that a retention payment based on a physician certification may ''not exceed the lower of the following: (1) An amount equal to 25 percent of the physician's current annual income (averaged over the previous 24 months) using a reasonable and consistent methodology that is calculated uniformly; or (2) the reasonable costs the hospital would otherwise have to expend to recruit a new physician to the geographic area served by the hospital in order to join the medical staff of the hospital to replace the retained physician'' (72 FR 51066). We intended the regulations to mirror the preamble language precisely. However, the regulations at § 411.357(t)(2)(iv) state that such retention payments may not exceed the lower of: (1) an amount equal to 25 percent of the physician's current income (measured over no more than a 24-month period), using a reasonable and consistent methodology that is calculated uniformly; or (2) the reasonable costs the hospital would otherwise have to expend to recruit a new physician. Thus, the current regulation text appears to permit entities to make retention payments that consider only part of the prior 24-month period instead of the entire period as we intended.

The policy stated in the Phase III preamble is correct and remains our policy at this time. Therefore, in order to avoid confusion due to potentially conflicting regulation text, we propose to modify our regulations at § 411.357(t)(2)(iv)(A) to reflect the regulatory intent we articulated in Phase III.

3. Reducing Burden and Improving Clarity Regarding the Writing, Term, and Holdover Provisions in Certain Exceptions and Other Regulations

The SRDP enables providers and suppliers to disclose actual or potential violations of the physician self-referral law to CMS and authorizes the Secretary to reduce the amount potentially due and owing for disclosed violations. Since the SRDP was established, we have received numerous submissions to the SRDP disclosing actual or potential violations relating to the writing requirements of various compensation exceptions (for example, failure to set an arrangement out in writing, failure to obtain the signatures of the parties in a timely fashion, or failure to renew an arrangement that expired on its own terms after at least 1 year). This proposed rule would clarify the writing requirements of various compensation exceptions by making the terminology in the compensation exceptions more consistent and by providing policy guidance on the writing and 1-year minimum term requirement in many exceptions. In addition, to reduce the regulatory burden, we propose to except certain holdover arrangements, provided certain safeguards are met.

a. Writing Requirements in Certain Compensation Exceptions and Other Regulatory Provisions

The exceptions for the rental of office space and the rental of equipment (section 1877(e)(1) of the Act; § 411.357(a) and § 411.357(b)) require that a lease be set out in writing. Several other compensation exceptions have similar writing requirements: the exception at § 411.357(d) for personal service arrangements; the exception at § 411.357(e) for physician recruitment; the exception at § 411.357(h) for certain group practice arrangements with a hospital; the exception at § 411.357(l) for fair market value compensation; the exception at § 411.357(p) for indirect compensation arrangements; the exception at § 411.357(r) for obstetrical malpractice insurance subsidies; the exception at § 411.357(t) for retention payments in underserved areas; the exception at § 411.357(v) for electronic prescribing items and services; and the exception at § 411.357(w) for electronic health records items and services. Through our experience administering the SRDP, we have learned that there is uncertainty in the provider community regarding the writing requirement of the leasing and other compensation exceptions. In particular, we have been asked whether an arrangement must be reduced to a single ''formal'' written contract (that is, a single document that includes all material aspects of the arrangement) in order to satisfy the writing requirement of the applicable exception.

The original exception for the rental of office space required ''a written agreement, signed by the parties, for the rental or lease of the space . . ..'' (Omnibus Budget Reconciliation Act of 1989, Pub. L. 101–386 section 6204(e)(1)). In OBRA 1993, the Congress clarified the exception for the rental of office space (H. Rept. 103–213 at 812). Section 13562(e)(1) of OBRA 1993 (codified at section 1877(e)(1) of the Act) provides exceptions for the rental of office space and equipment if ''the lease is set out in writing . . ..'' OBRA 1993 also excepted personal service arrangements if ''the arrangement is set out in writing . . ..'' (OBRA 1993 § 13562(e)(3), codified at section 1877(e)(3) of the Act). The current regulatory exceptions for the rental of office space and the rental of equipment require at § 411.357(a)(1) and § 411.357 (b)(1), respectively, that an ''agreement'' be set out in writing. In contrast, the regulatory exception for personal service arrangements requires at § 411.357(d)(1)(i) that the ''arrangement'' be set out in writing.

Despite the different terminology in the statutory and regulatory exceptions, we believe that the writing requirement for the leasing exceptions and the personal service arrangements exception is the same. Specifically, we interpret the term ''lease'' in sections 1877(e)(1)(A) and (B) of the Act to refer to the lease arrangement. Notably, in the statutory scheme of section 1877 of the Act, the exceptions for the rental of office space, the rental of equipment, and personal service arrangements are classified as ''Exceptions Relating to Other Compensation Arrangements.'' The lease arrangement is the underlying financial relationship between the parties (that is, payments for the use of office space or equipment for a period of time). To satisfy the writing requirement, the facts and circumstances of the lease arrangement must be sufficiently documented to permit the government to verify compliance with the applicable exception. (See Phase II (69 FR 16110) for a similar discussion regarding arrangements among components of an academic medical center.)

In most instances, a single written document memorializing the key facts of an arrangement provides the surest and most straightforward means of establishing compliance with the applicable exception. However, there is no requirement under the physician self-referral law that an arrangement be documented in a single formal contract. Depending on the facts and circumstances of the arrangement and the available documentation, a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties, may satisfy the writing requirement of the leasing exceptions and other exceptions that require that an arrangement be set out in writing.

Through the SRDP, we have learned that some stakeholders interpret the term ''agreement,'' as it is used in § 411.357(a)(1) and § 411.357 (b)(1), to mean that a single written contract is necessary to satisfy the writing requirement of the applicable exception. To clarify the exceptions for the rental

of office space and the rental of equipment, we propose to substitute the term ''lease arrangement'' for the term ''agreement'' in § 411.357(a)(1) and § 411.357(b)(1). We believe that this revision underscores the fact that the writing requirement at § 411.357(a)(1) and § 411.357(b)(1) for the rental of office space and the rental of equipment, respectively, is identical to the writing requirement at § 411.357(d)(1)(i) for personal service arrangements. Broadly speaking, we believe that there is no substantive difference among the writing requirements of the various compensation exceptions that require a writing. To emphasize the uniformity of the writing requirement in the compensation exceptions, we propose to remove the term ''agreement'' from the exception for physician recruitment at § 411.357(e)(4)(i), the exception for fair market value compensation at § 411.357(l)(1), the special rule on compensation that is set in advance at § 411.354(d)(1), and the special rule on physician referrals to a particular provider, practitioner, or supplier at § 411.354(d)(4)(i). To be clear, the revised rules would still require a writing. For instance, to satisfy the revised rule at § 411.354(d)(1) on compensation that is set in advance, the rate of compensation must be documented in writing before the services are performed. By removing the term ''agreement,'' we are simply clarifying that the rules do not require a particular kind of writing, for example, a formal contract.

In light of our proposal to clarify the writing requirement at § 411.354(d)(1), § 411.354(d)(4)(i), § 411.357(a)(1), § 411.357(b)(1), § 411.357(e)(4)(i), and § 411.357(1)(1) by removing the term ''agreement,'' we propose to make conforming changes where possible to other provisions in the compensation exceptions and the special rules on compensation. Specifically, we propose to replace the term ''agreement'' with the term ''lease arrangement'' in § 411.357(a)(2), § 411.357(a)(4), § 411.357(a)(5), § 411.357(a)(6), § 411.357(b)(3), § 411.357(b)(4), and § 411.357(b)(5). We propose to replace the term ''agreement'' with the term ''arrangement'' in § 411.357(c)(3) (exception for bona fide employment relationships) and § 411.357(f)(2) (exception for isolated transactions). Likewise, we propose to remove the phrase ''set forth in an agreement'' from the introductory language to the exception for fair market value compensation at § 411.357(l). Finally, we are also concerned that the words ''contract'' and ''contracted for,'' like the word ''agreement,'' may suggest that a formal contract or other specific kind of writing is required to satisfy the applicable exception. To address this issue, we propose to revise § 411.354(d)(4) by replacing the word ''contract'' as it relates to personal service arrangements with the word ''arrangement,'' and we propose similar changes to § 411.357(e)(1)(iv) and § 411.357(r)(2)(v), both of which refer back to § 411.354(d)(4). We propose to replace the phrase ''contracted for'' at § 411.357(d)(1)(iii) with the phrase ''covered by the arrangement.'' In the exception at § 411.357(p)(2) for indirect compensation arrangements, we propose to replace the phrase ''written contract'' with the word ''writing.''

Certain compensation exceptions use the phrase ''written agreement'': the exception at § 411.357(h) for certain group practice arrangements with a hospital; the exception at § 411.357(v) for electronic prescribing items and services; and the exception at § 411.357(w) for electronic health records items and services. Although these exceptions use the term ''written agreement,'' we are not proposing any revisions. The exception at § 411.357(h) is rarely used, because it only protects arrangements that began before, and continued without interruption since, December 19, 1989. The exceptions at § 411.357(v) and § 411.357(w) are aligned with the federal anti-kickback statute safe harbors at § 1001.952(x) and § 1001.952 (y) that protect the provision of these items and services. To avoid creating apparent inconsistencies between the physician self-referral law exceptions and the corresponding anti-kickback statute safe harbors, we are not modifying § 411.357(v) or § 411.357(w). However, we believe that the principles elucidated above regarding the writing requirements of the other compensation exceptions to the physician self-referral law also apply to § 411.357(v) and § 411.357(w).

b. Term Requirements in Certain Compensation Arrangements Exceptions

The exceptions at § 411.357(a), § 411.357(b), and § 411.357(d) for the rental of office space, the rental of equipment, and personal service arrangements, respectively, require that the compensation arrangement between an entity furnishing DHS and a referring physician has a term of at least 1 year. Parties submitting self-disclosures to the SRDP have asked whether the term of the arrangement must be in writing to satisfy the requirements of the relevant exceptions. We propose to revise § 411.357(a)(2), § 411.357(b)(3), and § 411.357(d)(1)(iv) to clarify the documentation requirements related to the term of lease arrangements for the rental of office space, lease arrangements for the rental of equipment, and personal service arrangements.

The statutory exceptions for the rental of office space and the rental of equipment in sections 1877(e)(1)(A)(iii) and (B)(iii) of the Act require that the lease provides for a term of rental or lease for at least 1 year. The statutory exception for personal service arrangements in section 1877(e)(3)(A)(iv) of the Act requires that the term of the arrangement is at least 1 year. Although our regulations at § 411.357(d)(1)(iv) (the exception for personal service arrangements) use language similar to the statutory exception for personal service arrangements, our current regulations at § 411.357(a)(2) and § 411.357(b)(3) (the exceptions for the rental of office space and equipment, respectively) use the term ''agreement'' in addressing the minimum term requirement. As explained elsewhere in this proposed rule, we interpret ''lease'' in section 1877(e)(1) of the Act to refer to the lease arrangement between the parties, and we also believe that the writing requirement of sections 1877(e)(1)(A) and (B) of the Act is identical to the requirement in section 1877(e)(3) of the Act.

We believe that some stakeholders have interpreted the term ''agreement'' in § 411.357(a)(2) and § 411.357(b)(3) to mean that a formal written contract or other document with an explicit provision identifying the term of the arrangement is necessary to satisfy the 1-year term requirement of the exceptions. As we noted in the 1998 proposed rule, the 1-year term requirement is satisfied ''as long as the arrangement clearly establishes a business relationship that will last for at least 1 year'' (63 FR 1713). An arrangement that lasts as a matter of fact for at least 1 year satisfies this requirement. Parties must have contemporaneous writings establishing that the arrangement lasted for at least 1 year, or be able to demonstrate that the arrangement was terminated during the first year and that the parties did not enter into a new arrangement for the same space, equipment, or services during the first year, as required by § 411.357(a)(2), § 411.357(b)(3), and § 411.357(d)(1)(iv), as applicable. Depending on the facts and circumstances of the arrangement and the available documentation, we believe that, as is the case with the writing requirement in these and other

exceptions, a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties, can establish that the arrangement in fact lasted for the required period of time. A formal contract or other document with an explicit ''term'' provision is generally not necessary to satisfy this element of the exception. To clarify that a written contract with a formalized ''term'' provision is not necessary to satisfy the regulations at § 411.357(a)(2) and § 411.357(b)(3), we propose to remove the word ''agreement'' and to revise the first sentence of these provisions to mirror the 1-year term requirement in the personal service arrangements exception at § 411.357(d)(1)(iv).

c. Holdover Arrangements

The exceptions at § 411.357(a), § 411.357(b), and § 411.357(d) currently permit a ''holdover'' arrangement for up to 6 months if an arrangement of at least 1 year expires, the arrangement satisfies the requirements of the exception when it expires, and the arrangement continues on the same terms and conditions after its stated expiration. We propose to amend the holdover provisions at § 411.357(a)(7), § 411.357(b)(6), and § 411.357(d)(1)(vii) to permit indefinite holdovers, provided that certain additional safeguards are met. In the alternative, we propose to extend the holdover to a definite period that is greater than 6 months (for example, 1 year, 2 years, or 3 years), provided that additional safeguards are met. Finally, we propose to revise the exception for fair market value compensation at § 411.357(l)(2) to permit renewals of arrangements of any length of time, including arrangements for 1 year or greater.

The holdover provisions in § 411.357(a), § 411.357(b), and § 411.357(d) developed over the course of our rulemaking in response to inquiries regarding the expiration, termination, and renewal of arrangements. In the 1998 proposed rule, we stated that month-to-month arrangements after an arrangement of at least 1 year expired would not satisfy the 1-year requirement in the applicable exceptions (63 FR 1713). We explained that the purpose of the 1-year requirement is to except ''stable arrangements that cannot be renegotiated frequently to reflect the current volume or value of a physician's referrals.'' Because we were concerned that month-to-month arrangements could be frequently renegotiated, we required parties to renew arrangements (after the original arrangement of at least 1 year expired) in at least 1-year increments.

In Phase II, we addressed criticism of our statements in the 1998 proposed rule regarding month-to-month arrangements following the expiration of an arrangement that lasted at least 1 year, as required under the exceptions at § 411.357(a), § 411.357(b), and § 411.357(d) (69 FR 16085 through 16086). One commenter suggested that there was little additional risk of program or patient abuse if a holdover rental continued on the same terms as the original lease arrangement. We agreed that there was little risk if a month-to-month holdover continued on the same terms and conditions as the original lease arrangement, but stated that our position related only to time-limited holdovers (that is, no more than 6 months) (69 FR 10685 through 10686). Thus, in Phase II we established the 6-month holdover provisions at § 411.357(a)(7) and § 411.357(b)(6) for lease arrangements. In Phase III, we declined to except an indefinite holdover for rental arrangements where a lessor is taking steps to remove a lessee, stating that 6 months is sufficient in the circumstances described by the commenter, which related to the lessee's refusal to vacate office space upon the expiration of a lease arrangement (72 FR 51045). Phase III also established at § 411.357(d)(vii) a 6-month holdover for personal service arrangements.

Through our administration of the SRDP, we have reviewed numerous rental and personal service arrangements that failed to satisfy the requirements of an applicable exception solely because the arrangement expired by its terms and the parties continued the arrangement on the same (compliant) terms and conditions after the 6-month holdover period ended. In our experience, an arrangement that continues beyond the 6-month period does not pose a risk of program or patient abuse, provided that the arrangement continues to satisfy the specific requirements of the applicable exception, including the requirements related to fair market value, compensation that does not take into account the volume or value of referrals or other business generated between the parties, and reasonableness of the arrangement. We have reconsidered our previous position and are proposing to eliminate the time limitations on holdovers with safeguards to address two potential sources of program or patient abuse: frequent renegotiation of short term arrangements based on a physician's referrals, and compensation or rental changes that become inconsistent with fair market value over time.

To prevent frequent renegotiation of short term arrangements, the holdover must continue on the same terms and conditions as the original arrangement. If the parties change the original terms and conditions of the arrangement during the holdover, we would consider this a new arrangement. The new arrangement would be subject to the 1-year term requirement at § 411.357(a)(2), § 411.357(b)(3), or § 411.357(d)(1)(iv) (or it must satisfy the requirements of the exception for fair market value compensation at § 411.357(l), if applicable). Specifically, the new arrangement must have a term of at least 1 year, and if the parties terminate the new arrangement with or without cause before the end of that year, they cannot enter into another arrangement for the same or similar space, equipment, or services until the expiration of the year. We believe that these safeguards, which are already incorporated into the current exceptions, prevent frequent renegotiations of short-term arrangements.

To ensure that compensation is consistent with or does not exceed fair market value, as applicable, the proposed holdover provisions require that the holdover arrangement satisfy all the elements of the applicable exception when the arrangement expires and on an ongoing basis during the holdover. Thus, if office space rental payments are fair market value when the lease arrangement expires, but the rental amount falls below fair market value at some point during the holdover, the lease arrangement would fail to satisfy the requirements of the applicable exception at § 411.357(a) as soon as the fair market value requirement is no longer satisfied, and DHS referrals by the physicians to the entity that is party to the arrangement would no longer be permissible. In addition, the entity could not bill the Medicare program for DHS furnished as a result of a referral made by the physician after the rental charges were no longer consistent with fair market value. The requirement that the arrangement is set out in writing continues to apply during the holdover. To satisfy this requirement, the parties must have documentary evidence that the arrangement in fact continued on the same terms and conditions. Depending on the facts and circumstances of the arrangement and the available documentation, the expired written agreement and a collection of documents, including contemporaneous documents evidencing the course of conduct

between the parties may satisfy the writing requirement for the holdover.

As noted above, we propose to revise the holdover provisions at § 411.357(a)(7), § 411.357(b)(6), and § 411.357(d)(1)(vii) to permit indefinite holdovers under certain conditions. Specifically, the arrangement must comply with the applicable exception when it expires by its own terms; the holdover must be on the same terms and conditions as the immediately preceding arrangement; and the holdover must continue to satisfy the requirements of the applicable exception. In the alternative, we propose to extend the holdover for a definite period (for example, a 1-, 2-, or 3-year holdover period) or for a period of time equivalent to the term of the immediately preceding arrangement (for example, a 2-year lease would be considered renewed for a new 2-year period). We believe that, if the holdover is extended for a definite period beyond 6 months, the safeguards outlined above for indefinite holdovers are necessary to prevent program or patient abuse. We are seeking comments on what additional safeguards, if any, are necessary to ensure that holdovers lasting longer than 6 months do not pose a risk of program or patient abuse.

In addition to our proposals to extend the holdover provisions at § 411.357(a)(7), § 411.357(b)(6), and § 411.357(d)(1)(vii), we propose to amend the exception at § 411.357(l) for fair market value compensation arrangements. Section 411.357(l)(2) currently allows arrangements for less than 1 year to be renewed any number of times, provided that the terms of the arrangement and the compensation for the same items or services do not change. We propose to amend § 411.357(l)(2) to permit arrangements of any timeframe, including arrangements for more than 1 year, to be renewed any number of times. We believe that the proposal does not pose a risk of patient or program abuse, because the arrangement must be renewed on the same terms and conditions, and the renewed arrangement must satisfy all the requirements of the exception at the time the physician makes a referral for DHS and the entity bills Medicare for the DHS. We seek comments as to whether the proposed revision of § 411.357(l)(2) would be necessary if we revise § 411.357(d)(1)(vii) to permit indefinite holdovers.

4. Definitions

In this proposed rule, we are proposing to revise several definitions in our regulations to improve clarity and ensure proper application of our policies. We describe below our specific proposals.

a. Remuneration (§ 411.351)

A compensation arrangement between a physician (or an immediate family member of such physician) and a DHS entity implicates the referral and billing prohibitions of the physician self-referral law. Section 1877(h)(1)(A) of the Act defines the term ''compensation arrangement'' as any arrangement involving any ''remuneration'' between a physician (or an immediate family member of such physician) and an entity. However, section 1877(h)(1)(C) of the Act identifies certain types of remuneration which, if provided, would not create a compensation arrangement subject to the referral and billing prohibitions of the physician self-referral law. Under section 1877(h)(1)(C)(ii) of the Act, the provision of the following items, devices, or supplies does not create a compensation arrangement between the parties: Items, devices, or supplies that are ''used solely'' to collect, transport, process, or store specimens for the entity providing the items, devices, or supplies, or to order or communicate the results of tests or procedures for such entity. Furthermore, under our regulations at § 411.351, the provision of such items, devices, or supplies is not considered to be remuneration.

We are concerned that the phrase ''used solely'' may misleadingly suggest that the provision of an item, device, or supply that can be used for two or more of the six purposes listed in section 1877(h)(C)(ii) of the Act constitutes remuneration between the parties giving rise to a compensation arrangement. In contrast, in the 1998 proposed rule, we interpreted the phrase ''solely'' to mean that the items must be used solely for the ''purposes listed in the statute'' (63 FR 1693). Importantly, the word ''purposes'' is used in the plural, and we did not state that an item must be used for only one purpose listed in the statute. We continue to believe that the phrase ''used solely'' means that an item, device, or supply cannot be used for any purpose other than the six purposes listed in the statute. Thus, if an item is used for two or more purposes listed in the statute, and it is not used for any other purpose (that is, any purpose not listed in the statute), then provision of the item does not constitute remuneration between the parties. We propose to revise the definition of ''remuneration'' at § 411.351 to make it clear that the item must be used solely for one or more of the six purposes listed in the statute.

Although we are not proposing regulatory revisions at this time, we are also concerned about potential confusion, especially for hospitals located in states included in the United States Court of Appeals for the Third Circuit, regarding whether remuneration is conferred by a hospital to a physician when both facility and professional services are provided to patients in a hospital-based department. Following commentary by the Third Circuit Court of Appeals in its decision in *United States ex rel. Kosenske v. Carlisle HMA*, 554 F.3d 88 (3d Cir. 2009), we received an advisory opinion request and several self-disclosures submitted to the SRDP asking whether certain so-called ''split bill'' arrangements between physicians and DHS entities involve remuneration between the parties that gives rise to a compensation arrangement for purposes of the physician self-referral law. We are taking the opportunity afforded by this rulemaking to address this issue.

In *Kosenske*, the Third Circuit Court of Appeals held that a physician's use of a hospital's resources (for example, examination rooms, nursing personnel, and supplies) when treating hospital patients constitutes remuneration under the physician self-referral law, even when the hospital bills the appropriate payor for the resources and services it provides (including the examination room and other facility services, nursing and other personnel, and supplies) and the physician bills the payor for his or her professional fees only. We do not believe that such an arrangement involves remuneration between the parties, because the physician and the DHS entity do not provide items, services, or other benefits to one another. Rather, the physician provides services to the patient and bills the payor for his or her services, and the DHS entity provides its resources and services to the patient and bills the payor for the resources and services. There is no remuneration between the parties for purposes of section 1877 of the Act.

In contrast, if a physician or a DHS entity bills a non-Medicare payor (that is, a commercial payor or self-pay patient) globally for both the physician's services and the hospital's resources and services, a benefit is conferred on the party receiving payment. Specifically, the party that bills globally receives payment for items or services provided by the other party. Such a global billing arrangement involves remuneration between the parties that implicates the physician self-referral law.

b. Compensation Arrangements –''Stand in the Shoes'' (§ 411.354(c))

Phase III included provisions under which all physicians would be treated as ''standing in the shoes'' of their physician organizations for purposes of applying the rules regarding direct and indirect compensation arrangements at § 411.354(c) (72 FR 51026 through 51030). (Since Phase II, we have considered a referring physician and the professional corporation of which he or she is the sole owner to be the same for purposes of the physician self-referral regulations (69 FR 16131).) The FY 2009 IPPS final rule amended § 411.354(c) to: (1) Treat a physician with an ownership or investment interest in a physician organization as standing in the shoes of that physician organization; and (2) permit parties to treat a physician who does not have an ownership or investment interest in a physician organization as standing in the shoes of that physician organization. An exception to the mandatory treatment of physicians with ownership or investment interests as standing in the shoes of their physician organizations was made for physicians with ''titular'' ownership or investment interests only (73 FR 48691 through 48700). A ''physician organization'' is defined at § 411.351 as a physician, a physician practice, or a group practice that complies with the requirements of § 411.352. Therefore, as of October 1, 2008, for purposes of determining whether a direct or indirect compensation arrangement exists between a physician and an entity to which the physician makes referrals for the furnishing of DHS, if the physician has an ownership or investment interest in the physician organization that is not merely titular, the physician stands in the shoes of the physician organization. The physician is considered to have the same compensation arrangements (with the same parties and on the same terms) as the physician organization in whose shoes he or she stands.

In Phase III, we established the rule at § 411.354(c)(3)(i), which provides that a physician who stands in the shoes of his or her physician organization is deemed to have the same compensation arrangements (with the same parties and on the same terms) as the physician organization. The regulation also states that, when applying the exceptions in § 411.355 and § 411.357 to arrangements in which a physician stands in the shoes of his or her physician organization, the relevant referrals and other business generated ''between the parties'' are referrals and other business generated between the entity furnishing DHS and the physician organization (including all members, employees, and independent contractor physicians). Our intent for this provision was to make clear that, under the Phase III ''stand in the shoes'' policy (which considered all physicians in a physician organization to stand in the shoes of the physician organization), each physician in the physician organization was considered a ''party'' to an arrangement between the physician organization and a DHS entity.

Following the FY 2009 IPPS final rule changes limiting the ''stand in the shoes'' rules only to physicians with ownership or investment interests in their physician organizations (other than those with merely a titular ownership or investment interests) and physicians who voluntarily stand in the shoes of their physician organizations, stakeholders inquired whether the change in the ''stand in the shoes'' policy meant that, when applying the exceptions in § 411.355 and § 411.357, for purposes of determining whether compensation takes into account the volume or value of referrals or other business generated between the ''parties,'' the only ''parties'' to consider are the physicians with ownership or investment interests in their physician organizations. This was not our intent in revising the ''stand in the shoes'' rules in the FY 2009 IPPS final rule.

To address the issue raised by the stakeholders, we are proposing to revise § 411.354(c)(3)(i) so that it is consistent with our work in the FY 2009 IPPS final rule. Our intent there was, and currently remains, that only physicians who stand in the shoes of their physician organization are considered parties to an arrangement for purposes of the signature requirements of the exceptions. For such purposes, we do not consider employees and independent contractors to be parties to a physician organization's arrangements unless they voluntarily stand in the shoes of the physician organization as permitted under § 411.354(c)(1)(iii) or § 411.354(c)(2)(iv)(B). Guidance regarding physicians who stand in the shoes of their physician organizations may be found on our Web site at *http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/FAQs.html*. Specifically, consistent with our response in Frequently Asked Question #12318, for purposes of satisfying the requirements of an exception to the physician self-referral prohibition, we consider a physician who is standing in the shoes of his or physician organization to have satisfied the signature requirement of an applicable exception when the authorized signatory of the physician organization has signed the writing evidencing the arrangement.

For purposes other than satisfying the signature requirements of the exceptions, we remain concerned about the referrals of *all* physicians who are part of a physician organization that has a compensation arrangement with a DHS entity when we analyze whether the compensation between the DHS entity and the physician organization takes into account the volume or value of referrals or other business generated between the parties. If we did not consider the referrals of all the physicians in the physician organization, and instead only considered the referrals of those physicians who stand in the shoes of the physician organization, DHS entities would be permitted to establish compensation methodologies that take into account the volume or value referrals or other business generated by non-owner physicians in a physician organization when entering into a compensation arrangement with the physician organization. Therefore, our proposal would amend § 411.354(c)(3)(i) to clarify that, for all purposes other than the signature requirements, all physicians in a physician organization are considered parties to the compensation arrangement between the physician organization and the DHS entity.

c. *Locum Tenens* Physician (§ 411.351)

The term ''*locum tenens* physician'' was first defined for purposes of the physician self-referral law in Phase I (66 FR 954). This definition is important because a *locum tenens* physician is considered a member of a group practice, and therefore the definition is relevant to whether a physician practice complies with the group practice requirements at § 411.352. In the Phase I preamble, we likened a *locum tenens* physician to one who is ''standing in the shoes'' of a regular physician, subject to certain requirements in CMS manual guidance (66 FR 900). Our regulations at § 411.351 have continuously defined a *locum tenens* physician as a physician who substitutes (that is, ''stands in the shoes'') in exigent circumstances for a physician, first within the definition of ''member of a group'' (66 FR 954) and later as a stand-alone defined term applicable to both group practices and other physicians (69 FR 16129). We note that the Phase I definition referenced the ''regular physician'' (66 FR 954).

As described in this section, in subsequent rulemaking, we established certain rules regarding when a physician ''stands in the shoes'' of his

or her physician organization. The ''stand in the shoes'' rules affect whether an arrangement may be analyzed as a direct or indirect compensation arrangement (See 72 FR 51027 through 51030, and 73 FR 48693 through 48700). The ''stand in the shoes'' provisions are specific to compensation arrangements and described in our regulations at § 411.354(c).

We propose to revise the definition of *locum tenens* physician to remove the reference to ''stand in the shoes.'' We believe that the definition of a *locum tenens* physician is clear without the phrase ''stands in the shoes.'' We also believe that it is clear that the ''stand in the shoes'' provisions specific to compensation arrangements are separate and distinct from the definition of a *locum tenens* physician. However, to eliminate unnecessary verbiage and to avoid any potential ambiguity, we propose to revise the definition of *locum tenens* physician at § 411.351 by removing the phrase ''stands in the shoes.''

5. Exception for Ownership of Publicly Traded Securities

Section 1877(c)(1) of the Act sets forth an exception for ownership in certain publicly traded securities and mutual funds. To qualify for the exception, securities must be:

- Investment securities (including shares or bonds, debentures, notes, or other debt instruments) which may be purchased on terms generally available to the public;
- Securities that are: (1) Listed on the New York Stock Exchange (NYSE), the American Stock Exchange, or any regional exchange in which quotations are published on a daily basis; (2) foreign securities listed on a recognized foreign, national, or regional exchange in which quotations are published on a daily basis; or (3) traded under the automated interdealer quotation system operated by the National Association of Securities Dealers (NASD); and
- In a corporation that had stockholder equity exceeding $75 million at the end of the corporation's most recent fiscal year or on average during the previous 3 fiscal years.

This exception is codified in our regulations at § 411.356(a), which closely mirrors section 1877(c) of the Act. Although we are aware of no public comment regarding publicly traded securities which are traded under an automated interdealer quotation system operated by the NASD, it has come to our attention that the NASD no longer exists and that it is no longer possible to purchase a publicly traded security traded under the automated interdealer quotation system it formerly operated. In response, we investigated whether we could modernize the exception for ownership of publicly traded securities by including currently existing systems that are equivalent to the NASD's now-obsolete automated interdealer quotation system.

In 1972, NASD launched a computerized stock trading system called the National Association of Securities Dealers Automated Quotation Systems (NASDAQ) stock market. In 2000, NASDAQ became an independent entity. In 2007, the United States Securities and Exchange Commission approved the formation of a new self-regulatory organization, the Financial Industry Regulatory Authority (FINRA), to be a successor to the NASD. The NASD and the member regulation, enforcement, and arbitration functions of the NYSE consolidated to form FINRA. Until November 2014, FINRA operated a quotation medium for over-the-counter (OTC) securities, including those not listed on NASDAQ or a national stock exchange. We are unable to locate a definition of ''automated interdealer quotation system'' and believe this is an antiquated term for which there is no modern day equivalent. However, we believe that electronic stock markets such as NASDAQ and FINRA's OTC market are outgrowths and modern day equivalents to an automated interdealer quotation system.

We propose to use our authority in section 1877(b)(4) of the Act to revise the regulations at § 411.356(a)(1) to include securities listed for trading on an electronic stock market or OTC quotation system in which quotations are published on a daily basis and trades are standardized and publicly transparent. Trades made through a physical exchange (such as the NYSE or the American Stock Exchange) are standardized and publicly transparent. To protect against risk of program or patient abuse, we believe that trades on the electronic stock markets and OTC quotation systems that are eligible for this exception must also be standardized and publicly transparent. Accordingly, we are not proposing to include any electronic stock markets or OTC quotation systems that trade unlisted stocks or that involve decentralized dealer networks. We also believe it is appropriate to limit the proposed exception to those electronic stock markets or OTC quotation systems that publish quotations on a daily basis, as physical exchanges must publish on that basis. We seek comment regarding whether fewer, different, or additional restrictions on electronic stock markets or OTC quotation systems are necessary to effectuate the Congress' intent and to protect against patient or program abuse.

6. New Exception for Timeshare Arrangements

a. Statutory and Regulatory Background

Section 1877(e)(1)(A) of the Act sets forth an exception for the rental of office space. Under this exception, lease arrangements must satisfy six specific criteria, one of which is that the office space rented or leased is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any other person or entity related to the lessor). The exception also permits payments by the lessee for the use of space consisting of common areas (which do not afford exclusive use to the lessee) if the payments do not exceed the lessee's pro rata share of expenses for the space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using the common areas. The 1995 final rule (60 FR 41959) incorporated the provisions of section 1877(e)(1)(A) of the Act into our regulations at § 411.357(a).

Section 1877(e)(8) of the Act sets forth an exception for: (1) Payments made by a physician to a laboratory in exchange for the provision of clinical laboratory services; and (2) payments made by a physician to an entity as compensation for items or services other than clinical laboratory services if the items or services are furnished at fair market value (the ''payments by a physician exception''). The 1995 final rule (60 FR 41929) incorporated the provisions of section 1877(e)(8) of the Act into our regulations at § 411.357(i). In the 1998 proposed rule (63 FR 1703), we proposed to interpret ''other items or services'' to mean any kind of items or services that a physician might purchase, but not including clinical laboratory services or those specifically excepted under another provision in §§ 411.355 through 411.357. In that proposal, we stated that we did not believe that the Congress meant for the payments by a physician exception to cover a rental arrangement as a service that a physician might purchase, because it had already included in the statute specific exceptions, with specific standards for such arrangements, in section 1877(e)(1) of the Act. In Phase II (69 FR 16099), we responded to commenters that disagreed with our position that the exception for payments by a physician is not available for

arrangements involving items and services addressed by another exception, stating that our position is consistent with the overall statutory scheme and purpose and is necessary to prevent the exception from negating the statute (69 FR 16099). We made no changes to the exception in Phase II to accommodate the commenters' concerns.

In the 1998 proposed rule (63 FR 1699), we proposed an exception for compensation arrangements that are based upon fair market value and meet certain other criteria. We finalized the exception at § 411.357(l) in Phase I, noting that, although it only covered services provided by a physician (or an immediate family member of a physician) to an entity furnishing DHS, it was available for some arrangements that are covered by other exceptions (66 FR 917 through 919). Although commenters requested that we expand the exception to cover the transfer, lease or license of real property, intangible property, property rights, or a covenant not to compete (69 FR 16111), we made no substantive changes to the exception for fair market value compensation in Phase II. In Phase III, we expanded the exception at § 411.357(l) for fair market value compensation to include arrangements involving compensation from a physician to an entity furnishing DHS. We reiterated that the exception for fair market value compensation does not protect office space lease arrangements; rather, arrangements for the rental of office space must satisfy the requirements of the exception at § 411.357(a) (72 FR 51059 through 51060).

In Phase III, a commenter suggested that ''timeshare'' leasing arrangements would be addressed more appropriately in the exception for fair market value compensation at § 411.357(l) or the exception for payments by a physician at § 411.357(i), instead of the exception for the rental of office space at § 411.357(a) (72 FR 51044). The commenter described a timeshare lease arrangement under which a physician or group practice pays the lessor for the right to use office space exclusively on a turnkey basis, including support personnel, waiting area, furnishings, and equipment, during a schedule of time intervals for a fair market value rate per interval of time or in the aggregate, and urged us to clarify that such timeshare arrangements may qualify under § 411.357(i) or § 411.357 (l), the exceptions for payments by a physician and fair market value compensation, respectively. We note that the commenter specifically described arrangements where the lessee had exclusive, but only periodic, use of the premises, equipment, and personnel. In response, we declined to permit space leases to be eligible for the fair market value exception at § 411.357(l), and stated that we were not persuaded that § 411.357(i) should protect space leases (72 FR 51044 through 51045).

b. Timeshare Arrangements

Through our administration of the SRDP, as well as stakeholder inquiries, we have been made aware of arrangements for the use of a licensor's premises, equipment, personnel, items, supplies or services by physicians who, for various legitimate reasons, do not require or are not interested in a traditional office space lease arrangement. For example, in a rural or underserved area, there may be a need in the community for certain specialty services but that need is not great enough to support the full-time services of a physician specialist. Under timeshare arrangements, a hospital or local physician practice may ask a specialist from a neighboring community to provide the services in space owned by the hospital or practice on a limited or as-needed basis. Most often, under such an arrangement, the specialist does not establish an additional medical practice office by renting office space and equipment, hiring personnel, and purchasing services and supplies necessary for the operation of a medical practice. Rather, it is common for a hospital or local physician practice to make available to the visiting independent physician on a ''timeshare'' basis the space, equipment and services necessary to treat patients. Under the timeshare arrangement, the hospital or physician practice may provide the physician with a medical office suite that is fully furnished and operational. The physician does not need to make any improvements to the space or to bring any medical or office supplies in order to begin seeing patients. Timeshare arrangements also may be attractive to a relocating physician whose prior medical practice office lease has not expired or to a new physician establishing his or her medical practice.

It is our understanding that a license to use the property of another person differs from a lease in that ownership and control of the property remains with the licensor. That is, a lease transfers dominion and control of the property from the lessor to the lessee, but a license is a mere privilege to act on another's property and does not confer a possessory interest in the property. We recognize that timeshare arrangements may differ from traditional lease and service arrangements. Often, a timeshare arrangement does not transfer dominion and control over the premises, equipment, personnel, items, supplies, and services of the licensor to the licensee, but rather confers a privilege (or license) to use (during specified periods of time) the premises, equipment, personnel, items, supplies, and services that are the subject of the license.

c. New Exception

Because timeshare arrangements generally include the use of office space, under our current regulations, an arrangement as it relates to office space must be analyzed under the exception for the rental of office space. However, where a timeshare arrangement is structured as a license to use the office space (and other property and personnel) of the licensor, it cannot satisfy the requirements of that exception because a license generally does not provide for exclusive use of the premises. Moreover, the arrangement may have a term of less than 1 year, which would not satisfy the term requirement at § 411.357(a)(2). The exceptions for payments by a physician and fair market value compensation arrangements, which do not have exclusive use or 1-year term requirements, are unavailable under our current regulations because of the inclusion of office space in the bundle of items and services in a typical timeshare arrangement.

We believe that timeshare arrangements that include the use of office space can be structured in a way that does not pose a risk of program or patient abuse. To address such arrangements, which we believe are often necessary to ensure adequate access to needed specialty care (especially in rural and underserved areas), we are using our authority at section 1877(b)(4) of the Act to propose a new exception at § 411.357(y) that would protect timeshare arrangements that meet certain criteria, including that: (1) The arrangement is set out in writing, signed by the parties, and specifies the premises, equipment, personnel, items, supplies and services covered by the arrangement; (2) the arrangement is between a hospital or physician organization (licensor) and a physician (licensee) for the use of the licensor's premises, equipment, personnel, items, supplies, or services; (3) the licensed premises, equipment, personnel, items, supplies, and services are used predominantly to furnish evaluation and management services to

patients of the licensee; (4) the equipment covered by the arrangement, if any: (i) Is located in the office suite where the physician performs evaluation and management services, (ii) is used only to furnish DHS that is incidental to the physician's evaluation and management services and furnished at the time of such evaluation and management services, and (iii) is not advanced imaging equipment, radiation therapy equipment, or clinical or pathology laboratory equipment (other than equipment used to perform CLIA-waived laboratory tests); (5) the arrangement is not conditioned on the licensee's referral of patients to the licensor; (6) the compensation over the term of the arrangement is set in advance, consistent with fair market value, and not determined in a manner that takes into account (directly or indirectly) the volume or value of referrals or other business generated between the parties; (7) the arrangement would be commercially reasonable even if no referrals were made between the parties; and (8) the arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act) or any federal or state law or regulation governing billing or claims submission.

