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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 906

[Doc. No. AMS–FV–15–0035; FV15–906–1 IR]

Oranges and Grapefruit Grown in Lower Rio Grande Valley in Texas; Decreased Assessment Rate

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Interim rule with request for comments.

SUMMARY: This rule implements a recommendation from the Texas Valley Citrus Committee (Committee) for a decrease in the assessment rate established for the 2015–16 and subsequent fiscal periods from $0.11 to $0.08 per 7/10-bushel carton or equivalent of oranges and grapefruit handled under the marketing order (order). The Committee locally administers the order, and is comprised of producers and handlers of oranges and grapefruit operating within the area of production. Assessments upon orange and grapefruit handlers are used by the Committee to fund reasonable and necessary expenses of the program. The fiscal period begins August 1 and ends July 31. The assessment rate will remain in effect indefinitely unless modified, suspended, or terminated.

DATES: Effective November 17, 2015. Comments received by January 15, 2016, will be considered prior to issuance of a final rule.

ADDRESSES: Interested persons are invited to submit written comments concerning this rule. Comments must be sent to the Docket Clerk, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Fax: (202) 720–8938; or Internet: *http://www.regulations.gov.* Comments should reference the document number and the date and page number of this issue of the **Federal Register** and will be available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: *http://www.regulations.gov.* All comments submitted in response to this rule will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting the comments will be made public on the internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Abigail Campos, Marketing Specialist, or Christian D. Nissen, Regional Director, Southeast Marketing Field Office, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; Telephone: (863) 324–3375, Fax: (863) 291–8614, or Email: *Abigail.Campos@ams.usda.gov* or *Christian.Nissen@ams.usda.gov.*

Small businesses may request information on complying with this regulation by contacting Jeffrey Smutny, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: *Jeffrey.Smutny@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: This rule is issued under Marketing Agreement and Order No. 906, as amended (7 CFR part 906), regulating the handling of oranges and grapefruit grown in the Lower Rio Grande Valley in Texas, hereinafter referred to as the ''order.'' The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the ''Act.''

The Department of Agriculture (USDA) is issuing this rule in conformance with Executive Orders 12866, 13563, and 13175.

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under the marketing order now in effect, orange and grapefruit handlers are subject to assessments. Funds to administer the order are derived from such assessments. It is intended that the assessment rate as issued herein will be applicable to all assessable oranges and grapefruit beginning August, 1, 2015, and continue until amended, suspended, or terminated.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This rule decreases the assessment rate established for the Committee for the 2015–16 and subsequent fiscal periods from $0.11 to $0.08 per 7/10-bushel carton or equivalent of oranges and grapefruit handled.

The Texas orange and grapefruit marketing order provides authority for the Committee, with the approval of USDA, to formulate an annual budget of expenses and collect assessments from handlers to administer the program. The members of the Committee are producers and handlers of Texas oranges and grapefruit. They are familiar with the Committee's needs and with the costs for goods and services in their local area and are thus in a position to formulate an appropriate budget and assessment rate. The assessment rate is formulated and discussed in a public meeting. Thus, all directly affected persons have an opportunity to participate and provide input.

For the 2014–15 and subsequent fiscal periods, the Committee recommended, and USDA approved, an assessment rate that would continue in effect from fiscal period to fiscal period unless modified, suspended, or terminated by USDA upon recommendation and information submitted by the Committee or other information available to USDA.

The Committee met on June 24, 2015, and unanimously recommended 2015–16 expenditures of $701,148 and an assessment rate of $0.08 per 7/10-bushel carton or equivalent of oranges and

grapefruit. In comparison, last year's budgeted expenditures were $809,500. The assessment rate of $0.08 is $0.03 lower than the rate currently in effect. The recommended 2015–16 expenditures include decreases in educational outreach and compliance, which were reduced by approximately $100,000. The Committee considered proposed expenses and recommended decreasing the assessment rate to more closely align assessment income to the lower budget.

The major expenditures recommended by the Committee for the 2015–16 year include $600,248 for the Mexican fruit fly control program, $77,200 for management and compliance, and $23,700 for operating expenses. Budgeted expenses for these items in 2014–15 were $503,000, $175,000, and $21,500, respectively.

The assessment rate recommended by the Committee was derived by dividing anticipated expenses by expected shipments of Texas oranges and grapefruit. Orange and grapefruit shipments for the 2015–16 year are estimated at 8 million 7/10-bushel cartons or equivalent, which should provide $640,000 in assessment income. Income derived from handler assessments, along with interest income and funds from the Committee's authorized reserve, will be adequate to cover budgeted expenses. Income in the reserve (currently around $230,000) will be kept within the maximum permitted by the order (approximately one fiscal period's expenses as stated in § 906.35).

The assessment rate established in this rule will continue in effect indefinitely unless modified, suspended, or terminated by USDA upon recommendation and information submitted by the Committee or other available information.

Although this assessment rate is effective for an indefinite period, the Committee will continue to meet prior to or during each fiscal period to recommend a budget of expenses and consider recommendations for modification of the assessment rate. The dates and times of Committee meetings are available from the Committee or USDA. Committee meetings are open to the public and interested persons may express their views at these meetings. USDA will evaluate Committee recommendations and other available information to determine whether modification of the assessment rate is needed. Further rulemaking will be undertaken as necessary. The Committee's 2015–16 budget and those for subsequent fiscal periods will be reviewed and, as appropriate, approved by USDA.

Initial Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) has considered the economic impact of this rule on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 170 producers of oranges and grapefruit in the production area and 13 handlers subject to regulation under the marketing order. Small agricultural producers are defined by the Small Business Administration as those having annual receipts less than $750,000, and small agricultural service firms are defined as those whose annual receipts are less than $7,000,000 (13 CFR 121.201).

According to Committee data and information from the National Agricultural Statistics Service, the weighted average grower price for Texas citrus during the 2013–14 season was around $13.89 per box and total shipments were near 7.4 million boxes. Using the weighted average price and shipment information, and assuming a normal distribution, the majority of growers would have annual receipts of less than $750,000. In addition, based on available information, the majority of handlers have annual receipts of less than $7,000,000 and could be considered small businesses under SBA's definition. Thus, the majority of Texas citrus producers and handlers may be classified as small entities.

This rule decreases the assessment rate established for the Committee and collected from handlers for the 2015–16 and subsequent fiscal periods from $0.11 to $0.08 per 7/10-bushel carton or equivalent of Texas citrus. The Committee unanimously recommended 2015–16 expenditures of $701,148 and an assessment rate of $0.08 per 7/10-bushel carton or equivalent handled. The assessment rate of $0.08 is $0.03 lower than the 2014–2015 rate. The quantity of assessable oranges and grapefruit for the 2015–16 fiscal period is estimated at 8 million 7/10-bushel cartons or equivalent. Thus, the $0.08 rate should provide $640,000 in assessment income. Income derived from handler assessments along with interest income and funds from Committee's authorized reserve, will be adequate to cover budgeted expenses.

The major expenditures recommended by the Committee for the 2015–16 year include $600,248 for the Mexican fruit fly control program, $77,200 for management and compliance, and $23,700 for operating expenses. Budgeted expenses for these items in 2014–15 were $503,000, $175,000, and $21,500, respectively.

The recommended 2015–16 expenditures include decreases in the amount budgeted for educational outreach and compliance. The Committee considered proposed expenses and recommended decreasing the assessment rate to more closely align assessment income to the lower budget.

Prior to arriving at this budget and assessment rate, the Committee considered information from various sources, such as the Committee's Budget and Personnel Committee and the Market Development Committee. Alternative expenditure levels were discussed by these groups, based upon the relative value of various activities to the Texas citrus industry. Based on estimated shipments, the recommended assessment rate of $0.08 should provide $640,000 in assessment income. The Committee determined that the assessment revenue, along with funds from reserves and interest income, would be adequate to cover budgeted expenses for the 2015–16 fiscal period.

A review of historical information and preliminary information pertaining to the upcoming fiscal period indicates that the average grower price for the 2015–16 season could be around $13.00 per 7/10-bushel carton or equivalent of oranges and grapefruit. Therefore, the estimated assessment revenue for the 2015–16 fiscal period, as a percentage of total grower revenue would be around 0.6 percent.

This action decreases the assessment obligation imposed on handlers. Assessments are applied uniformly on all handlers, and decreasing the assessment rate reduces the burden on handlers.

The Committee's meeting was widely publicized throughout the Texas citrus industry and all interested persons were invited to attend the meeting and participate in Committee deliberations on all issues. Like all Committee meetings, the June 24, 2015, meeting was a public meeting. All entities, both large and small, were able to express views on this issue. Interested persons are invited to submit comments on this interim rule, including the regulatory

and informational impacts of this action on small businesses.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the order's information collection requirements have been previously approved by the Office of Management and Budget (OMB) and assigned OMB No. 0581–0189 Generic Fruit Crops. No changes in those requirements are necessary as a result of this action. Should any changes become necessary, they would be submitted to OMB for approval.

This action imposes no additional reporting or recordkeeping requirements on either small or large Texas orange and grapefruit handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

AMS 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.

USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this rule.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *http://www.ams.usda.gov/MarketingOrdersSmallBusinessGuide.* Any questions about the compliance guide should be sent to Jeffrey Smutny at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

After consideration of all relevant material presented, including the information and recommendation submitted by the Committee and other available information, it is hereby found that this rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

Pursuant to 5 U.S.C. 553, it is also found and determined upon good cause that it is impracticable, unnecessary, and contrary to the public interest to give preliminary notice prior to putting this rule into effect, and that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** because: (1) The 2015–16 fiscal period began on August, 1, 2015, and the marketing order requires that the rate of assessment for each fiscal period apply to all assessable oranges and grapefruit handled during such fiscal period; (2) this action decreases the assessment rate for assessable oranges and grapefruit grown in Texas beginning with the 2015–16 fiscal period; (3) handlers are aware of this action which was recommended by the Committee at a public meeting and is similar to other assessment rate actions issued in past years; and (4) this interim rule provides a 60-day comment period, and all comments timely received will be considered prior to finalization of this rule.

List of Subjects in 7 CFR Part 906

Grapefruit, Marketing agreements, Oranges, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 906 is amended as follows:

PART 906—ORANGES AND GRAPEFRUIT GROWN IN LOWER RIO GRANDE VALLEY IN TEXAS

■ 1. The authority citation for 7 CFR part 906 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Section 906.235 is revised to read as follows:

§ 906.235 Assessment rate.

On and after August, 1, 2015, an assessment rate of $0.08 per 7/10-bushel carton or equivalent is established for oranges and grapefruit grown in the Lower Rio Grande Valley in Texas.

Dated: November 9, 2015.

Rex A. Barnes,

Associate Administrator, Agricultural Marketing Service.

[FR Doc. 2015–28913 Filed 11–13–15; 8:45 am]

BILLING CODE P

FEDERAL RESERVE SYSTEM

12 CFR Parts 208, 217, 225, and 252

[Regulations H, Q, Y, and YY; Docket Nos. R–1442 and R–1492]

RIN 7100 AE–87

Regulatory Capital Rules; Enhanced Prudential Standards for Bank Holding Companies and Foreign Banking Organizations; Correction

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule; correcting amendment.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) published a final rule in the **Federal Register** on October 11, 2013 (78 FR 62018) regarding Regulatory Capital Rules and another final rule on October 27, 2014 (79 FR 64025) regarding Capital Plan and Stress Test Rules. This publication removes certain expired transitional requirements in Regulations H and Y, resolves certain citation errors, replaces a wrongly duplicated paragraph in Regulation Q, and corrects a typographical error in Regulation YY.

DATES: The corrections are effective November 16, 2015, except that instructions 10.b and 10.f amending 12 CFR 208.43 are effective January 1, 2018.

FOR FURTHER INFORMATION CONTACT: Benjamin McDonough, Special Counsel, (202) 452–2036, Julie Anthony, Counsel, (202) 475–6682, or Mark Buresh, Senior Attorney, (202) 452–5270, Legal Division, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW., Washington, DC 20551. Telecommunications Device for the Deaf (TDD) users may contact (202) 263–4869.

SUPPLEMENTARY INFORMATION: The Board is correcting errors in and deleting certain expired transitional requirements from the final rule that was published in the **Federal Register** on October 11, 2013 (78 FR 62018). These revisions will remove text or footnotes in 12 CFR parts 208 and 225 describing certain transitional requirements that have expired, correct citations in 12 CFR 217.2 and 12 CFR 217.202(b)(10), and remove and replace a wrongly duplicated paragraph in 12 CFR 217.300(c)(3). The Board is also correcting a typographical error in the final rule that was published in the **Federal Register** on October 27, 2014 (79 FR 64025), which caused the unintended deletion of § 252.153(e)(2)–(5).

List of Subjects

12 CFR Part 208

Accounting, Agriculture, Banks, Banking, Confidential business information, Consumer protection, Crime, Currency, Global systemically important bank, Insurance, Investments, Mortgages, Reporting and recordkeeping requirements, Securities.

12 CFR Part 217

Administrative practice and procedure, Banks, Banking, Holding companies, Reporting and recordkeeping requirements, Securities.

12 CFR Part 225

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

12 CFR Part 252

Administrative practice and procedure, Banks, Banking, Federal Reserve System, Holding companies, Nonbank financial companies supervised by the Board, Reporting and recordkeeping requirements, Securities, Stress testing.

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

PART 208—MEMBERSHIP OF STATE BANKING INSTITUTIONS IN THE FEDERAL RESERVE SYSTEM

■ 1. The authority citation for part 208 continues to read as follows:

Authority: 12 U.S.C. 24, 36, 92a, 93a, 248(a), 248(c), 321–338a, 371d, 461, 481–486, 601, 611, 1814, 1816, 1818, 1820(d)(9), 1833(j), 1828(o), 1831, 1831o, 1831p–1, 1831r–1, 1831w, 1831x, 1835a, 1882, 2901–2907, 3105, 3310, 3331–3351, 3353, and 3905–3909; 15 U.S.C. 78b, 78l(b), 78l(i), 780–4(c)(5), 78q, 78q–1, 78w, 1681s, 1681w, 6801 and 6805; 31 U.S.C. 5318; 42 U.S.C. 4012a, 4104b, 4106, and 412

§ 208.2 [Amended]

■ 2. In § 208.2, remove footnote 2.

§ 208.3 [Amended]

■ 3. In § 208.3, redesignate footnote 3 as footnote 2.

§ 208.4 [Amended]

■ 4. In § 208.4, remove footnotes 4 and 5.

§ 208.5 [Amended]

■ 5. In § 208.5, redesignate footnote 6 as footnote 3 and footnote 7 as footnote 4.

§ 208.21 [Amended]

■ 6. In § 208.21, redesignate footnote 8 as footnote 5.

§ 208.24 [Amended]

■ 7. In § 208.24, redesignate footnote 9 as footnote 6.

■ 8. In § 208.40, revise paragraph (e) to read as follows:

§ 208.40 Authority, purpose, scope, other supervisory authority, and disclosure of capital categories.

* * * * *

(e) *Timing.* The calculation of the definitions of common equity tier 1 capital, the common equity tier 1 risk-based capital ratio, the leverage ratio, the supplementary leverage ratio, tangible equity, tier 1 capital, the tier 1 risk-based capital ratio, total assets, total leverage exposure, the total risk-based capital ratio, and total risk-weighted assets under this subpart is subject to the timing provisions at 12 CFR 217.1(f) and the transitions at 12 CFR part 217, subpart G.

* * * * *

§ 208.41 [Amended]

■ 9. In § 208.41, remove footnotes 10, 11, 12, 13, 14, and 15.