The proposed exception at § 411.357(y) would apply only to timeshare arrangements where the licensor is a hospital or physician organization; it would not protect arrangements where the licensor is another type of DHS entity. We believe that timeshare arrangements offered by independent diagnostic testing facilities and clinical laboratories, in particular, pose a heightened risk of program or patient abuse as they may serve to lock in referral streams from the physician licensee as a result of the physician's proximity to the DHS furnished by such entities. We do not believe that it is necessary to protect arrangements with these types of entities in order to achieve the goals of beneficiary access to care and improved outcomes. Similarly, we see no reason to protect timeshare arrangements in which the hospital or other entity furnishing DHS is the licensee and the referring physician is the licensor. We seek comment regarding whether the scope of the exception is sufficiently broad to improve beneficiary access to care (especially in rural or underserved areas), whether there is a compelling need to allow DHS entities other than hospitals and physician organizations to enter into timeshare arrangements with referring physicians, and whether the exception should apply if the licensor is a physician who is a source of DHS referrals to the licensee. We solicit comment on whether the exception should be limited to arrangements in rural and underserved areas.

We propose to protect only those timeshare arrangements under which the physician uses the licensed premises, equipment, personnel, items, supplies, and services predominantly for the evaluation and management of patients. The proposed exception at § 411.357(y) would not protect the license of office space used by the physician solely or primarily to furnish DHS to patients. We seek comment regarding whether ''predominant use'' is an appropriate measure of the use of the licensed premises and, if so, how we might define this standard, or whether we should include a different measure, such as one that would require that ''substantially all of the services furnished to patients on the licensed premises are not DHS.'' We also propose to limit the type and location of the equipment that may be licensed to only that which is used to furnish DHS that is incidental to the patient's evaluation and management visit and furnished contemporaneously with that visit. We note that this requirement does not affect the manner in which the DHS is billed (for example, ''incident to'' a physician's service or directly by a nonphysician practitioner). We believe that DHS that is ''incidental to'' the patient's evaluation and management includes a limited universe of diagnostic tests and other procedures, such as x-rays, rapid strep tests, and urine dipstick tests to diagnose pregnancy, that assist the physician in his or her diagnosis and treatment of the patient. For this reason, we propose to exclude from the protection of the exception the license of advanced imaging equipment, radiation therapy equipment, and clinical and pathology laboratory equipment (other than that which is used to furnish CLIA-waived laboratory tests). Finally, we propose to require that the equipment be located on the licensed premises; that is, in the office suite. For example, it is reasonable for an orthopedic surgeon to x-ray a patient to assist in the diagnosis and treatment of the patient's potential orthopedic injury or condition. Under the proposed exception, a hospital may license to the orthopedic surgeon the use of medical office space, an in-suite x-ray machine, an x-ray technician, and office and medical supplies, provided that all of the other requirements of the exception are satisfied. We seek comment on these requirements and limitations. Specifically we are interested in comments regarding whether the equipment location requirement should be expanded to include equipment located in the same building (as defined at § 411.351) as the licensed office suite or an off-site location, and whether we should prohibit the license of equipment in the absence of a corresponding license of office space.

We also propose to prohibit certain per unit-of-service and percentage compensation methodologies for determining the license fees under timeshare arrangements. Under the new exception, parties would be able to determine license fees on an hourly, daily, or other time-based basis, but would not be permitted to use a compensation methodology based on, for example, the number of patients seen. Parties also would not be permitted to use a compensation methodology based on the amount of revenue raised, earned, billed, collected, or otherwise attributable to the services provided by the licensee while using the licensor's premises, equipment, personnel, items, supplies or services. We are soliciting comments on whether these limitations on compensation methodologies for license fees are necessary and whether a timeshare arrangement for the use of a licensor's premises, equipment, personnel, items, supplies or services would pose a risk of program or patient abuse in the absence of this prohibition on per-click and percentage compensation methodologies for the license fees paid by the licensee to the licensor.

We note that the exception for the rental of office space would continue to be the only exception that would apply to traditional office space lease arrangements where dominion and control of the premises is transferred to the lessee for a specified period of time for the lessee's exclusive use of the leased premises. The proposed new exception would also not be available to protect part-time exclusive use office space *lease* arrangements. We solicit comments on the proposed new exception for timeshare arrangements and any additional criteria that may be necessary to safeguard against program or patient abuse.

7. Temporary Noncompliance With Signature Requirements (§ 411.353(g))

Several compensation arrangement exceptions to the physician self-referral law require that an arrangement be signed by the parties. Our current regulations at § 411.353(g) include a special rule for arrangements involving temporary noncompliance with signature requirements. The regulation permits an entity to submit a claim or

bill and receive payment for DHS if an arrangement temporarily does not satisfy the applicable exception's signature requirement but otherwise fully complies with the exception. Under the current rule, if the failure to comply with the signature requirement is inadvertent, the parties must obtain the required signature(s) within 90 days. If the failure to comply is not inadvertent, the parties must obtain the required signature(s) within 30 days.

In the FY 2009 IPPS final rule, we stated that we would evaluate our experience with the regulation at § 411.353(g) and propose more or less restrictive modifications at a later date (73 FR 48707). We are now proposing to modify the current regulation to allow parties 90 days to obtain the required signatures, regardless of whether or not the failure to obtain the signature(s) was inadvertent. We recognize that it is not uncommon for parties who are aware of a missing signature to take up to 90 days to obtain all required signatures. We are also proposing to revise § 411.353(g) to include reference to the new regulatory exceptions for payments to a physician to employ a nonphysician practitioner and timeshare arrangements that we are proposing at new § 411.357(x) and § 411.357(y), respectively, to ensure that all compensation exceptions with signature requirements are treated uniformly. We do not believe that allowing parties 90 days to obtain signatures while the arrangement otherwise complies with the physician self-referral law poses a risk of program or patient abuse.

The proposed regulation maintains the safeguards of the current rule. Specifically, the proposed regulation applies narrowly to the signature requirement only. To make use of the proposed revised provisions at § 411.353(g), an arrangement would have to satisfy all other requirements of an applicable exception, including the requirement that the arrangement be set out in writing. In addition, an entity may make use of the proposed regulation only once every 3 years with respect to the same referring physician. Given these safeguards, we believe that the proposed revision poses no risk of program or patient abuse.

8. Physician-Owned Hospitals

Section 6001(a) of the Affordable Care Act amended the rural provider and hospital ownership or investment interest exceptions to the physician self-referral law to impose additional restrictions on physician ownership and investment in hospitals. For purposes of these exceptions, the new legislation defined a ''physician owner or investor'' as a physician, or immediate family member of a physician, who has a direct or indirect ownership or investment interest in a hospital. We refer to hospitals with direct or indirect physician owners or investors as ''physician-owned hospitals.''

Section 6001(a)(3) of the Affordable Care Act established new section 1877(i) of the Act, which imposes additional requirements for physician-owned hospitals to qualify for the rural provider or hospital ownership exceptions. In part, section 1877(i) of the Act requires a physician-owned hospital to disclose the fact that the hospital is partially owned or invested in by physicians on any public Web site for the hospital and in any public advertising for the hospital; provides that a physician-owned hospital must have had a provider agreement in effect as of December 31, 2010; and provides that the percentage of the total value of the ownership or investment interests held in a hospital, or in an entity whose assets include the hospital, by physician owners or investors in the aggregate cannot exceed such percentage as of March 23, 2010.

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72240), we addressed many of the additional requirements that were established by the Affordable Care Act for a physician-owned hospital to avail itself of the rural provider or hospital ownership exceptions. In that final rule with comment period, among other things, we finalized regulations at § 411.362(b)(3)(ii)(C) that required a physician-owned hospital to disclose on any public Web site for the hospital and in any public advertising that the hospital is owned or invested in by physicians. We also finalized regulations at § 411.362(b)(1) that required a physician-owned hospital to have had a provider agreement in effect on December 31, 2010, and at § 411.362(b)(4)(i) to provide that the percentage of the total value of the ownership or investment interests held in a hospital (or in an entity whose assets include the hospital) by physician owners or investors in the aggregate cannot exceed such percentage as of March 23, 2010. We also revised the rural provider and hospital ownership exceptions at § 411.356(c)(1) and § 411.356(c)(3), respectively, to provide that a physician-owned hospital must meet the requirements in new § 411.362 not later than September 23, 2011, in order to avail itself of the applicable exception.

a. Preventing Conflicts of Interest: Public Web Site and Public Advertising Disclosure Requirement (§ 411.362(b)(3)(ii)(C))

Following publication of the CY 2011 OPPS/ASC final rule with comment period (75 FR 72240), we received numerous inquiries about many of the additional requirements that were established by the Affordable Care Act for the rural provider and hospital ownership exceptions, including the requirement that a physician-owned hospital must disclose on any public Web site for the hospital and in any public advertising that the hospital is owned or invested in by physicians. Specifically, industry stakeholders requested additional guidance to clarify the terms ''public Web site for the hospital'' and ''public advertising for the hospital,'' the range of statements that constitute a sufficient disclosure, and the period of noncompliance for a failure to disclose. We also received disclosures through the SRDP where the disclosing parties reasonably assessed that, based on existing CMS guidance, they could not certify compliance with this disclosure requirement and, therefore, the conduct constituted a violation of the law.

Given the inquiries and disclosures that we received, we have carefully considered both the disclosure requirement's purpose and our existing regulations addressing the requirement. We believe that, in establishing this requirement, the Congress decided that the public should be on notice if a hospital is physician-owned because that fact may inform an individual's medical decision-making. We do not interpret the public Web site and advertising disclosure requirements to be prescriptive requirements for the inclusion of specific wording in an undefined range of communication. Accordingly, we are proposing to provide physician-owned hospitals more certainty regarding the forms of communication that require a disclosure statement and the types of language that would constitute a sufficient statement of physician ownership or investment. We believe that our proposals would appropriately balance the industry's need for greater clarity with the public's need to be apprised of such information. Finally, we note that, in the event that a physician-owned hospital discovers that it failed to satisfy the public Web site or public advertising disclosure requirements, the SRDP is the appropriate means for reporting such overpayments. For more information, see the *Special Instructions for Submissions to the CMS Voluntary Self-*

Referral Disclosure Protocol for Physician-Owned Hospitals and Rural Providers that Failed to Disclose Physician Ownership on any Public Web site and in any Public Advertisement, available on our Web site at *http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self_Referral_Disclosure_Protocol.html*.

For the public Web site disclosure requirement, we are proposing to amend existing § 411.362(b)(3)(ii)(C) to list examples of the types of Web sites that do not constitute a ''public Web site for the hospital.'' We are proposing to revise § 411.362(b)(3)(ii)(C) to specify that a ''public Web site for the hospital'' does not include certain types of Web sites, even though limited information about the hospital may be found on such Web sites. For example, we do not consider social media Web sites to be ''public Web sites for the hospital,'' and the proposed regulation would clarify this. We do not believe that a hospital's communications (such as maintaining an individual page on a Web site, posting a video, or posting messages) via a social media Web site should be construed as a Web site that is ''for the hospital,'' given that the Web site is operated and maintained by a social networking service and that a multitude of users typically can become members of such a service. Further, we note that social media communications, which are used primarily for the development of social and professional contacts and for sharing information between interested parties, differ in scope from the provision of information typically found on a hospital's main Web site, such as the hospital's history, leadership and governance structure, mission, and a list of staff physicians. We also propose to specify at § 411.362(b)(3)(ii)(C) that a ''public Web site for the hospital'' does not include electronic patient payment portals, electronic patient care portals, or electronic health information exchanges, as these are not available to the general public. These portals are for the convenience of only those patients who have already been treated at the hospital and to whom the hospital's physician ownership likely would have already been disclosed. Our proposed examples of Web sites that do not constitute a ''public Web site for the hospital'' is not exhaustive. We recognize the difficulty in identifying every type of Web site that either currently exists or may emerge as technology develops that would not require a disclosure statement. We seek public comment on whether our proposed examples are appropriate given the statutory language and whether we should include different or additional examples of Web sites in the list. We also seek public comment on whether, in the alternative, we should provide an inclusive definition of what would be considered a ''public Web site for the hospital'' and, if so, we solicit recommendations for such a definition. Finally, we note that, even if a Web site does not constitute a public Web site for the hospital under our proposal, the online content may, depending on the facts and circumstances, constitute public advertising for the hospital that would require a disclosure statement.

For the public advertising disclosure requirement, we are proposing to define ''public advertising for the hospital'' at § 411.362(a). We note that our existing regulations at § 411.362(b)(3)(ii)(C) reference ''public advertising'' without explicitly specifying ''for the hospital,'' which is different from the statutory language of section 1877(i)(1)(C)(iv) of the Act. We are proposing to include that phrase in the definition and in the disclosure requirement to conform our regulations to the statutory language. To determine how best to clarify what we consider to be ''public advertising for the hospital,'' we consulted numerous sources for definitions of ''advertise'' and ''advertising.'' After considering the results of our research, we are proposing to define ''public advertising for the hospital,'' for purposes of the physician self-referral law, as any public communication paid for by the hospital that is primarily intended to persuade individuals to seek care at the hospital. We are proposing that the definition of ''public advertising for the hospital'' does not include, by way of example, communication made for the primary purpose of recruiting hospital staff (or other similar human resources activities), public service announcements issued by the hospital, and community outreach issued by the hospital. We believe that, as a general matter, communications related to recruitment are for the primary purpose of fulfilling a hospital's basic need for staff and that communications issued via public service announcements and community outreach are for the primary purpose of providing the general public healthcare-related information. Therefore, we are proposing to specify in our regulations that these types of communications would be excluded from our proposed definition of ''public advertising for the hospital.'' We note that these types of communications do not represent an exhaustive list of what we do not consider ''public advertising for the hospital.'' We seek public comment on our proposed definition of ''public advertising for the hospital'' as well as our proposed list of examples that do not constitute ''public advertising for the hospital.''

We note that a determination as to whether a certain communication constitutes public advertising for the hospital depends on the specific facts and circumstances of the communication. In the CY 2011 OPPS/ASC final rule with comment period, commenters asserted that a hospital should not be required to include disclosures in certain advertising, such as the kind found on billboards, or the kind aired via radio and television and that the requirement should be confined to print media such as newspapers, magazines, and other internally produced print material for public use (75 FR 72248). In response to the commenters, we stated that we have no flexibility to exclude certain types of advertising media, as the statute was very straightforward in its statement that the disclosure appear in ''any public advertising'' for the hospital. In this proposed rule, we are clarifying that the facts and circumstances of the communication, rather than the medium by which the message is communicated, determine whether a communication constitutes ''public advertising for the hospital.''

We also are proposing to clarify the types of statements that constitute a sufficient statement of physician ownership or investment. Specifically, we propose to amend § 411.362(b)(3)(ii)(C) to specify that any language that would put a reasonable person on notice that the hospital may be physician-owned is deemed a sufficient statement of physician ownership or investment. A statement such as ''this hospital is owned or invested in by physicians'' or ''this hospital is partially owned or invested in by physicians'' would certainly meet this standard. However, statements that the hospital is ''founded by physicians,'' ''managed by physicians,'' ''operated by physicians,'' or ''part of a health network that includes physician-owned hospitals'' would also meet this standard. We also believe that a hospital's name, by itself, could constitute language that meets this standard. For example, we believe that ''Doctors Hospital at Main Street, USA'' would put a reasonable person on notice that the hospital may be physician-owned. We seek public comment on our proposed revision to the public Web site and advertising disclosure requirements and on our proposed examples of language that would satisfy that standard. We also invite suggestions

regarding alternative standards for deeming language sufficient for these requirements.

For the location and legibility of disclosure statements, we continue to believe, as stated in the CY 2011 OPPS/ASC final rule with comment period, that the disclosure should be located in a conspicuous place on the Web site and on a page that is commonly visited by current or potential patients, such as the home page or ''about us'' section (75 FR 72248). Further, we believe that the disclosure should be displayed in a clear and readable manner and in a size that is generally consistent with other text on the Web site. We do not propose here to prescribe a specific location or font size for disclosure statements on either a public Web site or public advertising; rather, physician-owned hospitals have flexibility in determining exactly where and how to include the disclosure statements, provided that the disclosure would put a reasonable person on notice that the hospital may be physician-owned.

For those physician-owned hospitals that have identified non-compliance with the public Web site disclosure requirement, we are taking this opportunity to clarify that the period of noncompliance is the period during which the physician-owned hospital failed to satisfy the requirement. We note that September 23, 2011 is the date by which a physician-owned hospital had to be in compliance with the public Web site and advertising disclosure requirements (75 FR 72241), and, therefore, would be the earliest possible beginning date for noncompliance. For those physician-owned hospitals that have identified noncompliance with the public advertising disclosure requirement, we are clarifying that the period of noncompliance is the duration of the applicable advertisement's predetermined initial circulation, unless the hospital amends the advertisement to satisfy the requirement at an earlier date. For example, if a hospital pays for an advertisement to be included in one issue of a monthly magazine and the hospital fails to include the disclosure in the advertisement, the period of noncompliance likely would be the applicable month of circulation, even if the magazine continued to be available in the archives of the publisher, in waiting rooms of physician offices, or other public places. We seek public comment on additional guidance that may be necessary regarding the periods of noncompliance for both disclosure requirements.

b. Determining the *Bona Fide* Investment Level (§ 411.362(b)(4)(i))

As stated above, section 6001(a)(3) of the Affordable Care Act established new requirements for physician-owned hospitals to avail themselves of either the rural provider or hospital ownership exceptions to the physician self-referral law, including the requirement that the percentage of the total value of the ownership or investment interests held in a hospital, or in an entity whose assets include the hospital, by physician owners or investors in the aggregate cannot exceed such percentage as of March 23, 2010. In this proposed rule, we refer to the percentage of ownership or investment interests held by physicians in a hospital as the ''*bona fide* investment level'' and such percentage that was set as of March 23, 2010, as the ''baseline *bona fide* investment level.''

In the CY 2011 OPPS/ASC final rule with comment period (75 FR 72251), we codified the *bona fide* investment requirement at § 411.362(b)(4)(i). In that final rule we responded to commenters that asserted that the *bona fide* investment level should be calculated without regard to any ownership or investment interests held by physicians who do not make any referrals to the hospital, including physicians who are no longer practicing medicine (75 FR 72250). We stated that the ownership or investment interests of non-referring physicians need not be considered when calculating the baseline physician ownership level. In our response, we noted that section 1877(i)(5) of the Act defines ''physician owner or investor'' for purposes of that subsection to include any physician with a direct or indirect ownership or investment interest in the hospital and that, under our definition of ''indirect ownership or investment interest'' at § 411.354(b)(5), only ''referring physicians'' can have an indirect ownership or investment interest in a DHS entity. Although we did not explicitly address direct ownership or investment interests in our response, we note that only referring physicians can have a direct financial relationship under our existing regulations at § 411.354(a)(2)(i).

Following publication of the CY 2011 OPPS/ASC final rule with comment period, we received inquiries from industry stakeholders regarding our statement that the baseline *bona fide* investment level need not be calculated as including the ownership or investment interests of non-referring physicians. First, the stakeholders asserted that the statutory definition of physician owner or investor is broad and that if the Congress had intended to limit the definition to only referring physicians, the Congress would have included such qualifying language, as it did in a separate requirement established by the Affordable Care Act for physician-owned hospitals in section 1877(i)(C)(ii) of the Act. Second, the stakeholders asserted that including only referring physicians in the definition of physician owner or investor for purposes of establishing the baseline *bona fide* investment level frustrates the purpose of an explicit deadline set forth in the statute. The stakeholders noted that in the Affordable Care Act, the Congress required physician-owned hospitals that seek to avail themselves of the rural provider or hospital ownership exceptions to have had physician ownership or investment as of March 23, 2010, but allowed them until December 31, 2010 to obtain a provider agreement. The stakeholders asserted that our position makes the March 23, 2010 deadline meaningless because a pre-operational physician-owned hospital that did not have a provider agreement until December 31, 2010 likely would not have had physician owners or investors referring to the hospital as of the March 23 date. The stakeholders stated that our position regarding non-referring physicians in the CY 2011 OPPS/ASC final rule with comment period, in effect, precluded pre-operational hospitals from satisfying the requirement for physician ownership as of March 23, 2010, thus preventing the hospitals from availing themselves of the hospital ownership or rural provider exceptions.

Given the inquiries that we received after publication of the CY 2011 OPPS/ASC final rule with comment period, we have reconsidered our position that our regulations at § 411.354 necessarily limit the definition of physician owner or investor for purposes of establishing the baseline *bona fide* investment level (and any *bona fide* investment level thereafter). As we stated in the CY 2011 OPPS/ASC final rule with comment period, we recognize that the statutory definition of physician owner or investor is broad (75 FR 72250). Further, we understand the concern expressed by the stakeholders that our position may frustrate an explicit statutory deadline for certain physician-owned hospitals. We believe that the statutory revisions to the rural provider and hospital ownership exceptions must be read harmoniously and not in a way that makes any provision meaningless. Accordingly, we are proposing to revise our policy articulated in the CY 2011

OPPS/ASC final rule with comment period to require that the baseline *bona fide* investment level and the *bona fide* investment level include direct and indirect ownership and investment interests held by a physician if he or she satisfies the definition of ''physician'' in section 1861(r) of the Act and in § 411.351, regardless of whether the physician refers patients to the hospital (and therefore, irrespective of whether he or she is a ''referring physician'' for purposes of our regulatory definition of ownership or investment interest at § 411.354). Further, under our proposal, the direct or indirect ownership interests held by an individual who no longer practices medicine, as described in the comment summary above, would be counted if he or she satisfies the definition of ''physician'' in section 1861(r) of the Act and in § 411.351. We seek public comment regarding non-referring physicians and the *bona fide* investment level, including whether our proposal might alleviate the burden that some physician-owned hospitals reported when trying to determine whether a particular physician was a referring or non-referring physician for purposes of establishing their baseline *bona fide* investment levels and the *bona fide* investment levels generally.

In order to support our proposal and implement the requirements of the statute, we are proposing to amend our existing regulations to specify that, for purposes of § 411.362 (including for purposes of determining the baseline *bona fide* investment level and the *bona fide* investment level thereafter), the ownership or investment interests held by both referring and non-referring physicians are included. We propose to effectuate this change by establishing a definition of ownership or investment interest solely for purposes of § 411.362 that would apply to all types of owners or investors, regardless of their status as referring or non-referring physicians. Specifically, we propose to define ''ownership or investment interest'' at § 411.362(a) as a direct or indirect ownership or investment interest in a hospital. Under the proposed revision, a direct ownership or investment interest in a hospital exists if the ownership or investment interest in the hospital is held without any intervening persons or entities between the hospital and the owner or investor, and an indirect ownership or investment interest in a hospital exists if: (1) Between the owner or investor and the hospital there exists an unbroken chain of any number (but no fewer than one) of persons or entities having ownership or investment interests; and (2) the hospital has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the owner or investor has some ownership or investment interest (through any number of intermediary ownership or investment interests) in the hospital. We are also proposing that an indirect ownership or investment interest in a hospital exists even though the hospital does not know, or acts in reckless disregard or deliberate ignorance of, the precise composition of the unbroken chain or the specific terms of the ownership or investment interests that form the links in the chain. As used in § 411.362, the term ''physician'' would continue to have the meaning set forth in § 411.351; that is, an individual who meets the definition of ''physician'' set forth in section 1861(r) of the Act.

We believe that our proposed revision would make the prohibition set forth at § 411.362(b)(4)(i) consistent with the statutory definition of ''physician owner or investor'' in a hospital without unsettling long-standing definitions in our regulations. We seek public comment on our proposed revision to § 411.362, including whether such revision would adequately address the concerns expressed by the stakeholders after publication of the CY 2011 OPPS/ASC final rule with comment period.

We seek public comment on an alternate proposal that we believe also supports our policy and, thereby, effectuates the statute's purpose. Specifically, we seek public comment on whether, in the alternative, we should revise our regulations in an even more comprehensive manner and remove the references to a ''referring physician'' throughout existing § 411.354. We invite public comment on whether it would be helpful to retain the references to a ''referring physician'' for those specific provisions where the concept of a physician's referrals to a DHS entity is essential to the provision, such as our definition of an indirect compensation arrangement at § 411.354(c)(2)(ii).

Finally, we recognize that some physician-owned hospitals may have relied on the position that was articulated in the CY 2011 OPPS/ASC final rule with comment period concerning non-referring physicians and the baseline *bona fide* investment level. If we finalize one or more of the proposals described in this section of the proposed rule, these hospitals may have revised *bona fide* investment levels that exceed the baseline *bona fide* investment levels calculated under our current guidance. Therefore, we propose to delay the effective date of the new regulation until such time as physician-owned hospitals would have sufficient time to come into compliance with the new policy. For example, we could delay the effective date for 1 year from the date of publication in the **Federal Register** of the rulemaking in which we finalize the new regulation or on a specific date, such as January 1, 2017. We solicit comment on how long we should delay the effective date. We also seek comment on the impact of our proposed regulatory revisions on physician-owned hospitals and on the measures or actions physician-owned hospitals would need to undertake to come into compliance with our proposed revisions.

9. Solicitation of Comments: Perceived Need for Regulatory Revisions or Policy Clarification Regarding Permissible Physician Compensation

a. Background

In the 1998 proposed rule, we discussed the impetus for the physician self-referral law (63 FR 1662), noting that both the anti-kickback statute and section 1877 address Congress' concern that health care decision making can be unduly influenced by a profit motive. When physicians have a financial incentive to refer, this incentive can affect utilization, patient choice, and competition. Physicians can overutilize by ordering items and services for patients that, absent a profit motive, they would not have ordered. A patient's choice can be affected when physicians steer patients to less convenient, lower quality, or more expensive providers of health care, just because the physicians are sharing profits with, or receiving remuneration from, the providers. And lastly, where referrals are controlled by those sharing profits or receiving remuneration, the medical marketplace suffers since new competitors can no longer win business with superior quality, service, or price.

The referral and billing prohibitions of the statute (and the corresponding prohibitions in § 411.353) are intended to address these concerns, which remain valid today. (See section P.1. of this proposed rule for a detailed description of the prohibitions.) As explained elsewhere in this proposed rule, the prohibitions are absolute unless the financial relationship between the physician and entity to which he or she refers DHS satisfies the requirements of an applicable exception. The Congress provided for certain exceptions in sections 1877(b), (c), (d) and (e) of the Act, and granted the Secretary authority to establish additional exceptions for financial relationships that do not pose a risk of program or patient abuse. The Secretary has used the authority in

section 1877(b)(4) of the Act to establish numerous exceptions and has interpreted statutory and regulatory provisions in numerous rulemakings.

Many of the exceptions in section 1877(e) of the Act (''Exceptions Relating to Other Compensation Arrangements'') include a requirement that the compensation paid under the arrangement is not determined in a manner that takes into account the volume or value of referrals by the physician who is a party to the arrangement, and some exceptions also include a requirement that the compensation is not determined in a manner that takes into account other business generated between the parties. We refer to these as the ''volume or value'' and ''other business generated'' standards.

In the 1998 proposed rule, we discussed the volume or value standard as it pertains to the criteria that a group of physicians must meet to qualify as a ''group practice'' (63 FR 1690). We also stated that we would apply this interpretation of the volume or value standard throughout our regulations (63 FR 1699). In the discussion of group practices, we stated that ''[w]e believe that the 'volume or value' standard precludes a group practice from paying physician members for each referral they personally make or based on the volume or value of the referred services'' (63 FR 1690). We went on to state that ''[t]he most straightforward way for a group to demonstrate that it is meeting the requirements [for group practices] would be for the group to avoid a link between physician compensation and the volume or value of any referrals, regardless of whether the referrals involve Medicare or Medicaid patients'' (63 FR 1690). However, because our definition of ''referral'' at § 411.351 includes only referrals for DHS, ''a group that wants to compensate its members on the basis of non-Medicare and non-Medicaid referrals would be required to separately account for revenues and distributions related to referrals for [DHS] for Medicare and Medicaid patients'' (63 FR 1690). As noted in this section of the proposed rule, outside the group practice context, these principles apply generally to compensation from a DHS entity to a physician.

We also addressed the ''other business generated'' standard in the 1998 proposed rule, stating that we believe that the ''Congress may not have wished to except arrangements that include additional compensation for other business dealings'' and that ''[i]f a party's compensation contains payment for other business generated between the parties, we would expect the parties to separately determine if this extra payment falls within one of the exceptions'' (63 FR 1700).

In Phase I, we finalized our policy regarding the volume or value and other business generated standards, responding to comments on our proposals in the 1998 proposed rule. Most importantly, we revised the scope of the volume or value standard to permit time-based or unit of service-based compensation formulae (66 FR 876). We also stated that the phrase ''does not take into account other business generated between the parties'' means that ''the fixed, fair market value payment cannot take into account, or vary with, referrals of Medicare or Medicaid DHS or any other business generated by the referring physician, including other Federal and private pay business'' (66 FR 877), noting that the phrase ''generated between the parties'' means ''business generated by the referring physician'' for purposes of the physician self-referral law (66 FR 876). In Phase II, we clarified that personally performed services are not considered ''other business generated'' by the referring physician (69 FR 16068). ''Simply stated, section 1877 of the Act establishes a straightforward test that compensation should be at fair market value for the work or service performed or the equipment or [office] space leased—not inflated to compensate for the physician's ability to generate other revenue'' (66 FR 877). This remains our position, and we continue to apply this interpretation of the volume or value and other business generated standards uniformly to all provisions under section 1877 of the Act and part 411, subpart J, where the language appears. (See 66 FR 877.)

Also in Phase I, we established special rules on compensation at § 411.354(d) that deem compensation not to take into account the volume or value of referrals or other business generated between the parties if certain conditions are met (66 FR 876–77). These rules state that compensation will be deemed not to take into account the volume or value of referrals if the compensation is fair market value for services or items actually provided and does not vary during the course of the compensation arrangement in any manner that takes into account referrals of DHS. Compensation will be deemed not to take into account other business generated between the parties to a compensation arrangement if the compensation is fair market value and does not vary during the term of the compensation arrangement in any manner that takes into account referrals or other business generated by the referring physician, including private pay health care business. Both special rules apply to time-based or per-unit of service-based (per-click) compensation formulae. However, as we noted in Phase II, the special rules on compensation are intended to be safe harbors and there may be some situations not described in § 411.354(d) where an arrangement does not take into account the volume or value of referrals (69 FR 16070).

b. Changes in Health Care Delivery and Payment Systems Since the Enactment of the Physician Self-Referral Law

Since the enactment of section 1877 of the Act in 1989, significant changes in the delivery of health care services and the payment for such services have occurred, both within the Medicare and Medicaid programs and for non-federal payors and patients. For over a decade, we have engaged in efforts to align payment under the Medicare program with the quality of the care provided to our beneficiaries. Laws such as the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), the Deficit Reduction Act of 2005 (DRA), and the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) have guided our efforts to move toward health care delivery and payment reform. More recently, the Affordable Care Act required significant changes to the Medicare program's payment systems and provides the Secretary with broad authority to test models to implement these reforms. We highlight a few of the Affordable Care Act's notable provisions in this section of this proposed rule.

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 (VBP) 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. Section 1886(o)(1)(B) of the Act states that the Hospital VBP Program applies to payments for hospital discharges occurring on or after October 1, 2012. In accordance with section 1886(o)(6)(A) of the Act, we are required to make value-based incentive payments under the Hospital VBP Program to hospitals that meet or exceed performance standards for a performance period for a fiscal year. As further required by section 1886(o)(6)(C)(ii)(I) of the Act, we base each hospital's value-based payment percentage on the hospital's Total

Performance Score (TPS) for a specified performance period. (See 79 FR 49853, 50048.) A TPS score is awarded to hospitals during a VBP period (established as a fiscal year) and is derived from four domains: Clinical Process of Care, Patient Experience of Care, Outcome, and Efficiency. For more detailed information about each TPS domain, see our regulations at § 412.165(b); for more information regarding how TPS scores are calculated, see *http://www.medicare.gov/hospitalcompare/data/total-performance-scores.html*. As noted, participation in the Hospital VBP is mandatory.

Section 3021 of the Affordable Care Act, codified at section 1115A of the Act, established the Center for Medicare and Medicaid Innovation (CMMI) within CMS. The purpose of CMMI is to test innovative payment and service delivery models to reduce the cost of care provided to patients in the Medicare and Medicaid programs while preserving or enhancing the quality of care furnished to Medicare and Medicaid patients. Using its authority in section 1115A of the Act, CMMI has begun testing numerous health care delivery and payment models, including the Pioneer Accountable Care Organization (ACO) model, four models of the Bundled Payment for Care Improvements Initiative (BPCI), the Nursing Home Value-based Purchasing Demonstration, and the Community-based Care Transitions Program. Participation in these models is voluntary. For more information about CMMI's innovation models, see *http://innovation.cms.gov/initiatives/index.html#views=models*.

Section 3022 of the Affordable Care Act established the Medicare Shared Savings Program (MSSP). The Congress created the MSSP to facilitate coordination and cooperation among providers to improve the quality of care for Medicare fee-for-service (FFS) beneficiaries and reduce unnecessary costs. Physicians, hospitals, and other eligible providers and suppliers may participate in the MSSP by creating or participating in an ACO. The MSSP will reward ACOs that lower their growth in health care costs while meeting performance standards on quality of care. Participation in the MSSP is voluntary. For more information about the MSSP, see *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/index.html*.

Outside of the programs established or authorized under the laws noted above, we are moving away from Medicare payments to providers and suppliers that do not incorporate the value of the care provided. The Secretary recently set a goal of tying 30 percent of traditional, fee-for-service Medicare payments to quality or value through alternative payment models, such as ACOs or bundled payment arrangements, by the end of 2016, and 50 percent of payments to these models by the end of 2018. The Secretary also set a goal of tying 85 percent of all traditional Medicare payments to quality or value by 2016, and 90 percent of payments to quality or value by 2018, through programs such as the Hospital VBP Program and the Hospital Readmissions Reduction Program. (See press release titled ''Better, Smarter, Healthier: In historic announcement, HHS sets clear goals and timeline for shifting Medicare reimbursements from volume to value,'' U.S. Department of Health & Human Services (Jan. 26, 2015), *http://www.hhs.gov/news/press/2015pres/01/20150126a.html*.)

Value-based payment models and similar programs are receiving attention in the commercial payor sector as well. Some of the largest private carriers have made significant efforts to transition from fee-for-service models to global payment systems. For example, in 2009, Blue Cross and Blue Shield of Massachusetts (BC/BS Massachusetts) launched the Alternative Quality Contract (AQC), replacing a fee-for-service model with a modified global payment model for payments to hospitals and physicians. The AQC model merges a per-patient global budget with performance incentives based on national measures linked to health outcomes, quality, and patient satisfaction. The AQC model now includes approximately 85 percent of the hospitals and physicians in the BC/BS Massachusetts HMO network. (See Alternative Quality Contract, Blue Cross Blue Shield of Massachusetts *https://www.bluecrossma.com/visitor/about-us/affordability-quality/aqc.html*.) The AQC program initiated by BC/BS Massachusetts has met with initial success as shown in a 4-year study published in the New England Journal of Medicine in 2014. (See Song, Zuri, et al., Changes in Health Care Spending and Quality 4 Years into Global Payment, N. Engl. J. Med 371; 18, Oct. 30, 2014, *http://www.nejm.org/doi/full/10.1056/NEJMsa1404026#t=article*.) Specifically, the study found that spending grew an average of $62.21 per enrollee per quarter less in the AQC model contingent than in a control group. Similarly, in 2011, Blue Cross Blue Shield of Minnesota began a 3-year partnership with large health care providers within Minnesota to improve quality and lower costs through an Aligned Incentive Contracting Model. Under that model, increases to the fee-for-service components of payments decrease over time and are replaced by growing performance incentives tied to measurable improvements in quality outcomes and to managing total cost of care. (See Blue Plans Improving Healthcare Quality and Affordability through Innovative Partnerships with Clinicians, BlueCross BlueShield Association, Feb. 13, 2014, *http://www.bcbs.com/healthcare-news/press-center/BP-and-Quality-and-Plan-Innovations.pdf*.)

c. Financial Relationships in Alternative Delivery and Payment Systems

The physician self-referral law, by design, separates entities furnishing DHS from the physicians who refer Medicare patients to them. Evolving health care delivery and payment models, within both the Medicare and Medicaid programs and programs sponsored by non-federal payors, are premised on the close integration of a variety of different health care providers in order to achieve the goals of improving the experience of care, improving the health of populations, and reducing per capita costs of health care, often referred to as the ''three-part aim.'' Entities furnishing DHS face the predicament of trying to achieve clinical and financial integration with other health care providers, including physicians, while simultaneously having to satisfy the requirements of an exception to the physician self-referral law's prohibitions if they wish to compensate physicians to help them meet the triple aim and avoid financial penalties that may be imposed on low-value health care providers. Because all inpatient and outpatient services are considered DHS, hospitals must consider each and every service referred by a physician in their attempts to ensure that compensation paid to a physician does not take into account the volume or value of his or her referrals to the hospital. According to stakeholders, structuring incentive compensation and other payments can be particularly challenging for hospitals, even where the payments are to hospital-employed physicians.

Stakeholders have expressed concern that, outside of the MSSP or certain CMMI-sponsored care delivery and payment models—for which we have issued waivers of the prohibitions of the physician self-referral law—the physician self-referral law prohibits financial relationships necessary to achieve the clinical and financial

integration required for successful health care delivery and payment reform. These concerns apply equally to the participation of physicians and entities furnishing health care services in models sponsored and paid for solely by non-federal payors, where care is provided solely to non-federal program patients, because the financial arrangements between the parties that result from participation in these models must satisfy the requirements of an applicable exception to the physician self-referral law in order to avoid the law's referral and billing prohibitions on DHS referred for and furnished to Medicare beneficiaries. We also have received numerous stakeholder inquiries, unrelated to participation in alternative health care delivery or payment models, regarding whether certain compensation methodologies would be viewed as taking into account the volume or value of a physician's referrals or other business generated between the physician and the entity furnishing DHS that provides the compensation. Many of these inquiries relate to performance-based or incentive compensation. We have not issued any formal guidance to date, either through a binding advisory opinion or rulemaking.

The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10), enacted April 16, 2015, includes certain Medicare program integrity and fraud and abuse provisions. Notably, MACRA requires the Secretary to undertake two studies relating to the promotion of alternative payment models and to provide the Congress with a gainsharing study and report.

Section 101(e)(7) of MACRA requires the Secretary, in consultation with the Office of Inspector General (OIG), to study and report to the Congress on fraud related to alternative payment models under the Medicare program (the APM Report). The Secretary must study the applicability of the federal fraud prevention laws to items and services furnished under title XVIII of the Act for which payment is made under an alternative payment model, identify aspects of alternative payment models that are vulnerable to fraudulent activity, and examine the implications of waivers to the fraud prevention laws to support alternative payment models. The Secretary must include in the APM Report the results of her study and recommendations for actions to reduce the vulnerabilities of Medicare alternative payment models, including possible changes in federal fraud prevention laws to reduce such vulnerabilities. This report must be issued no later than 2 years after the enactment of MACRA.