■ 10. In § 208.43:

■ a. Revise paragraph (a);

■ b. Effective January 1, 2018, paragraph (a)(2)(iv)(C) as added on May 1, 2014 (79 FR 24540), and further amended on August 14, 2015 (80 FR 49102), is redesignated as paragraph (a)(4)(iii).

■ c. Remove paragraph (b);

■ d. Redesignate paragraphs (c) and (d) as paragraphs (b) and (c).

■ e. Revise the introductory text of newly redesignated paragraph (b); and

■ f. Effective January 1, 2018, paragraph (c)(1)(iv) as revised on May 1, 2014 (79 FR 24540), and further amended on August 14, 2015 (80 FR 49102), is redesignated as paragraph (b)(1)(iv).

The revisions read as follows:

§ 208.43 Capital measures and capital category definitions.

(a) *Capital measures.* For purposes of section 38 and this subpart, the relevant capital measures are:

(1) Total Risk-Based Capital Measure: The total risk-based capital ratio;

(2) Tier 1 Risk-Based Capital Measure: The tier 1 risk-based capital ratio;

(3) Common Equity Tier 1 Capital Measure: The common equity tier 1 risk-based capital ratio; and

(4) Leverage Measure:

(i) The leverage ratio; and

(ii) With respect to an advanced approaches bank, on January 1, 2018, and thereafter, the supplementary leverage ratio.

* * * * *

(b) *Capital categories applicable to all member banks.* For purposes of section 38 and this subpart, a member bank is deemed to be:

* * * * *

§ 208.102 [Amended]

■ 11. In § 208.102, redesignate footnote 16 as footnote 7.

§ 208.111 [Amended]

■ 12. In § 208.111, redesignate footnote 17 as footnote 8 and footnote 18 as footnote 9.

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. In § 217.2, in the definition of ''covered savings and loan holding company'', revise paragraph (1) to read as follows:

§ 217.2 Definitions

* * * * *

Covered savings and loan holding company * * *

(1) A top-tier savings and loan holding company that is:

(i) An institution that meets the requirements of section 10(c)(9)(C) of HOLA (12 U.S.C. 1467a(c)(9)(C)); and

(ii) As of June 30 of the previous calendar year, derived 50 percent or more of its total consolidated assets or 50 percent of its total revenues on an enterprise-wide basis (as calculated under GAAP) from activities that are not financial in nature under section 4(k) of the Bank Holding Company Act of 1956 (12 U.S.C. 1843(k));

* * * * *

§ 217.202 [Amended]

■ 15. In § 217.202(b), in paragraph (10)(ii) of the definition of ''securitization'', remove ''[12 CFR 208.34 (Board), 12 CFR 9.18 (OCC)]'' and add in its place ''12 CFR 208.34.''

■ 16. In § 217.300, revise paragraph (c)(3) to read as follows:

§ 217.300 Transitions.

* * * * *

(c) * * *

(3) *Depository institution holding companies under $15 billion and 2010 MHCs.* (i) Non-qualifying capital instruments issued by depository institution holding companies under $15 billion and 2010 MHCs prior to May 19, 2010, may be included in additional tier 1 or tier 2 capital if the instrument was included in tier 1 or tier 2 capital, respectively, as of January 1, 2014.

(ii) Non-qualifying capital instruments includable in tier 1 capital are subject to a limit of 25 percent of tier 1 capital elements, excluding any nonqualifying capital instruments and after applying all regulatory capital deductions and adjustments to tier 1 capital.

(iii) Non-qualifying capital instruments that are not included in tier 1 as a result of the limitation in paragraph (c)(3)(ii) of this section are includable in tier 2 capital.

* * * * *

PART 225—BANK HOLDING COMPANIES AND CHANGE IN BANK CONTROL (REGULATION Y)

■ 17. The authority citation for part 225 continues to read as follows:

Authority: 12 U.S.C. 1844(b), 3106 and 3108, 1817(j)(13), 1818(b), 1831i, 1972, 3310, 3331–3351 and 3353; 12 U.S.C. 3901, *et seq.;* and 12 U.S.C. 1841, *et seq.*

§ 225.2 [Amended]

■ 18. In § 225.2(r)(1), remove footnotes 3 and 4.

§ 225.4 [Amended]

■ 19. In § 225.4, remove footnote 1.

§ 225.12 [Amended]

■ 20. In § 225.12:
■ a. Remove footnote 1;
■ b. Redesignate footnote 2 as footnote 1.

§ 225.22 [Amended]

■ 21. In § 225.22, remove footnote 1.

§ 225.172 [Amended]

■ 22. In § 225.172, remove footnote 1.

PART 252—ENHANCED PRUDENTIAL STANDARDS (REGULATION YY)

■ 23. The authority citation for part 252 continues to read as follows:

Authority: 12 U.S.C. 321–338a, 1467a(g), 1818, 1831p–1, 1844(b), 1844(c), 5361, 5365, 5366.

■ 24. In § 252.153, add paragraphs (e)(2) through (5) to read as follows:

§ 252.153 U.S. intermediate holding company requirement for foreign banking organizations with U.S. non-branch assets of $50 billion or more.

* * * * *

(e) * * *

(2) *Capital requirements for a U.S. intermediate holding company*—(i) *Risk-based capital and leverage requirements.* (A) A U.S. intermediate holding company must calculate and meet all applicable capital adequacy standards set forth in 12 CFR part 217, other than subpart E of 12 CFR part 217, and comply with all restrictions associated with applicable capital buffers, in the same manner as a bank holding company.

(B) A U.S. intermediate holding company may choose to comply with subpart E of 12 CFR part 217.

(C) Notwithstanding 12 CFR 217.100(b), if a bank holding company is a subsidiary of a foreign banking organization that is subject to this section and the bank holding company is subject to subpart E of 12 CFR part 217, the bank holding company, with the Board's prior written approval, may elect not to comply with subpart E of 12 CFR part 217.

(ii) *Capital planning.* A U.S. intermediate holding company must comply with § 225.8 of Regulation Y in the same manner as a bank holding company.

(3) *Risk management and risk committee requirements*—(i) *General.* A U.S. intermediate holding company must establish and maintain a risk committee that approves and periodically reviews the risk management policies and oversees the risk-management framework of the U.S. intermediate holding company. The risk committee must be a committee of the board of directors of the U.S. intermediate holding company (or equivalent thereof). The risk committee may also serve as the U.S. risk committee for the combined U.S. operations required pursuant to § 252.155(a).

(ii) *Risk-management framework.* The U.S. intermediate holding company's risk-management framework must be commensurate with the structure, risk profile, complexity, activities, and size of the U.S. intermediate holding company and consistent with the risk management policies for the combined U.S. operations of the foreign banking organization. The framework must include:

(A) Policies and procedures establishing risk-management governance, risk-management procedures, and risk-control infrastructure for the U.S. intermediate holding company; and

(B) Processes and systems for implementing and monitoring compliance with such policies and procedures, including:

(*1*) Processes and systems for identifying and reporting risks and risk-management deficiencies at the U.S. intermediate holding company, including regarding emerging risks and ensuring effective and timely implementation of actions to address emerging risks and risk-management deficiencies;

(*2*) Processes and systems for establishing managerial and employee responsibility for risk management of the U.S. intermediate holding company;

(*3*) Processes and systems for ensuring the independence of the risk-management function of the U.S. intermediate holding company; and

(*4*) Processes and systems to integrate risk management and associated controls with management goals and the compensation structure of the U.S. intermediate holding company.

(iii) *Corporate governance requirements.* The risk committee of the U.S. intermediate holding company must meet at least quarterly and otherwise as needed, and must fully document and maintain records of its proceedings, including risk-management decisions.

(iv) *Minimum member requirements.* The risk committee must:

(A) Include at least one member having experience in identifying, assessing, and managing risk exposures of large, complex financial firms; and

(B) Have at least one member who:

(*1*) Is not an officer or employee of the foreign banking organization or its affiliates and has not been an officer or employee of the foreign banking organization or its affiliates during the previous three years; and

(*2*) Is not a member of the immediate family, as defined in § 225.41(b)(3) of the Board's Regulation Y (12 CFR 225.41(b)(3)), of a person who is, or has been within the last three years, an executive officer, as defined in § 215.2(e)(1) of the Board's Regulation O (12 CFR 215.2(e)(1)) of the foreign banking organization or its affiliates.

(v) The U.S. intermediate holding company must take appropriate measures to ensure that it implements the risk management policies for the U.S. intermediate holding company and it provides sufficient information to the U.S. risk committee to enable the U.S. risk committee to carry out the responsibilities of this subpart.

(4) *Liquidity requirements.* A U.S. intermediate holding company must comply with the liquidity risk-management requirements in § 252.156 and conduct liquidity stress tests and hold a liquidity buffer pursuant to § 252.157.

(5) *Stress test requirements.* A U.S. intermediate holding company must comply with the requirements of subparts E and F of this part in the same manner as a bank holding company.

* * * * *

By order of the Board of Governors of the Federal Reserve System, November 2, 2015.

Robert deV. Frierson,

Secretary of the Board.

[FR Doc. 2015–28294 Filed 11–13–15; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 95

[Docket No. 31048; Amdt. No. 523]

IFR Altitudes; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts miscellaneous amendments to the required IFR (instrument flight rules) altitudes and changeover points for certain Federal airways, jet routes, or direct routes for which a minimum or maximum en route authorized IFR altitude is prescribed. This regulatory action is needed because of changes occurring in the National Airspace System. These changes are designed to provide for the safe and efficient use of the navigable airspace under instrument conditions in the affected areas.

DATES: *Effective:* 0901 UTC, December 10, 2015.

FOR FURTHER INFORMATION CONTACT: Richard A. Dunham, Flight Procedure Standards Branch (AMCAFS–420), Flight Technologies and Programs Division, Flight Standards Service, Federal Aviation Administration, Mike Monroney Aeronautical Center, 6500 South MacArthur Blvd. Oklahoma City, OK. 73169 (Mail Address: P.O. Box 25082 Oklahoma City, OK. 73125) telephone: (405) 954–4164.

SUPPLEMENTARY INFORMATION: This amendment to part 95 of the Federal Aviation Regulations (14 CFR part 95) amends, suspends, or revokes IFR altitudes governing the operation of all aircraft in flight over a specified route or any portion of that route, as well as the changeover points (COPs) for Federal airways, jet routes, or direct routes as prescribed in part 95.

The Rule

The specified IFR altitudes, when used in conjunction with the prescribed changeover points for those routes, ensure navigation aid coverage that is adequate for safe flight operations and free of frequency interference. The reasons and circumstances that create the need for this amendment involve matters of flight safety and operational efficiency in the National Airspace System, are related to published aeronautical charts that are essential to the user, and provide for the safe and efficient use of the navigable airspace. In addition, those various reasons or circumstances require making this amendment effective before the next scheduled charting and publication date of the flight information to assure its timely availability to the user. The effective date of this amendment reflects those considerations. In view of the close and immediate relationship between these regulatory changes and safety in air commerce, I find that notice and public procedure before adopting this amendment are impracticable and contrary to the public interest and that good cause exists for making the amendment effective in less than 30 days.

Conclusion

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

List of Subjects in 14 CFR Part 95

Airspace Navigation (air).

Issued in Washington, DC, on November 6, 2015.

John Duncan,

Director, Flight Standards Service.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, part 95 of the Federal Aviation Regulations (14 CFR part 95) is amended as follows effective at 0901 UTC, December 10, 2015.

PART 95 [AMENDED]

■ 1. The authority citation for part 95 continues to read as follows:

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

■ 2. Part 95 is amended to read as follows:

REVISIONS TO IFR ALTITUDES & CHANGEOVER POINT

[Amendment 523 effective date, December 10, 2015]

From	To	MEA
§ 95.6001 Victor Routes–U.S.		
§ 95.6014 VOR Federal Airway V14 Is Amended To Read in Part		
ERIE, PA VORTAC #ERIE R–064 UNUSABLE, USE DUNKIRK R–245	DUNKIRK, NY VORTAC	#3400
§ 95.6043 VOR Federal Airway V43 Is Amended To Read in Part		
ERIE, PA VORTAC #UNUSABLE	U.S. CANADIAN BORDER	#
§ 95.6522 VOR Federal Airway V522 Is Amended To Read in Part		
FAILS, OH FIX #UNUSABLE	ERIE, PA VORTAC	#
ERIE, PA VORTAC #ERIE R–064 UNUSABLE, USE DUNKIRK R–245	DUNKIRK, NY VORTAC	#3400

From	To	MEA	MAA
§ 95.7001 Jet Routes § 95.7513 Jet Route J513 Is Amended To Delete			
U.S. CANADIAN BORDER #FOR THAT AIRSPACE OVER U.S. TERRITORY	U.S. CANADIAN BORDER	#18000	45000
U.S. CANADIAN BORDER #FOR THAT AIRSPACE OVER U.S. TERRITORY.	SUDBURY, CA VOR/DME	#24000	45000

Airway segment		Changeover points	From
From	To	Distance	
§ 95.8003 VOR Federal Airway Changeover Point V298 Is Amended To Add Changeover Point			
SEATTLE, WA VORTAC	ELLENSBURG, WA VORTAC	47	SEATTLE.

[FR Doc. 2015–28625 Filed 11–13–15; 8:45 am]
BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 730

[Docket No. 140613501–5956–03]

RIN 0694–AG13

Export Administration Regulations: Removal of Special Comprehensive License Provisions

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule; correcting amendment.

SUMMARY: The Bureau of Industry and Security (BIS) publishes this final rule to amend the Export Administration Regulations (EAR) Supplement that lists ''Information Collection Requirements Under the Paperwork Reduction Act: OMB Control Numbers'' to remove certain citations related to Special Comprehensive Licenses listed under Collection number 0607–0152. This final rule is precipitated by an error contained in a final rule published on August 26, 2015 that resulted in the retention of these citations. This action will ensure the accurate and complete implementation of the purposes of the August 26, 2015 final rule: To remove all Special Comprehensive License provisions and related provisions from the EAR.

DATES: This rule is effective November 16, 2015.

FOR FURTHER INFORMATION CONTACT: Thomas Andrukonis, Director, Export Management and Compliance, Office of Exporter Services, Bureau of Industry and Security, by telephone at (202) 482–6396 or by email at *Thomas.Andrukonis@bis.doc.gov.*

SUPPLEMENTARY INFORMATION: On August 26, 2015, the Bureau of Industry and Security (BIS) published the final rule ''Export Administration Regulations: Removal of Special Comprehensive License Provisions'' (80 FR 51725), effective September 25, 2015. In that rule, BIS amended the Export Administration Regulations (EAR) by removing the Special Comprehensive License (SCL) provisions and made conforming amendments.

The August 26 rule included amendatory instructions to revise or remove certain Collection numbers in Supplement No. 1 to part 730 (Information Collection Requirements Under the Paperwork Reduction Act: OMB Control Numbers). However, the amendatory instruction erroneously identified Collection number ''0607–0152'' as Collection number ''0694–0152,'' and as a result, the entry for Collection number 0607–0152 was not amended. In this final rule, BIS amends the Supplement by revising Collection number ''0607–0152'' to remove references to ''§§ 752.7(b) and 752.15(a)'' under the ''Reference in the EAR'' Column as originally intended. This correction will ensure the accurate and complete implementation of the purposes of the August 26, 2015 final rule: To remove all the SCL provisions and related provisions from the EAR.