Section 512(b) of MACRA requires the Secretary, in consultation with OIG, to submit to the Congress a report with options for amending existing fraud and abuse laws and regulations through exceptions, safe harbors or other narrowly tailored provisions, to permit gainsharing arrangements that would otherwise be subject civil money penalties in paragraphs (1) and (2) of section 1128A(b) of the Act and similar arrangements between physicians and hospitals that improve care while reducing waste and increasing efficiency (the Gainsharing Report). The Gainsharing Report must address whether the recommended changes should apply to ownership interests, compensation arrangements, or other relationships. The Gainsharing Report must also describe how the recommendations address accountability, transparency, and quality, including how best to limit inducements to stint on care, discharge patients prematurely, or otherwise reduce or limit medically necessary care. Further, the Secretary's Gainsharing Report must consider whether a portion of any savings generated by such arrangements should accrue to the Medicare program. This report must be issued no later than 12 months after the enactment of MACRA.

d. Solicitation of Comments

To inform the APM Report and Gainsharing Report required under sections 101(e)(7) and 512(b) of MACRA, respectively, as well as to aid us in determining whether additional rulemaking or guidance is desirable or necessary, we are soliciting comments regarding the impact of the physician self-referral law on health care delivery and payment reform. We are interested in comments regarding perceived barriers to achieving clinical and financial integration posed by the physician self-referral law generally and, in particular, the ''volume or value'' and ''other business generated'' standards set out in our regulations. We are also interested in learning whether stakeholders see a need for guidance on the application of our regulations as they relate to physician compensation that is unrelated to participation in alternative payment models. On this subject, we specifically solicit comments regarding the ''volume or value'' and ''other business generated'' standards, but welcome comments regarding any of our rules for determining physician compensation. To encourage robust commentary from stakeholders, we pose the following topics and questions for discussion:

- Does the physician self-referral law generally and, in particular, the ''volume or value'' and ''other business generated'' standards set out in our regulations, pose barriers to or limitations on achieving clinical and financial integration? If so, are the barriers or limitations more pronounced for hospitals than for other providers or suppliers because all Medicare revenue is from DHS (and, thus, any compensation might be considered to take into account the volume or value of referrals or other business generated by the physician to whom it is paid)?
- Which exceptions to the physician self-referral law apply to financial relationships created or necessitated by alternative payment models? Are they adequate to protect such financial relationships?
- Is there a need for new exceptions to the physician self-referral law to support alternative payment models? If so, what types of financial relationships should be excepted? What conditions should we place on such financial relationships to protect against program or patient abuse? Should a new exception be structured to protect services, rather than a specific type of financial relationship, when established conditions are met (similar to the in-office ancillary services exception at § 411.355(b), which protects referrals for certain services performed by physician practices that meet the requirements of § 411.352)? Would legislative action be necessary to establish exceptions to support alternative payment models?
- Which aspects of alternative payment models are particularly vulnerable to fraudulent activity?
- Is there need for new exceptions to the physician self-referral law to support shared savings or ''gainsharing'' arrangements? If so, what types of financial relationships should be excepted? What conditions should we place on such financial relationships to address accountability, transparency, and quality, including how best to limit inducements to stint on care, discharge patients prematurely, or otherwise reduce or limit medically necessary care? Would legislative action be necessary to establish exceptions to support shared savings or ''gainsharing'' arrangements?
- Should certain entities, such as those considered to provide high-value care to our beneficiaries, be permitted to compensate physicians in ways that other entities may not? For example, should we permit hospitals that meet established quality and value metrics under the Hospital VBP to pay bonus

compensation from DHS revenues to physicians who help the hospital meet those metrics? If so, what conditions should we impose to protect against program and patient abuse? How should we define ''high-value care'' or ''high-value entity''? Are there standards other than the value of the care provided to patients that would be appropriate as threshold standards for permitting a hospital or other entity furnishing DHS to compensate physicians in ways that other entities may not?

- Could existing exceptions, such as the exception at § 411.357(n) for risk-sharing arrangements, be expanded to protect certain physician compensation, for example, compensation paid to a physician who participates in an alternative care delivery and payment model sponsored by a non-federal payor? If so, what conditions should we impose to protect against program and patient abuse from the compensation arrangements resulting from participation in such models?
- Have litigation and judicial rulings on issues such as compensation methodologies, fair market value, or commercial reasonableness) generated a need for additional guidance from CMS on the interpretation of the physician self-referral law or the application of its exceptions? We are particularly interested in the need for guidance in the context of delivery system reform.
- Is there a need for revision to or clarification of the rules regarding indirect compensation arrangements or the exception at § 411.357(p) for indirect compensation arrangements?
- Given the changing incentives for health care providers under delivery system reform, should we deem certain compensation not to take into account the volume or value of referrals or other business generated by a physician? If so, what criteria should we impose for this deemed status to ensure that compensation paid to a physician is sufficiently attenuated from the volume or value of his referrals to or other business generated for the entity paying the compensation? Should we apply such a deeming provision only to certain types of entities furnishing DHS, such as hospitals that provide high value care to our beneficiaries?

10. Technical Corrections

We have become aware that some of the manual citations listed in our regulations are no longer correct. We therefore propose to update regulations at § 411.351, definitions of ''entity'', '''incident to' services or services 'incident to'''', ''parenteral and enteral nutrients, equipment, and supplies'', and ''physician in the group practice'', with the correct citations. We also propose to modernize the regulatory text by changing ''Web site'' to ''Web site'' in § 411.351, definition of ''list of CPT/HCPCS Codes'', § 411.357(k)(2), § 411.357(m)(2) through (m)(3), § 411.357(m)(5), § 411.362(c)(2)(iv) through (c)(2)(iv)(v), § 411.362(c)(5), and § 411.384(b). Lastly, we are removing the hyphen from ''publicly-traded'' in § 411.356(a) and § 411.361(d), and we are correcting a minor typographical error in § 411.357(p)(1)(ii)(A).

O. Private Contracting/Opt-Out

1. Background

Effective January 1, 1998, section 1802(b) of the Act permits certain physicians and practitioners to opt out of Medicare if certain conditions are met, and to furnish through private contracts services that would otherwise be covered by Medicare. For those physicians and practitioners who opt out of Medicare in accordance with section 1802(b) of the Act, the mandatory claims submission and limiting charge rules of section 1848(g) of the Act do not apply. As a result, if the conditions necessary for an effective opt-out are met, physicians and practitioners are permitted to privately contract with Medicare beneficiaries and to charge them without regard to Medicare's limiting charge rules.

a. Provisions of the Proposed Regulation

The private contracting/opt out law at section 1802(b) of the Act was recently amended by section 106(a) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Public Law 114–10). Prior to the MACRA amendments, the law specified that physicians and practitioners may opt out for a 2 year period. Individuals that wished to renew their opt-out at the end of a 2 year opt-out period were required to file new affidavits with their Medicare Administrative contractors (MAC). Section 106(a) of MACRA amends section 1802(b)(3) of the Act to require that opt-out affidavits filed on or after June 16, 2015, automatically renew every 2 years. Therefore, physicians and practitioners that file opt-out affidavits on or after June 16, 2015 will no longer be required to file renewal affidavits in order to continue their opt-out status. The amendments further provide that physicians and practitioners who have filed opt-out affidavits on or after June 16, 2015, and who do not want their opt-out status to automatically renew at the end of a 2 year opt-out period may cancel the automatic extension by notifying us at least 30 days prior to the start of the next 2 year opt-out period.

We propose to revise the regulations governing the requirements and procedures for private contracts at 42 CFR part 405, subpart D so that they conform with these statutory changes. Specifically, we propose to revise the following:

- The definition of ''Opt-out period'' at § 405.400 so that opt-out affidavits automatically renew unless the physician or practitioner properly cancels opt-out.
- Sections 405.405(b), 405.410(c)(1) and (2), 405.415(h), (m), and (o), 405.425, 405.435(a)(4), 405.435(b)(8), 405.435(d), and 405.445(b)(2) so those sections conform with the revised definition of ''Opt-out period''.
- Section 405.445(a) so that proper cancellation of opt-out requires a physician or practitioner to submit written notice, not later than 30 days before the end of the current 2-year opt-out period, that the physician or practitioner does not want to extend the application of the opt-out affidavit for a subsequent 2-year period.
- Section 405.450(a) so that failure to properly cancel opt-out is included as an initial determination for purposes of § 498.3(b).

To update the terminology in our regulations, we also propose to amend sections 405.410(d), 405.435(d), and 405.445(b)(2) so that the term ''carrier'' is replaced with ''Medicare Administrative contractor''.

IV. 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, PRA section 3506(c)(2)(A) requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our burden estimates.
- The quality, utility, and clarity of the information to be collected.
- Our effort to minimize the information collection burden on the affected public, including the use of automated collection techniques.

We are soliciting public comment on each of the section 3506(c)(2)(A)-required issues for the following information collection requirements.

A. Wage Estimates

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2014 National Occupational Employment and Wage Estimates for all salary estimates (www.bls.gov/oes/current/oes_nat.htm). In this regard, Table 37 presents the mean hourly wage, the cost of fringe benefits, and the adjusted hourly wage.

TABLE 37—ESTIMATED HOURLY WAGES

Occupation title	Occupation code	Mean hourly wage ($/hr)	Fringe benefit ($/hr)	Adjusted hourly wage ($/hr)
Billing and Posting Clerks	43–3021	17.10	* 9.58	26.68
Business Operations Specialists	13–1000	33.69	33.69	67.38
Computer Systems Analysts	15–1121	41.98	41.98	83.96
Medical and Health Services Managers	11–9111	49.84	49.84	99.68
Medical Secretaries	43–6013	16.12	16.12	32.24
Physicians and Surgeons	29–1060	93.71	93.71	187.48

* For fringe benefits, we are using the December 2014 Employer Costs for Employee Compensation (*http://www.bls.gov/news.release/archives/ecec_03112015.pdf*).

Except where noted, 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.

B. Proposed Information Collection Requirements (ICRs)

1. ICRs Regarding 42 CFR Part 405, Subpart D

Section 106(a) of MACRA indicates that valid opt-out affidavits filed on or after June 16, 2015, automatically renew every 2 years. Previously, physicians and practitioners wanting to renew their opt-out were required to file new valid affidavits with their Medicare Administrative Contractors (MAC).

To be consistent with section 106(a), we propose to revise 42 CFR part 405, subpart D governing the submission of opt-out affidavits. We estimate that 150 physicians/practitioners will submit new affidavits at 2 hr per submission or 300 hr (total). Previously, we estimated that 600 physicians/practitioners would submit renewal affidavits at 2 hr per submission or 1,200 hr (total). In this regard, the burden will decrease by −900 hr (300 hr − 1,200 hr) when physicians and practitioners no longer need to submit renewal affidavits starting on June 16, 2017. We also estimate that a Medical Secretary will perform this duty at $32.24/hr for a savings of −$29,016 (−900 hr × $32.24/hr).

Under § 405.445(a), physicians and practitioners that file valid opt-out affidavits on or after June 16, 2015 and do not want to extend their opt-out status at the end of a 2 year opt-out period may cancel by notifying us at least 30 days prior to the start of the next 2 year opt-out period. The burden associated with this new requirement is the time to draft, sign and submit the writing to the MAC. We estimate it will take 60 physicians/practitioners approximately 10 minutes each for a total of 10 burden hours. We also estimate that a Medical Secretary will perform this duty at $32.24/hr for a cost of $322.40 (10 hr × $32.24/hr).

The requirements and burden will be submitted to OMB under control number 0938–0730 (CMS–R–234).

2. ICRs Regarding the Payment for RHC and FQHC Services (§ 405.2462) and What Constitutes a Visit (§ 405.2463)

In §§ 405.2462(d) and 405.2463(c)(4), we propose that clinics that were provider-based to an IHS hospital on or before April 7, 2000, and are now tribally-operated clinics contracted or compacted under the ISDEAA, may seek to become certified as grandfathered tribal FQHCs. To become certified, an eligible tribe or tribal organization must submit an enrollment application (CMS–855A, OMB control number 0938–0685) and all required accompanied documentation, including an attestation of compliance with the Medicare FQHC Conditions for Coverage at part 491, to the Jurisdiction H Medicare Administrative Contractor (A/B MAC).

We estimate that between 3 and 5 grandfathered tribal clinics that were provider-based to an IHS hospital on or before April 7, 2000, and are now tribally-operated clinics contracted or compacted under the ISDEAA, would seek to become certified as grandfathered tribal FQHCs. Since we estimate fewer than 10 respondents, the information collection requirements are exempt (5 CFR 1320.3(c)) from the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

3. ICRs Regarding the Payment for RHC and FQHC Services (§ 405.2462)

In § 405.2462(g)(3), we propose that RHCs must report Healthcare Common Procedure Coding System (HCPCS) and other codes as required in reporting services furnished to a Medicare beneficiary during a RHC visit effective for dates of service on or after January 1, 2016.

The ongoing burden associated with the requirements under § 405.2462(g)(3) is the time and effort it would take each of the approximately 4,000 Medicare certified RHCs to report the services furnished to a Medicare beneficiary during a RHC visit using HCPCS and other codes as required. We believe that most RHCs are already familiar with the use of HCPCS coding since RHCs typically record HCPCS coding through their billing software or electronic health record systems and they could be subject to HCPCS reporting in accordance with the National Uniform Billing Committee and Accredited Standards Committee X12 standards. In our estimates below, we do not disregard any RHCs that may already be reporting HCPCS coding but we do take into the account the range of time it will take for inexperienced RHCs compared to experienced RHCs. We recognize some RHCs may need to make minor updates in their systems, but more so, RHC billing staff will need education in HCPCS coding associated with Medicare payable RHC visits. Due to the scope of services payable as a RHC visit, we do not anticipate RHCs will face a significant burden in training and education of billing staff. We plan to

provide educational information on how RHCs are to report HCPCS and other codes as required and clarify other appropriate RHC billing procedures through sub-regulatory guidance.

We estimate that it will take 2 to 5 additional minutes to report HCPCS codes on RHC claims to Medicare and, for most RHCs, we believe that billing staff will require closer to 2 min when the RHCs become more experienced with including HCPCS coding on Medicare claims. As noted previously, for some RHCs, this requirement may not require any additional coding time since they already could be capturing HCPCS coding in their billing or electronic health record systems. Whereas, other RHCs may need up to 5 additional minutes to include HCPCS coding on Medicare claims. In this regard, we estimate a median of 3.5 additional minutes in the following calculations:

(8,964,208 Medicare claims in 2013 × 3.5 min)/60 min = 522,912.13 hr (aggregate)
522,912.13 hr/4,000 RHCs = 130.73 hr (per RHC)
522,912.13 hr × $26.68/hr = $13,951,295.63 additional cost (aggregate)
$13,951,295.63/4,000 RHCs = $3,487.82 per RHC

In deriving these figures, we analyzed claims data and RHC certification data maintained by CMS. We also used wage data from the Bureau of Labor Statistics (see Table 37).

The burden for the aforementioned requirements will be submitted to OMB for approval under control number 0938–New (CMS–10568).

4. ICRs Regarding Exceptions to the Referral Prohibition Related to Compensation Arrangements (§ 411.357)

Section 411.357 would be revised to establish two new exceptions: An exception to permit remuneration to independent physicians to assist in employing nonphysician practitioners in the geographic service area of the hospital, FQHC, or RHC providing the remuneration; and an exception to permit timeshare arrangements for the use of premises, equipment, personnel, items, supplies or services. Arrangements covered by these new exceptions must be in writing. We have also proposed clarifications to the writing requirements for compensation arrangements in § 411.357(a), (b), (d), (e), (l), (p), and (r). The burden associated with these requirements would be the time and effort necessary to prepare written documents and obtain signatures of the parties.

While these requirements are subject to the PRA, we believe the associated burden is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2). We believe that the time, effort, and financial resources necessary to comply with the aforementioned requirements would be incurred by persons during the normal course of their activities and, therefore, should be considered a usual and customary business practice.

5. ICRs Regarding [the] Physician Quality Reporting System (PQRS) (§ 414.90 and Section K of This Preamble)

With respect to the PQRS, the burden associated with the requirements of this voluntary reporting initiative is the time and effort associated with individual eligible professionals and group practices identifying applicable quality measures for which they can report the necessary information, selecting a reporting option, and reporting the information on their selected measures or measures group to CMS using their selected reporting option. We assume that most eligible professionals participating in the PQRS will attempt to meet the criteria for satisfactory reporting for the 2018 PQRS payment adjustment.

For individual eligible professionals, the burden associated with the requirements of this reporting initiative is the time and effort associated with eligible professionals identifying applicable quality measures for which they can report the necessary information, collecting the necessary information, and reporting the information needed to report the eligible professional's measures. We believe it is difficult to accurately quantify the burden because eligible professionals may have different processes for integrating the PQRS into their practice's work flows. Moreover, the time needed for an eligible professional to review the quality measures and other information, select measures applicable to his or her patients and the services he or she furnishes to them, and incorporate the use of quality data codes into the office work flows is expected to vary along with the number of measures that are potentially applicable to a given professional's practice. Since eligible professionals are generally required to report on at least nine measures covering at least three National Quality Strategy domains criteria for satisfactory reporting (or, in lieu of satisfactory reporting, satisfactory participation in a QCDR) for the 2018 PQRS payment adjustment, we will assume that each eligible professional reports on an average of nine measures for this burden analysis.

For eligible professionals who are participating in PQRS, we estimate that it will take 5 hr for an eligible professional's billing clerk to review the PQRS Measures List, review the various reporting options, select the most appropriate reporting option, identify the applicable measures or measures groups for which they can report the necessary information, review the measure specifications for the selected measures or measures groups, and incorporate reporting of the selected measures or measures groups into the office work flows. The measures list contains the measure title and brief summary information for the eligible professional to review. Assuming the eligible professional has received no training from his/her specialty society, we estimate it will take an eligible professional's billing clerk up to 2 hr to review this list, review the reporting options, and select a reporting option and measures on which to report. If an eligible professional has received training, then we believe this would take less time. CMS believes that 3 hours is sufficient time for an eligible professional to review the measure specifications of nine measures or one measures group they select to report for purposes of participating in PQRS and to develop a mechanism for incorporating reporting of the selected measures or measures groups into the office work flows. Therefore, we believe that the start-up cost for an eligible professional to report PQRS quality measures data is 5 hr × $26.68/hr = $133.40.

We continue to expect the ongoing cost associated with PQRS participation to decline based on an eligible professional's familiarity with and understanding of the PQRS, experience with participating in the PQRS, and increased efforts by CMS and stakeholders to disseminate useful educational resources and best practices.

We believe the burden associated with actually reporting the quality measures will vary depending on the reporting mechanism selected by the eligible professional. As such, we break down the burden estimates by eligible professionals and group practices participating in the GPRO according to the reporting mechanism used.

The proposed requirements and burden estimates will be submitted to OMB under control number 0938–1059 (CMS–10276).

a. Burden Estimate for PQRS Reporting by Individual Eligible Professionals and Group Practices: Claims-Based Reporting Mechanism

Under the claims-based reporting option, eligible professionals must

gather the required information, select the appropriate quality data codes (QDCs), and include the appropriate QDCs on the claims they submit for payment. The PQRS collects QDCs as additional (optional) line items on the CMS–1500 claim form or the electronic equivalent HIPAA transaction 837–P, approved under OMB control number 0938–0999. This rule does not propose any changes to these forms. Beginning in 2014, CMS made changes on how Critical access hospitals (CAHs) were billed under Medicare which made it possible for eligible professionals in CAH method II payment to participate in PQRS.

Based on our experience with the Physician Voluntary Reporting Program (PVRP), we continue to estimate that the time needed to perform all the steps necessary to report each measure (that is, reporting the relevant quality data code(s) for nine measures) would range from 15 sec (0.25 min) to over 12 min for complicated cases and/or measures, with the median time being 1.75 min. To report nine measures, we estimate that it would take approximately 2.25 min (0.25 min × 9) to 108 min (12 min × 9) to perform all the steps necessary to report nine measures.

At an adjusted labor rate of $83.96/hr for a computer systems analyst, the per measure cost would range from $0.35 [($83.96/hr/60) × 0.25 min] to $16.79 [($83.96/hr/60) × 12 min], with a median cost of $2.45 [($83.96/hr/60) × 1.75 min]. To report nine measures we estimate that the cost would range from *$3.15* ($0.35 × 9) to *$151.11* ($16.79 × 9), with a median cost of *$22.05* ($2.45 × 9).

The total estimated annual burden will vary along with the volume of claims on which quality data is reported. In previous years, when we required reporting on 80 percent of eligible cases for claims-based reporting we found that, on average, the median number of reporting instances for each of the PQRS measures was nine. Since we reduced the required reporting rate by over one-third to 50 percent, we assume that an eligible professional or eligible professional in a group practice will need to report each selected measure for six reporting instances. The actual number of cases on which an eligible professional or group practice is required to report quality measures data will vary with the eligible professional's or group practice's patient population and the types of measures on which the eligible professional or group practice chooses to report (each measure's specifications includes a required reporting frequency). For the 2018 payment adjustment, eligible professionals will also report on one cross-cutting measure if they see at least one Medicare patient. However, we do not see any additional burden impact as they are still reporting on the same number of measures.

Based on these assumptions, we estimate that the per individual eligible professional reporting burden would range from 13.5 min (0.25 min per measure × 9 measures × 6 cases per measure) to 648 min (12 min per measure × 9 measures × 6 cases per measure), with a median burden of 94.5 min (1.75 min per measure × 9 measures × 6 cases). We also estimate that the cost would range from *$18.90* [13.5 min ($83.96/hr/60)] to *$906.66* [648 min ($83.96/hr/60)], with a median cost of *$132.30* [94.5 min ($83.96/hr/60)].

Based on the assumptions discussed above, Table 38 provides an estimate of the range of total annual burden associated with eligible professionals using the claims-based reporting mechanism.

TABLE 38—SUMMARY OF BURDEN ESTIMATES FOR ELIGIBLE PROFESSIONALS USING THE CLAIMS-BASED REPORTING MECHANISM

	Minimum burden estimate	Median burden estimate	Maximum burden estimate
Estimated # of Participating Eligible Professionals (a)	350,000	350,000	350,000
Estimated # of Measures Per Eligible Professional Per Year (b)	9	9	9
Estimated # of Cases Per Measure Per Eligible Professional Per Year (c)	6	6	6
Total Estimated # of Cases Per Eligible Professional Per Year (d) = (b)*(c)	54	54	54
Estimated Burden Hours Per Case (e)	0.00415	0.02917	0.19992
Estimated Total Burden Hours For Measures Per Eligible Professional Per Year (f) = (d)*(e)	0.2241	1.57518	10.79568
Estimated Burden Hours Per Eligible Professional to Prepare for PQRS Participation (g)	5	5	5
Estimated Total Annual Burden Hours Per Eligible Professional (h) = (f) + (g)	5.2241	6.57518	15.79568
Estimated Total Annual Burden Hours (i) = (a)*(h)	1,828,435	2,301,313	5,528,488
Estimated Cost Per Case (j)	$0.35	$2.45	$16.79
Total Estimated Cost of Cases Per Eligible Professional Per Year (k) = (d)*(j)	$18.90	$132.30	$906.66
Estimated Cost Per Eligible Professional to Prepare for PQRS Participation (l)	$133.40	$133.40	$133.40
Estimated Total Annual Cost Per Eligible Professional (m) = (k) + (l)	$152.30	$265.70	$1,040.06
Estimated Total Annual Burden Cost (n) = (a)*(m)	$53,305,000	$92,995,000	$364,021,000

b. Burden Estimate for PQRS Reporting by Individual Eligible Professionals and Group Practices: Qualified Registry-Based and QCDR-Based Reporting Mechanisms

For qualified registry-based and QCDR-based reporting, there will be no additional time for eligible professionals or group practices to report data to a qualified registry as eligible professionals and group practices opting for qualified registry-based reporting or use of a QCDR will more than likely already be reporting data to the qualified registry for other purposes and the qualified registry will merely be re-packaging the data for use in the PQRS. Little, if any, additional data will need to be reported to the qualified registry or QCDR solely for purposes of participation in the PQRS. However, eligible professionals and group practices 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 CMS on their behalf. We estimate that the time and effort associated with this requirement will be approximately 5 min per eligible professional or eligible professional within a group practice.

Based on the assumptions discussed above, Table 39 provides an estimate of the total annual burden hours and cost associated with eligible professionals using the qualified registry-based or QCDR-based reporting mechanism. Please note that, unlike the claims-based reporting mechanism that would require an eligible professional to report data to CMS on quality measures on multiple

occasions, an eligible professional would not be required to submit this data to CMS, as the qualified registry or QCDR would perform this function on the eligible professional's behalf.

TABLE 39—SUMMARY OF BURDEN ESTIMATES FOR ELIGIBLE PROFESSIONALS (PARTICIPATING INDIVIDUALLY OR AS PART OF A GROUP PRACTICE) USING THE QUALIFIED REGISTRY-BASED AND QCDR-BASED REPORTING MECHANISMS

	Burden estimate
Estimated # of Participating Eligible Professionals (a) ..	212,000
Estimated Burden Hours Per Eligible Professional to Authorize the Qualified registry or QCDR to Report on Eligible Professional's Behalf (b)	0.083
Estimated Burden Hours Per Eligible Professional to Report PQRS Data to Qualified registry or QCDR (c) ..	3
Estimated Burden Hours Per Eligible Professional to Prepare for PQRS Participation (d)	5
Estimated Total Annual Burden Hours Per Eligible Professional (e) = (b) + (c) + (d)	8.083
Estimated Total Annual Burden Hours (f) = (a)*(e)	1,713,596
Estimated Cost Per Eligible Professional to Authorize Qualified registry or QCDR to Report on Eligible Professional's Behalf (g)	$6.97
Estimated Cost Per Eligible Professional to Report PQRS Data to Qualified registry or QCDR (h)	$251.88
Estimated Cost Per Eligible Professional to Prepare for PQRS Participation (i)	$133.40
Estimated Total Annual Cost Per Eligible Professional (j) = (g) + (h) + (i)	$392.25
Estimated Total Annual Burden Cost (k) = (a)*(j)	$83,157,000

c. Burden Estimate for PQRS Reporting by Individual Eligible Professionals and Group Practices: EHR-Based Reporting Mechanism

For EHR-based reporting, which includes EHR reporting via a direct EHR product and an EHR data submission vendor's product, the eligible professional or group practice must review the quality measures on which we will be accepting PQRS data extracted from EHRs, select the appropriate quality measures, extract the necessary clinical data from his or her EHR, and submit the necessary data to the CMS-designated clinical data warehouse.

Under this reporting mechanism the individual eligible professional or group practice may either submit the quality measures data directly to CMS from their EHR or utilize an EHR data submission vendor to submit the data to CMS on the eligible professional's or group practice's behalf. To submit data to CMS directly from their EHR, the eligible professional or eligible professional in a group practice must have access to a CMS-specified identity management system, such as IACS, which we believe takes less than 1 hour to obtain. Once an eligible professional or eligible professional in a group practice has an account, he or she will need to extract the necessary clinical data from his or her EHR, and submit the necessary data to the CMS-designated clinical data warehouse.

With respect to submitting the actual data file for the respective reporting period, we believe that this will take an eligible professional or group practice no more than 2 hr, depending on the number of patients on which the eligible professional or group practice is submitting. We also believe that once the EHR is programmed by the vendor to allow data submission to CMS, the burden to the eligible professional or group practice associated with submission of data on quality measures should be minimal as all of the information required to report the measure should already reside in the eligible professional's or group practice's EHR.

In this rule, we are proposing that group practices with 25 or more eligible professionals must report on CAHPS for PQRS (OMB control number 0938–1222, CMS–10450). Therefore, a group practice of 25 or more eligible professionals would be required to report six or more measures covering two domains of their choosing. At this point, we do not believe the requirement to report CAHPS for PQRS adds or reduces the burden on group practices, as we consider reporting the CAHPS for PQRS survey as reporting three measures covering one domain.

Based on the assumptions discussed above, Table 40 provides an estimate of the total annual burden hours and cost associated with EHR-based reporting for individual eligible professionals or group practices. Please note that, unlike the claims-based reporting mechanism that would require an eligible professional to report data to CMS on quality measures on multiple occasions, an eligible professional would not be required to submit this data to CMS, as the EHR product would perform this function on the eligible professional's behalf.

TABLE 40—SUMMARY OF BURDEN ESTIMATES FOR ELIGIBLE PROFESSIONALS (PARTICIPATING INDIVIDUALLY OR AS PART OF A GROUP PRACTICE) USING THE EHR-BASED REPORTING MECHANISM

	Burden estimate
Estimated # of Participating Eligible Professionals (a) ..	50,000
Estimated Burden Hours Per Eligible Professional to Obtain IACS Account (b) ..	1
Estimated Burden Hours Per Eligible Professional to Submit Test Data File to CMS (c)	1
Estimated Burden Hours Per Eligible Professional to Submit PQRS Data File to CMS (d)	2
Estimated Burden Hours Per Eligible Professional to Prepare for PQRS Participation (e)	5
Estimated Total Annual Burden Hours Per Eligible Professional (f) = (b) + (c) + (d) + (e)	9
Estimated Total Annual Burden Hours (g) = (a)*(f)	450,000
Estimated Cost Per Eligible Professional to Obtain IACS Account (h)	$83.96
Estimated Cost Per Eligible Professional to Submit PQRS Data File to CMS (includes 1hr for submitting test file, which is optional) (i)	$251.88
Estimated Cost Per Eligible Professional to Prepare for PQRS Participation (j)	$133.40
Estimated Total Annual Burden Cost Per Eligible Professional (k) = (h) + (i) + (j)	$469.24
Estimated Total Annual Burden Cost (m) = (a)*(k)	$23,462,000

d. Burden Estimate for PQRS Reporting by Group Practices Using the GPRO Web Interface

With respect to the process for group practices to be treated as satisfactorily submitting quality measures data under the PQRS, group practices interested in participating in the PQRS through the group practice reporting option (GPRO) must complete a self-nomination process similar to the self-nomination process required of qualified registries. However, since a group practice using the GPRO web interface would not need to determine which measures to report under PQRS, we believe that the self-nomination process is handled by a group practice's administrative staff

(billing and posting clerk). Therefore, we estimate that the self-nomination process for the group practices for the PQRS involves approximately 2 hr per group practice to review the PQRS GPRO and make the decision to participate as a group rather than individually and an additional 2 hr per group practice to draft the letter of intent for self-nomination, gather the requested TIN and NPI information, and provide this requested information. It is estimated that each self-nominated entity will also spend 2 hr undergoing the vetting process with CMS officials. We assume that the group practice staff involved in the self-nomination process has an adjusted labor rate of $26.68/hr. Therefore, assuming the time associated with the group practice self-nomination process is 6 hr per group practice, at a cost of $160.08 ($26.68/hr × 6 hr per group practice).

The burden associated with the group practice reporting requirements under the GPRO is the time and effort associated with the group practice submitting the quality measures data. For physician group practices, this would be the time associated with the physician group completing the web interface. We estimate that the time and effort associated with using the GPRO web interface is comparable to the time and effort associated to using the PAT. As stated above, the information collection components of the PAT have been reviewed by OMB and are approved under OMB control number 0938–0941 (CMS–10136) for use in the PGP, MCMP, and EHR demonstrations. As the GPRO was only recently implemented in 2010, it is difficult to determine the time and effort associated with the group practice submitting the quality measures data. As such, we will use the same burden estimate for group practices participating in the GPRO as we use for group practices participating in the PGP, MCMP, and EHR demonstrations. Since these changes will not have any impact on the information collection requirements associated with the PAT and we will be using the same data submission process used in the PGP demonstration, we estimate that the burden associated with a group practice completing data for PQRS under the web interface will be the same as for the group practice to complete the PAT for the PGP demonstration. In other words, we estimate that, on average, it will take each group practice 79 hr to submit quality measures data via the GPRO web interface at a cost of $83.96/hr. Therefore, the annual cost is estimated at $6,632.84 per group practice.

Based on the assumptions discussed above, Table 41 provides an estimate of the total annual burden hours and cost associated with the group practice reporting of quality measures.

TABLE 41—SUMMARY OF BURDEN ESTIMATES FOR GROUP PRACTICES USING THE GPRO WEB INTERFACE REPORTING MECHANISM

	Burden estimate
Estimated # of Eligible Group Practices in 2013/2014 (a)	500
Estimated # of Burden Hours Per Group Practice to Self-Nominate to Participate in PQRS Under the Group Practice Reporting Option (b)	6
Estimated # of Burden Hours Per Group Practice to Report (c)	79
Estimated Total Annual Burden Hours Per Group Practice (d) = (b) + (c)	85
Estimated Total Annual Burden Hours (e) = (a)*(d)	42,500
Estimated Cost Per Group Practice to Self-Nominate to Participate in PQRS Under the Group Practice Reporting Option (at a labor rate of $26.68/hr) (f)	$160.08
Estimated Cost Per Group Practice to Report (g)	$6,632.84
Estimated Total Annual Cost Per Group Practice (h) = (f) + (g)	$6,792.92
Estimated Total Annual Burden Cost (i) = (a)*(h)	$3,396,460

Please note that, beginning in 2013, we are requiring group practices that use the GPRO web interface reporting mechanism to administer a CAHPS survey. Please note that the burden estimates of implementing this survey is provided in a separate PRA package submission.

e. Total Estimated Burden of This Information Collection Requirement for 2013 and 2014

It is difficult to accurately estimate the total annual burden hours and costs associated with the submission of the quality measures data for the PQRS. For example, there are a number of reporting mechanisms available that eligible professionals can choose to use to report the PQRS measures. It may be more burdensome for some practices to use some reporting mechanisms to report the PQRS measures and/or electronic prescribing measure than others. This will vary with each practice. We have no way of determining which reporting mechanism an individual eligible professional will use in a given year, especially since EHR reporting and group practice reporting were new options for the 2010 PQRS and the QCDR option is new for the 2014 PQRS. Therefore, Table 42 provides a range of estimates for individual eligible professionals or group practices using the claims, qualified registry, or EHR-based reporting mechanisms. The lower range of the estimate assumes that eligible professionals will only participate in PQRS to avoid the PQRS payment adjustments that begin in 2015. The upper range assumes that eligible professionals participate in PQRS for purposes of earning an incentive as well as avoiding the PQRS payment adjustments. This upper range represents the sum of the estimated maximum hours and cost per eligible professional from Tables 37, 38, and 40. We are updating our previously approved estimates for the upper range of the estimates provided in Table 42.

TABLE 42—SUMMARY OF BURDEN ESTIMATES FOR ELIGIBLE PROFESSIONALS AND/OR GROUP PRACTICES USING THE CLAIMS, QUALIFIED REGISTRY, AND EHR-BASED REPORTING MECHANISMS

	Minimum burden estimate	Maximum burden estimate
Estimated Annual Burden Hours for Claims-based Reporting (for individual eligible professionals only)	1,828,435	5,528,488
Estimated Annual Burden for Qualified Registry-based or QCDR-based Reporting	1,713,596	1,713,596
Estimated Annual Burden Hours for EHR-based Reporting	450,000	450,000
Estimated Total Annual Burden Hours for Eligible Professionals or Eligible Professionals in a Group Practice	3,992,031	7,692,084
Estimated Cost for Claims-based Reporting (for individual eligible professionals only)	$53,305,000	$364,021,000
Estimated Cost for Qualified Registry-based Reporting	$83,157,000	$83,157,000
Estimated Cost for EHR-based Reporting	$23,462,000	$23,462,000

TABLE 42—SUMMARY OF BURDEN ESTIMATES FOR ELIGIBLE PROFESSIONALS AND/OR GROUP PRACTICES USING THE CLAIMS, QUALIFIED REGISTRY, AND EHR-BASED REPORTING MECHANISMS—Continued

	Minimum burden estimate	Maximum burden estimate
Estimated Total Annual Cost for Eligible Professionals or Eligible Professionals in a Group Practice	$159,924,000	$470,640,000

For purposes of estimating the reporting burden for group practices, Table 43 provides a summary of an estimate for group practices to participate in PQRS under the group practice reporting option using the GPRO web interface during 2015 (that is, Table 41).

TABLE 43—SUMMARY OF BURDEN ESTIMATES FOR GROUP PRACTICES USING THE GPRO WEB INTERFACE REPORTING MECHANISM

	Maximum burden estimate
Estimated # of Participating Group Practices	500
Estimated # of Burden Hours Per Group Practice to Self-Nominate to Participate in PQRS and the Electronic Prescribing Incentive Program Under the Group Practice Reporting Option	6
Estimated # of Burden Hours Per Group Practice to Report Quality Measures	79
Estimated Total Annual Burden Hours Per Group Practice	85
Estimated Total Annual Burden Hours for Group Practices	42,500
Estimated Cost Per Group Practice to Self-Nominate to Participate in PQRS for the Group Practice Reporting Option	$160.08
Estimated Cost Per Group Practice to Report Quality Measures	$6,632.84
Estimated Total Annual Cost Per Group Practice	$6,792.12
Annual Burden Cost for Group Practices	$3,396,460

6. ICRs Regarding Appropriate Use Criteria for Advanced Diagnostic Imaging Services (§ 414.94)

Consistent with section 1834(q) of the statute (as amended by section 218(b) of the PAMA), CMS is proposing specific requirements for the development of appropriate use criteria (AUC) that can be specified under § 414.94 as part of the Medicare program. Provider-led organizations that use processes meeting certain requirements and want to be recognized as qualified provider-led entities for the purpose of this section may apply to CMS.

Applications must be submitted electronically and demonstrate how the organization's processes meet the requirements specified in § 414.94(c)(1) which include: A systematic literature review of the clinical topic and relevant imaging studies; AUC development led by at least one multidisciplinary team with autonomous governance; a process for identifying team members' conflicts of interest; publication of individual appropriate use criterion on each organizations Web site; identification of key decision points for individual criterion as evidence-based or consensus-based and strength of evidence grading per a formal, published, and widely recognized methodology; a transparent process for the timely and continual updating of each criterion; and a process for developing, modifying or endorsing AUC publicly posted on the entity's Web site.

To be identified as a qualified provider-led entity by CMS, organizations must demonstrate adherence to the requirements in their application and use the application process identified in § 414.94(c)(2) which includes: Only entities meeting the definition of provider-led entity are eligible to submit applications documenting adherence to each AUC development requirement; applications may be accepted annually by January 1; all approved provider-led entities will be posted to our Web site by June 30; and all qualified provider-led entities must re-apply every 6 years and applications must be submitted by January 1 during the 5th year of approval.

The one-time burden associated with the requirements under § 414.94(c)(2) is the time and effort it would take each of the 30 organizations that have expressed interests in developing AUC to compile, review and submit documentation demonstrating adherence to the proposed AUC development requirements. We anticipate 30 respondents based on the number of national professional medical specialty societies and other organizations that have expressed interest in participating in this program as well as other entities we have not heard from but would expect to participate.

We estimate it will take 20 hr at $67.38/hr for a business operations specialist to compile, prepare and submit the required information, 5 hr at $99.68/hr for a medical and health services manager to review and approve the submission, and 5 hr at $187.48/hr for a physician to review and approve the submission materials. In this regard, we estimate 30 hr per submission at a cost of $2,783.40 per organization. In aggregate, we estimate 900 hr (30 hr × 30 submissions) at $83,502 ($2,783.40 × 30 submissions).