Although the Export Administration Act expired on August 20, 2001, the President, through Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as amended by Executive Order 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013) and as extended by the Notice of August 7, 2015, 80 FR 48233 (August 11, 2015), has continued the Export Administration Regulations in effect under the International Emergency Economic Powers Act. BIS continues to carry out the provisions of the Export Administration Act, as appropriate and to the extent permitted by law, pursuant to Executive Order 13222 as amended by Executive Order 13637.

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 effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. This rule has been determined to be a not significant regulatory action for purposes of Executive Order 12866.

2. This rule does not contain an information collection subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

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

4. The provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed

rulemaking and the opportunity for public participation are waived for good cause because they are unnecessary and contrary to the public interest. (See 5 U.S.C. 553(b)(B)). The changes contained in this rule are technical corrections of a previously published final rule. This rule is necessary to prevent confusion caused by the continued inclusion in Supplement No. 1 to part 730 of references to the sections of the EAR that were removed by the August 26, 2015 rule. Collection number, ''0607–0152,'' needs to be revised for purposes of removing all the SCL provisions from the EAR. Therefore, this change is essential to ensure the accurate and complete implementation of the changes intended by the August 26, 2015 final rule.

The provision of the Administrative Procedure Act (5 U.S.C. 553) requiring a 30-day delay in effectiveness is also waived for good cause. (5 U.S.C. 553(d)(3)). The correction contained in this final rule is merely a technical correction necessitated by a typographical error in a previously published rule, for which a notice, comment and delay were completed. The revisions made in this rule are technical corrections which should be in place as soon as possible to avoid confusion caused by the incorrect inclusion of references to sections of the EAR removed by the August 26, 2015 rule in OMB Collection number 0607–0152 in Supplement No. 1 to part 730. This change is necessary to ensure immediate, accurate and complete implementation of the purposes of the August 26, 2015 final rule.

Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this final rule. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule under the Administrative Procedure Act or by any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable. Therefore, this regulation is issued in final form.

List of Subjects in CFR Part 730

Administrative practice and procedure, Advisory committees, Exports, Reporting and recordkeeping requirements, Strategic and critical materials.

For the reasons stated in the preamble, part 730 of the Export Administration Regulations (15 CFR parts 730–774) is amended as follows:

PART 730—[AMENDED]

■ 1. The authority citation for 15 CFR part 730 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c; 22 U.S.C. 2151 note; 22 U.S.C. 3201 *et seq.;* 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 15 U.S.C. 1824a; 50 U.S.C. app. 5; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 11912, 41 FR 15825, 3 CFR, 1976 Comp., p. 114; E.O. 12002, 42 FR 35623, 3 CFR, 1977 Comp., p. 133; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12214, 45 FR 29783, 3 CFR, 1980 Comp., p. 256; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12854, 58 FR 36587, 3 CFR, 1993 Comp., p. 179; E.O. 12918, 59 FR 28205, 3 CFR, 1994 Comp., p. 899; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 12947, 60 FR 5079, 3 CFR, 1995 Comp., p. 356; E.O. 12981, 60 FR 62981, 3 CFR, 1995 Comp., p. 419; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp., p. 219; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; E.O. 13338, 69 FR 26751, 3 CFR, 2004 Comp., p 168; E.O. 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013); Notice of September 17, 2014, 79 FR 56475 (September 19, 2014); Notice of November 7, 2014, 79 FR 67035 (November 12, 2014); Notice of January 21, 2015, 80 FR 3461 (January 22, 2015); Notice of May 6, 2015, 80 FR 26815 (May 8, 2015); Notice of August 7, 2015, 80 FR 48233 (August 11, 2015); Notice of September 18, 2015, 80 FR 57281 (September 22, 2015).

Supplement No. 1 to Part 730—[Amended]

■ 2. Supplement No. 1 to part 730 is amended by revising the entry for Collection number ''0607–0152'' to read as follows:

SUPPLEMENT NO. 1 TO PART 730—INFORMATION COLLECTION REQUIREMENTS UNDER THE PAPERWORK REDUCTION ACT: OMB CONTROL NUMBERS

*	*	*	*	*	*	*
Collection No.		Title			Reference in the EAR	
*	*	*	*	*	*	*
0607–0152		Automated Export System (AES) Program			§§ 740.1(d), 740.3(a)(3), 754.2(h), 754.4(c), 758.1, 758.2, and 758.3 of the EAR.	

Dated: November 5, 2015.

Karen H. Nies-Vogel,

Director, Office of Exporter Services.

[FR Doc. 2015–29084 Filed 11–13–15; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 774

[Docket No.150825777–5777–01]

RIN 0694–AG70

Amendment to the Export Administration Regulations to Add XBS Epoxy System to the List of 0Y521 Series; Technical Amendment to Update Other 0Y521 Items

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Interim final rule with request for comments.

SUMMARY: In this interim final rule, the Bureau of Industry and Security (BIS) amends the Export Administration Regulations (EAR) to make certain items subject to the EAR and to impose on those items a license requirement for export and reexport to all destinations, except Canada. Specifically, this rule classifies the specified XBS Epoxy System under Export Control Classification Number (ECCN) 0C521 on the Commerce Control List (CCL). As described in the final rule that established the 0Y521 series and that

was published in the **Federal Register** on April 13, 2012, items are added to the 0Y521 series upon a determination by the Department of Commerce, with the concurrence of the Departments of Defense and State, that the items should be controlled for export because the items provide at least a significant military or intelligence advantage to the United States or foreign policy reasons justify control. The items identified in this rule are controlled for regional stability (RS) Column 1 reasons. The only license exception available for these items is for exports, reexports, and transfers (in-country) made by or consigned to a department or agency of the U.S. Government. In this rule, BIS also removes technology and software related to aircraft wing folding systems.

DATES: This rule is effective November 16, 2015. Comments must be received by January 15, 2016. Comments requested on the addition of the 0C521 item only.

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

- *Federal eRulemaking Portal: http://www.regulations.gov.* The identification number for this rulemaking is BIS–2015–0043.
- *By email directly to: publiccomments@bis.doc.gov.* Include RIN 0694–AG70 in the subject line.
- By mail or delivery to Regulatory Policy Division, Bureau of Industry and Security, U.S. Department of Commerce, Room 2099B, 14th Street and Pennsylvania Avenue NW., Washington, DC 20230. Refer to RIN 0694–AG70.

FOR FURTHER INFORMATION CONTACT: Michael Rithmire, Electronics and Materials Division, Office of National Security and Technology Transfer Controls by phone at (202) 482–6105 or by email at *Michael.Rithmire@bis.doc.gov.*

SUPPLEMENTARY INFORMATION:

Background

BIS established the ECCN 0Y521 series to identify items that warrant control on the CCL but are not yet identified in an existing ECCN (77 FR 22191, April 13, 2012). Items are added to the ECCN 0Y521 series by the Department of Commerce, with the concurrence of the Departments of Defense and State, upon a determination that an item should be controlled because it provides at least a significant military or intelligence advantage to the United States or because foreign policy reasons justify such control. The ECCN 0Y521 series is a temporary holding classification with a limitation that while an item is temporarily classified under ECCN 0Y521, the U.S. Government works to adopt a control through the relevant multilateral regime(s), to determine an appropriate longer-term control over the item, or that the item does not warrant control on the CCL.

Items classified under ECCN 0Y521, including the item identified in this interim final rule as an 0C521 item, remain so-classified for one year from the date a final rule identifying the item is published in the **Federal Register** amending the EAR, unless the item is re-classified under a different ECCN, under an EAR99 designation, or the 0Y521 classification is extended. During this time, the U.S. Government determines whether it is appropriate to submit a proposed control to the applicable export control regime (*e.g.,* the Wassenaar Arrangement) for potential multilateral control, with the understanding that multilateral controls are preferable when practical. An item's ECCN 0Y521 classification may be extended for two one-year periods to provide time for the U.S. Government and multilateral regime(s) to reach agreement on controls for the item, and provided that the U.S. Government has submitted a proposal to obtain multilateral controls over the item. Further extension beyond three years may occur only if the Under Secretary for Industry and Security makes a determination that such extension is in the national security or foreign policy interests of the United States. An extension or re-extension, including a determination by the Under Secretary for Industry and Security, will be published in the **Federal Register**.

License Requirements, Policies and Exceptions

The license requirements and policies for the ECCN 0Y521 series appear in § 742.6(a)(7) of the EAR. ECCN 0Y521 items are subject to a nearly worldwide license requirement (*i.e.,* for every country except Canada) with a case-by-case license review policy, through regional stability (RS Column 1) controls. The description and status of ECCN 0Y521 items appear in Supplement No. 5 to part 774 of the EAR, along with any item-specific license exceptions, where applicable. Unless otherwise indicated, License Exception GOV is the only license exception available and is applicable to all ECCN 0Y521 series items, including those items identified in this document, if the item is within the scope of § 740.11(b)(2)(ii) (Exports, reexports, and transfers (in-country) made by or consigned to a department or agency of the U.S. Government), as provided in § 740.2(a)(14).

Addition of ECCN 0C521 Item: XBS Epoxy System

In this rule, BIS amends the EAR to make the specified XBS Epoxy System subject to the EAR and impose a license requirement on the item. This item is being added to the 0Y521 series pursuant to a determination by the Department of Commerce, with the concurrence of the Departments of State and Defense, that the item should be controlled because it provides a significant military or intelligence advantage to the United States or because foreign policy reasons justify such controls. The specified XBS Epoxy System is classified under ECCN 0C521 No. 1. The control, which appears in the table found in Supplement No. 5 to part 774 of the EAR, covers an Epoxy system designed to obfuscate critical technology components against X-ray and terahertz microscopy imaging attempts.

License Applications for the New ECCN 0C521 Item

License applications for this item may be submitted through SNAP–R in accordance with § 748.6 of the EAR. Exporters are directed to include detailed descriptions and technical specifications with the license application, and identify the item as 0C521.

Technical Amendment: Removal of No. 3 0D521 and No. 2 0E521 Items, Aircraft Wing Folding Systems, From Supplement No. 5 to Part 774

In this rule, BIS also removes references to aircraft wing folding systems ''software'' and related ''technology'' listed, prior to this rule, as entries No. 3 0D521 and No. 2 0E521, respectively, in Supplement No. 5 to part 774. The references to these items are obsolete because, in accordance with procedure established in the April 13, 2012, final rule, the U.S. Government adopted a control through the relevant multilateral regime(s), which determined an appropriate longer-term control over the item. The wing fold system ''software'' is now controlled by ECCN 9D001, and the ''technology'' is controlled by ECCN 9E003.j on the CCL. A final rule published in the **Federal Register** May 21, 2015 (80 FR 29431), and which went into effect the same day, implemented the 2014 Wassenaar Plenary Agreements by establishing new controls on the items, rendering their 0Y521 status obsolete. BIS is not soliciting public comments on the removal provisions.

The rule is being issued in interim final form because while the

government believes that it is in the national security interests of the United States to immediately implement these controls, it also wants to provide the interested public with an opportunity to comment on the new controls of the XBS Epoxy System. Comments may be submitted in accordance with the **DATES** and **ADDRESSES** sections of this rule.

Export Administration Act

Although the Export Administration Act expired on August 20, 2001, the President, through Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as amended by Executive Order 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013) and as extended by the Notice of August 7, 2015, 80 FR 48233 (August 11, 2015), has continued the Export Administration Regulations in effect under the International Emergency Economic Powers Act. BIS continues to carry out the provisions of the Export Administration Act, as appropriate and to the extent permitted by law, pursuant to Executive Order 13222 as amended by Executive Order 13637.

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 effects, distribute impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been determined to be not significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to, nor is subject to a penalty for failure to comply with, a collection of information, subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid OMB control number. This rule affects two approved collections: (1) The Simplified Network Application Processing + System (control number 0694–0088), which carries a burden hour estimate of 43.8 minutes, including the time necessary to submit license applications, among other things, as well as miscellaneous and other recordkeeping activities that account for 12 minutes per submission; and (2) License Exceptions and Exclusions (0694–0137). With these initial 0Y521 series items, BIS does not believe that this rule will materially increase the number of submissions under these collections.

3. This rule does not contain policies with Federalism implications as that term is defined under E.O. 13132.

4. The provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring prior notice, the opportunity for public comment and a delay in effective date are inapplicable because this regulation involves a military or foreign affairs function of the United States (*See* 5 U.S.C. 553(a)(1)). BIS, with the concurrence of the U.S. Departments of Defense and State, is implementing this rule because the item identified for the ECCN 0Y521 series in this rule provide a significant military or intelligence advantage to the United States. Immediate imposition of a license requirement is necessary to effect the national security and foreign policy goals of this rule. Immediate implementation will allow BIS to prevent exports of these items to users and for uses that pose a national security threat to the United States or its allies. If BIS delayed this rule to allow for prior notice and opportunity for public comment, the resulting delay in implementation would afford an opportunity for the export of these items to users and uses that pose such a national security threat, thereby undermining the purpose of the rule. In addition, if parties receive notice of the U.S. Government's intention to control these items under 0Y521 once a final rule was published, they might have an incentive to either accelerate orders of these items or attempt to have the items exported prior to the imposition of the control. In addition, prior notice and opportunity for public comment is unnecessary for the amendment to remove references to wing folding technology and software. The removal of the references updates Supplement No. 5 to part 774 and ensures that it accurately reflects the legal status of those items now classified under other ECCNs under the EAR. This amendment also serves to avoid confusing readers about the items' current status.

Further, BIS finds good cause to waive the 30-day delay in effectiveness under 5 U.S.C. 553(d)(3). Immediate implementation of these changes will allow BIS to prevent exports of these items to users and for uses that pose a national security threat to the United States or its allies. If BIS delayed this rule to allow for a 30-day delay in effectiveness, the resulting delay in implementation would afford an opportunity for the export of these items to users and uses that pose such a national security threat, thereby undermining the purpose of the rule. BIS also finds good cause to waive the 30-delay in effectiveness for the implementation of the amendment to remove items because the amendment will assist in clarifying the current status of the wing folding technology and software, eliminating any possible confusion. Furthermore, the amendment is not a substantive change. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.,* are not applicable. Accordingly, no regulatory flexibility analysis is required and none has been prepared. Although notice and opportunity for comment are not required, BIS is issuing this rule as an interim final rule with a request for comments. All comments must be in writing and submitted via one or more of the methods listed under the **ADDRESSES** caption to this document. All comments (including any personal identifiable information) will be available for public inspection and copying. Those wishing to comment anonymously may do so by submitting their comment via regulations.gov and leaving the fields for identifying information blank.

List of Subjects in 15 CFR Part 774

Exports, Reporting and recordkeeping requirements.

Accordingly, part 774 of the Export Administration Regulations (15 CFR parts 730–774) is amended as follows:

PART 774—[AMENDED]

■ 1. The authority citation for part 774 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq.;* 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 15 U.S.C. 1824a; 50 U.S.C. app. 5; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 7, 2015, 80 FR 48233 (August 11, 2015).

■ 2. Supplement No. 5 to part 774 is revised to read as follows:

SUPPLEMENT NO. 5 TO PART 774—ITEMS CLASSIFIED UNDER ECCNS 0A521, 0B521, 0C521, 0D521 AND 0E521

The following table lists items subject to the EAR that are not listed elsewhere in the CCL, but which the Department of Commerce, with the concurrence of the Departments of Defense and State, has

identified warrant control for export or reexport because the items provide at least a significant military or intelligence advantage to the United States or for foreign policy reasons.