After the anticipated initial 30 respondents, we expect less than 10 applicants to apply to become qualified provider-led entities annually. Since we estimate fewer than ten respondents, the information collection requirements are exempt (5 CFR 1320.3(c)) from the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq).

Qualified provider-led entities must re-apply every 6 years. Therefore in years 7–10, we expect that the initial 30 entities will re-apply. The ongoing burden for re-applying is expected to be half the burden of the initial application process. The provider-led entity will be able to make modifications to their original application which should result in a burden of 10 hr at $67.38/hr for a business operations specialist to compile, prepare and submit the required information, 2.5 hr at $99.68/hr for a medical and health services manager to review and approve the submission, and 2.5 hr at $187.48/hr for a physician to review and approve the submission materials. Annually, we estimate 15 hr per submission at a cost of $1,391.70 per organization. In aggregate, we estimate 450 hr (15 hr × 30 submissions) at $41,751 ($1,391.70 × 30 submissions).

The proposed requirements and burden will be submitted to OMB under control number 0938–New (CMS–10570).

7. ICRs Regarding the Comprehensive Primary Care (CPC) Initiative and the Medicare EHR Incentive Program (Section L of This Preamble)

Section L outlines an aligned reporting option between the Comprehensive Primary Care (CPC) initiative and the Medicare EHR Incentive Program whereby a practice site participating in CPC can report at least nine clinical quality measures as defined by the model that are across three domains and receive credit for reporting to the model as well as receive credit for the clinical quality measure reporting requirement of the Medicare EHR Incentive Program. While the reporting of quality measures is an information collection, the requirement is exempt from the PRA in accordance with section 1115A(d)(3) of the Social Security Act.

8. ICRs Regarding the Medicare Shared Savings Program (Section M of This Preamble)

While the proposed measures discussed in section M of this preamble is a collection of information, section 3022 of the Affordable Care Act exempts any collection of information associated with the Medicare Shared Savings Program from the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.). Consequently, we are not setting out any burden for OMB approval.

C. Summary of Proposed Annual Burden Estimates

TABLE 44—PROPOSED ANNUAL RECORDKEEPING AND REPORTING REQUIREMENTS

Section(s) in title 42 of the CFR	OMB No. (CMS ID No.)	Respondents	Responses (total)	Burden per response	Total annual burden (hr)	Labor rate for reporting ($/hr)	Total cost ($)
Part 405, subpart D	0938–0730 (CMS–R–234).	−450	−450	2 hr	−900	67.38	−60,642
405.445(a)	0938–0730 (CMS–R–234).	60	60	10 min	10	67.38	674
405.2462(g)(3)	0938–New (CMS–10568).	4,000	8,964,208	3.5 min	522,912.13	26.68	13,951,296
414.90 and section K of this preamble.	0938–1059 (CMS–10276).	350,000 (claims-based reporting).	54 (9 × 6)	5.2 hr (5 hr + 12 min).	5,528,488	varies (see Table 1).	364,021,000
		212,000 (qualified registry-based and QCDR-based reporting).	212,000	8.083 hr	1,713,596	varies (see Table 2).	83,157,000
		50,000 (EHR-based reporting).	50,000	9	450,000	varies (see Table 3).	23,462,000
		500 (GPRO web interface).	500	85	42,500	varies (see Table 4).	3,396,460
414.94(c)(1) and (2)	0938–New (CMS–10570).	30	30	5 hr	150	187.48	28,113
				5 hr	150	99.68	14,952
				20 hr	600	67.38	40,332
Total					8,257,506		488,011,185

D. Submission of PRA-Related Comments

We have submitted a copy of this proposed rule to OMB for its review of the rule's information collection and recordkeeping requirements. 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 above, please visit CMS' Web site at *www.cms.hhs.gov/Paperwork@cms.hhs.gov,* 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–1631–P).

PRA-related comments must be received on/by September 8, 2015.

V. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

VI. Regulatory Impact Analysis

A. Statement of Need

This proposed rule is necessary to make payment and policy changes under the Medicare PFS and to make required statutory changes under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) and the Achieving a Better Life Experience Act of 2014 (ABLE). This proposed rule is also necessary to make changes to Part B payment policy and other Part B related policies.

B. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (February 2, 2013), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits

(including potential economic, environmental, public health and safety effects, distributive impacts, and equity). 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 PFS provisions included in this proposed rule will redistribute more than $100 million in 1 year. 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. The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals, practitioners and most other providers and suppliers are small entities, either by nonprofit status or by having annual revenues that qualify for small business status under the Small Business Administration standards. (For details see the SBA's Web site at *http://www.sba.gov/content/table-small-business-size-standards* (refer to the 620000 series)). Individuals and States are not included in the definition of a small entity.

The RFA requires that we analyze regulatory options for small businesses and other entities. We prepare a regulatory flexibility analysis unless we certify that a rule would not have a significant economic impact on a substantial number of small entities. The analysis must include a justification concerning the reason action is being taken, the kinds and number of small entities the rule affects, and an explanation of any meaningful options that achieve the objectives with less significant adverse economic impact on the small entities.

Approximately 95 percent of practitioners, other providers and suppliers are considered to be small entities, based upon 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 section as well as elsewhere in this proposed rule is intended to comply with the RFA requirements.

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 rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of 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 rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 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 2015, that threshold is approximately $144 million. This proposed rule would impose no mandates on state, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

We have prepared the following analysis, which together with the information provided in the rest of this preamble, 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 proposing to implement a variety of changes to our regulations, payments, or payment policies to ensure that our payment systems reflect changes in medical practice and the relative value of services, and to implement statutory provisions. We provide information for each of the policy changes in the relevant sections of this proposed rule. 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 Relative Value Unit (RVU) Impacts

1. Resource-Based Work, PE, and MP RVUs

Section 1848(c)(2)(B)(ii)(II) of the Act requires that increases or decreases in RVUs may not cause the amount of expenditures for the year to differ by more than $20 million from what expenditures would have been in the absence of these changes. If this threshold is exceeded, we make adjustments to preserve budget neutrality.

Our estimates of changes in Medicare revenues for PFS services compare payment rates for CY 2015 with proposed payment rates for CY 2016 using CY 2014 Medicare utilization. The payment impacts in this proposed rule reflect averages by specialty based on Medicare utilization. The payment impact for an individual physician could vary from the average and would depend on the mix of services the practitioner furnishes. The average percentage change in total revenues would be less than the impact displayed here because practitioners and other entities generally furnish services to both Medicare and non-Medicare patients. In addition, practitioners and other entities may receive substantial Medicare revenues for services under other Medicare payment systems. For instance, independent laboratories receive approximately 83 percent of their Medicare revenues from clinical laboratory services that are paid under the Clinical Lab Fee Schedule.

The annual update to the PFS conversion factor (CF) was previously calculated based on a statutory formula; for details about this formula, we refer readers to the CY 2015 PFS final rule with comment period (79 FR 67741 through 67742). The Medicare Access and CHIP Reauthorization Act (MACRA) of 2015 established the update factor for calendar years 2015 through 2025. To calculate the conversion factor for the update year, we multiply the product of the current year conversion factor and the update factor by the budget neutrality adjustment. We estimate the CY 2016 PFS conversion factor to be $36.1096, which reflects a budget neutrality adjustment of 0.9999 and the 0.5 percent update factor specified under MACRA. We estimate the CY 2016 anesthesia conversion factor to be $22.6296, which reflects the 0.9999 budget neutrality adjustment, a 0.99602 anesthesia fee schedule adjustment practice expense and malpractice adjustment, and the 0.5 percent update specified under the MACRA. We note that Section 220(d) of the PAMA added

a new paragraph at section 1848(c)(2)(O) of the Act to establish an annual target for reductions in PFS expenditures resulting from adjustments to relative values of misvalued codes. Under section 1848(c)(2)(O)(ii) of the Act, if the net reduction in expenditures for the year is equal to or greater than the target for the year, reduced expenditures attributable to such adjustments shall be redistributed in a budget-neutral manner within the PFS in accordance with the existing budget neutrality requirement under section 1848(c)(2)(B)(ii)(II) of the Act.

As we discuss in section II.F.4 of this proposed rule, because CY 2016 represents a transition year in our new process of proposing values for new, revised and misvalued codes in the proposed rule, rather than establishing them as interim final in the final rule with comment period, we will not be able to calculate a realistic estimate of the target amount at the time the proposed rule is published. Therefore, we did not incorporate the impact of the target into the calculation of the proposed conversion factor. However, we did estimate the net reduction in expenditures as a result of proposed adjustments to the relative value established for misvalued codes in this proposed rule, not including interim final changes that will be established in the CY 2016 PFS final rule. The net reduction is approximately 0.25 percent of the estimated amount of expenditures under the fee schedule for CY 2016.

Table 45 shows the payment impact on PFS services of the proposals contained in this proposed rule. To the extent that there are year-to-year changes in the volume and mix of services provided by practitioners, the actual impact on total Medicare revenues will be different from those shown in Table 45 (CY 2016 PFS Proposed Rule Estimated Impact on Total Allowed Charges by Specialty). The following is an explanation of the information represented in Table 45.

- *Column A (Specialty):* Identifies the specialty for which data is shown.
- *Column B (Allowed Charges):* The aggregate estimated PFS allowed charges for the specialty based on CY 2014 utilization and CY 2015 rates. That is, allowed charges are the PFS amounts for covered services and include coinsurance and deductibles (which are the financial responsibility of the beneficiary). These amounts have been summed across all services furnished by physicians, practitioners, and suppliers within a specialty to arrive at the total allowed charges for the specialty.
- *Column C (Impact of Work RVU Changes):* This column shows the estimated CY 2016 impact on total allowed charges of the proposed changes in the work RVUs, including the impact of changes due to potentially misvalued codes.
- *Column D (Impact of PE RVU Changes):* This column shows the estimated CY 2016 impact on total allowed charges of the proposed changes in the PE RVUs.
- *Column E (Impact of RVU Changes):* This column shows the estimated CY 2016 impact on total allowed charges of the proposed changes in the MP RVUs, which are primarily driven by the required five-year review and update of MP RVUs.
- *Column F (Combined Impact):* This column shows the estimated CY 2016 combined impact on total allowed charges of all the proposed changes in the previous columns. Column F may not equal the sum of columns C, D, and E due to rounding.

TABLE 45—CY 2016 PFS PROPOSED RULE ESTIMATED IMPACT ON TOTAL ALLOWED CHARGES BY SPECIALTY *

Specialty (A)	Allowed charges (mil) (B)	Impact of work RVU changes % (C)	Impact of PE RVU changes % (D)	Impact of MP RVU changes % (E)	Combined Impact ** % (F)
TOTAL	$88,408	0	0	0	0
ALLERGY/IMMUNOLOGY	220	0	1	0	1
ANESTHESIOLOGY	1,959	0	2	−2	0
AUDIOLOGIST	60	0	−1	1	−0
CARDIAC SURGERY	340	0	0	0	0
CARDIOLOGY	6,462	0	0	0	0
CHIROPRACTOR	781	0	0	0	0
CLINICAL PSYCHOLOGIST	713	0	0	0	0
CLINICAL SOCIAL WORKER	552	0	0	0	0
COLON AND RECTAL SURGERY	160	−1	0	−1	−1
CRITICAL CARE	293	0	0	0	0
DERMATOLOGY	3,207	0	0	0	1
DIAGNOSTIC TESTING FACILITY	719	0	1	0	1
EMERGENCY MEDICINE	3,099	0	0	0	0
ENDOCRINOLOGY	452	0	0	0	0
FAMILY PRACTICE	6,043	0	0	0	0
GASTROENTEROLOGY	1,829	−2	−1	−1	−5
GENERAL PRACTICE	471	0	0	0	0
GENERAL SURGERY	2,186	0	0	0	0
GERIATRICS	213	0	0	0	0
HAND SURGERY	169	0	1	0	1
HEMATOLOGY/ONCOLOGY	1,781	0	0	0	0
INDEPENDENT LABORATORY	823	1	8	0	9
INFECTIOUS DISEASE	655	0	0	0	0
INTERNAL MEDICINE	10,964	0	0	0	0
INTERVENTIONAL PAIN MGMT	715	0	1	0	1
INTERVENTIONAL RADIOLOGY	296	0	1	0	1
MULTISPECIALTY CLINIC/OTHER PHYS	95	0	0	0	0
NEPHROLOGY	2,187	0	0	0	0
NEUROLOGY	1,512	0	0	0	0
NEUROSURGERY	770	0	0	−1	−1
NUCLEAR MEDICINE	46	0	0	0	0

TABLE 45—CY 2016 PFS PROPOSED RULE ESTIMATED IMPACT ON TOTAL ALLOWED CHARGES BY SPECIALTY *—Continued

Specialty (A)	Allowed charges (mil) (B)	Impact of work RVU changes % (C)	Impact of PE RVU changes % (D)	Impact of MP RVU changes % (E)	Combined Impact ** % (F)
NURSE ANES/ANES ASST	1,181	0	2	−2	0
NURSE PRACTITIONER	2,528	0	0	0	0
OBSTETRICS/GYNECOLOGY	664	0	0	0	0
OPHTHALMOLOGY	5,490	0	0	0	0
OPTOMETRY	1,167	0	0	0	0
ORAL/MAXILLOFACIAL SURGERY	45	0	0	0	0
ORTHOPEDIC SURGERY	3,653	0	0	0	0
OTHER	25	0	0	0	0
OTOLARNGOLOGY	1,195	0	−1	0	0
PATHOLOGY	1,316	4	4	0	8
PEDIATRICS	59	0	0	0	0
PHYSICAL MEDICINE	1,027	0	0	0	0
PHYSICAL/OCCUPATIONAL THERAPY	3,077	0	0	0	0
PHYSICIAN ASSISTANT	1,716	0	0	0	0
PLASTIC SURGERY	371	0	0	0	1
PODIATRY	1,978	0	0	0	0
PORTABLE X-RAY SUPPLIER	103	0	0	0	0
PSYCHIATRY	1,300	0	0	0	0
PULMONARY DISEASE	1,769	0	0	0	0
RADIATION ONCOLOGY	1,769	0	−3	0	−3
RADIATION THERAPY CENTERS	52	0	−9	0	−9
RADIOLOGY	4,472	0	0	0	0
RHEUMATOLOGY	534	0	0	0	0
THORACIC SURGERY	346	0	0	0	0
UROLOGY	1,789	0	0	0	0

** Column F may not equal the sum of columns C, D, and E due to rounding.

2. CY 2016 PFS Impact Discussion

a. Changes in RVUs

The most widespread specialty impacts of the RVU changes are generally related to two major factors. The first factor, as discussed in section II. of this proposed rule, is the number of changes to RVUs for specific services resulting from the Misvalued Code Initiative, including the establishment of RVUs for new and revised codes. Several specialties, including radiation therapy centers, radiation oncology, and gastroenterology, will experience significant decreases to payments to services that they frequently furnish as a result of widespread revisions to the structure and the inputs used to develop RVUs for the codes that describe particular services. Other specialties, including pathology and independent laboratories, will experience significant increases to payments for similar reasons.

The second factor relates to a technical improvement that refines the MP RVU methodology, which we are proposing to make as part of our annual update of malpractice RVUs. This technical improvement will result in small negative impacts to the portion of PFS payments attributable to malpractice for gastroenterology, colon and rectal surgery, and neurosurgery.

b. Combined Impact

Column F of Table 45 displays the estimated CY 2016 combined impact on total allowed charges by specialty of all the proposed RVU changes. Table 46 (Impact of Proposed Rule on CY 2016 Payment for Selected Procedures) shows the estimated impact on total payments for selected high volume procedures of all of the proposed changes. We selected these procedures for sake of illustration from among the most commonly furnished by a broad spectrum of specialties. The change in both facility rates and the nonfacility rates are shown. For an explanation of facility and nonfacility PE, we refer readers to Addendum A found on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/*.

TABLE 46—IMPACT OF PROPOSED RULE ON CY 2016 PAYMENT FOR SELECTED PROCEDURES

CPT/HCPCS [1]	MOD	Short descriptor	Facility			Non Facility		
			CY 2015 [2]	CY 2016 [3]	% Change	CY 2015 [2]	CY 2016 [3]	% Change
11721		Debride nail 6 or more	$25.15	$25.64	2	$45.28	$46.22	2
17000		Destruct premalg lesion	53.90	54.88	2	67.20	68.24	2
27130		Total hip arthroplasty	1,407.87	1,411.02	0	NA	NA	NA
27244		Treat thigh fracture	1,277.80	1,285.37	1	NA	NA	NA
27447		Total knee arthroplasty	1,407.52	1,411.38	0	NA	NA	NA
33533		Cabg arterial single	1,952.63	1,963.08	1	NA	NA	NA
35301		Rechanneling of artery	1,203.41	1,204.14	0	NA	NA	NA

TABLE 46—IMPACT OF PROPOSED RULE ON CY 2016 PAYMENT FOR SELECTED PROCEDURES—Continued

CPT/ HCPCS [1]	MOD	Short descriptor	Facility			Non Facility		
			CY 2015 [2]	CY 2016 [3]	% Change	CY 2015 [2]	CY 2016 [3]	% Change
43239		Egd biopsy single/multiple	154.15	152.72	−1	412.52	409.80	−1
66821		After cataract laser surgery	316.21	318.10	1	334.90	336.87	1
66984		Cataract surg w/iol 1 stage	650.40	646.65	−1	NA	NA	NA
67210		Treatment of retinal lesion	508.82	513.07	1	526.79	531.12	1
71010		Chest x-ray 1 view frontal	NA	NA	NA	22.64	22.75	0
71010	26	Chest x-ray 1 view frontal	9.34	9.39	1	9.34	9.39	1
77056		Mammogram both breasts	NA	NA	NA	116.42	117.35	1
77056	26	Mammogram both breasts	44.56	44.78	0	44.56	44.78	0
77057		Mammogram screening	NA	NA	NA	83.01	83.40	0
77057	26	Mammogram screening	35.93	36.11	0	35.93	36.11	0
77427		Radiation tx management x5	187.57	196.42	5	187.57	196.42	5
88305	26	Tissue exam by pathologist	39.17	39.72	1	39.17	39.72	1
90935		Hemodialysis one evaluation	73.66	74.01	0	NA	NA	NA
92012		Eye exam establish patient	53.18	53.79	1	86.24	86.65	0
92014		Eye exam&tx estab pt 1/>vst	80.85	81.24	0	124.69	125.65	1
93000		Electrocardiogram complete	NA	NA	NA	17.25	16.97	−2
93010		Electrocardiogram report	8.62	8.67	1	8.62	8.67	1
93015		Cardiovascular stress test	NA	NA	NA	77.26	76.54	−1
93307	26	Tte w/o doppler complete	45.99	46.22	0	45.99	46.22	0
93458	26	L hrt artery/ventricle angio	323.76	324.96	0	323.76	324.96	0
98941		Chiropract manj 3–4 regions	35.21	35.03	−1	41.32	41.53	0
99203		Office/outpatient visit new	77.98	78.35	0	109.60	110.12	0
99213		Office/outpatient visit est	51.38	51.99	1	73.30	74.01	1
99214		Office/outpatient visit est	79.41	79.43	0	108.88	109.04	0
99222		Initial hospital care	139.06	139.01	0	NA	NA	NA
99223		Initial hospital care	205.90	205.80	0	NA	NA	NA
99231		Subsequent hospital care	39.53	40.08	1	NA	NA	NA
99232		Subsequent hospital care	73.30	73.65	0	NA	NA	NA
99233		Subsequent hospital care	105.64	105.79	0	NA	NA	NA
99236		Observ/hosp same date	220.99	220.97	0	NA	NA	NA
99239		Hospital discharge day	108.88	109.04	0	NA	NA	NA
99283		Emergency dept visit	62.88	63.18	0	NA	NA	NA
99284		Emergency dept visit	119.66	119.87	0	NA	NA	NA
99291		Critical care first hour	227.46	227.83	0	279.20	279.82	0
99292		Critical care addl 30 min	113.55	114.10	0	124.33	125.29	1
99348		Home visit est patient	NA	NA	NA	84.80	85.57	1
99350		Home visit est patient	NA	NA	NA	178.95	180.17	1
G0008		Immunization admin	NA	NA	NA	25.51	25.64	0

[1] CPT codes and descriptions are copyright 2015 American Medical Association. All Rights Reserved. Applicable FARS/DFARS apply.
[2] Payments based on the 2015 conversion factor of 35.9335.
[3] Payments based on the estimated 2016 conversion factor of $36.1096.

D. Effect of Proposed Changes in Telehealth List

As discussed in section II.E. of this proposed rule, we are proposing to add several new codes to the list of Medicare telehealth services. Although we expect these changes to increase access to care in rural areas, based on recent utilization of similar services already on the telehealth list, we estimate no significant impact on PFS expenditures from the proposed additions.

E. Other Provisions of the Proposed Regulation

1. Ambulance Fee Schedule

As discussed in section III.A.2 of this proposed rule, section 203 of the Medicare Access and CHIP Reauthorization Act of 2015 amended section 1834(l)(12)(A) and (l)(13)(A) of the Act to extend the payment add-ons set forth in those subsections through December 31, 2017. These statutory ambulance extender provisions are self-implementing. As a result, there are no policy proposals associated with these provisions or associated impact in this rule. We are proposing only to correct the dates in the Code of Federal Regulations (CFR) at § 414.610(c)(1)(ii) and § 414.610(c)(5)(ii) to conform the regulations to these self-implementing statutory provisions.

For CY 2016 and subsequent CYs, we are proposing to continue implementation of the revised OMB delineations and the most recent modifications of the RUCA codes for purposes of payment under the ambulance fee schedule, as originally finalized and implemented in the CY 2015 PFS final rule with comment period as corrected (79 FR 67744 through 67750; 79 FR 78716 through 78719). The proposed continued use of the revised OMB delineations and the updated RUCA codes for CY 2016 and subsequent CYs would mean the continued recognition of urban and rural boundaries based on the population migration that occurred over a 10-year period, between 2000 and 2010. For the RUCA codes, we would continue to designate any census tracts falling at or above RUCA level 4.0 as rural areas. In addition, none of the super rural areas would lose their status based on our continued implementation of the revised OMB delineations and updated RUCA codes. As discussed in section III.A.3. of this proposed rule, the implementation of the revised OMB delineations and updated RUCA codes for CY 2016 and subsequent CYs would continue to affect whether certain areas are designated as urban or rural, and whether or not transports would be

eligible for rural adjustments under the ambulance fee schedule statute and regulations. Descriptions of our proposals and accompanying rationale are set forth in more detail in section III.A.3. of this proposed rule. We estimate that our proposal to continue implementation of the revised OMB delineations and updated RUCA codes for CY 2016 and subsequent CYs would result in a minimal fiscal impact on the Medicare program as compared to CY 2015. We also estimate that our continued implementation of these geographic delineations would result in a minimal fiscal impact on ambulance providers and suppliers as compared to CY 2015, because we would be continuing implementation of the same revised OMB delineations and updated RUCA codes that were in effect in CY 2015. We note that there may be minimal impacts due to changes in ZIP codes based on updates by the USPS that we receive every two months.

As previously discussed in this section, most providers and suppliers, including ambulance companies, are small entities, either by their nonprofit status or by having annual revenues that qualify for small business status under the Small Business Administration standards. Although, we do not believe that the proposed continued implementation of the revised OMB delineations and updated RUCA codes would have a significant economic impact on ambulance providers and suppliers as compared to CY 2015, we have included an analysis in section III.A.3. of this proposed rule describing certain impacts associated with implementation of these geographic delineations and have invited public comments on any alternative methods for implementing the revised OMB delineations and the updated RUCA codes. As further discussed in section III.A.3. of this proposed rule, Table 16 sets forth an analysis of the number of ZIP codes that changed urban and rural status in each U.S. state and territory after CY 2014 due to our implementation of the revised OMB delineations and updated RUCA codes, using an updated April 2015 USPS ZIP code file, the revised OMB delineations, and the updated RUCA codes (including the RUCA ZIP code approximation file discussed in that section).

In addition, we are proposing to revise § 410.41(b) to require that all Medicare-covered ambulance transports must be staffed by at least two people who meet both the requirements of applicable state and local laws where the services are being furnished and the current Medicare requirements under § 410.41(b). In addition, we are proposing to revise the definition of Basic Life Support (BLS) in § 414.605 to include the proposed revised staffing requirements discussed in this section for § 410.41(b). Since we expect ambulance providers and suppliers are already in compliance with their state and local laws, we expect that this proposal would have a minimal impact on ambulance providers and suppliers. Similarly, we do not expect any significant impact on the Medicare program.

Furthermore, we are proposing to revise § 410.41(b) and the definition of BLS in § 414.605 to clarify that, for BLS vehicles, at least one of the staff members must be certified at a minimum as an EMT-Basic, which we believe would more clearly state our current policy. Also, for the reasons discussed in section III.A.4. of this proposed rule, we are proposing to delete the last sentence of our definition of BLS in § 414.605. Because these proposals do not change our current policies, we expect that they would have a minimal impact on ambulance providers and suppliers and do not expect any significant impact on the Medicare program.

2. Chronic Care Management (CCM) Services for Rural Health Clinics (RHCs) and Federally Qualified Health Centers (FQHCs)

As discussed in section III.B of this proposed rule, we are proposing to establish payment, beginning on January 1, 2016, for RHCs and FQHCs who furnish a minimum of 20 minutes of qualifying CCM services during a calendar month to patients with multiple (two or more) chronic conditions that are expected to last at least 12 months or until the death of the patient, and that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline. We also are proposing that payment for CCM be based on the PFS national average non-facility payment rate when CPT code 99490 is billed alone or with other payable services on a RHC or FQHC claim.

In the CY 2015 PFS final rule (79 FR 67715 through 67730), we estimated that 65 percent of Medicare beneficiaries in fee-for-service practices had 2 or more chronic conditions, and that 30 percent of those beneficiaries would choose to receive CCM services. We also estimated that for those patients, there would be an average of 6 CCM billable payments per year.

We do not have the data to determine the percentage of Medicare beneficiaries in RHCs or FQHCs with 2 or more chronic conditions, but we have no reason to believe that the percentage would be different for patients in a RHC or FQHC. We also assume that the rate of acceptance, and the number of billable visits per year, would be the same for RHCs and FQHCs as it is for practitioners in non-RHC and FQHC settings that are billing under the PFS.

Based on these assumptions, we estimate that the 5-year cost impact of CCM payment in RHCs and FQHCs would be $ 850 million, of which $210 million is the premium offset and $640 million is the Part B payment. We estimate that the 10-year cost impact of CCM payment in RHCs and FQHCs would be $1.970 billion, of which $480 million is the premium offset and $1.490 billion is the Part B payment.

These estimates were derived by first multiplying the number of Medicare beneficiaries in RHCs and FQHCs per year by 0.65 percent, (the estimated percentage of Medicare beneficiaries with 2 or more chronic conditions). This number was then multiplied by 0.30 (the estimated percentage of Medicare beneficiaries with 2 or more chronic conditions that will choose to receive CCM services). This number was then multiplied by $42.91 (the national average payment rate per beneficiary per calendar month). Finally, this number was multiplied by 6 (the estimated number of CCM payments per beneficiary receiving CCM services). Table 47 provides the yearly estimates (figures are in millions):

TABLE 47—YEARLY ESTIMATES

[In millions]

	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	5 Year impact 2016–2020	10 Year impact 2016–2025
FY Cash Impact—Part B:												
Benefits	$90	$170	$190	$200	$200	$210	$220	$220	$230	$230	$850	$1,970

TABLE 47—YEARLY ESTIMATES—Continued
[In millions]

	2016	2017	2018	2019	2020	2021	2022	2023	2024	2025	5 Year impact 2016–2020	10 Year impact 2016–2025
Premium Offset	−20	−40	−50	−50	−50	−50	−50	−50	−50	−60	−210	−480
Total Part B	70	130	140	150	150	160	170	170	170	180	640	1,490

3. Healthcare Common Procedure Coding System (HCPCS) Coding for Rural Health Clinics (RHCs)

As discussed in section III.C. of this proposed rule, we are proposing to require HCPCS coding for all services furnished by RHCs to Medicare beneficiaries effective for dates of service on or after January 1, 2016. There will be no cost impact on the Medicare program since this proposal does not change the payment methodology for RHC services. This proposal would necessitate some RHCs to make changes to their billing practices; however, we estimate no significant cost impact on RHCs.

4. Payment to Grandfathered Tribal FQHCs That Were Provider-Based Clinics on or Before April 7, 2000

As discussed in section III.D. of this proposed rule, we are proposing that clinics that were provider-based to an IHS hospital on or before April 7, 2000, and are now tribally-operated clinics contracted or compacted under the ISDEAA, may seek to become certified as grandfathered tribal FQHCs. We also propose that these grandfathered tribal FQHCs retain their Medicare outpatient per visit payment rate, as set annually by the IHS, rather than the FQHC PPS per visit base rate of $158.85. Since we are not proposing any changes to their payment rate, there will be no cost impact as a result of this proposal.

5. Part B Drugs—Payment for Biosimilar Biological Products Under Section 1847A

In section III.E. of this rule we discussed the payment of biosimilar biological products under section 1847A of the Act and proposed to clarify existing regulation text. The updated regulation text states that the payment amount for a biosimilar biological product is based on the average sales prices (ASP) of all NDCs assigned to the biosimilar biological products included within the same billing and payment code.

We anticipate that biosimilar biological products will have lower ASPs than the corresponding reference products, and we expect the Medicare Program will realize savings from the utilization of biosimilar biological products. However, at the time of writing this proposed rule, we have not yet received ASP data for any biosimilar biological products that have been approved under the FDA's biosimilar approval pathway. Further, it is not clear how many biosimilar products will be approved, when approval and marketing of various products will occur, what the market penetration of biosimilars in Medicare will be, and what the cost differences between the biosimilars as well as the price differences between the biosimilars and the reference products will be. Therefore, using available data, we are not able to quantify with certainty the potential savings to Medicare part B. Similarly, we are not able to quantify the impact, if any, on physician offices that administer biosimilar biological products.

6. Appropriate Use Criteria for Advanced Diagnostic Imaging Services

We are proposing and requesting public comment on Appropriate Use Criteria development process requirements as well as an application process that organizations must comply with to become qualified provider-led entities. These proposals would not impact CY 2016 physician payments under the PFS.

7. Oncology Care Model and Overlap With Care Management Services Under PFS

The participation requirements and financial incentives of the Oncology Care Model (OCM) are outlined in the model's Request for Applications (*http://innovation.cms.gov/initiatives/Oncology-Care/*) and in the model's announcement in the **Federal Register** on February 17, 2015 (80 FR 8323). The proposals for OCM set forth in the CY 2016 MPFS proposed rule articulate restrictions in OCM providers' ability to bill the model's Per-Beneficiary-Per-Month (PBPM) fee and for other MPFS care coordination services in the same month for the same beneficiary, given that the enhanced services required of each overlap in scope. Since the proposed policies are designed to limit the likelihood that Medicare double pays for similar services, these proposals are not expected to have a fiscal impact on the Medicare program.

8. Physician Compare

We do not estimate any impact as a result of the proposals for the Physician Compare Web site.

9. Physician Quality Reporting System

a. Burden Estimate for PQRS Reporting by Individual Eligible Professionals: Reporting in General

According to the 2013 Reporting Experience, ''more than 1.25 million eligible professionals were eligible to participate in the 2013 PQRS, Medicare Shared Savings Program, and Pioneer ACO Model.'' [10] In this burden estimate, we assume that 1.25 million eligible professionals, the same number of eligible professionals eligible to participate in the PQRS in 2013, will be eligible to participate in the PQRS. Since all eligible professionals are subject to the 2018 PQRS payment adjustment, we estimate that ALL 1.25 million eligible professionals will participate in the PQRS in 2016 for purposes of meeting the criteria for satisfactory reporting (or, in lieu of satisfactory reporting, satisfactory participation in a QCDR) for the 2018 PQRS payment adjustment.

Historically, the PQRS has never experienced 100 percent participation in reporting for the PQRS. In the 2013 PQRS and eRx Reporting Experience Report more than 1.25 million professionals were eligible to participate in the 2013 PQRS (including group practices reporting under the GPRO, Medicare Shared Savings Program, and Pioneer ACO Model). Therefore, we believe that although 1.25 million eligible professionals will be subject to the 2018 PQRS payment adjustment, not all eligible participants will actually report quality measures data for purposes of the 2018 PQRS payment adjustment. In this burden estimate, we will only provide burden estimates for the eligible professionals and group

[10] Centers for Medicare and Medicaid Services, *2012 Reporting Experience Including Trends (2007–2013): Physician Quality Reporting System and Electronic Prescribing (eRx) Incentive Program,* March 14, 2014, at xiii.

practices who attempt to submit quality measures data for purposes of the 2018 PQRS payment adjustment.

In 2013, 641,654 eligible professionals (51 percent) eligible professionals (including those who belonged to group practices that reported under the GPRO and eligible professionals within an ACO that participated in the PQRS via the GPRO) participated in the PQRS, Medicare Shared Savings Program, or Pioneer ACO Model.[11] We expect to see a steady increase in participation in reporting for the PQRS in 2016 than 2013. Eligible professionals have become more familiar with the PQRS payment adjustments since eligible professionals are currently experiencing the implementation of the first PQRS payment adjustment—the 2015 PQRS payment adjustment. Therefore, we estimate that we will see a 70 percent participation rate in 2016. Therefore, we estimate that 70 percent of eligible professionals (or approximately 875,000 eligible professionals) will report quality measures data for purposes of the 2018 PQRS payment adjustment.

With respect to the PQRS, the burden associated with the requirements of this voluntary reporting initiative is the time and effort associated with individual eligible professionals and group practices identifying applicable quality measures for which they can report the necessary information, selecting a reporting option, and reporting the information on their selected measures or measures group to CMS using their selected reporting option. We assume that most eligible professionals participating in the PQRS will attempt to meet both the criteria for satisfactory reporting for the 2018 PQRS payment adjustment.

We believe the labor associated with eligible professionals and group practices reporting quality measures data in the PQRS is primarily handled by an eligible professional's or group practice's billing clerk or computer analyst trained to report quality measures data. Therefore, we will consider the hourly wage of a billing clerk and computer analyst in our estimates. For purposes of this burden estimate, we will assume that a billing clerk will handle the administrative duties associated with participating in the PQRS.

For individual eligible professionals, the burden associated with the requirements of this reporting initiative is the time and effort associated with eligible professionals identifying applicable quality measures for which they can report the necessary information, collecting the necessary information, and reporting the information needed to report the eligible professional's measures. We believe it is difficult to accurately quantify the burden because eligible professionals may have different processes for integrating the PQRS into their practice's work flows. Moreover, the time needed for an eligible professional to review the quality measures and other information, select measures applicable to his or her patients and the services he or she furnishes to them, and incorporate the use of quality data codes into the office work flows is expected to vary along with the number of measures that are potentially applicable to a given professional's practice. Since eligible professionals are generally required to report on at least 9 measures covering at least 3 National Quality Strategy domains criteria for satisfactory reporting (or, in lieu of satisfactory reporting, satisfactory participation in a QCDR) for the 2018 PQRS payment adjustment, we will assume that each eligible professional reports on an average of 9 measures for this burden analysis.

For eligible professionals who are participating in PQRS, we will assign 5 total hours as the amount of time needed for an eligible professional's billing clerk to review the PQRS Measures List, review the various reporting options, select the most appropriate reporting option, identify the applicable measures or measures groups for which they can report the necessary information, review the measure specifications for the selected measures or measures groups, and incorporate reporting of the selected measures or measures groups into the office work flows. The measures list contains the measure title and brief summary information for the eligible professional to review. Assuming the eligible professional has received no training from his/her specialty society, we estimate it will take an eligible professional's billing clerk up to 2 hours to review this list, review the reporting options, and select a reporting option and measures on which to report. If an eligible professional has received training, then we believe this would take less time. CMS believes 3 hours is plenty of time for an eligible professional to review the measure specifications of 9 measures or 1 measures group they select to report for purposes of participating in PQRS and to develop a mechanism for incorporating reporting of the selected measures or measures groups into the office work flows. Therefore, we believe that the start-up cost for an eligible professional to report PQRS quality measures data is 5 hr × $26.68/hr = $127.25.

We continue to expect the ongoing costs associated with PQRS participation to decline based on an eligible professional's familiarity with and understanding of the PQRS, experience with participating in the PQRS, and increased efforts by CMS and stakeholders to disseminate useful educational resources and best practices.

We believe the burden associated with actually reporting the quality measures will vary depending on the reporting mechanism selected by the eligible professional. As such, we break down the burden estimates by eligible professionals and group practices participating in the GPRO according to the reporting mechanism used.

b. Burden Estimate for PQRS Reporting by Individual Eligible Professionals: Claims-Based Reporting Mechanism

According to the 2011 PQRS and eRx Experience Report, 229,282 of the 320,422 eligible professionals (or 72 percent) of eligible professionals used the claims-based reporting mechanism. According to the 2012 Reporting Experience, 248,206 eligible professionals participated in the PQRS using the claims-based reporting mechanism in 2012.[12] According to the 2013 PQRS and eRx Experience Report, 641,654 eligible professionals participated as individuals or group practices through one of the PQRS reporting mechanism, a 47 percent increase from those that participated in 2012 (435,931). Through the individual claims-based reporting mechanism, 331,668 of those eligible professionals (or 52 percent) reported using this mechanism. Increased claims based reporting to 350,000 (approximately 5 percent increase over 2013). Though claims reporting was declining, we did see an increase in 2013 once the payment adjustment was applied to all participants, so we assume a slight increase in 2016.

According to the historical data cited above, although the claims-based reporting mechanism is still the most widely-used reporting mechanism, we are seeing a decline in the use of the claims-based reporting mechanism in the PQRS. There was a slight increase in 2013, which may be reflected by the use of administrative claims-based reporting mechanism by individual eligible professionals and group practices only

[11] Id. at XV.

[12] Id. at xvi. *See* Figure 4.

for the 2015 PQRS payment adjustment (in CY2013).

Although these eligible professionals continue to participate in the PQRS, these eligible professionals have started to shift towards the use of other reporting mechanisms—mainly the GPRO web interface (whether used by a PQRS GPRO or an ACO participating in the PQRS via the Medicare Shared Savings Program), registry, or the EHR-based reporting mechanisms. For purposes of this burden estimate, based on PQRS participation using the claims-based reporting mechanism in 2012 and 2013, we will assume that approximately 350,000 eligible professionals will participate in the PQRS using the claims-based reporting mechanism.

For the claims-based reporting option, eligible professionals must gather the required information, select the appropriate quality data codes (QDCs), and include the appropriate QDCs on the claims they submit for payment.

We estimate the cost for an eligible professional to review the list of quality measures or measures groups, identify the applicable measures or measures groups for which they can report the necessary information, incorporate reporting of the selected measures into the office work flows, and select a PQRS reporting option to be approximately *$419.80* per eligible professional ($83.96 per hour × 5 hours).

Based on our experience with the Physician Voluntary Reporting Program (PVRP), we continue to estimate that the time needed to perform all the steps necessary to report each measure (that is, reporting the relevant quality data code(s) for 9 measures measure) would range from 15 seconds (0.25 minutes) to over 12 minutes for complicated cases and/or measures, with the median time being 1.75 minutes. To report 9 measures, we estimate that it would take approximately 2.25 minutes to 108 minutes to perform all the steps necessary to report 9 measures.

Per measure, at an average labor cost of $83.96/hour per practice, the cost associated with this burden will range from $0.17 in labor to about $8.40 in labor time for more complicated cases and/or measures, with the cost for the median practice being $1.20. To report 9 measures, using an average labor cost of $42/hour, we estimated that the time cost of reporting for an eligible professional via claims would range from *$3.15* (2.25 minutes or 0.0375 hours × $83.96/hour) to $151.13 (108 minutes or 1.8 hours × $83.96/hour) per reported case.

The total estimated annual burden for this requirement will also vary along with the volume of claims on which quality data is reported. In previous years, when we required reporting on 80 percent of eligible cases for claims-based reporting, we found that on average, the median number of reporting instances for each of the PQRS measures was 9. Since we reduced the required reporting rate by over one-third to 50 percent, then for purposes of this burden analysis we will assume that an eligible professional or eligible professional in a group practice will need to report each selected measure for 6 reporting instances. The actual number of cases on which an eligible professional or group practice is required to report quality measures data will vary, however, with the eligible professional's or group practice's patient population and the types of measures on which the eligible professional or group practice chooses to report (each measure's specifications includes a required reporting frequency). For the 2018 payment adjustment, EPs will also report on 1 cross-cutting measure if they see at least 1 Medicare patient. However, we do not see any additional burden impact as they are still reporting on the same number of measures.

c. Burden Estimate for PQRS Reporting by Individual Eligible Professionals and Group Practices: Qualified Registry-Based and Qualified Clinical Data Registry (QCDR)-Based Reporting Mechanisms

In 2011, approximately 50,215 (or 16 percent) of the 320,422 eligible professionals participating in PQRS used the qualified registry-based reporting mechanism. In 2012, 36,473 eligible professionals reported individual measures via the registry-based reporting mechanism, and 10,478 eligible professionals reporting measures groups via the registry-based reporting mechanism in 2012.[13] According to the 2013 Reporting Experience, approximately 67,896 eligible professionals participated in the PQRS using the registry-based reporting mechanism (51,473 for individual measures and 16,423 for measures groups). Please note that we currently have no data on participation in the PQRS via a Qualified Clinical Data Registry (QCDR), as 2014 is the first year in which an eligible professional may participate in the PQRS via a QCDR.

We believe that the rest of the eligible professionals not participating in other PQRS reporting mechanisms will use either the registry or QCDR reporting mechanisms for the following reasons:

- The PQRS measures set is moving away from use of claims-based measures and moving towards the use of registry-based measures
- We believe the number of QCDR vendors will increase as the QCDR reporting mechanism evolves.

Therefore, based on these assumptions, we expect to see a significant jump from 47,000 eligible professionals to approximately 212,000 eligible professionals using either the registry-based reporting mechanism or QCDR in 2016. We believe the majority of these eligible professionals will participate in the PQRS using a QCDR, as we presume QCDRs will be larger entities with more members.

For qualified registry-based and QCDR-based reporting, there will be no additional time burden for eligible professionals or group practices to report data to a qualified registry as eligible professionals and group practices opting for qualified registry-based reporting or use of a QCDR will more than likely already be reporting data to the qualified registry for other purposes and the qualified registry will merely be repackaging the data for use in the PQRS. Little, if any, additional data will need to be reported to the qualified registry or QCDR solely for purposes of participation in the PQRS. However, eligible professionals and group practices 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 CMS on their behalf. We estimate that the time and effort associated with this will be approximately 5 minutes per eligible professional or eligible professional within a group practice.

Please note that, unlike the claims-based reporting mechanism that would require an eligible professional to report data to CMS on quality measures on multiple occasions, an eligible professional would not be required to submit this data to CMS, as the qualified registry or QCDR would perform this function on the eligible professional's behalf.

For CY 2014, 90 qualified registries and 50 QCDRs were qualified to report quality measures data to CMS for purposes of the PQRS.[14] Therefore, a total of 140 entities are currently classified as qualified registries and/or QCDRs under the PQRS. Although we believe the number of qualified registries will remain the same in 2015,

[13] Id. at xvi. *See* Figure 4.

[14] The full list of qualified registries for 2014 is available at *http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/PQRS/Downloads/2014QualifiedRegistryVendors.pdf.*

we believe we will see a slight increase in the number of entities that become a QCDR in 2015. We estimate that an additional 10 entities (bringing the total number of QCDRs to 60 in 2015) will become QCDRs in 2015. We attribute this slight increase to entities that wish to become QCDRs but, for some reason (lack of information regarding the QCDR option, rejected during the qualification process, the inability to get its self-nomination info provided in time, etc.), were not selected to be QCDRs in 2014. Therefore, we estimate that a total of 150 entities will become qualified registries and/or QCDRs under the PQRS in 2015.

Qualified registries or QCDRs interested in submitting quality measures results and numerator and denominator data on quality measures to CMS on their participants' behalf will need to complete a self-nomination in order to be considered qualified to submit on behalf of eligible professionals or group practices unless the qualified registry or clinical data qualified registry was qualified to submit on behalf of eligible professionals or group practices for prior program years and did so successfully. We estimate that the self-nomination process for qualifying additional qualified registries or qualified clinical data registries to submit on behalf of eligible professionals or group practices for the PQRS will involve approximately 1 hour per qualified registry or qualified clinical data registry to draft the letter of intent for self-nomination.

In addition to completing a self-nomination statement, qualified registries and QCDRs will need to perform various other functions, such as develop a measures flow and meet with CMS officials when additional information is needed. In addition, QCDRs must perform other functions, such as benchmarking and calculating their measure results. We note, however, that many of these capabilities may already be performed by QCDRs for purposes other than to submit data to CMS for the PQRS. 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 PQRS qualified entity.

We estimate that the staff involved in the qualified registry or QCDR self-nomination process will have an average labor cost of $83.96/hour. Therefore, assuming the total burden hours per qualified registry or QCDR associated with the self-nomination process is 10 hours, we estimate that the total cost to a qualified registry or QCDR associated with the self-nomination process will be approximately $839.60 ($83.96 per hour × 10 hours per qualified registry).

The burden associated with the qualified registry-based and QCDR reporting requirements of the PQRS will be the time and effort associated with the qualified registry calculating quality measures results from the data submitted to the qualified registry or QCDR by its participants and submitting the quality measures results and numerator and denominator data on quality measures to CMS on behalf of their participants. We expect that the time needed for a qualified registry or QCDR to review the quality measures and other information, calculate the measures results, and submit the measures results and numerator and denominator data on the quality measures on their participants' behalf will vary along with the number of eligible professionals reporting 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. Therefore, there may not necessarily be a burden on a particular qualified registry or QCDR associated with calculating the measure results and submitting the measures results and numerator and denominator data on the quality measures to CMS on behalf of their participants. Whether there is any additional burden to the qualified registry or QCDR as a result of the qualified registry's or QCDR's participation in the PQRS will depend on the number of measures that the qualified registry or QCDR intends to report to CMS and how similar the qualified registry's measures are to CMS's PQRS measures.

In this proposed rule, we are proposing that group practices of 25 or more eligible professionals must report on CAHPS for PQRS. Therefore, a group practice of 25 or more eligible professionals would be required to report on the CAHPS for PQRS, 6 or more measures covering 2 domains of their choosing. At this point, we do not believe the requirement to report CAHPS for PQRS adds or reduces the burden to the group practices, as we consider reporting the CAHPS for PQRS survey as reporting 3 measures covering 1 domain.

d. Burden Estimate for PQRS Reporting by Individual Eligible Professionals and Group Practices: EHR-Based Reporting Mechanism

According to the 2011 PQRS and eRx Experience Report, 560 (or less than 1 percent) of the 320,422 eligible professionals participating in PQRS used the EHR-based reporting mechanism. In 2012 there was a sharp increase in reporting via the EHR-based reporting mechanism. Specifically, according to the 2012 Reporting Experience, 19,817 eligible professionals submitted quality data for the PQRS through a qualified EHR.[15] According to the 2013 PQRS and eRx Experience Report, 23,194 (3.6 percent) eligible professionals participating in PQRS used the EHR-based reporting mechanism.

As can be seen in the 2013 Experience Report, the number of eligible professionals and group practices using the EHR-based reporting mechanism are steadily increasing as eligible professionals become more familiar with EHR products and more eligible professionals participate in programs encouraging use of an EHR, such as the EHR Incentive Program. In particular, we believe eligible professionals will transition from using the claims-based to the EHR-based reporting mechanisms. To account for this anticipated increase, we continue to estimate that approximately 50,000 eligible professionals, whether participating as an individual or part of a group practice under the GPRO, would use the EHR-based reporting mechanism in CY 2016.

For EHR-based reporting, which includes EHR reporting via a direct EHR product and an EHR data submission vendor's product, the eligible professional or group practice must review the quality measures on which we will be accepting PQRS data extracted from EHRs, select the appropriate quality measures, extract the necessary clinical data from his or her EHR, and submit the necessary data to the CMS-designated clinical data warehouse.

For EHR-based reporting for the PQRS, the individual eligible professional or group practice may either submit the quality measures data directly to CMS from their EHR or utilize an EHR data submission vendor to submit the data to CMS on the eligible professional's or group practice's behalf. To submit data to CMS directly from their EHR, the eligible professional or eligible professional in a group practice must have access to a

[15] Id. at XV.

CMS-specified identity management system, such as IACS, which we believe takes less than 1 hour to obtain. Once an eligible professional or eligible professional in a group practice has an account for this CMS-specified identity management system, he or she will need to extract the necessary clinical data from his or her EHR, and submit the necessary data to the CMS-designated clinical data warehouse. With respect to submitting the actual data file for the respective reporting period, we believe that this will take an eligible professional or group practice no more than 2 hours, depending on the number of patients on which the eligible professional or group practice is submitting. We believe that once the EHR is programmed by the vendor to allow data submission to CMS, the burden to the eligible professional or group practice associated with submission of data on quality measures should be minimal as all of the information required to report the measure should already reside in the eligible professional's or group practice's EHR.

In this proposed rule, we are proposing that group practices of 25 or more eligible professionals must report on CAHPS for PQRS. Therefore, a group practice of 25 or more eligible professionals would be required to report on the CAHPS for PQRS, 6 or more measures covering 2 domains of their choosing. At this point, we do not believe the requirement to report CAHPS for PQRS adds or reduces the burden to the group practices, as we consider reporting the CAHPS for PQRS survey as reporting 3 measures covering 1 domain.

Please note that, unlike the claims-based reporting mechanism that would require an eligible professional to report data to CMS on quality measures on multiple occasions, an eligible professional would not be required to submit this data to CMS, as the EHR product would perform this function on the eligible professional's behalf.

e. Burden Estimate for PQRS Reporting by Group Practices Using the GPRO Web Interface

As noted in the 2011 Experience Report, approximately 200 group practices participated in the GPRO in 2011. According to the 2012 Reporting Experience, 66 practices participated in the PQRS GPRO.[16] In addition, 144 ACOs participated in the PQRS GPRO through either the Medicare Shared Savings Program (112 ACOs) or Pioneer ACO Model (32 practices).[17] These group practices encompass 134,510 eligible professionals (or approximately 140,000 eligible professionals).[18] According to the 2013 PQRS and eRx Experience Report, 677 group practices self-nominated to participate via the PQRS GPRO (compared to 68 total that self-nominated in 2012), 550 moved on to become PQRS group practices, another 220 practices were approved by CMS to participate as Medicare MSSP ACOs, and 23 were eligible under the Pioneer ACO model. The number of eligible professionals (from the 2013 Experience Report) participating in one of these reporting methods include: 131,690 in PQRS group practices, 21,678 in Pioneer ACO, and 85,059 in MSSP ACO. Group practices participating in PQRS GPRO are increasing each year, from roughly 200 group practices in 2011 and 2012, to 860 eligible practices in 2013 (including all GPRO, Pioneer ACO, and MSSP ACO. However, not all group practices use the Web Interface to report. We will assume, based on these numbers that 500 group practices (accounting for approximately 228,000 eligible professional) will continue to participate in the PQRS using the GPRO Web Interface in 2016.

With respect to the process for group practices to be treated as satisfactorily submitting quality measures data under the PQRS, group practices interested in participating in the PQRS through the group practice reporting option (GPRO) must complete a self-nomination process similar to the self-nomination process required of qualified registries. However, since a group practice using the GPRO web interface would not need to determine which measures to report under PQRS, we believe that the self-nomination process is handled by a group practice's administrative staff. Therefore, we estimate that the self-nomination process for the group practices for the PQRS involves approximately 2 hours per group practice to review the PQRS GPRO and make the decision to participate as a group rather than individually and an additional 2 hours per group practice to draft the letter of intent for self-nomination, gather the requested TIN and NPI information, and provide this requested information. It is estimated that each self-nominated entity will also spend 2 hours undergoing the vetting process with CMS officials. We assume that the group practice staff involved in the group practice self-nomination process has an average practice labor cost of $26.68 per hour. Therefore, assuming the total burden hours per group practice associated with the group practice self-nomination process is 6 hours, we estimate the total cost to a group practice associated with the group practice self-nomination process to be approximately $160.08 ($26.68 per hour × 6 hours per group practice).

The burden associated with the group practice reporting requirements under the GPRO is the time and effort associated with the group practice submitting the quality measures data. For physician group practices, this would be the time associated with the physician group completing the web interface. We estimate that the time and effort associated with using the GPRO web interface will be comparable to the time and effort associated to using the PAT. As stated above, the information collection components of the PAT have been reviewed by OMB and was approved under OMB control number 0938–0941—Form 10136, with an expiration date of December 31, 2011 for use in the PGP, MCMP, and EHR demonstrations. As the GPRO was only recently implemented in 2010, it is difficult to determine the time and effort associated with the group practice submitting the quality measures data. As such, we will use the same burden estimate for group practices participating in the GPRO as we use for group practices participating in the PGP, MCMP, and EHR demonstrations. Since these changes will not have any impact on the information collection requirements associated with the PAT and we will be using the same data submission process used in the PGP demonstration, we estimate that the burden associated with a group practice completing data for PQRS under the web interface will be the same as for the group practice to complete the PAT for the PGP demonstration. In other words, we estimate that, on average, it will take each group practice 79 hours to submit quality measures data via the GPRO web interface at a cost of $83.96 per hour. Therefore, the total estimated annual cost per group practice is estimated to be approximately $6,632.84.

10. EHR Incentive Program

The changes to the EHR Incentive Program in section III.L of this proposed rule would not impact the current burden estimate for the EHR Incentive Program.

11. Comprehensive Primary Care (CPC) Initiative and Meaningful Use Aligned Reporting

The establishment of an aligned reporting option between CPC and the Medicare EHR Incentive Program does

[16] Id. at xv.

[17] Id. at xvi.

[18] Id. at 18.

not impact the CY 2016 payments under PFS.

12. Potential Expansion of the Comprehensive Primary Care (CPC) Initiative

The solicitation of public input regarding potential CPC expansion does not impact CY2016 payments under the PFS, because no actual expansion is being proposed at this time.

13. Medicare Shared Saving Program

The requirements for participating in the Medicare Shared Saving Program and the impacts of these requirements were established in the final rule implementing the Medicare Shared Savings Program that appeared in the **Federal Register** on November 2, 2011 (76 FR 67802). In this rule, we are proposing a change to the quality measure set. We are also proposing to establish rules for maintaining a measure as pay for reporting, or reverting a pay for performance measure to pay for reporting if a measure owner determines the measure no longer meets best clinical practices due to clinical guidelines updates or clinical evidence suggests that continued application of the measure may result in harm to patients. In addition, we are proposing to update the assignment methodology to include claims submitted by electing teaching amendment hospitals. Since the proposed policies are not expected to increase the quality reporting burden for ACOs participating in the Shared Savings Program and their ACO participants or change the financial calculations, there is no impact for these proposals.

14. Value-Based Payment Modifier and the Physician Feedback Program

Section 1848(p) of the Act requires that we establish a value-based payment modifier (VM) and apply it to specific physicians and groups of physicians the Secretary determines appropriate starting January 1, 2015 and to all physicians and groups of physicians by January 1, 2017. Section 1848(p)(4)(C) of the Act requires the VM to be budget neutral. Budget-neutrality means that, in aggregate, the increased payments to high performing physicians and groups of physicians equal the reduced payments to low performing physicians and groups of physicians. Unless specified, the proposed changes to the VM in section III.N of this proposed rule would not impact CY 2016 physician payments under the PFS. We finalized the VM policies that would impact the CY 2016 physician payments under the PFS in the CY 2013 PFS final rule with comment period (77 FR 69306 through 69326) and the CY 2014 PFS final rule with comment period (78 FR 74764 through 74787).

In the CY 2013 PFS final rule with comment period, we finalized policies to phase-in the VM by applying it starting January 1, 2015 to payments under the Medicare PFS for physicians in groups of 100 or more eligible professionals (EPs). We identify a group of physicians as a single taxpayer identification number (TIN). We apply the VM to the items and services billed by physicians under the TIN, not to other EPs that also may bill under the TIN. We established CY 2014 as the performance period for the VM that will be applied to payments during CY 2016 (77 FR 69314). We also finalized that we will not apply the VM in CYs 2015 and 2016 to any group of physicians that is participating in the Medicare Shared Savings Program, the Pioneer ACO Model, or the Comprehensive Primary Care Initiative, or other similar Innovation Center or CMS initiatives (77 FR 69313).

In the CY 2014 PFS final rule with comment period (78 FR 74765–74770), we finalized a policy to apply the VM in CY 2016 to physicians in groups with 10 or more EPs. We also adopted a policy to categorize groups of physicians subject to the VM in CY 2016 based on a group's participation in the PQRS. Specifically, we categorize groups of physicians eligible for the CY 2016 VM into two categories. Category 1 includes groups of physicians that (a) meet the criteria for satisfactory reporting of data on PQRS quality measures through the GPRO for the CY 2016 PQRS payment adjustment or (b) do not register to participate in the PQRS as a group practice in CY 2014 and that have at least 50 percent of the group's eligible professionals meet the criteria for satisfactory reporting of data on PQRS quality measures as individuals for the CY 2016 PQRS payment adjustment, or in lieu of satisfactory reporting, satisfactorily participate in a PQRS-qualified clinical data registry for the CY 2016 PQRS payment adjustment. For a group of physicians that is subject to the CY 2016 VM to be included in Category 1, the criteria for satisfactory reporting (or the criteria for satisfactory participation, if the PQRS-qualified clinical data registry reporting mechanism is selected) must be met during the CY 2014 reporting period for the PQRS CY 2016 payment adjustment. For the CY 2016 VM, Category 2 includes those groups of physicians that are subject to the CY 2016 VM and do not fall within Category 1. For those groups of physicians in Category 2, the VM for CY 2016 is −2.0 percent.

In addition, for the CY 2016 VM, we adopted that quality-tiering, which is the method for evaluating performance on quality and cost measures for the VM, is mandatory for groups of physicians with 10 or more EPs. In CY 2016, groups of physicians with between 10 and 99 EPs would not be subjected to a downward payment adjustment (that is, they will either receive an upward or neutral adjustment) determined under the quality-tiering methodology, and groups of physicians with 100 or more EPs, however, would either receive upward, neutral, or downward adjustments under the quality-tiering methodology.

Under the quality-tiering approach, each group's quality and cost composites are classified into high, average, and low categories depending upon whether the composites are at least one standard deviation above or below the mean and statistically different from the mean. We compare the group's quality of care composite classification with the cost composite classification to determine the VM adjustment for the CY 2016 payment adjustment period according to the amounts in Table 48.

TABLE 48—2016 VM AMOUNTS UNDER QUALITY-TIERING

Cost/quality	Low quality	Average quality	High quality
Low Cost	+0.0%	* +1.0x	* +2.0x
Average Cost	−1.0%	+0.0%	* +1.0x
High Cost	−2.0%	−1.0%	+0.0%

* Groups of physicians eligible for an additional +1.0x if (1) reporting Physician Quality Reporting System quality measures and (2) average beneficiary risk score is in the top 25 percent of all beneficiary risk scores.

To ensure budget neutrality, we first aggregate the downward payment adjustments in Table 48 for those groups in Category 1 with the −2.0 percent downward payment adjustments for groups of physicians subject to the VM that fall within Category 2. Using the aggregate downward payment adjustment amount, we then calculate the upward payment adjustment factor (x). These calculations will be done after the performance period has ended.

At the time of this proposed rule, we have not completed the analysis of the impact of the VM in CY 2016 on physicians in groups with 10 or more EPs based on their performance in CY 2014. In the CY 2016 PFS final rule with comment period, we will present the actual number of groups of physicians that will be subject to the VM in CY 2016.

15. Physician Self-Referral Updates

The physician self-referral update provisions are discussed in section II.P of this proposed rule. Physicians and Designated Health Services (DHS) entities have been complying with the requirements set forth in the physician self-referral law for many years, specifically in regard to clinical laboratory services since 1992 and to referrals for all other DHS since 1995. The majority of our proposals would reduce burden by clarifying previous guidance. We believe these proposals would allow parties to determine with greater certainty whether their financial relationships comply with an exception.

We also proposed new exceptions and a new definition that would accommodate legitimate financial arrangements while continuing to protect against program and patient abuse:

- In section II.P.2.A of this proposed rule, we proposed a limited exception for hospitals, FQHCs, and RHCs that wish to provide remuneration to physicians to assist with the employment of a non-physician practitioner. This new exception would promote access to primary care services, a goal of the Secretary and the Affordable Care Act.
- In section II.P.2.B of this proposed rule, we described our proposal to revise the physician recruitment exception to add a new definition of the geographic area served by an FQHC or RHC. This proposal would provide certainty to FQHCs and RHCs that their physician recruitment arrangements satisfy the requirements of the exception.
- In section II.P.7 of this proposed rule, we proposed a new exception that would protect timeshare arrangements that meet certain criteria. This proposal would help ensure beneficiary access to care, particularly in rural and underserved areas.

To the extent that the new exceptions and definition permit additional legitimate arrangements to comply with the law, this rule would reduce the potential costs of restructuring such arrangements, and the consequences of noncompliance may be avoided entirely.

- In section II.P.9.B of this proposed rule, we discussed our proposal that the physician-owned hospital baseline bona fide investment level and the bona fide investment level include direct and indirect ownership and investment interests held by a physician regardless of whether the physician refers patients to the hospital. We recognize that some physician-owned hospitals may have relied on earlier guidance that the ownership or investment interests of non-referring physicians need not be considered when calculating the baseline bona fide physician ownership level and that, if one or more of our proposals described in section II.P.9.B are finalized, may have revised bona fide investment levels that may exceed the baseline bona fide investment levels calculated under our current guidance. We seek public comment on the impact of our proposed regulatory and policy revisions on physician-owned hospitals and on the measures or actions physician-owned hospitals would need to undertake to come into compliance with our proposed revisions.

16. Opt Out Change

We propose revising the regulations governing the requirements and procedures for private contracts at part 405, subpart D so that they conform with the statutory changes made by section 106(a) of the MACRA. We anticipate no or minimal impact as a result of these revisions.

F. Alternatives Considered

This proposed rule contains a range of policies, including some provisions related to specific statutory provisions. The preceding preamble provides descriptions of the statutory provisions that are addressed, identifies those policies when discretion has been exercised, presents rationale for our final policies and, where relevant, alternatives that were considered.

G. 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 many of the proposed changes, including those intended to improve accuracy in payment through revisions to the inputs used to calculate payments under the PFS will have a positive impact and improve the quality and value of care provided to Medicare beneficiaries.

Most of the aforementioned proposed policy changes could result in a change in beneficiary liability as relates to coinsurance (which is 20 percent of the fee schedule amount if applicable for the particular provision after the beneficiary has met the deductible). To illustrate this point, as shown in Table 46, the CY 2015 national payment amount in the nonfacility setting for CPT code 99203 (Office/outpatient visit, new) is $109.60, which means that in CY 2015, a beneficiary would be responsible for 20 percent of this amount, or $21.92. Based on this proposed rule, using the estimated CY 2016 CF, the CY 2016 national payment amount in the nonfacility setting for CPT code 99203, as shown in Table 46, is $110.13, which means that, in CY 2016, the proposed beneficiary coinsurance for this service would be $22.03.

H. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf*), in Table 49 (Accounting Statement), we have prepared an accounting statement. This estimate includes growth in incurred benefits from CY 2015 to CY 2016 based on the FY 2016 President's Budget baseline. Note that subsequent legislation changed the updates for 2016 from those shown in the 2016 President's Budget baseline.

TABLE 49—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

Category	Transfers
CY 2016 Annualized Monetized Transfers	Estimated increase in expenditures of $670 million for PFS CF update.
From Whom To Whom?	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.

TABLE 49—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES—Continued

Category	Transfers
CY 2016 Annualized Monetized Transfers	Estimated increase in payment of $473 million.
From Whom To Whom?	Federal Government to eligible professionals who satisfactorily participate in the Physician Quality Reporting System (PQRS).

TABLE 50—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS, TRANSFER, AND SAVINGS

Category	Transfer
CY 2016 Annualized Monetized Transfers of beneficiary cost coinsurance.	$100 million.
From Whom to Whom?	Federal Government to Beneficiaries.

I. Conclusion

The analysis in the previous sections, together with the remainder of this preamble, provides an initial Regulatory Flexibility Analysis. The previous analysis, together with the preceding portion of this preamble, provides a Regulatory Impact Analysis.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 405

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medical devices, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 411

Kidney diseases, Medicare, Physician Referral, Reporting and recordkeeping requirements.

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 425

Administrative practice and procedure, Health facilities, Health professions, Medicare, and Reporting and recordkeeping requirements.

42 CFR Part 495

Administrative practice and procedure, Electronic health records, Health facilities, Health professions, Health maintenance organizations (HMO), Medicaid, Medicare, Penalties, Privacy, 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 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

■ 1. The authority citation for part 405 continues to read as follows:

Authority: Secs. 205(a), 1102, 1861, 1862(a), 1869, 1871, 1874, 1881, and 1886(k) of the Social Security Act (42 U.S.C. 405(a), 1302, 1395x, 1395y(a), 1395ff, 1395hh, 1395kk, 1395rr and 1395ww(k)), and sec. 353 of the Public Health Service Act (42 U.S.C. 263a).

■ 2. Section 405.400 is amended by revising the definition of ''Opt-out period'' to read as follows:

§ 405.400 Definitions

* * * * *

Opt-out period means, with respect to an affidavit that meets the requirements of § 405.420, a 2-year period beginning on the date the affidavit is signed, as specified by § 405.410(c)(1) or § 405.410(c)(2) as applicable, and each successive 2-year period unless the physician or practitioner properly cancels opt-out in accordance with § 405.445.

* * * * *

■ 3. Section 405.405 is amended by revising paragraph (b) to read as follows:

§ 405.405 General rules.

* * * * *

(b) A physician or practitioner who enters into at least one private contract with a Medicare beneficiary under the conditions of this subpart, and who submits one or more affidavits in accordance with this subpart, opts out of Medicare for the opt-out period described in § 405.400 unless the opt-out is terminated early according to § 405.445.

* * * * *

■ 4. Section 405.410 is amended by revising paragraphs (b), (c)(1), (c)(2), and (d) to read as follows:

§ 405.410 Conditions for properly opting-out of Medicare.

* * * * *

(b) The physician or practitioner must submit an affidavit that meets the specifications of § 405.420 to each Medicare Administrative contractor with which he or she would file claims absent the opt-out.

(c) * * *

(1) The initial 2-year opt-out period begins the date the affidavit meeting the requirements of § 405.420 is signed, provided the affidavit is filed within 10 days after he or she signs his or her first private contract with a Medicare beneficiary.

(2) If the physician or practitioner does not timely file the opt-out affidavit(s) as specified in the previous paragraph, the initial 2-year opt-out period begins when the last such affidavit is filed. Any private contract entered into before the last required affidavit is filed becomes effective upon the filing of the last required affidavit, and the furnishing of any items or services to a Medicare beneficiary under such contract before the last required affidavit is filed is subject to standard Medicare rules.

(d) A participating physician may properly opt-out of Medicare at the beginning of any calendar quarter, provided that the affidavit described in § 405.420 is submitted to the participating physician's Medicare Administrative contractors at least 30 days before the beginning of the selected calendar quarter. A private contract entered into before the beginning of the selected calendar quarter becomes effective at the beginning of the selected calendar quarter, and the furnishing of any items or services to a Medicare

beneficiary under such contract before the beginning of the selected calendar quarter is subject to standard Medicare rules.

■ 5. Section 405.415 is amended by revising paragraphs (h), (m), and (o) to read as follows:

§ 405.415 Requirements of the private contract.

* * * * *

(h) State the expected or known effective date and the expected or known expiration date of the current 2-year opt-out period.

* * * * *

(m) Be retained (original signatures of both parties required) by the physician or practitioner for the duration of the current 2-year opt-out period.

* * * * *

(o) Be entered into for each 2-year opt-out period.

■ 6. Section 405.425 is amended by revising the introductory text to read as follows:

§ 405.425 Effects of opting-out of Medicare.

If a physician or practitioner opts-out of Medicare in accordance with this subpart, the following results obtain during the opt-out period:

* * * * *

■ 7. Section 405.435 is amended by revising paragraphs (a)(4), (b)(8), and (d) to read as follows:

§ 405.435 Failure to maintain opt-out.

(a) * * *

(4) He or she fails to retain a copy of each private contract that he or she has entered into for the duration of the current 2-year period for which the contracts are applicable or fails to permit CMS to inspect them upon request.

(b) * * *

(8) The physician or practitioner may not attempt to once more meet the criteria for properly opting-out until the current 2-year period expires.

* * * * *

(d) If a physician or practitioner demonstrates that he or she has taken good faith efforts to maintain opt-out (including by refunding amounts in excess of the charge limits to beneficiaries with whom he or she did not sign a private contract) within 45 days of a notice from the Medicare Administrative contractor of a violation of paragraph (a) of this section, then the requirements of paragraphs (b)(1) through (8) of this section are not applicable. In situations where a violation of paragraph (a) of this section is not discovered by the Medicare Administrative contractor during the current 2-year period when the violation actually occurred, then the requirements of paragraphs (b)(1) through (8) of this section are applicable from the date that the first violation of paragraph (a) of this section occurred until the end of the 2-year period during which the violation occurred (unless the physician or practitioner takes good faith efforts, within 45 days of any notice from the Medicare Administrative contractor that the physician or practitioner failed to maintain opt-out, or within 45 days of the physician's or practitioner's discovery of the failure to maintain opt-out, whichever is earlier, to correct his or her violations of paragraph (a) of this section. Good faith efforts include, but are not limited to, refunding any amounts collected in excess of the charge limits to beneficiaries with whom he or she did not sign a private contract.

■ 8. Section 405.445 is amended by revising the section heading and paragraphs (a) and (b)(2) to read as follows:

§ 405.445 Properly cancel opt-out and early termination of opt-out.

(a) A physician or practitioner may cancel opt-out by submitting a written request (that indicates the physician or practitioner does not want to extend the application of his or her affidavit for a subsequent 2-year period) with each Medicare contractor with which he or she would file claims absent completion of opt-out, provided the written requests are submitted not later than 30 days before the end of the previous 2-year period.

(b) * * *

(2) Notify all Medicare contractors, with which he or she filed an affidavit, of the termination of the opt-out no later than 90 days after the effective date of the initial 2-year period.

* * * * *

■ 9. Section 405.450 is amended by revising paragraph (a) to read as follows:

§ 405.450 Appeals.

(a) A determination by CMS that a physician or practitioner has failed to properly opt out, failed to maintain opt-out, failed to timely renew opt-out, failed to privately contract, failed to properly terminate opt-out, or failed to properly cancel opt-out is an initial determination for purposes of § 498.3(b) of this chapter.

* * * * *

■ 10. Section 405.2410 is amended by revising paragraph (b)(1) introductory text and (b)(1)(i) to read as follows:

§ 405.2410 Application of Part B deductible and coinsurance.

* * * * *

(b) * * *

(1) For RHCs that are authorized to bill on the basis of the reasonable cost system—

(i) A coinsurance amount that does not exceed 20 percent of the RHC's reasonable customary charge for the covered service; and

* * * * *

■ 11. Section 405.2415 is amended by revising the section heading to read as follows:

§ 405.2415 Incident to Services and direct supervision.

* * * * *

■ 12. Section § 405.2448 is amended by revising paragraph (a)(2) to read as follows:

§ 405.2448 Preventive primary services.

(a) * * *

(2) Are furnished by a or under the direct supervision of a physician, nurse practitioner, physician assistant, certified nurse midwife, clinical psychologist or clinical social worker employed by or under contract with the FQHC.

* * * * *

■ 13. Section § 405.2462 is amended by—

■ a. Revising paragraph (a) introductory text, the heading of paragraph (b), and paragraphs (b)(1) and (c) introductory text.

■ b. Amending paragraph (b)(2) by removing the reference ''paragraphs (e)(1) and (2)'' and adding in its place the reference ''paragraphs (f)(1) and (2)''.

■ c. Redesignating paragraphs (d), (e), and (f) as paragraphs (e), (f), and (g), respectively.

■ d. Adding paragraph (d).

■ e.. Revising newly redesignated paragraphs (e)(1)(i) and (ii).

■ f. Adding paragraph (g)(3).

The revisions and additions read as follows:

§ 405.2462 Payment for RHC and FQHC services.

(a) *Payment to provider-based RHCs that are authorized to bill under the reasonable cost system.* A RHC that is authorized to bill under the reasonable cost system is paid in accordance with parts 405 and 413 of this subchapter, as applicable, if the RHC is—

* * * * *

(b) *Payment to independent RHCs that are authorized to bill under the reasonable cost system.* (1) RHCs that are authorized to bill under the reasonable cost system are paid on the basis of an all-inclusive rate for each

beneficiary visit for covered services. This rate is determined by the MAC, in accordance with this subpart and general instructions issued by CMS.

* * * * *

(c) *Payment to FQHCs that are authorized to bill under the PPS.* A FQHC that is authorized to bill under the PPS is paid a single, per diem rate based on the prospectively set rate for each beneficiary visit for covered services. Except as noted in paragraph (d) of this section, this rate is adjusted for the following:

* * * * *

(d) *Payment to grandfathered tribal FQHCs.* (1) A ''grandfathered tribal FQHC'' is a FQHC that:

(i) Is operated by a tribe or tribal organization under the Indian Self-Determination Education and Assistance Act (ISDEAA);

(ii) Was provider-based to an IHS hospital on or before April 7, 2000; and

(iii) Is not operating as a provider-based department of an IHS hospital.

(2) A grandfathered tribal FQHC is paid at the Medicare outpatient per visit rate as set annually by the IHS.

(3) The payment rate is not adjusted:

(i) By the FQHC Geographic Adjustment Factor;

(ii) For new patients, annual wellness visits, or initial preventive physical examinations; or

(iii) Annually by the Medicare Economic Index or a FQHC PPS market basket.

(4) The payment rate is adjusted annually by the IHS under the authority of sections 321(a) and 322(b) of the Public Health Service Act (42 U.S.C. 248 and 249(b)), Pub. L. 83–568 (42 U.S.C. 2001(a)), and the Indian Health Care Improvement Act (25 U.S.C. 1601 et seq.).

(e) * * *

(1) * * *

(i) 80 percent of the lesser of the FQHC's actual charge or the PPS encounter rate for FQHCs authorized to bill under the PPS; or

(ii) 80 percent of the lesser of a grandfathered tribal FQHC's actual charge, or the outpatient rate for Medicare as set annually by the IHS for tribal FQHCs that are authorized to bill at this rate.

* * * * *

(g) * * *

(3) FQHCs, RHCs, whether or not exempt from electronic reporting under § 424.32(d)(3) of this subchapter, are required to submit HCPCS and other codes as required in reporting services furnished.

■ 14. Section 405.2463 is amended by revising paragraph (c)(4) introductory text to read as follows:

§ 405.2463 What constitutes a visit.

* * * * *

(c) * * *

(4) For FQHCs billing under the PPS, and grandfathered tribal FQHCs that are authorized to bill as a FQHC at the outpatient per visit rate for Medicare as set annually by the Indian Health Service—

* * * * *

■ 15. Section 405.2464 is amended by—

■ a. Revising the heading of paragraph (a), paragraphs (a)(1), (a)(2), and (a)(5), the heading of paragraph (b), and paragraph (b)(1).

■ b. Adding paragraphs (c) and (d).

The revisions and additions read as follows:

§ 405.2464 Payment rate.

(a) *Payment rate for RHCs that are authorized to bill under the reasonable cost system.* (1) Except as specified in paragraph (c) of this section, a RHC that is authorized to bill under the reasonable cost system is paid an all-inclusive rate that is determined by the MAC at the beginning of the cost reporting period.

(2) The rate is determined by dividing the estimated total allowable costs by estimated total visits for RHC services.

* * * * *

(5) The RHC may request the MAC to review the rate to determine whether adjustment is required.

(b) *Payment rate for FQHCs billing under the prospective payment system.* (1) Except as specified in paragraph (c) of this section, a per diem rate is calculated by CMS by dividing total FQHC costs by total FQHC daily encounters to establish an average per diem cost.

* * * * *

(c) *Payment for chronic care management services.* Payment to RHCs and FQHCs for qualified chronic care management services is at the physician fee schedule national average payment rate.

(d) *Determination of the payment rate for FQHCs that are authorized to bill as grandfathered tribal FQHCs.* These rates are paid at the outpatient per visit rate for Medicare as set annually by the Indian Health Service for each beneficiary visit for covered services. There are no adjustments to this rate.

§ 405.2467 [Amended]

■ 16. Section 405.2467 is amended by removing paragraph (b) and redesignating paragraphs (c) and (d) as paragraphs (b) and (c), respectively.

■ 17. Section 405.2469 is amended by revising paragraphs (a) and (b)(2) and adding paragraph (b)(3) to read as follows:

§ 405.2469 FQHC supplemental payments.

(a) *Eligibility for supplemental payments.* FQHCs under contract (directly or indirectly) with MA organizations are eligible for supplemental payments for FQHC services furnished to enrollees in MA plans offered by the MA organization to cover the difference, if any, between their payments from the MA plan and what they would receive under one of the following:

(1) The PPS rate if the FQHC is authorized to bill under the PPS; or

(2) The Medicare outpatient per visit rate as set annually by the Indian Health Service for grandfathered tribal FQHCs.

(b) * * *

(2) Payments received by the FQHC from the MA plan as determined on a per visit basis and the FQHC PPS rate as set forth in this subpart, less any amount the FQHC may charge as described in section 1857(e)(3)(B) of the Act; or

(3) Payments received by the FQHC from the MA plan as determined on a per visit basis and the FQHC outpatient rate as set forth in this section under paragraph (a)(2) of this section, less any amount the FQHC may charge as described in section 1857(e)(3)(B) of the Act.

* * * * *

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

■ 18. The authority citation for part 410 continues to read as follows:

Authority: Secs. 1102, 1834, 1871, 1881, and 1893 of the Social Security Act (42 U.S.C. 1302. 1395m, 1395hh, and 1395ddd.

■ 19. Section 410.26 is amended by revising paragraphs (a)(1) and (b)(5) to read as follows:

§ 410.26 Services and supplies incident to a physician's professional services: Conditions.

(a) * * *

(1) *Auxiliary personnel* means any individual who is acting under the supervision of a physician (or other practitioner), regardless of whether the individual is an employee, leased employee, or independent contractor of the physician (or other practitioner) or of the same entity that employs or contracts with the physician (or other practitioner), has not been excluded from the Medicare program or had his or her Medicare enrollment revoked, and meets any applicable requirements to provide the services, including licensure, imposed by the State in which the services are being furnished.