Item descriptor. *Note:* The description must match by model number or a broader descriptor that does not necessarily need to be company specific	Date of initial or subsequent BIS classification (ID = initial date; SD = subsequent date)	Date when the item will be designated EAR99, unless reclassified in another ECCN or the 0Y521 classification is reissued	Item-specific license exception eligibility
0A521. Systems, Equipment and Components			
[RESERVED]			
0B521. Test, Inspection and Production Equipment			
[RESERVED]			
0C521. Materials			
No. 1 XBS Epoxy system designed to obfuscate critical technology components against x-ray and terahertz microscopy imaging attempts.	November 16, 2015 (ID) ...	November 16, 2016	License Exception GOV under § 740.11(b)(2)(ii) only
No. 2 [RESERVED]	[RESERVED]	[RESERVED]	[RESERVED]
0D521. Software			
[RESERVED]			
0E521. Technology			
[RESERVED]			

Dated: November 9, 2015.

Kevin J. Wolf,

Assistant Secretary for Export Administration.

[FR Doc. 2015–28978 Filed 11–13–15; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 25

[Docket No. FDA–2013–N–1282]

National Environmental Policy Act; Environmental Assessments for Tobacco Products; Categorical Exclusions; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; correction.

SUMMARY: The Food and Drug Administration (FDA or we) is correcting the preamble to a final rule that appeared in the **Federal Register** of September 24, 2015. This final rule provided FDA with categorical exclusions from the requirement to prepare environmental assessments for certain actions regarding the marketing of tobacco products under the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). The final rule also included amendments to certain environmental impact regulations to include tobacco products, where appropriate, in light of its authority under the Tobacco Control Act.

The document published with technical errors in reference numbers cited in the document. This document corrects those errors. We are placing a corrected copy of the rule in the docket.

DATES: Effective on November 16, 2015.

FOR FURTHER INFORMATION CONTACT: Katherine Collins, Center for Tobacco Products, Food and Drug Administration, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 877–287–1373, *CTP Regulations@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is correcting the preamble to the September 24, 2015 (80 FR 57531), final rule entitled, ''National Environmental Policy Act; Environmental Assessments for Tobacco Products; Categorical Exclusions.'' The document published with three technical errors in reference numbers cited in the document. This document corrects those errors. We are correcting reference 2 and adding new reference 3. We are also placing a corrected copy of the rule in the docket.

In FR Doc. 2015–24219, appearing on page 57531 in the **Federal Register** of Thursday, September 24, 2015 (80 FR 57531), FDA is making the following corrections:

1. On page 57533, in the second column, under the Response for Comment 1, add ''(Ref. 3)'' at the end of the second sentence.

2. On page 57535, in the first column, under section IX, ''2. Statement of RADM David Ashley, Ph.D. and Hoshing Chang, Ph.D., 'Impact of Tobacco Products on the Environment.' '' is corrected to read ''2. 'Final Regulatory Impact Analysis,' Food and Drug Administration, available at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*'

3. On page 57535, in the first column, under section IX, add ''3. Statement of RADM David Ashley, Ph.D. and Hoshing Chang, Ph.D., 'Impact of Tobacco Products on the Environment.'

Dated: November 9, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–28848 Filed 11–13–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–419F]

Schedules of Controlled Substances: Placement of Eluxadoline Into Schedule IV

Correction

In notice document 2015–28718, beginning on page 69861 in the issue of Thursday, November 12, 2015, make the following correction:

On page 69861, in the first column, in the eighteenth and nineteenth lines from the bottom, ''December 17, 2015'' should read ''December 14, 2015''.

[FR Doc. C1–2015–28718 Filed 11–13–15; 8:45 am]

BILLING CODE 1505–01–D

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9743]

RIN 1545–BL62

Transitional Amendments To Satisfy the Market Rate of Return Rules for Hybrid Retirement Plans

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final regulations that provide guidance regarding certain amendments to applicable defined benefit plans. Applicable defined benefit plans are defined benefit plans that use a lump sum-based benefit formula, including cash balance plans and pension equity plans, as well as other plans that have formulas with an effect similar to a lump sum-based benefit formula. These final regulations relate to previously issued final regulations that specify permitted interest crediting rates for purposes of the requirement that an applicable defined benefit plan not provide for interest credits (or equivalent amounts) at an effective rate that is greater than a market rate of return. These final regulations permit a plan sponsor of an applicable defined benefit plan that does not comply with the market rate of return requirement to amend the plan in order to change to an interest crediting rate that is permitted under the previously issued final hybrid plan regulations without violating the anti-cutback rules of section 411(d)(6). These regulations affect sponsors, administrators, participants, and beneficiaries of these plans.

DATES: *Effective Date:* These regulations are effective on November 16, 2015.

Applicability Date: These regulations generally apply to plan amendments made on or after September 18, 2014 (or an earlier date as elected by the taxpayer). These regulations cease to apply for amendments made on or after the first day of the first plan year that begins on or after January 1, 2017 (or, for collectively bargained plans, on or after a later date specified in the regulations).

FOR FURTHER INFORMATION CONTACT: Neil S. Sandhu or Linda S.F. Marshall at (202) 317–6700 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

This document contains amendments to the Income Tax Regulations (26 CFR part 1) under sections 411(a)(13) and 411(b)(5) of the Internal Revenue Code (Code).

Generally, a defined benefit pension plan must satisfy the minimum vesting standards of section 411(a) and the accrual requirements of section 411(b) in order to be qualified under section 401(a) of the Code. Sections 411(a)(13) and 411(b)(5), which modify the minimum vesting standards of section 411(a) and the accrual requirements of section 411(b), were added to the Code by section 701(b) of the Pension Protection Act of 2006, Public Law 109–280 (120 Stat. 780 (2006)) (PPA '06). Sections 411(a)(13) and 411(b)(5) and certain related effective date provisions were subsequently amended by the Worker, Retiree, and Employer Recovery Act of 2008, Public Law 110–458 (122 Stat. 5092 (2008)) (WRERA '08).

Under section 411(b)(5)(B)(i), a statutory hybrid plan is treated as failing to satisfy the requirements of section 411(b)(1)(H) (which provides that the rate of an employee's benefit accrual must not be reduced because of the attainment of any age) if the terms of the plan provide any interest credit (or an equivalent amount) for any plan year at a rate that is in excess of a market rate of return. Section 411(b)(5)(B)(i) is generally effective for plan years beginning after December 31, 2007.

Section 411(d)(6) provides generally that a plan does not satisfy section 411 if an amendment to the plan decreases a participant's accrued benefit. For this purpose, a plan amendment that has the effect of eliminating or reducing an early retirement benefit or a retirement-type subsidy or eliminating an optional form of benefit with respect to benefits attributable to service before the amendment is treated as reducing accrued benefits.

Sections 204(b)(5)(B)(i) and 204(g) of the Employee Retirement Income Security Act of 1974, Public Law 93–406 (88 Stat. 829 (1974)), as amended (ERISA), contain rules that are parallel to sections 411(b)(5)(B)(i) and 411(d)(6), respectively. Under section 101 of Reorganization Plan No. 4 of 1978 (43 FR 47713), the Secretary of the Treasury has interpretive jurisdiction over the subject matter addressed in these final regulations for purposes of ERISA, as well as the Code. Thus, these final regulations apply for purposes of sections 411(b)(5)(B)(i) and 411(d)(6) of the Code, as well as for purposes of sections 204(b)(5)(B)(i) and 204(g) of ERISA.

Section 1.411(d)–4, A–2(b)(1), of the Income Tax Regulations provides, in part, that the Commissioner may, consistent with the provisions of § 1.411(d)–4, provide for the elimination or reduction of section 411(d)(6) protected benefits that have already accrued to the extent that such elimination or reduction is necessary to permit compliance with other requirements of section 401(a). The Commissioner may exercise this authority only through the publication of revenue rulings, notices, and other documents of general applicability.

Section 1.411(d)–4, A–2(b)(2)(i), provides that a plan may be amended to eliminate or reduce a section 411(d)(6) protected benefit, within the meaning of § 1.411(d)–4, A–1, if the following three requirements are met: The amendment constitutes timely compliance with a change in law affecting plan qualification; there is an exercise of section 7805(b) relief by the Commissioner; and the elimination or reduction of the section 411(d)(6) protected benefit is made only to the extent necessary to enable the plan to continue to satisfy the requirements for qualified plans.