* * * * *

(b) * * *

(5) Services and supplies must be furnished under the direct supervision of the billing physician (or other billing practitioner) who is enrolled under Medicare Part B at the time the services are furnished. Services and supplies furnished incident to transitional care management and chronic care management services can be furnished under the general supervision of the physician (or other practitioner) when these services or supplies are provided by clinical staff.

* * * * *

■ 20. Section 410.41 is amended by revising paragraph (b) to read as follows:

§ 410.41 Requirements for ambulance suppliers.

* * * * *

(b) *Vehicle staff.* A vehicle furnishing ambulance services must be staffed by at least two people who meet the requirements of state and local laws where the services are being furnished, and at least one of the staff members must, for:

(1) *BLS vehicles.* (i) Be certified at a minimum as an emergency medical technician-basic by the State or local authority where the services are furnished; and

(ii) Be legally authorized to operate all lifesaving and life-sustaining equipment on board the vehicle;

(2) *ALS vehicles.* (i) Meet the requirements of paragraph (b)(1) of this section; and

(ii) Be certified as a paramedic or an emergency medical technician, by the State or local authority where the services are being furnished, to perform one or more ALS services.

* * * * *

■ 21. Section 410.78 is amended by adding paragraph (b)(2)(ix) to read as follows:

§ 410.78 Telehealth services.

* * * * *

(b) * * *

(2) * * *

(ix) A certified registered nurse anesthetist as described in § 410.69.

* * * * *

■ 22. Section 410.160 is amended by revising paragraph (b)(8) to read as follows:

§ 410.160 Part B annual deductible.

* * * * *

(b) * * *

(8) Beginning January 1, 2011, for a surgical service, and beginning January 1, 2015, for an anesthesia service, furnished in connection with, as a result of, and in the same clinical encounter as a planned colorectal cancer screening test. A surgical or anesthesia service furnished in connection with, as a result of, and in the same clinical encounter as a colorectal cancer screening test means—a surgical or anesthesia service furnished on the same date as a planned colorectal cancer screening test as described in § 410.37.

* * * * *

PART 411—EXCLUSIONS FROM MEDICARE AND LIMITATIONS ON MEDICARE PAYMENT

■ 23. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1860D–1 through 1860D–42, 1871, and 1877 of the Social Security Act (42 U.S.C. 1302, 1395w–101 through 1395w–152, 1395hh, and 1395nn).

■ 24. Section 411.351 is amended by—

■ a. Amending the definition of ''Entity'' by revising paragraph (3).

■ b. Revising the definitions of '' 'Incident to' services or services 'incident to' '', ''List of CPT/HCPCS Codes'', and ''Locum tenens physician''.

■ c. Amending the definition of ''Parenteral and enteral nutrients, equipment, and supplies'' by revising paragraphs (1) and (2).

■ d. Revising the definition of ''Physician in the group practice''.

■ e. Amending the definition of ''Remuneration'' by revising paragraph (2).

The revisions read as follows:

§ 411.351 Definitions.

* * * * *

Entity * * *

(3) For purposes of this subpart, ''entity'' does not include a physician's practice when it bills Medicare for the technical component or professional component of a diagnostic test for which the anti-markup provision is applicable in accordance with § 414.50 of this chapter and Pub. 100–04, Medicare Claims Processing Manual, Chapter 1, Section 30.2.9, as amended or replaced from time to time.

* * * * *

''Incident to'' services or services ''incident to'' means those services and supplies that meet the requirements of section 1861(s)(2)(A) of the Act, § 410.26 of this chapter, and Pub. 100–02, Medicare Benefit Policy Manual, Chapter 15, Sections 60, 60.1, 60.2, 60.3, and 60.4 as amended or replaced from time to time.

* * * * *

List of CPT/HCPCS Codes means the list of CPT and HCPCS codes that identifies those items and services that are DHS under section 1877 of the Act or that may qualify for certain exceptions under section 1877 of the Act. It is updated annually, as published in the **Federal Register**, and is posted on the CMS Web site at *http://www.cms.hhs.gov/PhysicianSelfReferral/11_List_of_Codes.asp#TopOfPage.*

Locum tenens physician (or substitute physician) is a physician who substitutes in exigent circumstances for another physician, in accordance with section 1842(b)(6)(D) of the Act and Pub. 100–04, Medicare Claims Processing Manual, Chapter 1, Section 30.2.11, as amended or replaced from time to time.

* * * * *

Parenteral and enteral nutrients, equipment, and supplies * * *

(1) *Parenteral nutrients, equipment, and supplies*, meaning those items and supplies needed to provide nutriment to a patient with permanent, severe pathology of the alimentary tract that does not allow absorption of sufficient nutrients to maintain strength commensurate with the patient's general condition, as described in Pub. 100–03, Medicare National Coverage Determinations Manual, Chapter 1, Section 180.2, as amended or replaced from time to time; and

(2) *Enteral nutrients, equipment, and supplies*, meaning items and supplies needed to provide enteral nutrition to a patient with a functioning gastrointestinal tract who, due to pathology to or nonfunction of the structures that normally permit food to reach the digestive tract, cannot maintain weight and strength commensurate with his or her general condition, as described in Pub. 100–03, Medicare National Coverage Determinations Manual, Chapter 1, Section 180.2, as amended or replaced from time to time.

* * * * *

Physician in the group practice means a member of the group practice, as well as an independent contractor physician during the time the independent contractor is furnishing patient care services (as defined in this section) for the group practice under a contractual arrangement directly with the group practice to provide services to the group practice's patients in the group practice's facilities. The contract must contain the same restrictions on compensation that apply to members of the group practice under § 411.352(g) (or the contract must satisfy the requirements of the personal service arrangements exception in § 411.357(d)), and the independent contractor's arrangement with the group practice must comply with the reassignment

rules in § 424.80(b)(2) of this chapter (see also Pub. 100–04, Medicare Claims Processing Manual, Chapter 1, Section 30.2.7, as amended or replaced from time to time). Referrals from an independent contractor who is a physician in the group practice are subject to the prohibition on referrals in § 411.353(a), and the group practice is subject to the limitation on billing for those referrals in § 411.353(b).

* * * * *

Remuneration * * *

(2) The furnishing of items, devices, or supplies (not including surgical items, devices, or supplies) that are used solely for one or more of the following purposes:

(i) Collecting specimens for the entity furnishing the items, devices or supplies;

(ii) Transporting specimens for the entity furnishing the items, devices or supplies;

(iii) Processing specimens for the entity furnishing the items, devices or supplies;

(iv) Storing specimens for the entity furnishing the items, devices or supplies;

(v) Ordering tests or procedures for the entity furnishing the items, devices or supplies; or

(vi) Communicating the results of tests or procedures for the entity furnishing the items, devices or supplies.

* * * * *

■ 25. Section 411.353 is amended by revising paragraphs (g)(1)(i) and (ii) to read as follows:

§ 411.353 Prohibition on certain referrals by physicians and limitations on billing.

* * * * *

(g) * * *

(1) * * *

(i) The compensation arrangement between the entity and the referring physician fully complies with an applicable exception in § 411.355, § 411.356 or § 411.357, except with respect to the signature requirement in § 411.357(a)(1), § 411.357(b)(1), § 411.357(d)(1)(i), § 411.357(e)(1)(i), § 411.357(e)(4)(i), § 411.357(l)(1), § 411.357(p)(2), § 411.357(q) (incorporating the requirement contained in § 1001.952(f)(4)), § 411.357(r)(2)(ii), § 411.357(t)(1)(ii) or (t)(2)(iii) (both incorporating the requirements contained in § 411.357(e)(1)(i)), § 411.357(v)(7)(i), § 411.357(w)(7)(i), § 411.357(x)(1)(i), or § 411.357(y)(1); and

(ii) The parties obtain the required signature(s) within 90 consecutive calendar days immediately following the date on which the compensation arrangement became noncompliant (without regard to whether any referrals occur or compensation is paid during such 90-day period) and the compensation arrangement otherwise complies with all criteria of the applicable exception.

* * * * *

■ 26. Section 411.354 is amended by revising paragraphs (c)(3)(i), (d)(1), (d)(4) introductory text, (d)(4)(i), (d)(4)(iv)(A), and (d)(4)(v) to read as follows:

§ 411.354 Financial relationship, compensation, and ownership or investment interest.

* * * * *

(c) * * *

(3)(i) For purposes of paragraphs (c)(1)(ii) and (c)(2)(iv) of this section, a physician who ''stands in the shoes'' of his or her physician organization is deemed to have the same compensation arrangements (with the same parties and on the same terms) as the physician organization. When applying the exceptions in § 411.355 and § 411.357 to arrangements in which a physician stands in the shoes of his or her physician organization, the ''parties to the arrangements'' are considered to be—

(A) With respect to a signature requirement, the physician organization and any physician who ''stands in the shoes'' of the physician organization as required under paragraphs (c)(1)(ii) or (c)(2)(iv)(A) of this section; and

(B) With respect to all other requirements of the exception, including the relevant referrals and other business generated between the parties, the entity furnishing DHS and the physician organization (including all members, employees, and independent contractor physicians).

* * * * *

(d) * * *

(1) Compensation is considered ''set in advance'' if the aggregate compensation, a time-based or per-unit of service-based (whether per-use or per-service) amount, or a specific formula for calculating the compensation is set out in writing before the furnishing of the items or services for which the compensation is to be paid. The formula for determining the compensation must be set forth in sufficient detail so that it can be objectively verified, and the formula may not be changed or modified during the course of the arrangement in any manner that takes into account the volume or value of referrals or other business generated by the referring physician.

* * * * *

(4) A physician's compensation from a *bona fide* employer or under a managed care contract or other arrangement for personal services may be conditioned on the physician's referrals to a particular provider, practitioner, or supplier, provided that the compensation arrangement meets all of the following conditions. The compensation arrangement:

(i) Is set in advance for the term of the arrangement.

* * * * *

(iv) * * *

(A) The requirement to make referrals to a particular provider, practitioner, or supplier is set out in writing and signed by the parties.

* * * * *

(v) The required referrals relate solely to the physician's services covered by the scope of the employment, the arrangement for personal services, or the contract, and the referral requirement is reasonably necessary to effectuate the legitimate business purposes of the compensation arrangement. In no event may the physician be required to make referrals that relate to services that are not provided by the physician under the scope of his or her employment, arrangement for personal services, or contract.

■ 27. Section 411.356 is amended by revising paragraphs (a) introductory text and (a)(1)(i) and (ii), and adding paragraph (a)(1)(iii) to read as follows:

§ 411.356 Exceptions to the referral prohibition related to ownership or investment interests.

* * * * *

(a) *Publicly traded securities.* Ownership of investment securities (including shares or bonds, debentures, notes, or other debt instruments) that at the time the DHS referral was made could be purchased on the open market and that meet the requirements of paragraphs (a)(1) and (a)(2) of this section.

(1) * * *

(i) Listed for trading on the New York Stock Exchange, the American Stock Exchange, or any regional exchange in which quotations are published on a daily basis, or foreign securities listed on a recognized foreign, national, or regional exchange in which quotations are published on a daily basis;

(ii) Traded under an automated interdealer quotation system operated by the National Association of Securities Dealers; or

(iii) Listed for trading on an electronic stock market or over-the-counter quotation system in which quotations are published on a daily basis and

trades are standardized and publicly transparent.

* * * * *

■ 28. Section 411.357 is amended by—

■ A. Revising paragraphs (a) introductory text, (a)(1) through (4), (a)(5) introductory text, (a)(6), (a)(7), (b)(1) through (3), (b)(4) introductory text, (b)(5), (b)(6), (c)(3), (d)(1)(iii), (d)(1)(iv), (d)(1)(vii), (e)(1)(iii), (e)(1)(iv), (e)(4)(i), (e)(4)(iv), (e)(6), (f)(2), (k)(2), (l) introductory text, (l)(1), (l)(2), (m)(1), (m)(2), (m)(3), (m)(5), (p)(1)(ii)(A), (p)(2), (r)(2)(iv), (r)(2)(v), (s)(1), (t)(2)(iv)(A).

■ B. Adding paragraphs (x) and (y).

The revisions and additions read as follows:

§ 411.357 Exceptions to the referral prohibition related to compensation arrangements.

* * * * *

(a) *Rental of office space*. Payments for the use of office space made by a lessee to a lessor if the arrangement meets the following requirements:

(1) The lease arrangement is set out in writing, is signed by the parties, and specifies the premises it covers.

(2) The term of the lease arrangement is at least 1 year. To meet this requirement, if the lease arrangement is terminated with or without cause, the parties may not enter into a new lease arrangement for the same space during the first year of the original lease arrangement.

(3) The space rented or leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease arrangement and is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor), except that the lessee may make payments for the use of space consisting of common areas if the payments do not exceed the lessee's pro rata share of expenses for the space based upon the ratio of the space used exclusively by the lessee to the total amount of space (other than common areas) occupied by all persons using the common areas.

(4) The rental charges over the term of the lease arrangement are set in advance and are consistent with fair market value.

(5) The rental charges over the term of the lease arrangement are not determined—

* * * * *

(6) The lease arrangement would be commercially reasonable even if no referrals were made between the lessee and the lessor.

(7) If the lease arrangement expires after a term of at least 1 year, a holdover lease arrangement immediately following the expiration of the lease arrangement satisfies the requirements of paragraph (a) of this section if the following conditions are met:

(i) The lease arrangement met the conditions of paragraphs (a)(1) through (6) of this section when the arrangement expired;

(ii) The holdover lease arrangement is on the same terms and conditions as the immediately preceding arrangement; and

(iii) The holdover lease arrangement continues to satisfy the conditions of paragraphs (a)(1) through (6) of this section.

(b) * * *

(1) The lease arrangement is set out in writing, is signed by the parties, and specifies the equipment it covers.

(2) The equipment leased does not exceed that which is reasonable and necessary for the legitimate business purposes of the lease arrangement and is used exclusively by the lessee when being used by the lessee (and is not shared with or used by the lessor or any person or entity related to the lessor).

(3) The term of the lease arrangement is at least 1 year. To meet this requirement, if the lease arrangement is terminated with or without cause, the parties may not enter into a new lease arrangement for the same equipment during the first year of the original lease arrangement.

(4) The rental charges over the term of the lease arrangement are set in advance, are consistent with fair market value, and are not determined—

* * * * *

(5) The lease arrangement would be commercially reasonable even if no referrals were made between the parties.

(6) If the lease arrangement expires after a term of at least 1 year, a holdover lease arrangement immediately following the expiration of the lease arrangement satisfies the requirements of paragraph (b) of this section if the following conditions are met:

(i) The lease arrangement met the conditions of paragraphs (b)(1) through (5) of this section when the arrangement expired;

(ii) The holdover lease arrangement is on the same terms and conditions as the immediately preceding lease arrangement; and

(iii) The holdover lease arrangement continues to satisfy the conditions of paragraphs (b)(1) through (5) of this section.

(c) * * *

(3) The remuneration is provided under an arrangement that would be commercially reasonable even if no referrals were made to the employer.

* * * * *

(d) * * *

(1) * * *

(iii) The aggregate services covered by the arrangement do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement(s).

(iv) The term of each arrangement is for at least 1 year. To meet this requirement, if an arrangement is terminated with or without cause, the parties may not enter into the same or substantially the same arrangement during the first year of the original arrangement.

* * * * *

(vii) If the arrangement expires after a term of at least 1 year, a holdover arrangement immediately following the expiration of the arrangement satisfies the requirements of paragraph (d) of this section if the following conditions are met:

(A) The arrangement met the conditions of paragraphs (d)(1)(i) through (vi) of this section when the arrangement expired;

(B) The holdover arrangement is on the same terms and conditions as the immediately preceding arrangement; and

(C) The holdover arrangement continues to satisfy the conditions of paragraphs (d)(1)(i) through (vi) of this section.

* * * * *

(e) * * *

(1) * * *

(iii) The amount of remuneration under the arrangement is not determined in a manner that takes into account (directly or indirectly) the volume or value of any actual or anticipated referrals by the physician or other business generated between the parties; and

(iv) The physician is allowed to establish staff privileges at any other hospital(s) and to refer business to any other entities (except as referrals may be restricted under an employment or services arrangement that complies with § 411.354(d)(4)).

* * * * *

(4) * * *

(i) The writing in paragraph (e)(1) of this section is also signed by the physician practice.

* * * * *

(iv) Records of the actual costs and the passed-through amounts are maintained for a period of at least 6 years and made available to the Secretary upon request.

* * * * *

(6)(i) This paragraph (e) applies to remuneration provided by a federally qualified health center or a rural health

clinic in the same manner as it applies to remuneration provided by a hospital, provided that the arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(ii) The ''geographic area served'' by a federally qualified health center or a rural health clinic is the area composed of the lowest number of contiguous zip codes from which the federally qualified health center or rural health clinic draws at least 90 percent of its patients, as determined on an encounter basis. If the federally qualified health center or rural health clinic draws fewer than 90 percent of its patients from all of the contiguous zip codes from which it draws patients, the ''geographic area served'' by the federally qualified health center or rural health clinic may include noncontiguous zip codes, beginning with the noncontiguous zip code in which the highest percentage of the federally qualified health center's or rural health clinic's patients reside, and continuing to add noncontiguous zip codes in decreasing order of percentage of patients. The geographic area served by the federally qualified health center or rural health clinic may include one or more zip codes from which the federally qualified health center or rural health clinic draws no patients, provided that such zip codes are entirely surrounded by zip codes in the geographic area described above from which the federally qualified health center or rural health clinic draws at least 90 percent of its patients.

(f) * * *

(2) The remuneration is provided under an arrangement that would be commercially reasonable even if the physician made no referrals to the entity.

* * * * *

(k) * * *

(2) The annual aggregate nonmonetary compensation limit in this paragraph (k) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index—Urban All Items (CPI–U) for the 12-month period ending the preceding September 30. CMS displays after September 30 each year both the increase in the CPI–U for the 12-month period and the new nonmonetary compensation limit on the physician self-referral Web site at *http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI-U_Updates.asp.*

* * * * *

(l) *Fair market value compensation.* Compensation resulting from an arrangement between an entity and a physician (or an immediate family member) or any group of physicians (regardless of whether the group meets the definition of a group practice set forth in § 411.352) for the provision of items or services (other than the rental of office space) by the physician (or an immediate family member) or group of physicians to the entity, or by the entity to the physician (or an immediate family member) or a group of physicians, if the arrangement meets the following conditions:

(1) The arrangement is in writing, signed by the parties, and covers only identifiable items or services, all of which are specified in writing.

(2) The writing specifies the timeframe for the arrangement, which can be for any period of time and contain a termination clause, provided that the parties enter into only one arrangement for the same items or services during the course of a year. An arrangement may be renewed any number of times if the terms of the arrangement and the compensation for the same items or services do not change.

* * * * *

(m) * * *

(1) The compensation is offered to all members of the medical staff practicing in the same specialty (but not necessarily accepted by every member to whom it is offered) and is not offered in a manner that takes into account the volume or value of referrals or other business generated between the parties.

(2) Except with respect to identification of medical staff on a hospital Web site or in hospital advertising, the compensation is provided only during periods when the medical staff members are making rounds or are engaged in other services or activities that benefit the hospital or its patients.

(3) The compensation is provided by the hospital and used by the medical staff members only on the hospital's campus. Compensation, including, but not limited to, internet access, pagers, or two-way radios, used away from the campus only to access hospital medical records or information or to access patients or personnel who are on the hospital campus, as well as the identification of the medical staff on a hospital Web site or in hospital advertising, meets the ''on campus'' requirement of this paragraph (m) of this section.

* * * * *

(5) The compensation is of low value (that is, less than $25) with respect to each occurrence of the benefit (for example, each meal given to a physician while he or she is serving patients who are hospitalized must be of low value). The $25 limit in this paragraph (m)(5) is adjusted each calendar year to the nearest whole dollar by the increase in the Consumer Price Index—Urban All Items (CPI–I) for the 12 month period ending the preceding September 30. CMS displays after September 30 each year both the increase in the CPI–I for the 12 month period and the new limits on the physician self-referral Web site at *http://www.cms.hhs.gov/PhysicianSelfReferral/10_CPI-U_Updates.asp.*

* * * * *

(p) * * *

(1) * * *

(ii) * * *

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services performed or business generated in the office space or to the services performed on or business generated through the use of the equipment; or

* * * * *

(2) The compensation arrangement described in § 411.354(c)(2)(ii) is set out in writing, signed by the parties, and specifies the services covered by the arrangement, except in the case of a *bona fide* employment relationship between an employer and an employee, in which case the arrangement need not be set out in writing, but must be for identifiable services and be commercially reasonable even if no referrals are made to the employer.

* * * * *

(r) * * *

(2) * * *

(iv) The hospital, federally qualified health center, or rural health clinic does not determine the amount of the payment in a manner that takes into account (directly or indirectly) the volume or value of any actual or anticipated referrals by the physician or any other business generated between the parties.

(v) The physician is allowed to establish staff privileges at any hospital(s), federally qualified health center(s), or rural health clinic(s) and to refer business to any other entities (except as referrals may be restricted under an employment arrangement or services arrangement that complies with § 411.354(d)(4)).

* * * * *

(s) * * *

(1) The professional courtesy is offered to all physicians on the entity's *bona fide* medical staff or in such entity's local community or service area, and the offer does not take into account

the volume or value of referrals or other business generated between the parties;

* * * * *

(t) * * *

(2) * * *

(iv) * * *

(A) An amount equal to 25 percent of the physician's current annual income (averaged over the previous 24 months), using a reasonable and consistent methodology that is calculated uniformly; or

* * * * *

(x) *Assistance to employ a nonphysician practitioner.* (1) Remuneration provided by a hospital to a physician to employ a nonphysician practitioner to provide patient care services, if all of the following conditions are met:

(i) The arrangement is set out in writing and signed by the hospital, the physician, and the nonphysician practitioner.

(ii) The arrangement is not conditioned on—

(A) The physician's referrals to the hospital; or

(B) The nonphysician practitioner's referrals to the hospital.

(iii) The remuneration from the hospital—

(A) Does not exceed the lower of—

(*1*) 50 percent of the actual salary, signing bonus, and benefits paid by the physician to the nonphysician practitioner during a period not to exceed the first 2 consecutive years of employment; or

(*2*) An amount calculated by subtracting all receipts attributable to services furnished by the nonphysician practitioner from the actual salary, signing bonus, and benefits paid to the nonphysician practitioner by the physician during a period not to exceed the first 2 consecutive years of employment; and

(B) Is not determined in a manner that takes into account (directly or indirectly) the volume or value of any actual or anticipated referrals by—

(*1*) The physician (or any physician in the physician's practice) or other business generated between the parties; or

(*2*) The nonphysician practitioner (or any nonphysician practitioner in the physician's practice) or other business generated between the parties.

(iv) The salary, signing bonus, and benefits paid to the nonphysician practitioner by the physician does not exceed fair market value for the patient care services furnished by the nonphysician practitioner to patients of the physician's practice.

(v) The nonphysician practitioner has not, within 3 years of becoming employed by the physician (or the physician organization in whose shoes the physician stands under § 411.354(c) of this subpart)—

(A) Practiced in the geographic area served by the hospital; or

(B) Been employed or otherwise engaged to provide patient care services by a physician or a physician organization that has a medical practice site located in the geographic area served by the hospital, regardless of whether the nonphysician practitioner furnished services at the medical practice site located in the geographic area served by the hospital.

(vi) The nonphysician practitioner—

(A) Is a *bona fide* employee of the physician or the physician organization in whose shoes the physician stands under § 411.354(c) of this subpart; and

(B) Furnishes only primary care services to patients of the physician's practice.

(vii) The physician does not impose practice restrictions on the nonphysician practitioner that unreasonably restrict the nonphysician practitioner's ability to provide patient care services in the geographic area served by the hospital.

(viii) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act), or any Federal or State law or regulation governing billing or claims submission.

(2) Records of the actual amount of remuneration provided under paragraph (x)(1) of this section by the hospital to the physician, and by the physician to the nonphysician practitioner, must be maintained for a period of at least 6 years and made available to the Secretary upon request.

(3) For purposes of this paragraph (x), ''nonphysician practitioner'' means a physician assistant as defined in section 1861(aa)(5) of the Act, a nurse practitioner or clinical nurse specialist as defined in section 1861(aa)(5) of the Act, or a certified nurse-midwife as defined in section 1861(gg) of the Act.

(4) For purposes of paragraphs (x)(1)(ii)(B) and (x)(1)(iii)(B)(*2*) of this section, ''referral'' means a request by a nonphysician practitioner that includes the provision of any designated health service for which payment may be made under Medicare, the establishment of any plan of care by a nonphysician practitioner that includes the provision of such a designated health service, or the certifying or recertifying of the need for such a designated health service, but not including any designated health service personally performed or provided by the nonphysician practitioner.

(5) For purposes of paragraph (x)(1) of this section, ''geographic area served by the hospital'' has the meaning set forth in paragraph (e)(2) of this section.

(6)(i) This paragraph (x) applies to remuneration provided by a federally qualified health center or a rural health clinic in the same manner as it applies to remuneration provided by a hospital.

(ii) The ''geographic area served'' by a federally qualified health center or a rural health clinic has the meaning set forth in paragraph (e)(6)(ii) of this section.

(y) *Timeshare arrangements.* Remuneration provided by a licensee to a licensor under an arrangement for the use of the licensor's premises, equipment, personnel, items, supplies or services if the following conditions are met:

(1) The arrangement is set out in writing, signed by the parties, and specifies the premises, equipment, personnel, items, supplies, and services covered by the arrangement.

(2) The licensor is a hospital or physician organization.

(3) The licensed premises, equipment, personnel, items, supplies and services are used predominantly for the provision of evaluation and management services to patients.

(4) The licensed equipment is—

(i) Located in the office suite where the evaluation and management services are furnished;

(ii) Not used to furnish designated health services other than those incidental to the evaluation and management services furnished by the physician at the time of the patient's evaluation and management visit; and

(iii) Not advanced imaging equipment, radiation therapy equipment, or clinical or pathology laboratory equipment (other than equipment used to perform CLIA-waived laboratory tests).

(5) The arrangement is not conditioned on the licensee's referral of patients to the licensor.

(6) The compensation over the term of the arrangement is set in advance, consistent with fair market value, and not determined—

(i) In a manner that takes into account (directly or indirectly) the volume or value of referrals or other business generated between the parties; or

(ii) Using a formula based on—

(A) A percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services provided by the licensee while using the licensor's premises, equipment, personnel, items, supplies or services; or

(B) Per-unit of service license fees that are not time-based, to the extent that

such fees reflect services provided to patients referred by the licensor to the licensee.

(7) The arrangement would be commercially reasonable even if no referrals were made between the parties.

(8) The arrangement does not violate the anti-kickback statute (section 1128B(b) of the Act) or any Federal or State law or regulation governing billing or claims submission.

■ 29. Section 411.361 is amended by revising paragraph (d) to read as follows:

§ 411.361 Reporting requirements.

* * * * *

(d) *Reportable financial relationships.* For purposes of this section, a reportable financial relationship is any ownership or investment interest, as defined at § 411.354(b) or any compensation arrangement, as defined at § 411.354(c), except for ownership or investment interests that satisfy the exceptions set forth in § 411.356(a) or § 411.356(b) regarding publicly traded securities and mutual funds.

* * * * *

■ 30. Section 411.362 is amended by—

■ a. Amending paragraph (a) by adding the definitions of ''Ownership or investment interest'' and ''Public advertising for the hospital'' in alphabetical order.

■ b. Revising paragraphs (b)(3)(ii)(C), (c)(2)(iv), (c)(2)(v), and (c)(5) introductory text.

The additions and revisions read as follows:

§ 411.362 Additional requirements concerning physician ownership and investment in hospitals.

(a) * * *

Ownership or investment interest means for purposes of this section a direct or indirect ownership or investment interest in a hospital.

(1) A direct ownership or investment interest in a hospital exists if the ownership or investment interest in the hospital is held without any intervening persons or entities between the hospital and the owner or investor.

(2) An indirect ownership or investment interest in a hospital exists if—

(i) Between the owner or investor and the hospital there exists an unbroken chain of any number (but no fewer than one) of persons or entities having ownership or investment interests; and

(ii) The hospital has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the owner or investor has some ownership or investment interest (through any number of intermediary ownership or investment interests) in the hospital.

(3) An indirect ownership or investment interest in a hospital exists even though the hospital does not know, or acts in reckless disregard or deliberate ignorance of, the precise composition of the unbroken chain or the specific terms of the ownership or investment interests that form the links in the chain.

* * * * *

Public advertising for the hospital means any public communication paid for by the hospital that is primarily intended to persuade individuals to seek care at the hospital.

(b) * * *

(3) * * *

(ii) * * *

(C) Disclose on any public Web site for the hospital and in any public advertising for the hospital that the hospital is owned or invested in by physicians. Any language that would put a reasonable person on notice that the hospital may be physician-owned would be deemed a sufficient statement of physician ownership or investment. For purposes of this section, a public Web site for the hospital does not include, by way of example: Social media Web sites; electronic patient payment portals; electronic patient care portals; and electronic health information exchanges.

* * * * *

(c) * * *

(2) * * *

(iv) *Average bed capacity.* Is located in a State in which the average bed capacity in the State is less than the national average bed capacity during the most recent fiscal year for which HCRIS, as of the date that the hospital submits its request, contains data from a sufficient number of hospitals to determine a State's average bed capacity and the national average bed capacity. CMS will provide on its Web site State average bed capacities and the national average bed capacity. For purposes of this paragraph, ''sufficient number'' means the number of hospitals, as determined by CMS that would ensure that the determination under this paragraph would not materially change after additional hospital data are reported.

(v) *Average bed occupancy.* Has an average bed occupancy rate that is greater than the average bed occupancy rate in the State in which the hospital is located during the most recent fiscal year for which HCRIS, as of the date that the hospital submits its request, contains data from a sufficient number of hospitals to determine the requesting hospital's average bed occupancy rate and the relevant State's average bed occupancy rate. A hospital must use filed hospital cost report data to determine its average bed occupancy rate. CMS will provide on its Web site State average bed occupancy rates. For purposes of this paragraph, ''sufficient number'' means the number of hospitals, as determined by CMS that would ensure that the determination under this paragraph would not materially change after additional hospital data are reported.

* * * * *

(5) *Community input and timing of complete request.* Upon submitting a request for an exception and until the hospital receives a CMS decision, the hospital must disclose on any public Web site for the hospital that it is requesting an exception and must also provide actual notification that it is requesting an exception, in either electronic or hard copy form, directly to hospitals whose data are part of the comparisons in paragraphs (c)(2)(ii) and (c)(3)(ii) of this section. Individuals and entities in the hospital's community may provide input with respect to the hospital's request no later than 30 days after CMS publishes notice of the hospital's request in the **Federal Register**. Such input must take the form of written comments. The written comments must be either mailed or submitted electronically to CMS. If CMS receives written comments from the community, the hospital has 30 days after CMS notifies the hospital of the written comments to submit a rebuttal statement.

* * * * *

■ 31. Section 411.384 is amended by revising paragraph (b) to read as follows:

§ 411.384 Disclosing advisory opinions and supporting information.

* * * * *

(b) Promptly after CMS issues an advisory opinion and releases it to the requestor, CMS makes available a copy of the advisory opinion for public inspection during its normal hours of operation and on the CMS Web site.

* * * * *

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

■ 32. 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)).

■ 33. Section 414.90 is amended by—

■ a. Adding paragraphs (j)(8) and (j)(9).

■ b. Revising paragraphs (k) introductory text, and (k)(2).

■ c. Redesignating paragraphs (l)(4) and (l)(5) as (k)(4) and (l)(4), respectively.
■ d. Adding new paragraph (k)(5).

§ 414.90 Physician Quality Reporting System (PQRS).

* * * * *

(j) * * *

(8) *Satisfactory reporting criteria for individual eligible professionals for the 2018 PQRS payment adjustment.* An individual eligible professional who wishes to meet the criteria for satisfactory reporting for the 2018 PQRS payment adjustment must report information on PQRS quality measures identified by CMS in one of the following manners:

(i) *Via claims.* (A) For the 12-month 2018 PQRS payment adjustment reporting period—

(*1*)(*i*) Report at least 9 measures, covering at least 3 of the NQS domains AND report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Of the measures reported, if the eligible professional sees at least 1 Medicare patient in a face-to-face encounter, the eligible professional will report on at least 1 measure contained in the proposed cross-cutting measure set. If less than 9 measures apply to the eligible professional, the eligible professional must report on each measure that is applicable, AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.

(*ii*) [Reserved]

(*2*) [Reserved]

(B) [Reserved]

(ii) *Via qualified registry.* (A) For the 12-month 2018 PQRS payment adjustment reporting period—

(*1*)(*i*) Report at least 9 measures, covering at least 3 of the NQS domains AND report each measure for at least 50 percent of the eligible professional's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Of the measures reported, if the eligible professional sees at least 1 Medicare patient in a face-to-face encounter, the eligible professional will report on at least 1 measure contained in the proposed cross-cutting measure set. If less than 9 measures apply to the eligible professional, the eligible professional must report on each measure that is applicable to the eligible professional, AND report each measure for at least 50 percent of the Medicare Part B FFS patients seen during the reporting period to which the measure applies.

(*ii*) Report at least 1 measures group and report each measures group for at least 20 patients, a majority of which much be Medicare Part B FFS patients.

(*2*) Measures with a 0 percent performance rate or measures groups containing a measure with a 0 percent performance rate will not be counted.

(B) [Reserved]

(iii) *Via EHR direct product.* For the 12-month 2018 PQRS payment adjustment reporting period, report 9 measures covering at least 3 of the NQS domains. If an eligible professional's direct EHR product or EHR data submission vendor product does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional must report all of the measures for which there is Medicare patient data. An eligible professional must report on at least 1 measure for which there is Medicare patient data.

(iv) *Via EHR data submission vendor.* For the 12-month 2018 PQRS payment adjustment reporting period, report 9 measures covering at least 3 of the NQS domains. If an eligible professional's direct EHR product or EHR data submission vendor product does not contain patient data for at least 9 measures covering at least 3 domains, then the eligible professional would be required to report all of the measures for which there is Medicare patient data. An eligible professional would be required to report on at least 1 measure for which there is Medicare patient data.

(9) *Satisfactory reporting criteria for group practices for the 2018 PQRS payment adjustment.* A group practice who wishes to meet the criteria for satisfactory reporting for the 2018 PQRS payment adjustment must report information on PQRS quality measures identified by CMS in one of the following manners:

(i) *Via the GPRO web interface.* For the 12-month 2018 PQRS payment adjustment reporting period, for a group practice of 25 or more eligible professionals, report on all measures included in the web interface; AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice must report on 100 percent of assigned beneficiaries. In some instances, the sampling methodology will not be able to assign at least 248 patients on which a group practice may report, particularly those group practices on the smaller end of the range of 25–99 eligible professionals. If the group practice is assigned less than 248 Medicare beneficiaries, then the group practice must report on 100 percent of its assigned beneficiaries. A group practice must report on at least 1 measure for which there is Medicare patient data.

(ii) *Via qualified registry.* For a group practice of 2 or more eligible professionals, for the 12-month 2018 PQRS payment adjustment reporting period, report at least 9 measures, covering at least 3 of the NQS domains. Of these measures, if a group practice sees at least 1 Medicare patient in a face-to-face encounter, the group practice would report on at least 1 measure in the cross-cutting measure set. If less than 9 measures covering at least 3 NQS domains apply to the group practice, the group practice would report on each measure that is applicable to the group practice, AND report each measure for at least 50 percent of the group's Medicare Part B FFS patients seen during the reporting period to which the measure applies. Measures with a 0 percent performance rate would not be counted.

(iii) *Via EHR direct product.* For a group practice of 2 or more eligible professionals, for the 12-month 2018 PQRS payment adjustment reporting period, report 9 measures covering at least 3 domains. If the group practice's direct EHR product or EHR data submission vendor product does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report all of the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

(iv) *Via EHR data submission vendor.* For a group practice of 2 or more eligible professionals, for the 12-month 2018 PQRS payment adjustment reporting period, report 9 measures covering at least 3 domains. If the group practice's direct EHR product or EHR data submission vendor product does not contain patient data for at least 9 measures covering at least 3 domains, then the group practice must report all of the measures for which there is Medicare patient data. A group practice must report on at least 1 measure for which there is Medicare patient data.

(v) *Via a certified survey vendor in addition to a qualified registry.* For a group practice of 25 or more eligible professionals that elects to report via a certified survey vendor in addition to a qualified registry for the 12-month 2018 PQRS payment adjustment reporting period, the group practice must have all

CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor, and report at least 6 additional measures, outside of CAHPS for PQRS, covering at least 2 of the NQS domains using the qualified registry. If less than 6 measures apply to the group practice, the group practice must report on each measure that is applicable to the group practice. Of the additional measures that must be reported in conjunction with reporting the CAHPS for PQRS survey measures, if any eligible professional in the group practice sees at least 1 Medicare patient in a face-to-face encounter, the group practice must report on at least 1 measure in the cross-cutting measure set.

(vi) *Via a certified survey vendor in addition to a direct EHR product or EHR data submission vendor.* For a group practice of 25 or more eligible professionals that elects to report via a certified survey vendor in addition to a direct EHR product or EHR data submission vendor for the 12-month 2018 PQRS payment adjustment reporting period, the group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor, and report at least 6 additional measures, outside of CAHPS for PQRS, covering at least 2 of the NQS domains using the direct EHR product or EHR data submission vendor product. If less than 6 measures apply to the group practice, the group practice must report all of the measures for which there is patient data. Of the additional 6 measures that must be reported in conjunction with reporting the CAHPS for PQRS survey measures, a group practice would be required to report on at least 1 measure for which there is Medicare patient data.

(vii) *Via a certified survey vendor in addition to the GPRO web interface.* (A) For a group practice of 25 or more eligible professionals, for the 12-month 2018 PQRS payment adjustment reporting period, the group practice must have all CAHPS for PQRS survey measures reported on its behalf via a CMS-certified survey vendor. In addition, the group practice must report on all measures included in the GPRO web interface; AND populate data fields for the first 248 consecutively ranked and assigned beneficiaries in the order in which they appear in the group's sample for each module or preventive care measure. If the pool of eligible assigned beneficiaries is less than 248, then the group practice must report on 100 percent of assigned beneficiaries. A group practice will be required to report on at least 1 measure for which there is Medicare patient data.

(viii) If the CAHPS for PQRS survey is applicable to the practice, group practices comprised of 25 or more eligible professionals who elect to use the GPRO web interface must administer the CAHPS for PQRS survey.

(k) *Satisfactory participation requirements for the payment adjustments for individual eligible professionals and group practices.* In order to satisfy the requirements for the PQRS payment adjustment for a particular program year through participation in a qualified clinical data registry, an individual eligible professional, as identified by a unique TIN/NPI combination, or group practice must meet the criteria for satisfactory participation as specified in paragraph (k)(3) for such year, by reporting on quality measures identified by a qualified clinical data registry during a reporting period specified in paragraph (k)(1) of this section, using the reporting mechanism specified in paragraph (k)(2) of this section.

* * * * *

(2) *Reporting mechanism.* An individual eligible professional or group practice who wishes to meet the criteria for satisfactory participation in a qualified clinical data registry must use the qualified clinical data registry to report information on quality measures identified by the qualified clinical data registry.

* * * * *

(5) *Satisfactory participation criteria for individual eligible professionals and group practices for the 2018 PQRS payment adjustment.* An individual eligible professional or group practice who wishes to meet the criteria for satisfactory participation in a QCDR for the 2018 PQRS payment adjustment must report information on quality measures identified by the QCDR in the following manner:

(i) For the 12-month 2018 PQRS payment adjustment reporting period, report at least 9 measures available for reporting under a QCDR covering at least 3 of the NQS domains, and report each measure for at least 50 percent of the eligible professional's patients. Of these measures, report on at least 3 outcome measures, or, if 3 outcomes measures are not available, report on at least 2 outcome measures and at least 1 of the following types of measures—resource use, patient experience of care, or efficiency/appropriate use.

(ii) [Reserved]

* * * * *

■ 34. Section 414.94 is added to Subpart B to read as follows:

§ 414.94 Appropriate use criteria for advanced diagnostic imaging services.

(a) *Basis and scope.* This section implements the following provisions of the Act:

(1) Section 1834(q)—Recognizing Appropriate Use Criteria for Certain Imaging Services.

(2) Section 1834(q)(1)—Program Established.

(3) Section 1834(q)(2)—Establishment of Applicable Appropriate Use Criteria.

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

Advanced diagnostic imaging service means an imaging service as defined in section 1834(e)(1)(B) of the Act.

Applicable imaging service means an advanced diagnostic imaging service (as defined in section 1834(e)(1)(B) of the Act for which the Secretary determines—

(i) One or more applicable appropriate use criteria apply;

(ii) There are one or more qualified clinical decision support mechanisms listed; and

(iii) One or more of such mechanisms is available free of charge.

Applicable setting means a physician's office, a hospital outpatient department (including an emergency department), an ambulatory surgical center, and any other provider-led outpatient setting determined appropriate by the Secretary.

Appropriate use criteria (AUC) means criteria only developed or endorsed by national professional medical specialty societies or other provider-led entities, to assist ordering professionals and furnishing professionals in making the most appropriate treatment decision for a specific clinical condition for an individual. To the extent feasible, such criteria must be evidence-based. AUC are a collection of individual appropriate use criteria. Individual criteria is information presented in a manner that links: A specific clinical condition or presentation; one or more services; and, an assessment of the appropriateness of the service(s).

Furnishing professional means a physician (as defined in section 1861(r) of the Act) or a practitioner described in section 1842(b)(18)(C) of the Act who furnishes an applicable imaging service.

Ordering professional means a physician (as defined in section 1861(r) of the Act) or a practitioner described in section 1842(b)(18)(C) of the Act who orders an applicable imaging service.

Priority clinical areas means clinical topics, clinical topics and imaging modalities, or imaging modalities identified by CMS through annual rulemaking and in consultation with stakeholders which may be used in the

determination of outlier ordering professionals.

Provider-led entity means a national professional medical specialty society, or an organization that is comprised primarily of providers and is actively engaged in the practice and delivery of healthcare.

Specified applicable appropriate use criteria means AUC developed, modified or endorsed by a qualified provider-led entity.

(c) *Qualified provider-led entities.* Provider-led entities (PLEs) must follow appropriate, evidence-based processes for the development of AUC and demonstrate adherence to the requirements below to be qualified by CMS. AUC developed, modified or endorsed by qualified PLEs are specified applicable AUC. Qualified PLEs may develop AUC, modify AUC developed by another entity, or provide endorsement to AUC developed by other entities.

(1) *Requirements for developing, modifying or endorsing AUC.* All of the following requirements must be met:

(i) An evidentiary review process that includes:

(A) A systematic literature review of the clinical topic and relevant imaging studies; and

(B) An assessment of the evidence using a formal, published and widely recognized methodology for grading evidence. Consideration of relevant published consensus statements by professional medical specialty societies must be part of the evidence assessment.

(ii) At least one multidisciplinary team with autonomous governance, decision making and accountability for developing, modifying or endorsing AUC. At a minimum the team must be comprised of three members including one with expertise in the clinical topic related to the criterion and one with expertise in the imaging modality related to the criterion.

(iii) A publicly transparent process for identifying potential conflicts of interest of members on the multidisciplinary team. The following information is identified and made timely available in response to a public request for a period of not less than 5 years, coincident with the AUC publication of the related recommendation:

(A) Direct or indirect financial relationships that exist between individuals or the spouse or minor child of individuals who have substantively participated in the development of AUC and companies or organizations that may financially benefit from the AUC. This may include, for example, compensation arrangements such as salary, grant, speaking or consulting fees, contract, or collaboration agreements between individuals or the spouse or minor child of individuals who have substantively participated in the development of AUC and companies or organizations that may financially benefit from the AUC.

(B) Ownership or investment interests between individuals or the spouse or minor child of individuals who have substantively participated in the development of AUC and companies or organizations that may financially benefit from the AUC.

(iv) Individual criteria must be published on the provider-led entity's Web site and include an identifying title, authors, and key references used to establish the evidence. If relevant to a CMS identified priority clinical area, such a statement must be included.

(v) Key points in individual criteria must be identified as evidence-based or consensus-based, and graded in terms of strength of evidence using a formal, published and widely recognized methodology.

(vi) The provider-led entity must have a transparent process for the timely and continual updating of each criterion.

(vii) The provider-led entity's process for developing, modifying or endorsing AUC is publicly posted on the entity's Web site.

(2) *Process to identify qualifying provider-led entities.* Provider-led entities must meet all of the following criteria:

(i) Provider-led entities must submit an application to CMS that documents adherence to each of the AUC development requirements outlined in paragraph (c)(1) of this section;

(ii) Applications will be accepted by CMS only from provider-led entities that meet the definition in paragraph (b) of this section;

(iii) Applications must be received by CMS annually by January 1;

(iv) All approved provider-led entities from each year of submissions will be posted to the CMS Web site by June 30; and

(v) Qualified provider-led entities are required to re-apply every 6 years. The application must be submitted by January 1 during the 5th year of their approval.

(d) *Identifying priority clinical areas.* (1) CMS must identify priority clinical areas through annual rulemaking and in consultation with stakeholders.

(2) CMS will consider incidence and prevalence of disease, volume variability of utilization, and strength of evidence for imaging services. We will also consider applicability of the clinical area to a variety of care settings and to the Medicare population.

(3) The Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) may make recommendations to CMS.

(4) Priority clinical areas will be used by CMS to identify outlier ordering professionals (section 1834(q)(5) of the Act).

(e) *Identification of non-evidence based AUC.* (1) CMS will accept public comment to facilitate identification of individual or groupings of AUC that fall within a priority clinical area and are not evidence-based. CMS may also independently identify AUC of concern.

(2) The evidentiary basis of the identified AUC may be reviewed by the MEDCAC.

■ 35. Section 414.605 is amended by revising the definition of ''Basic life support (BLS)'' to read as follows:

§ 414.605 Definitions.

* * * * *

Basic life support (BLS) means transportation by ground ambulance vehicle and medically necessary supplies and services, plus the provision of BLS ambulance services. The ambulance must be staffed by at least two people who meet the requirements of state and local laws where the services are being furnished. Also, at least one of the staff members must be certified, at a minimum, as an emergency medical technician-basic (EMT-Basic) by the State or local authority where the services are furnished and be legally authorized to operate all lifesaving and life-sustaining equipment on board the vehicle. These laws may vary from State to State.

* * * * *

§ 414.610 [Amended]

■ 36. In § 414.610, amend paragraphs (c)(1)(ii) introductory text and (c)(5)(ii), by removing the date ''March 31, 2015'' and adding in its place the date ''December 31, 2017''.

■ 37. Section 414.904 is amended by revising paragraph (j) to read as follows:

§ 414.904 Average sales price as the basis for payment.

* * * * *

(j) *Biosimilar biological products.* Effective January 1, 2016, the payment amount for a biosimilar biological drug product (as defined in § 414.902) for all NDCs assigned to such product is the sum of the average sales price of all NDCs assigned to the biosimilar biological products included within the same billing and payment code as determined under section 1847A(b)(6) of the Act and 6 percent of the amount determined under section 1847A(b)(4)

of the Act for the reference drug product (as defined in § 414.902).

■ 38. Section 414.1205 is amended by adding the definition of ''Certified registered nurse anesthetist (CRNA)'' and ''Physician assistant (PA), nurse practitioner (NP), and clinical nurse specialist (CNS)'' in alphabetical order to read as follows:

§ 414.1205 Definitions.

* * * * *

Certified registered nurse anesthetist (CRNA) has the same meaning given this term under section 1861(bb)(2) of the Act.

* * * * *

Physician assistant (PA), nurse practitioner (NP), and clinical nurse specialist (CNS) have the same meanings given these terms under section 1861(aa)(5) of the Act.

* * * * *

■ 39. Section 414.1210 is amended by—

■ a. Revising paragraph (a)(4), (b)(2)(i)(B), (b)(2)(i)(C), (b)(2)(i)(D), (b)(3)(i), (b)(4) and (c).

■ b. Adding paragraphs (b)(2)(i)(E), (b)(2)(i)(F), (b)(3)(ii) and (b)(3)(iii).

The revisions and additions read as follows:

§ 414.1210 Application of the value-based payment modifier.

(a) * * *

(4) For the CY 2018 payment adjustment period, to nonphysician eligible professionals who are physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists in groups with 2 or more eligible professionals and to physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists who are solo practitioners based on the performance period for the payment adjustment period as described at § 414.1215.

(b) * * *

(2) * * *

(i) * * *

(B) The quality composite score is calculated under § 414.1260(a) using quality data reported by the ACO for the performance period through the ACO GPRO Web interface as required under § 425.504(a)(1) of this chapter or another mechanism specified by CMS and the ACO all-cause readmission measure. Groups and solo practitioners that participate in two or more ACOs during the applicable performance period receive the quality composite score of the ACO that has the highest numerical quality composite score. For the CY 2018 payment adjustment period, the CAHPS for ACOs survey also will be included in the quality composite score.

(C) For the CY 2017 payment adjustment period, the value-based payment modifier adjustment will be equal to the amount determined under § 414.1275 for the payment adjustment period, except that if the ACO does not successfully report quality data as described in paragraph (b)(2)(i)(B) of this section for the performance period, such adjustment will be equal to −4% for groups with 10 or more eligible professionals and equal to −2% for groups with two to nine eligible professionals and for solo practitioners. If the ACO has an assigned beneficiary population during the performance period with an average risk score in the top 25 percent of the risk scores of beneficiaries nationwide, and a group or solo practitioner that participates in the ACO during the performance period is classified as high quality/average cost under quality-tiering for the CY 2017 payment adjustment period, the group or solo practitioner receives an upward adjustment of +3x (rather than +2x) if the group has 10 or more eligible professionals or +2x (rather than +1x) if a solo practitioner or the group has two to nine eligible professionals.

(D) For the CY 2018 payment adjustment period, the value-based payment modifier adjustment will be equal to the amount determined under § 414.1275 for the payment adjustment period, except that if the ACO does not successfully report quality data as described in paragraph (b)(2)(i)(B) of this section for the performance period, such adjustment will be equal to the downward payment adjustment amounts described at § 414.1270(d)(1). If the ACO has an assigned beneficiary population during the performance period with an average risk score in the top 25 percent of the risk scores of beneficiaries nationwide, and a group or solo practitioner that participates in the ACO during the performance period is classified as high quality/average cost under quality-tiering for the CY 2018 payment adjustment period, the group or solo practitioner receives an upward adjustment of +3x (rather than +2x) if the group has 10 or more eligible professionals, +2x (rather than +1x) if a solo practitioner or the group has two to nine eligible professionals, or +2.0x (rather than +1.x) if a solo practitioner or group consisting of nonphysician eligible professionals.

(E) For the CY 2017 payment adjustment period and each subsequent calendar year payment adjustment period, the value-based payment modifier for groups and solo practitioners that participate in an ACO under the Shared Savings Program during the applicable performance period is determined as described under § 414.1210(b)(2), regardless of whether any eligible professionals in the group or the solo practitioner also participate in an Innovation Center model during the performance period.

(F) The same value-based payment modifier adjustment will be applied in the payment adjustment period to all groups based on size as specified under § 414.1275 and solo practitioners that participated in the ACO during the performance period.

* * * * *

(3) * * *

(i) For the CY 2017 payment adjustment period, the value-based payment modifier is waived under section 1115A(d)(1) of the Act for physicians in groups with 2 or more eligible professionals and for physicians who are solo practitioners that participate in the Pioneer ACO Model or the Comprehensive Primary Care (CPC) Initiative during the performance period for the payment adjustment period as described at § 414.1215.

(ii) For the CY 2018 payment adjustment period, the value-based payment modifier is waived under section 1115A(d)(1) of the Act for physicians and nonphysician eligible professionals in groups with 2 or more eligible professionals and for physicians and nonphysician eligible professionals who are solo practitioners that participate in the Pioneer ACO Model or the Comprehensive Primary Care (CPC) Initiative during the performance period for the payment adjustment period as described at § 414.1215.

(iii) For purposes of the value-based payment modifier, a group or solo practitioner is considered to be participating in the Pioneer ACO Model or CPC Initiative if at least one eligible professional billing under the TIN in the performance period for the payment adjustment period as described at § 414.1215 is participating in the Pioneer ACO Model or CPC Initiative in the performance period.

(4) *Application of the value-based payment modifier to participants in other similar Innovation Center models.* (i) For the CY 2017 payment adjustment period, the value-based payment modifier is waived under section 1115A(d)(1) of the Act for physicians in groups with 2 or more eligible professionals and for physicians who are solo practitioners that participate in other similar Innovation Center models during the performance period for the payment adjustment period as described at § 414.1215.

(ii) For the CY 2018 payment adjustment period, the value-based

payment modifier is waived under section 1115A(d)(1) of the Act for physicians and nonphysician eligible professionals in groups with 2 or more eligible professionals and for physicians and nonphysician eligible professionals who are solo practitioners that participate in other similar Innovation Center models during the performance period for the payment adjustment period as described at § 414.1215.

(iii) For purposes of the value-based payment modifier, a group or solo practitioner is considered to be participating in a similar Innovation Center model if at least one eligible professional billing under the TIN in the performance period for the payment adjustment period as described at § 414.1215 is participating in the similar model in the performance period.

(c) *Group size and composition determination.* (1) The list of groups of physicians subject to the value-based payment modifier for the CY 2015 payment adjustment period is based on a query of PECOS on October 15, 2013. For each subsequent calendar year payment adjustment period, the list of groups and solo practitioners subject to the value-based payment modifier is based on a query of PECOS that occurs within 10 days of the close of the Physician Quality Reporting System group registration process during the applicable performance period described at § 414.1215. Groups are removed from the PECOS-generated list if, based on a claims analysis, the group did not have the required number of eligible professionals, as defined in § 414.1210(a), that submitted claims during the performance period for the applicable calendar year payment adjustment period. Solo practitioners are removed from the PECOS-generated list if, based on a claims analysis, the solo practitioner did not submit claims during the performance period for the applicable calendar year payment adjustment period.

(2) Beginning with the CY 2016 payment adjustment period, the size of a group during the applicable performance period will be determined by the lower number of eligible professionals as indicated by the PECOS-generated list or claims analysis.

(3) For the CY 2018 payment adjustment period, the composition of a group during the applicable performance period will be determined based on whether the group includes physicians, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and/or other types of nonphysician eligible professionals as indicated by the PECOS-generated list or claims analysis.

■ 40. Section 414.1215 is amended by adding paragraph (d) to read as follows:

§ 414.1215 Performance and payment adjustment periods for the value-based payment modifier.

* * * * *

(d) The performance period is calendar year 2016 for value-based payment modifier adjustments made in the calendar year 2018 payment adjustment period.

■ 41. Section 414.1235 is amended by adding paragraphs (c)(4) and (c)(5) to read as follows:

§ 414.1235 Cost measures.

* * * * *

(c) * * *

(4) Beginning with the CY 2016 payment adjustment period, the cost measures of a group and solo practitioner subject to the value-based payment modifier are adjusted to account for the group's and solo practitioner's specialty mix, by computing the weighted average of the national specialty specific expected costs and comparing this to the group's actual risk adjusted costs. Each national specialty-specific expected cost is weighted by the proportion of Part B payments incurred by each specialty within the group.

(5) The national specialty-specific expected costs referenced in paragraph (c)(4) of this section are derived by calculating, for each specialty, the weighted average of the risk-adjusted costs computed across all groups, where the weight for each group is equal to the number of beneficiaries attributed to the group, times the number of eligible professionals in the group with the relevant specialty, times the proportion of eligible professionals in the group with the relevant specialty.

■ 42. Section 414.1250 is amended by revising paragraph (a) to read as follows:

§ 414.1250 Benchmarks for quality of care measures.

(a) The benchmark for quality of care measures reported through the PQRS using the claims, registries, or web interface is the national mean for that measure's performance rate (regardless of the reporting mechanism) during the year prior to the performance period. In calculating the national benchmark, solo practitioners' and groups' (or individual eligible professionals' within such groups) performance rates are weighted by the number of beneficiaries used to calculate the solo practitioners' or groups' (or individual eligible professionals' within such groups) performance rate. Beginning with the CY 2016 performance period, eCQMs reported via EHRs are excluded from the overall benchmark for quality of care measures and separate benchmarks are used for eCQMs. The eCQM benchmark is the national mean for the measure's performance rate during the year prior to the performance period. In calculating the national benchmark, solo practitioners' and groups' (or individual eligible professionals' within such groups) performance rates are weighted by the number of beneficiaries used to calculate the solo practitioners' or groups' (or individual eligible professionals' within such groups) performance rate.

* * * * *

■ 43. Section 414.1255 is amended by revising paragraph (b) and removing paragraph (c) to read as follows:

§ 414.1255 Benchmarks for cost measures.

* * * * *

(b) Beginning with the CY 2016 payment adjustment period, the benchmark for each cost measure is the national mean of the performance rates calculated among all groups and solo practitioners that meet the minimum number of cases for that measure under § 414.1265(a). In calculating the national benchmark, groups and solo practitioners' performance rates are weighted by the number of beneficiaries used to calculate the group or solo practitioner's performance rate.

■ 44. Section 414.1265 is amended by adding paragraph (a)(2), and revising paragraph (b) to read as follows:

§ 414.1265 Reliability of measures.

* * * * *

(a) * * *

(2) Starting with the CY 2017 payment adjustment period, the Medicare Spending Per Beneficiary measure described at § 414.1235(a)(6) is an exception to this paragraph (a). In a performance period, if a group or a solo practitioner has fewer than 100 cases for this MSPB measure, that measure is excluded from its domain and the remaining measures in the domain are given equal weight.

(b)(1) For the CY 2015 payment adjustment period, if a reliable quality of care composite or cost composite cannot be calculated, payments will not be adjusted under the value-based payment modifier.

(2) Beginning with the CY 2016 payment adjustment period, a group and a solo practitioner subject to the value-based payment modifier will receive a quality composite score that is classified as ''average'' under § 414.1275(b)(1) if such group and solo practitioner do not have at least one quality measure that

meets the minimum number of cases under paragraph (a) of this section.

(3) Beginning with the CY 2016 payment adjustment period, a group and a solo practitioner subject to the value-based payment modifier will receive a cost composite score that is classified as ''average'' under § 414.1275(b)(2) if such group and solo practitioner do not have at least one cost measure that meets the minimum number of cases under paragraph (a) of this section.

■ 45. Section 414.1270 is amended by removing paragraphs (b)(5) and (c)(5), and adding paragraph (d) to read as follows:

§ 414.1270 Determination and calculation of Value-Based Payment Modifier adjustments.

* * * * *

(d) For the CY 2018 payment adjustment period:

(1) A downward payment adjustment of −2.0 percent will be applied to a group with two to nine eligible professionals and a solo practitioner, a downward payment adjustment of −4.0 percent will be applied to a group with 10 or more eligible professionals, and a downward payment adjustment of −2.0 percent will be applied to a group or solo practitioner consisting of nonphysician eligible professionals subject to the value-based payment modifier if, during the applicable performance period as defined in § 414.1215, the following apply:

(i) Such group does not meet the criteria as a group to avoid the PQRS payment adjustment for CY 2018 as specified by CMS; and

(ii) Fifty percent of the eligible professionals in such group do not meet the criteria as individuals to avoid the PQRS payment adjustment for CY 2018 as specified by CMS; or

(iii) Such solo practitioner does not meet the criteria as an individual to avoid the PQRS payment adjustment for CY 2018 as specified by CMS.

(2) For a group composed of 10 or more eligible professionals that is not included in paragraph (d)(1) of this section, the value-based payment modifier adjustment will be equal to the amount determined under § 414.1275(c)(4)(i).

(3) For a group composed of between two to nine eligible professionals and a solo practitioner that are not included in paragraph (d)(1) of this section, the value-based payment modifier adjustment will be equal to the amount determined under § 414.1275(c)(4)(ii).

(4) For a group and a solo practitioner consisting of nonphysician eligible professionals that are not included in paragraph (d)(1) of this section, the value-based payment modifier adjustment will be equal to the amount determined under § 414.1275(c)(4)(iii).

(5) If at least 50 percent of the eligible professionals in the group meet the criteria as individuals to avoid the PQRS payment adjustment for CY 2018 as specified by CMS, and all of those eligible professionals use a qualified clinical data registry and CMS is unable to receive quality performance data for them, the quality composite score for such group will be classified as ''average'' under § 414.1275(b)(1).

■ 46. Section 414.1275 is amended by adding paragraphs (c)(4) and (d)(3) to read as follows:

§ 414.1275 Value-based payment modifier quality-tiering scoring methodology.

(c) * * *

(4) The following value-based payment modifier percentages apply to the CY 2018 payment adjustment period:

(i) For physicians, physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists in groups with 10 or more eligible professionals:

CY 2018 VALUE-BASED PAYMENT MODIFIER AMOUNTS FOR THE QUALITY-TIERING APPROACH FOR PHYSICIANS, PHYSICIAN ASSISTANTS, NURSE PRACTITIONERS, CLINICAL NURSE SPECIALISTS, AND CERTIFIED REGISTERED NURSE ANESTHETISTS IN GROUPS WITH 10 OR MORE ELIGIBLE PROFESSIONALS

Cost/quality	Low quality	Average quality	High quality
Low Cost	+0.0%	+2.0x*	+4.0x*
Average Cost	−2.0%	+0.0%	+2.0x*
High Cost	−4.0%	−2.0%	+0.0%

* Groups eligible for an additional +1.0x if reporting Physician Quality Reporting System quality measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.

(ii) For physicians, physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists in groups with two to nine eligible professionals and physician solo practitioners:

CY 2018 VALUE-BASED PAYMENT MODIFIER AMOUNTS FOR THE QUALITY-TIERING APPROACH FOR PHYSICIANS, PHYSICIAN ASSISTANTS, NURSE PRACTITIONERS, CLINICAL NURSE SPECIALISTS, AND CERTIFIED REGISTERED NURSE ANESTHETISTS IN GROUPS WITH TWO TO NINE ELIGIBLE PROFESSIONALS AND PHYSICIAN SOLO PRACTITIONERS

Cost/quality	Low quality	Average quality	High quality
Low Cost	+0.0%	+1.0x*	+2.0x*
Average Cost	−1.0%	+0.0%	+1.0x*
High Cost	−2.0%	−1.0%	+0.0%

* Groups and solo practitioners eligible for an additional +1.0x if reporting Physician Quality Reporting System quality measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.

(iii) For physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists in groups that consist of nonphysician eligible professionals, and solo practitioners who are physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists:

CY 2018 VALUE-BASED PAYMENT MODIFIER AMOUNTS FOR THE QUALITY-TIERING APPROACH FOR PHYSICIAN ASSISTANTS, NURSE PRACTITIONERS, CLINICAL NURSE SPECIALISTS, AND CERTIFIED REGISTERED NURSE ANESTHETISTS IN GROUPS CONSISTING OF NONPHYSICIAN ELIGIBLE PROFESSIONALS, AND SOLO PRACTITIONERS WHO ARE PHYSICIAN ASSISTANTS, NURSE PRACTITIONERS, CLINICAL NURSE SPECIALISTS, AND CERTIFIED REGISTERED NURSE ANESTHETISTS

Cost/quality	Low quality	Average quality	High quality
Low Cost	+0.0%	+1.0x*	+2.0x*
Average Cost	+0.0%	+0.0%	+1.0x*
High Cost	+0.0%	+0.0%	+0.0%

*Groups and solo practitioners eligible for an additional +1.0x if reporting Physician Quality Reporting System quality measures and average beneficiary risk score is in the top 25 percent of all beneficiary risk scores, where 'x' represents the upward payment adjustment factor.

(d) * * *

(3) Groups and solo practitioners subject to the value-based payment modifier that have an attributed beneficiary population with an average risk score in the top 25 percent of the risk scores of beneficiaries nationwide and for the CY 2018 payment adjustment period are subject to the quality-tiering approach, receive a greater upward payment adjustment as follows:

(i) Classified as high quality/low cost receive an upward adjustment of +5x (rather than +4x) if the group has 10 or more eligible professionals, +3x (rather than +2x) if a solo practitioner or the group has two to nine eligible professionals, or +3x (rather than +2x) if a solo practitioner or group consisting of nonphysician eligible professionals; and

(ii) Classified as either high quality/average cost or average quality/low cost receive an upward adjustment of +3x (rather than +2x) if the group has 10 or more eligible professionals, +2x (rather than +1x) if a solo practitioner or the group has two to nine eligible professionals, or +2x (rather than +1x) if a solo practitioner or group consisting of nonphysician eligible professionals.

PART 425—MEDICARE SHARED SAVINGS PROGRAM

■ 47. The authority citation for part 425 continues to read as follows:

Authority: Secs. 1102, 1106, 1871, and 1899 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 48. Section 425.20, as amended on June 9, 2015 (80 FR 32833) and effective on August 10, 2015, is further amended in the definition of ''Primary care services'' by—

■ a. Revising paragraph (2) introductory text.

■ b. Adding paragraph (2)(v).

■ c. Adding paragraph (4).

The revision and additions read as follows:

§ 425.20 Definitions.

* * * * *

Primary care services * * *

(2) For performance year 2016 as follows:

* * * * *

(v) G0463 for services furnished in ETA hospitals.

* * * * *

(4) For performance years 2017 and subsequent years as follows:

(i) 99201 through 99215.

(ii) 99304–99318 (excluding claims including the POS 31 modifier) and 99319–99340

(iii) 99341 through 99350.

(iv) 99495, 99496 and 99490.

(v) G0402 (the code for the Welcome to Medicare visit).

(vi) G0438 and G0439 (codes for the annual wellness visits).

(vii) Revenue center codes 0521, 0522, 0524, 0525 submitted by FQHCs (for services furnished prior to January 1, 2011), or by RHCs.

(viii) G0463 for services furnished in ETA hospitals.

■ 49. Section 425.102 is amended by—

■ a. Adding paragraph (a)(8).

■ b. In paragraph (b), removing the phrase ''eligible participate'' and adding in its place the phrase ''eligible to participate''.

The addition reads as follows:

§ 425.102 Eligible providers and suppliers.

(a) * * *

(8) Teaching hospitals that have elected under § 415.160 of this chapter to receive payment on a reasonable cost basis for the direct medical and surgical services of their physicians.

* * * * *

■ 50. Section 425.402, as amended on June 9, 2015 (80 FR 32841) and effective on August 10, 2015, is further amended by adding paragraph (d) to read as follows:

§ 425.402 Basic assignment methodology.

* * * * *

(d) When considering services furnished by ACO professionals in teaching hospitals that have elected under § 415.160 of this subchapter to receive payment on a reasonable cost basis for the direct medical and surgical services of their physicians in the assignment methodology under paragraph (b) of this section, CMS uses an estimated amount based on the amounts payable under the physician fee schedule for similar services in the geographic location of the teaching hospital as a proxy for the amount of the allowed charges for the service.

■ 51. Section 425.502 is amended by adding paragraph (a)(5) to read as follows:

§ 425.502 Calculating the ACO quality performance score.

(a) * * *

(5) CMS reserves the right to redesignate a measure as pay for reporting when the measure owner determines the measure no longer aligns with clinical practice or causes patient harm.

* * * * *

§ 425.504 [Amended]

■ 52. In § 425.504—

■ a. Amend paragraph (a)(1) by removing the phrase ''their ACO provider/suppliers who are eligible professionals'' and adding in its place the phrase ''eligible professionals who bill under the TIN of an ACO participant''.

■ b. Amend paragraphs (b)(1) and (c)(1) by removing the phrase ''their ACO providers/suppliers who are eligible professionals'' and adding in its place the phrase ''eligible professionals who bill under the TIN of an ACO participant''.

■ c. Amend paragraphs (a)(2)(ii), (b)(2)(ii), (b)(3) and (c)(3), by removing the phrase ''its ACO providers/suppliers who are eligible professionals'' and adding in its place the phrase ''eligible professionals who bill under the TIN of an ACO participant''.

■ d. Amend paragraphs (a)(2)(i), (b)(2)(i), and (c)(2) by removing the phrase ''ACO providers/suppliers that are eligible professionals'' and adding in

its place the phrase ''eligible professionals who bill under the TIN of an ACO participant''.

■ e. Amend paragraphs (a)(3), (a)(4), and (b)(4), by removing the phrase ''ACO providers/suppliers who are eligible professionals'' and adding in its place the phrase ''eligible professionals who bill under the TIN of an ACO participant''.

■ f. Amend paragraph (b)(3) by removing the phrase ''each ACO supplier/provider who is an eligible professional'' and adding in its place the phrase ''each eligible professional who bills under the TIN of an ACO participant''.

■ g. Amend paragraph (c)(3) by removing the phrase ''each ACO provider/supplier who is an eligible professional'' and adding in its place the phrase ''each eligible professional who bills under the TIN of an ACO participant''.

PART 495—STANDARDS FOR THE ELECTRONIC HEALTH RECORD TECHNOLOGY INCENTIVE PROGRAM

■ 53. The authority citation for part 495 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

■ 54. In § 495.4 the definition of ''Certified electronic health record technology (CEHRT)'', as proposed to be revised on March 30, 2015 (80 FR 16795), is proposed to be further amended by revising paragraphs (1)(ii)(C)(2) and (2)(iii)(B) to read as follows:

§ 495.4 Definitions.

* * * * *

Certified electronic health record technology (CEHRT) * * *

(1) * * *

(ii) * * *

(C) * * *

(2) Clinical quality measure certification criteria that support the calculation and reporting of clinical quality measures at 45 CFR 170.314(c)(2) and (c)(3); or 45 CFR 170.315(c)(2), (c)(3)(i) and (c)(3)(ii); and can be electronically accepted by CMS if the provider is submitting electronically.

* * * * *

(2) * * *

(iii) * * *

(B) Clinical quality measure certification criteria that support the calculation and reporting of clinical quality measures under the 2015 Edition certification criteria 45 CFR 170.315(c)(2), (c)(3)(i) and (c)(3)(ii), and can be electronically accepted by CMS.

* * * * *

Dated: June 24, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: June 30, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2015–16875 Filed 7–8–15; 4:15 pm]

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Part IV

The President

Proclamation 9297—Establishment of the Basin and Range National Monument

Proclamation 9298—Establishment of the Berryessa Snow Mountain National Monument

Proclamation 9299—Establishment of the Waco Mammoth National Monument

Federal Register
Vol. 80, No. 135
Wednesday, July 15, 2015

Presidential Documents

Title 3—

The President

Proclamation 9297 of July 10, 2015

Establishment of the Basin and Range National Monument

By the President of the United States of America

A Proclamation

The Basin and Range area of southeastern Nevada is an iconic American landscape. The area is one of the most undisturbed corners of the broader Great Basin region, which extends from the Sierra Nevada Mountains in the west to the Colorado Plateau in the east. The pattern of basin, fault, and range that characterizes this region creates a dramatic topography that has inspired inhabitants for thousands of years. The vast, rugged landscape redefines our notions of distance and space and brings into sharp focus the will and resolve of the people who have lived here. The unbroken expanse is an invaluable treasure for our Nation and will continue to serve as an irreplaceable resource for archaeologists, historians, and ecologists for generations to come.

Over both geologic and historical time, the Basin and Range area has been a landscape in motion. The area exemplifies the unique topography and geologic history of the Great Basin region and has long been the subject of studies of the tectonic and volcanic mechanisms responsible for this landscape, including crustal extension, deformation, and rifting. The thrust and fault block formations found here, along with the area's stratigraphy, have been instrumental in understanding the nearly 500 million-year history of the region. Among the geologic features found in the Basin and Range area are natural arches, caves, and sheer cliffs that offer stunning vistas. Evidence of the Alamo bolide impact, a high-velocity impact from space about 367 million years ago, can also be found here.

Volcanism and magmatism in this area during the Tertiary period contributed to the formation of numerous mountain ranges that interrupt the area's basins. The Golden Gate Range runs north-south through the center of the Basin and Range area, separating Garden Valley in the west from Coal Valley in the east. The range's block-faulted mountains are split by alluvial gaps carved by water from the valleys' now-dry lake beds. The Mount Irish Range in the southern portion of the area is topped by the steep and rugged 8,743-foot Mount Irish. The Worthington Mountains in the southwest corner of the Basin and Range area are composed of sheer limestone ridges reaching an elevation of 8,850 feet. These mountains were formed by thrust faults and contain at least three known caves, including the Leviathan Cave, which features stalactites, stalagmites, flow stones, soda straws, a cave shield, and rim pools. Data collected from these cave formations has contributed to research of the area's prehistoric climate.

The Basin and Range area spans the transition between the Mojave Desert and the sagebrush steppe of the Great Basin region. The area is one of the largest ecologically intact landscapes in the Great Basin region, providing habitat connectivity and migration corridors for a wide variety of animal species and affording researchers the ability to conduct studies over broad scales. At lower elevations, alluvial fans provide a home for sagebrush communities and mixed desert scrublands, where visitors can see big sagebrush, black sagebrush, little sagebrush, yellow rabbitbrush, saltbush, and mormon tea. Among the herbaceous species here are Indian ricegrass, Sandberg bluegrass, needlegrass, and needle and thread. Pockets of native

grasslands can be found in Coal Valley, and the Basin and Range area is home to the endemic White River catseye. A more arid ecosystem can also be found in some of the lowest elevations, where cholla, spinystar, Engelmann's hedgehog cactus, Mojave kingcup cactus, tulip pricklypear, grizzlybear pricklypear, Blaine fishhook cactus, and other cactus species dominate. At middle elevations, sagebrush gives way to singleleaf pinyon, Utah juniper, curl-leaf mountain mahogany, quaking aspen, and other conifers, along with Idaho fescue and bluebunch wheatgrass. At higher elevations, ponderosa and limber pines become more common. Bristlecone pines over 2,000 years old stand sentinel in the high peaks of the Worthington Mountains.

The area provides important habitat for game species including desert bighorn sheep, mule deer, Rocky Mountain elk, and pronghorn. Other mammal species, including mountain lion, bobcat, kit fox, cottontail rabbit, pygmy rabbit, black-tailed jackrabbit, pale kangaroo mouse, and dark kangaroo mouse, also make their homes here. Many bat species reside in the Basin and Range area's caves and use its lowlands for foraging. The area provides habitat for lizards such as the greater short-horned lizard, desert spiny lizard, yellow-backed spiny lizard, Great Basin collared lizard, common zebra-tailed lizard, long-nosed leopard lizard, Great Basin fence lizard, northern sagebrush lizard, common side-blotched lizard, desert horned lizard, Great Basin skink, and Great Basin whiptail, and likely habitat for gila monsters. Snakes including the desert nightsnake, Great Basin rattlesnake, long-nosed snake, Sonoran mountain kingsnake, striped whipsnake, ringneck snake, gopher snake, and western terrestrial garter snake also make their home in this area. Great Basin spadefoot toads, western toads, and Baja California treefrogs can also be found in the area.

A number of bird species grace the landscape. These include game species such as the chukar, Gambel's quail, and a variety of dove and pigeon species. The dry basins provide habitat for sage thrasher, Brewer's sparrow, and western burrowing owl. Numerous bird species inhabit the Worthington Mountains, including pinyon jay, Clark's nutcracker, mountain bluebird, loggerhead shrike, and green-tailed towhee, along with raptors including golden eagles, Cooper's hawks, and ferruginous hawks.

The land tells the story of a rich cultural tradition. From the earliest human inhabitants 13,000 years ago, to miners and ranchers in the past century and a half, to a modern artist in recent decades, the area's residents have created and maintain notable legacies. The earliest Paleo-Indian inhabitants of the Basin and Range area exploited food sources along the shores of now-dry lakes. These nomadic people left important traces of their presence, including a rare obsidian Clovis point in the Coal Valley Water Gap and a succession of significant campsites and artifacts around the prehistoric Coal Valley Lake.

Starting about 8,000 years ago, a drier, warmer climate forced inhabitants to move beyond the lake beds to take advantage of the rock shelters, caves, and springs that dot the landscape. These people, from the Desert Archaic to the Fremont people about 1,500 years ago, to ancestors of the Western Shoshone and Southern Paiute Tribes about 1,000 years ago, used the land in accordance with seasonal changes in foraging and hunting resources. Similar to their Paleo-Indian predecessors, these cultural groups lacked intensive settlements in this area but left a rich archaeological record, including the excavated Civa Shelter II in the Golden Gate Range. Occupied first by the Fremont people about 1,400 years ago, the cave was later intermittently used by the Shoshone, who left a diverse set of artifacts, including worked bone, shell beads, seed processing equipment, animal remains, clay stockpiles, and over 100 projectile points, suggesting pronounced and extended use for hunting, gathering, and pottery making.

In the south and southeastern reaches of the Basin and Range area, early humans' stories are told at numerous petroglyph sites, including rock art in the White River Narrows Historic District, Mount Irish Archaeological

Area, and the Shooting Gallery rock art site. Listed in the National Register of Historic Places, the White River Narrows Archaeological District represents one of the largest concentrations of prehistoric rock art in eastern Nevada and includes panels dating back 4,000 years and contains the northernmost known examples of the Pahranagat style of rock art. Both the Mount Irish Archaeological Site and the Shooting Gallery area are well known for bighorn sheep motifs, among other styles of rock art. Additionally, the rock features of the Shooting Gallery area may have been used by early inhabitants as hunting blinds. Much of the Basin and Range area has not been comprehensively studied for archaeological resources, though recent surveys suggest that additional resources may be found across the area. Protection of the area will therefore provide important opportunities for archaeologists and historians to further study and understand the evolving relationship between this unique landscape and its human inhabitants.

The Basin and Range area was mostly unknown to European-Americans until the 1820s, when explorers and fur trappers first visited, including Jedediah Smith, part-owner of the Rocky Mountain Fur Company and arguably the most famous of the ''Mountain Men.'' Mormon settlers came to the area in the mid-19th century. About the same time, the explorer, politician, and military officer John C. Frémont traversed this area while surveying for a transcontinental railroad. Mining began in the area in the 1860s when, reportedly, Native Americans escorted prospectors out to ore veins in outcroppings in the north end of the Worthington Mountains. Here the miners established what was originally called the Worthington Mining District, and subsequently renamed the Freiberg Mining District. The silver, lead, zinc, copper, and tungsten deposits found there supported modest historical production. Head frames, mining cabins, and other structures associated with the region's mining history can be found in the Mount Irish area. Explorer and conservationist John Muir reported that he holed up in a canyon in the Golden Gate Range for a week in 1878. During the late 19th century, Basque and other ranchers brought sheep and cattle ranching into Garden Valley, and ranching remains to this day.

The location of a recent work of land art in the Basin and Range area reflects the rugged landscape and confirms its importance as a unique geologic area. The artist Michael Heizer chose the area for his work *City,* begun in 1972 and now nearing completion. Sitting on privately-held land in Garden Valley, *City* is one of the most ambitious examples of the distinctively American land art movement. Built into and out of the vast undeveloped expanse of Garden Valley, the work combines modern abstract architecture and engineering with ancient American aesthetic influences on a monumental scale, roughly the size of the National Mall, and evokes the architectural forms of ancient Mesoamerican ceremonial cities like Teotihuacán and Chichén Itzá. The presence of *City* in this stark and silent landscape provides the visitor a distinctive lens through which to experience and interact with Garden Valley.

The protection of the Basin and Range area will preserve its cultural, prehistoric, and historic legacy and maintain its diverse array of natural and scientific resources, ensuring that the prehistoric, historic, and scientific values of this area remain for the benefit of all Americans.

WHEREAS, section 320301 of title 54, United States Code (known as the ''Antiquities Act''), authorizes the President, in his discretion, to declare by public proclamation historic landmarks, historic and prehistoric structures, and other objects of historic or scientific interest that are situated upon the lands owned or controlled by the Federal Government to be national monuments, and to reserve as a part thereof parcels of land, the limits of which in all cases shall be confined to the smallest area compatible with the proper care and management of the objects to be protected;

WHEREAS, it is in the public interest to preserve the objects of scientific and historic interest on the Basin and Range lands;

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by the authority vested in me by section 320301 of title 54, United States Code, hereby proclaim the objects identified above that are situated upon lands and interests in lands owned or controlled by the Federal Government to be the Basin and Range National Monument (monument) and, for the purpose of protecting those objects, reserve as part thereof all lands and interests in lands owned or controlled by the Federal Government within the boundaries described on the accompanying map, which is attached to and forms a part of this proclamation. These reserved Federal lands and interests in lands encompass approximately 704,000 acres. The boundaries described on the accompanying map are confined to the smallest area compatible with the proper care and management of the objects to be protected.

All Federal lands and interests in lands within the boundaries of the monument are hereby appropriated and withdrawn from all forms of entry, location, selection, sale, or other disposition under the public land laws, from location, entry, and patent under the mining laws, and from disposition under all laws relating to mineral and geothermal leasing, other than by exchange that furthers the protective purposes of the monument.

The establishment of the monument is subject to valid existing rights. If the Federal Government acquires any lands or interests in lands not owned or controlled by the Federal Government within the boundaries described on the accompanying map, such lands and interests in lands shall be reserved as a part of the monument, and objects identified above that are situated upon those lands and interests in lands shall be part of the monument, upon acquisition of ownership or control by the Federal Government.

The Secretary of the Interior (Secretary) shall manage the monument through the Bureau of Land Management (BLM) as a unit of the National Landscape Conservation System, pursuant to applicable legal authorities to protect the objects identified above.

For purposes of the care and management of the objects identified above, the Secretary, through BLM, shall within 3 years of the date of this proclamation prepare and maintain a management plan for the monument and shall provide for maximum public involvement in the development of that plan including, but not limited to, consultation with State, tribal, and local governments.

Nothing in this proclamation shall be deemed to limit the authority of the Secretary, under applicable law other than this proclamation, to undertake or authorize activities on public land in the vicinity of the sculpture *City* for the purpose of preventing harm to the artwork, including activities to improve drainage and to prevent erosion, consistent with the care and management of the objects identified above. The management plan for the monument shall provide for reasonable use of existing roads within the monument to facilitate public access to *City.*

Except for emergency or authorized administrative purposes, motorized vehicle use in the monument shall be permitted only on roads existing as of the date of this proclamation. Non-motorized mechanized vehicle use shall be permitted only on roads and trails designated for their use consistent with the care and management of the objects identified above. The Secretary shall prepare a transportation plan that designates the roads and trails where motorized or non-motorized mechanized vehicle use will be permitted.

Except as necessary for the care and management of the objects identified above or for the purpose of permitted livestock grazing, no new rights-of-way for electric transmission or transportation shall be authorized within the monument. Other rights-of-way may be authorized only if consistent with the care and management of the objects identified above.

Nothing in this proclamation shall be deemed to enlarge or diminish the rights of any Indian tribe. The Secretary shall, to the maximum extent permitted by law and in consultation with Indian tribes, ensure the protection

of Indian sacred sites and cultural sites in the monument and provide access to the sites by members of Indian tribes for traditional cultural and customary uses, consistent with the American Indian Religious Freedom Act (42 U.S.C. 1996) and Executive Order 13007 of May 24, 1996 (Indian Sacred Sites).

Nothing in this proclamation shall be deemed to affect authorizations for livestock grazing, or administration thereof, on Federal lands within the monument. Livestock grazing within the monument shall continue to be governed by laws and regulations other than this proclamation.

This proclamation does not alter or affect the valid existing water rights of any party, including the United States. This proclamation does not reserve water as a matter of Federal law.

Nothing in this proclamation shall be deemed to enlarge or diminish the jurisdiction of the State of Nevada, including its jurisdiction and authority with respect to fish and wildlife management.

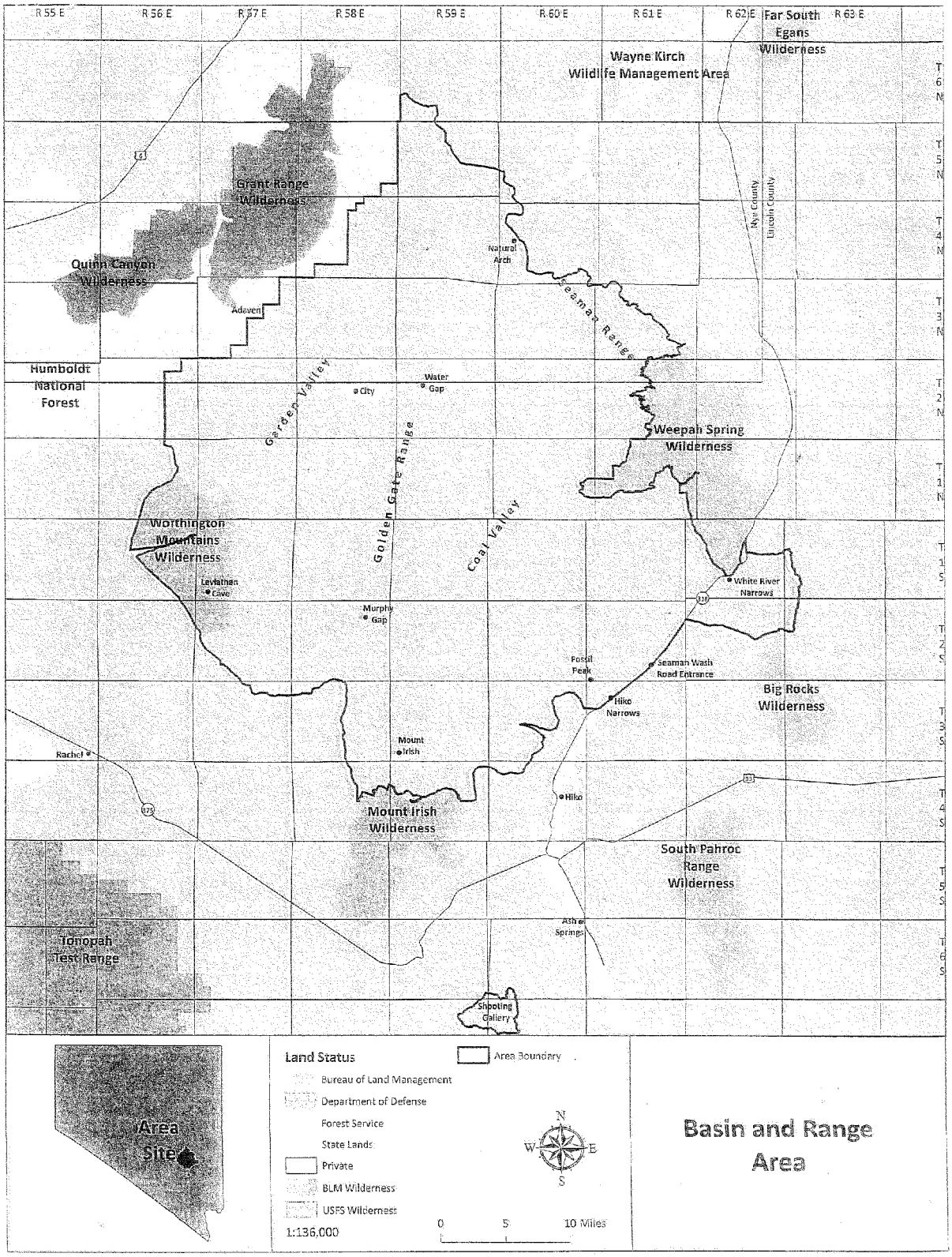
Nothing in this proclamation shall preclude low-level overflights of military aircraft, the designation of new units of special use airspace, or the use or establishment of military flight training routes over the lands reserved by this proclamation. Nothing in this proclamation shall preclude air or ground access for: (i) emergency response; (ii) existing or new electronic tracking and communications; (iii) landing and drop zones; and (iv) readiness training by Air Force, Joint, and Coalition forces, including training using motorized vehicles both on- and off-road, in accordance with applicable interagency agreements. Nothing in this proclamation shall preclude the Secretary of Defense from entering into new or renewed agreements with the Secretary of the Interior concerning these uses, consistent with the care and management of the objects to be protected.

Nothing in this proclamation shall be deemed to revoke any existing withdrawal, reservation, or appropriation; however, the monument shall be the dominant reservation.

Warning is hereby given to all unauthorized persons not to appropriate, injure, destroy, or remove any feature of the monument and not to locate or settle upon any of the lands thereof.

IN WITNESS WHEREOF, I have hereunto set my hand this tenth day of July, in the year of our Lord two thousand fifteen, and of the Independence of the United States of America the two hundred and fortieth.

Billing code 3295–F5–P



[FR Doc. 2015–17549

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Billing code 4310–10–C

Presidential Documents

Proclamation 9298 of July 10, 2015

Establishment of the Berryessa Snow Mountain National Monument

By the President of the United States of America

A Proclamation

The Berryessa Snow Mountain area is the heart of northern California's wild Inner Coast Range. Once covered by ocean waters, it is a landscape shaped by geologic forces of staggering power overlain with bountiful but fragile biodiversity. Anchored in the north by Snow Mountain's remote forests and in the south by scenic Berryessa Mountain, this area stretches through unbroken wildlands and important wildlife corridors, a mosaic of native grasslands, picturesque oak woodlands, rare wetlands, and wild chaparral.

Home to the headwaters of the Eel River, and the Stony, Cache, and Putah creeks, Berryessa's waters are a crucial element of this landscape and a vital link to the water supply for millions of people. This dramatic and diverse landscape is a biological hotspot providing refuge for rare plant and animal species and showcasing the human history of north-central California.

Native Americans have inhabited these lands for at least the last 11,000 years. Many tribes, including the Yuki, Nomlaki, Patwin, Pomo, Huchnom, Wappo, and Lake Miwok, and Wintum all played a role in the history of this region, one of the most linguistically diverse in California.

The region's abundant natural resources helped to shape these distinct cultures. Early inhabitants subsisted upon protein-rich acorns in addition to seed and nut crops cultivated through traditional burning practices. Obsidian, chert, and basalt provided important source material for tool production, such as flaked tools and projectile points. The inhabitants also processed and produced both shell and magnesite beads, which they traded with other tribes.

Dense with cultural resources, the Berryessa Snow Mountain area contains a range of ancient settlements from mineral collection sites, and seasonal hunting and gathering camps in the high country, to major villages with subterranean, earth-covered round buildings in the lowlands. In addition to trade routes winding through the hills and mountains, the area is rich with sites that tell the story of early Native peoples: chert quarries where stone was gathered to make tools, task sites where tools were re-sharpened during hunting excursions, food sites where acorn and seeds were ground on large grindstones, and areas with pitted boulder petroglyphs where individuals illustrated their life experiences. The Cache Creek Archeological District, designated on the National Register of Historic Places, illustrates the area's archeological importance.

In the early 19th century, both Spanish and Mexican expeditions explored the region, as did fur trappers for the Hudson Bay Company. These explorers and trappers were often just brief visitors to this landscape, but their explorations and documentation opened the region to further European-American settlement by providing information about conditions, resources, and geography. This later settlement began during the 1840s gold rush. Farming

in the region was limited due to the difficult terrain and soils, while cattle and sheep ranching were much more profitable.

From the mid to late 1800s, many small sawmills operated within the forests of the area. The restored 1860s-era Nye homestead cabin, the historic Prather Mill, and remnants of associated railroad logging operations are tangible reminders of these historic uses. Around the turn of the 20th century, the mineral-laden waters and hot springs of the area attracted visitors to resorts and spas advertising their therapeutic benefits. Remains of the foundations of the mineral spring resorts at Bartlett Springs can be spotted by observant visitors today.

Native populations were displaced by the European-American settlement and development of the region in the early to mid-1800s. Many traditional hunting and gathering grounds were converted to grazing and logging and new diseases brought into the area spread to the Native people, greatly impacting the local Native populations and pushing them off of their homelands. Nevertheless, the region's landscape and resources retain deep cultural significance for modern Native communities, including roughly two dozen federally recognized tribes.

The Berryessa Snow Mountain area tells a dynamic geologic story. A relic of ancient times, scientists theorize that Snow Mountain formed as an underwater mountain during the Jurassic Period, 145–199 million years ago. Much of the region is prone to landslides due to weak and pervasively fractured rock, resulting in a diverse topography, including sag ponds and springs, with important values for wildlife and plants. The seismically active Bartlett Springs fault zone has remarkable features including hot springs and geologic outliers with marine invertebrate fossils dating to the Cretaceous Period and Cenozoic Era. The area has two important tension-crack caves, likely also created by landslides. These are classified as significant under the Federal Cave Resources Protection Act of 1988 and provide habitat for the Townsend's big-eared bat.

Rising from near sea-level in the south to over 7,000 feet in the mountainous north, and stretching across 100 miles and dozens of ecosystems, the area's species richness is among the highest in California. This internationally recognized biodiversity hotspot is located at the juncture between California's Klamath, North Coast, and Sacramento Vallejo ecoregions and provides vital habitat and migration corridors for diverse wildlife, including several endemic plant and animal species.

The Berryessa Snow Mountain area is notable for its significant concentration of serpentine soils arising from frequent seismic activity and influence from ancient oceans. Serpentine, California's State rock, is formed from the clashing, subduction, and rising of massive geologic forces, and can be found in significant quantity in the area. These soils lack the nutrients most plants need and often contain heavy metals toxic to many plants, resulting in plants that are unique and endemic to this region. Serpentine outcrops in the area have been the subject of a great deal of botanical, ecological, and evolutionary research, and hold promise for future scientific explorations. Many serpentine plants are listed as rare, sensitive, or threatened under Federal or State law. Examples are: the endemic bent-flowered fiddleneck and brittlescale, the Brewer's jewelflower, Purdy's fringed onion, musk brush, serpentine sunflower, bare monkeyflower, Indian Valley brodiaea, Red Mountain catchfly, and Snow Mountain buckwheat, along with numerous other herbs such as the Lake County stonecrop, coastal bluff morning glory, Cobb Mountain lupine, Contra Costa goldfields, and Napa western flax. There are also plant species that are near-endemics and almost entirely restricted to serpentine soils, such as MacNab cypress, leather oak, swamp larkspur, and Purdy's fritillary.

The Berryessa Snow Mountain area is replete with wild and unique landscapes and climatic micro-regions. These include Cedar Roughs, an important refuge for black bear and a 3,000-acre stand of endemic Sargent's cypress

trees. Cache Creek, a California Wild and Scenic River, provides an exceptional, intact riparian habitat and one of the largest wintering populations of bald eagles in the State. Remnants of the grassland prairies that once covered much of interior California still exist at Upper Cache Creek, where there are stands of native grasses with creeping wild rye and meadow barley, and some smaller relict patches of upland bunchgrass.

The 6,000-foot Goat Mountain is home to highly unusual plant assemblages that have created one of the most diverse butterfly regions in California. The Hale Ridge Research Natural Area hosts an important stand of knobcone pine. The ecological sky island of the 7,000-foot Snow Mountain serves as important habitat to a number of key plant and animal species.

The headwaters of the Bear Creek Watershed are a particularly excellent example of the area's serpentinite-based endemism and biodiversity with over 450 plant species, including a magnificent array of wildflowers, along with cypress, manzanita, and willow. Nearly half of California's 108 species of dragonfly and damselfly are found here, as well as 16 reptiles and amphibians, 6 rare insects, and 80 species of butterflies. This area has been an important focus of scientific studies on climate change, including studies of range shifts and isolated populations of species during Pleistocene changes in climate, and on post-fire succession.

The Berryessa Snow Mountain area's wide variety of elevations, many streams, ponds, and rivers as well as diverse plant communities provide excellent habitat for fish, wildlife, and amphibians. The streams and creeks in the Berryessa Snow Mountain area have served as centers for scientific research on hydrology and riparian ecosystems for decades. The riparian habitat linking the Sacramento River, Putah Creek, and Cache Creek provides a home for native birds such as the spotted sandpiper and the rare tricolored blackbird.

Waterways in the area harbor several native fish, including Pacific lamprey, western brook lamprey, rainbow trout, California roach, Sacramento pikeminnow, speckled dace, hardhead minnow, Clear Lake hitch, Sacramento sucker, and prickly and riffle sculpins. The area also provides historic habitat for coastal chinook salmon, Northern California steelhead, and California Central Valley steelhead.

Ponds and seeps throughout the area provide rare aquatic habitat for important plants like eelgrass pondweed, few-flowered navarretia, marsh checkerbloom, and Boggs Lake hedge-hyssop. This aquatic habitat is also home to amphibious species like the foothill yellow-legged frog, California red-legged frog, California newt, Pacific tree frog, western toad, and the northwestern pond turtle.

Numerous reptiles live in the Berryessa Snow Mountain area, including the St. Helena mountain king snake, western fence lizard, western skink, western whiptail, alligator lizard, gopher snake, common king snake, rubber boa, common garter snake, western terrestrial garter snake, western aquatic garter snake, and the northern Pacific rattlesnake.

Many large and small mammals co-exist in this diverse landscape, such as Tule elk, bobcats, mountain lions, black bears, mule deer, beaver, river otter, Pacific fishers, American badgers, Humboldt martens, and the San Joaquin pocket mouse. Most of the animal species in the area have special State or Federal status as sensitive, at-risk or threatened.

Raptors such as burrowing owls, prairie falcon, peregrine falcon, northern goshawk, and bald and golden eagles live and hunt throughout the upland areas. The Berryessa Snow Mountain area also serves as an important migratory corridor for neotropical birds and is home to a plethora of bat and insect species, including the threatened valley elderberry longhorn beetle and the vulnerable pallid bat, western sulphur butterfly, gray marble butterfly, Muir's hairstreak, and Lindsay's skipper.

The protection of the Berryessa Snow Mountain area will preserve its prehistoric and historic legacy and maintain its diverse array of scientific resources, ensuring that the prehistoric, historic, and scientific values remain for the benefit of all Americans. Today, the area is important for ranching and also provides outdoor recreation opportunities, including hunting, fishing, hiking, mountain biking, and horseback riding to a burgeoning population center.

WHEREAS, section 320301 of title 54, United States Code (known as the ''Antiquities Act''), authorizes the President, in his discretion, to declare by public proclamation historic landmarks, historic and prehistoric structures, and other objects of historic or scientific interest that are situated upon the lands owned or controlled by the Federal Government to be national monuments, and to reserve as a part thereof parcels of land, the limits of which shall be confined to the smallest area compatible with the proper care and management of the objects to be protected;

WHEREAS, it is in the public interest to preserve the objects of scientific and historic interest on the lands of the Berryessa Snow Mountain area;

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by the authority vested in me by section 320301 of title 54, United States Code, hereby proclaim the objects identified above that are situated upon lands and interests in lands owned or controlled by the Federal Government to be the Berryessa Snow Mountain National Monument (monument) and, for the purpose of protecting those objects, reserve as part thereof all lands and interests in lands owned or controlled by the Federal Government within the boundaries described on the accompanying map, which is attached to and forms a part of this proclamation. These reserved Federal lands and interests in lands encompass approximately 330,780 acres. The boundaries described on the accompanying map are confined to the smallest area compatible with the proper care and management of the objects to be protected.

All Federal lands and interests in lands within the boundaries described on the accompanying map are hereby appropriated and withdrawn from all forms of entry, location, selection, sale, or other disposition under the public land laws or laws applicable to the U.S. Forest Service, from location, entry, and patent under the mining laws, and from disposition under all laws relating to mineral and geothermal leasing, other than by exchange that facilitates the remediation, monitoring, or reclamation of historic mining operations under applicable law or otherwise furthers the protective purposes of the monument.

The establishment of the monument is subject to valid existing rights. If the Federal Government acquires any lands or interests in lands not owned or controlled by the Federal Government within the boundaries of the monument, such lands and interests in lands shall be reserved as a part of the monument, and objects identified above that are situated upon those lands and interests in lands shall be part of the monument, upon acquisition of ownership or control by the Federal Government.

The Secretary of Agriculture and the Secretary of the Interior (Secretaries) shall manage the monument through the U.S. Forest Service (USFS) and the Bureau of Land Management (BLM), pursuant to their respective applicable legal authorities, to implement the purposes of this proclamation. The USFS shall manage that portion of the monument within the boundaries of the National Forest System (NFS), and BLM shall manage the remainder of the monument. The lands administered by USFS shall be managed as part of the Mendocino National Forest. The lands administered by BLM shall be managed as a unit of the National Landscape Conservation System, pursuant to applicable legal authorities.

For purposes of protecting and restoring the objects identified above, the Secretaries shall jointly prepare a management plan for the monument and shall promulgate such regulations for its management as deemed appropriate.

In developing any management plans and any management rules and regulations governing NFS lands within the monument, the Secretary of Agriculture, through USFS, shall consult with the Secretary of the Interior through BLM. The Secretaries shall provide for public involvement in the development of the management plan including, but not limited to, consultation with tribal, State, and local governments. In the development and implementation of the management plan, the Secretaries shall maximize opportunities, pursuant to applicable legal authorities, for shared resources, operational efficiency, and cooperation.

In managing the monument, the Secretaries may authorize activities or uses related to remediation, monitoring, and reclamation of mining sites and to provide for the beneficial public use of water associated with reclamation of such sites, consistent with the care and management of the objects identified above.

Except for emergency or authorized administrative purposes, motorized and mechanized vehicle use in the monument shall be allowed only on roads and trails designated for such use, consistent with the care and management of the objects identified above.

Nothing in this proclamation shall be deemed to enlarge or diminish the rights of any Indian tribe. The Secretaries shall, to the maximum extent permitted by law and in consultation with Indian tribes, ensure the protection of Indian sacred sites and traditional cultural properties in the monument and provide access by members of Indian tribes for traditional cultural and customary uses, consistent with the American Indian Religious Freedom Act (42 U.S.C. 1996) and Executive Order 13007 of May 24, 1996 (Indian Sacred Sites).

Laws, regulations, and policies followed by USFS or BLM in issuing and administering grazing permits or leases on lands under their jurisdiction shall continue to apply with regard to the lands in the monument, consistent with the care and management of the objects identified above.

Nothing in this proclamation shall be construed to alter the valid existing water rights of any party, including the United States. This proclamation does not reserve water as a matter of Federal law.

Nothing in this proclamation shall preclude low level overflights of military aircraft, the designation of new units of special use airspace, the use or establishment of military flight training routes over the lands reserved by this proclamation, or related military uses, consistent with the care and management of the objects to be protected.

Nothing in this proclamation shall be deemed to enlarge or diminish the jurisdiction of the State of California, including its jurisdiction and authority with respect to fish and wildlife management.

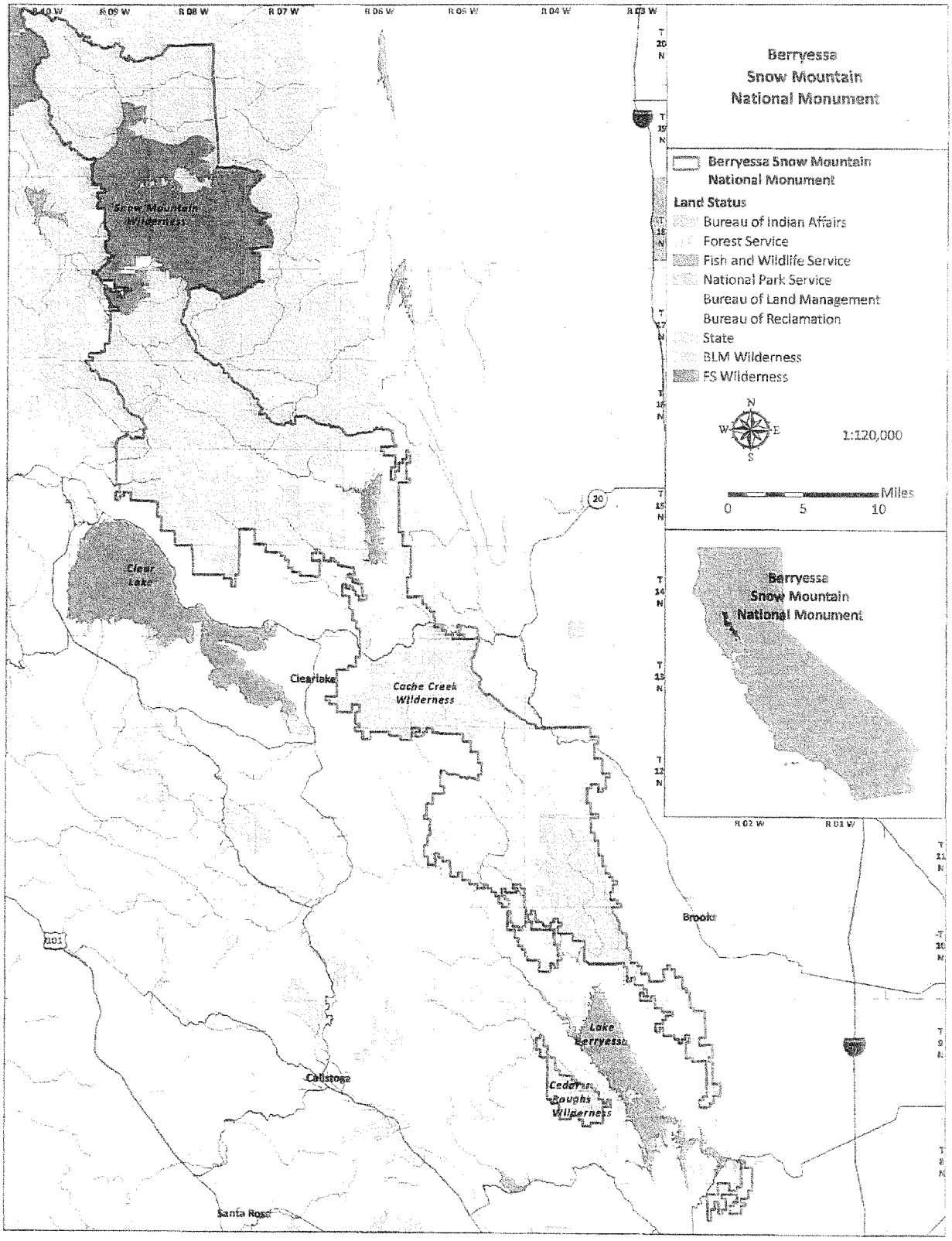
Nothing in this proclamation shall be construed to alter the authority or responsibility of any party with respect to emergency response activities within the monument, including wildland fire response.

Nothing in this proclamation shall be deemed to revoke any existing withdrawal, reservation, or appropriation; however, the monument shall be the dominant reservation.

Warning is hereby given to all unauthorized persons not to appropriate, injure, destroy, or remove any feature of the monument and not to locate or settle upon any of the lands thereof.

IN WITNESS WHEREOF, I have hereunto set my hand this tenth day of July, in the year of our Lord two thousand fifteen, and of the Independence of the United States of America the two hundred and fortieth.

Billing code 3295–F5–P



[FR Doc. 2015–17560

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Presidential Documents

Proclamation 9299 of July 10, 2015

Establishment of the Waco Mammoth National Monument

By the President of the United States of America

A Proclamation

In 1978, two young fossil hunters found a large bone protruding from an eroded ravine near the Bosque River about 4.5 miles north of the center of Waco, Texas. They took the bone to nearby Baylor University, where it was identified as part of the femur (upper leg bone) of a Columbian Mammoth (*Mammuthus columbi*), a dominant species in North America during the Pleistocene Epoch. The Columbian Mammoth, the largest of all mammoth species, stood with a shoulder height reaching 12 to 14 feet and weighed an estimated 7 to 8 tons. Over the next 20 years, Baylor University oversaw the excavation of the site, where the remains of 24 Columbian Mammoths were found, along with the remains of associated animals of the late Pleistocene, including Western Camel (*Camelops hesternus*), saber-toothed cat (*Homotherium*), dwarf antelope (*cf. Capromeryx*), American Alligator (*Alligator mississippiensis*), and giant tortoise (*Hesperotestudo*).

These remains contain the Nation's only recorded discovery of a nursery herd (females and offspring) of Pleistocene mammoths, comprising at least 18 of the unearthed mammoths. The nursery herd appears to have drowned in a single natural event near the confluence of the ancient Bosque and Brazos Rivers between 65,000 and 72,000 years ago. Because the nursery herd was buried rapidly in the mud associated with the rising waters, the remains of the herd include nearly intact skeletons apparently positioned as at the moment of death. The herd's preservation in this manner provides unparalleled evidence of the group's age structure and behavior during a natural catastrophe. For example, the herd apparently formed a circular defensive position with the adults attempting to rescue the offspring. In two cases, the bones of a juvenile lay across the tusks of an adult, suggesting that these adults were trying to lift the juveniles to safety.

Including the nursery herd, the remains of 22 Columbian Mammoths have been documented in the excavation area, and evidence of 2 more was discovered during construction of the Dig Shelter that protects the excavation area. One of the skeletons discovered in sediments above the nursery herd is a large bull mammoth with a broken but healed rib, suggesting a fight with another bull during the mammoth equivalent of modern elephants' musth, or rutting season. The presence of mammoths in the excavation area at sediment levels representing a span of several thousands of years suggests that the species had an affinity for this area at the interface of two ecosystems, the Great Plains and the Gulf Coastal Plains.

The excavation area, as well as the land extending beyond it toward the Brazos and Bosque Rivers, offer excellent opportunities for further exploration and research. More than half of the area protected by the Dig Shelter remains unexcavated, and virtually all the acreage outside the Dig Shelter remains unsurveyed for paleontological resources. Future discoveries are anticipated both within and outside the Dig Shelter.

While Baylor University oversaw the excavation, study, and preservation of the fossils, the City of Waco acquired the parcels of land containing and surrounding the excavation area and assembled a city park known

as the Waco Mammoth Site, which opened to the public in 2009. Although most of the excavated bones of the mammoths and associated fauna are now at Baylor University's Mayborn Museum awaiting preparation and curation, some exposed bones remain at the Site, protected by the climate-controlled Dig Shelter, which facilitates public viewing, interpretation, and study.

WHEREAS, section 320301 of title 54, United States Code (known as the ''Antiquities Act''), authorizes the President, in his discretion, to declare by public proclamation historic landmarks, historic and prehistoric structures, and other objects of historic or scientific interest that are situated upon the lands owned or controlled by the Federal Government to be national monuments, and to reserve as a part thereof parcels of land, the limits of which shall be confined to the smallest area compatible with the proper care and management of the objects to be protected;

WHEREAS, the City of Waco has been operating the approximately 108.5 acre Waco Mammoth Site (including the excavation area and surrounding lands) as a park since 2009, in partnership with Baylor University and with support from the nonprofit Waco Mammoth Foundation, Inc.;

WHEREAS, the City of Waco, Baylor University, the Waco Mammoth Foundation, Inc., and other members of the Waco community have demonstrated support for the establishment of a national monument to be administered by the National Park Service;

WHEREAS, the National Park Service conducted a special resource study of the Waco Mammoth Site, pursuant to Public Law 107–341, and determined that the Site met the criteria for inclusion in the National Park System;

WHEREAS, in support of the establishment of a national monument to be administered by the National Park Service, the City has donated certain lands and appurtenant easements to the Federal Government;

WHEREAS, the City of Waco and Baylor University have also indicated their intent to transfer ownership of the excavated specimens and archival records to the Federal Government for monument purposes;

WHEREAS, the City of Waco intends that the partnership between the City of Waco, Baylor University, and the Waco Mammoth Foundation, Inc., continue to cooperatively manage, oversee, and maintain the Waco Mammoth Site and expand the partnership to include the National Park Service;

WHEREAS, it is in the public interest to preserve and protect the scientific objects at the Waco Mammoth Site;

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by the authority vested in me by section 320301 of title 54, United States Code, hereby proclaim the objects identified above that are situated upon lands and interests in lands owned or controlled by the Federal Government to be the Waco Mammoth National Monument (monument) and, for the purpose of protecting those objects, reserve as a part thereof all lands and interests in lands owned or controlled by the Federal Government within the boundaries described on the accompanying map entitled, ''Waco Mammoth National Monument,'' which is attached to and forms a part of this proclamation. The reserved Federal lands and interests in lands encompass approximately 7.11 acres, including appurtenant easements for all necessary purposes. The boundaries described on the accompanying map are confined to the smallest area compatible with the proper care and management of the objects to be protected.

All Federal lands and interests in lands within the boundaries described on the accompanying map are hereby appropriated and withdrawn from all forms of entry, location, selection, sale, or other disposition under the public land laws, from location, entry, and patent under the mining laws, and from disposition under all laws relating to mineral and geothermal leasing.

The establishment of the monument is subject to valid existing rights. Lands and interests in lands not owned or controlled by the Federal Government within the boundaries described on the accompanying map shall be reserved as a part of the monument, and objects identified above that are situated upon those lands and interests in lands shall be part of the monument, upon acquisition of ownership or control by the Federal Government.

The Secretary of the Interior (Secretary) shall manage the monument through the National Park Service, pursuant to applicable legal authorities, consistent with the purposes and provisions of this proclamation. The Secretary shall prepare a management plan for the monument, with full public involvement, within 3 years of the date of this proclamation. The management plan shall ensure that the monument fulfills the following purposes for the benefit of present and future generations: (1) to preserve and protect the objects of scientific interest associated with the monument; (2) to foster and facilitate appropriate research; (3) to promote understanding and stewardship of the monument's resources and values through interpretive and educational opportunities; and (4) to provide for the enjoyment of the monument's resources and values in a manner that is compatible with their preservation. The management plan shall address the desired relationship of the monument to other sites with paleontological resources both within and outside the National Park System.

The National Park Service shall use available authorities, as appropriate, to enter into agreements with governmental and nongovernmental organizations, including the City of Waco, Baylor University, the Waco Mammoth Foundation, Inc., to further the purposes of the monument, address common interests, and promote management efficiencies.

Nothing in this proclamation shall be deemed to revoke any existing withdrawal, reservation, or appropriation; however, the monument shall be the dominant reservation.

Warning is hereby given to all unauthorized persons not to appropriate, injure, destroy, or remove any feature of this monument and not to locate or settle upon any of the lands thereof.

IN WITNESS WHEREOF, I have hereunto set my hand this tenth day of July, in the year of our Lord two thousand fifteen, and of the Independence of the United States of America the two hundred and fortieth.

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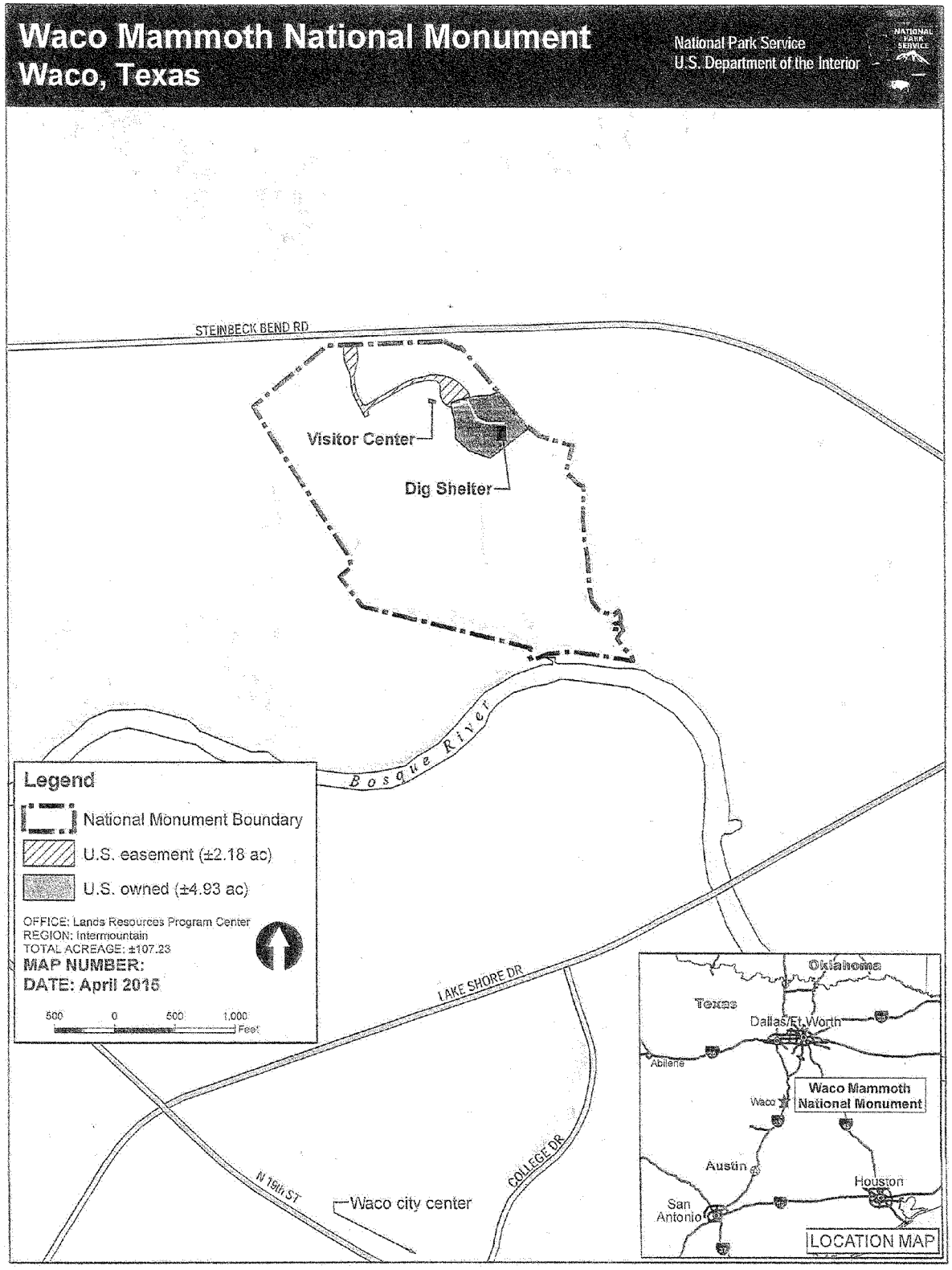

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