Final regulations (TD 9505) (2010 final hybrid plan regulations) were published by the Treasury Department and the IRS in the **Federal Register** on October 19, 2010 (75 FR 64123). Additional final regulations (TD 9693) (2014 final hybrid plan regulations) were published by the Treasury Department and the IRS in the **Federal Register** on September 19, 2014 (79 FR 56442) (collectively, the 2010 and 2014 final hybrid plan regulations are referred to herein as the final hybrid plan regulations). The final hybrid plan regulations provide, effective for plan years that begin on or after January 1, 2016, a list of interest crediting rates

and combinations of rates that satisfy the requirement of section 411(b)(5)(B)(i) that a plan not provide an effective rate of return in excess of a market rate of return, while not permitting other rates. The provisions that provide for a list of rates are set forth at § 1.411(b)(5)–1(d)(1)(iii), (d)(1)(vi), and (d)(6)(i).

Interest crediting rates can be broadly characterized as either investment-based rates or rates that are not investment-based rates. An investment-based rate is a rate of return provided by actual investments, taking into account the return attributable to any change in the value of the underlying investments. A rate of return that is based on the rate of return for an index that measures the change in the value of investments can also be considered to be an investment-based rate. Rates that are not investment-based rates are either fixed rates of interest or bond-based rates (such as yields to maturity of bonds).

Section 1.411(b)(5)–1(d)(3) and (d)(4) sets forth permitted rates that are not investment-based rates, such as the third segment rate described in section 417(e)(3)(D) or 430(h)(2)(C)(iii), the yield on 30-year Treasury Constant Maturities, and a fixed 6 percent rate of interest. Section 1.411(b)(5)–1(d)(5) sets forth permitted investment-based rates, such as the rate of return on certain regulated investment companies (RICs), as defined in section 851, and the rate of return on plan assets. As provided in § 1.411(b)(5)–1(d)(6), certain annual (or more frequent) floors are permitted in combination with the bond-based rates and cumulative floors (in excess of the cumulative zero floor required under section 411(b)(5)(i)(II)) are permitted in combination with either the bond-based rates or the investment-based rates.

Section 1.411(b)(5)–1(e)(3) provides that the right to future interest credits determined in the manner specified under the plan and not conditioned on future service is a factor that is used to determine the participant's accrued benefit for purposes of section 411(d)(6). Accordingly, section 411(d)(6) protection applies not only to interest credits that have already been credited but also to future interest credits that are not conditioned on future service.

Proposed hybrid plan transition regulations (REG–111839–13) (2014 proposed regulations) were published by the Treasury Department and the IRS in the **Federal Register** on September 19, 2014 (79 FR 56305). The 2014 proposed regulations would permit an amendment to change the interest crediting rate under a hybrid plan from a rate not on the list to a rate on the list of interest crediting rates and combinations of rates that satisfy the requirement of section 411(b)(5)(B)(i) for plan years that begin on or after January 1, 2016.

Written comments in response to the 2014 proposed regulations were received, and a public hearing was held on January 9, 2015. After consideration of the comments received, the provisions in the 2014 proposed regulations are adopted by this Treasury decision, subject to a number of changes that are summarized in this preamble.

Explanation of Provisions

A number of commenters requested that the regulations provide for sufficient time for plan sponsors to implement amendments pursuant to these regulations to change a plan's interest crediting rate to a permissible rate. In addition, these commenters pointed out that these amendments are often interrelated with amendments required to comply with the 2014 final hybrid plan regulations, and that plan sponsors often consider and implement all of the required amendments at the same time. In response to these comments, these final regulations delay the applicability date of certain provisions under sections 411(a)(13) and 411(b)(5) in the final hybrid plan regulations, including those provisions that provide a list of interest crediting rates and combinations of rates that satisfy the requirement of section 411(b)(5)(B)(i) that the plan not provide an effective rate of return in excess of a market rate of return. Under these regulations, these provisions are generally effective for plan years that begin on or after January 1, 2017.

Prior to the first day of the first plan year that begins on or after January 1, 2017, a plan that uses an interest crediting rate that is not permitted under the final hybrid plan regulations must be amended to change to an interest crediting rate that is permitted under those regulations. Although a plan is permitted to be amended to change the interest crediting rate with respect to benefits that have not yet accrued, an amendment that reduces the interest crediting rate with respect to benefits that have already accrued would ordinarily be impermissible under section 411(d)(6).

In order to resolve the conflict between the market rate of return rules of section 411(b)(5)(B)(i) and the anti-cutback rules of section 411(d)(6), these regulations permit a plan with a noncompliant interest crediting rate to be amended with respect to benefits that have already accrued so that its interest crediting rate complies with the market rate of return rules. If the applicable requirements of these regulations are satisfied, such an amendment is permitted with respect to benefits that have already accrued, but only with respect to interest credits that are credited for interest crediting periods that begin on or after the later of the effective date of the amendment or the date the amendment is adopted (the applicable amendment date within the meaning of § 1.411(d)–3(g)(4)).[1] To qualify for this treatment, the amendment must be adopted prior to and effective no later than the applicability date of the regulatory market rate of return rules (generally, the first day of the first plan year that begins on or after January 1, 2017, with a delayed applicability date for collectively bargained plans).

Like the 2014 proposed regulations, these regulations permit amendments that bring the plan into compliance by changing the specific feature that causes the plan's interest crediting rate to be noncompliant, while not changing other features of the existing rate. If the noncompliant interest crediting rate has more than one noncompliant feature, then each noncompliant feature must be addressed separately in the prescribed manner. Examples are included to illustrate the application of these rules.

The standard in these final regulations for resolving this conflict between section 411(d)(6) and section 411(b)(5)(B)(i) is generally comparable to the standard under the rules of § 1.411(d)–4, A–2(b)(1) and (b)(2)(i) with respect to the Commissioner's exercise of authority to resolve a conflict between section 411(d)(6) and another qualification requirement under section 401(a). The Treasury Department and the IRS believe this approach is the most appropriate manner to resolve the conflict between the market rate of return rules of section 411(b)(5)(B)(i) and the anti-cutback rules of section 411(d)(6).[2]

If a noncompliant rate involves one or more variable rates or a variable rate together with a fixed rate, it is not

[1] Thus, these regulations do not permit a reduction in the hypothetical account balance as of the applicable amendment date.

[2] A plan may have been amended to change its interest crediting rate under the rules of section 1107 of PPA '06. Section 1107 of PPA '06 provided relief from the requirements of section 411(d)(6) for amendments made pursuant to a change in law under PPA '06 if the amendment was adopted by the last day of the first plan year that began on or after January 1, 2009 (or 2011, in the case of a governmental plan as defined in section 414(d)). If an interest crediting rate adopted under the rules of section 1107 of PPA '06 is not permitted under the final hybrid plan regulations, then these final regulations permit a subsequent amendment to change the rate to a rate permitted under the final hybrid plan regulations.

always readily apparent which specific feature or component rate causes the rate to be noncompliant. In addition, if either the existing rate or any of the potential corrections involves variable components, it is impossible to determine with certainty at the time of amendment the single amendment that in all cases that will result in the least reduction to the participant's accrued benefit as of the participant's annuity starting date. Thus, in response to a number of comments on the 2014 proposed regulations that more flexibility to amend noncompliant features be provided, the final regulations in many cases permit a plan sponsor to choose one of two or more alternative amendments in order to bring a plan into compliance.

A number of commenters specifically requested that the rules in the transition regulations permit any noncompliant bond-based rate to be capped at the third segment rate. The Treasury Department and the IRS agree that this is an appropriate approach. Accordingly, an additional option has been added in each case involving bond-based rates so that any noncompliant variable rate that is not an investment-based rate (including the greater of two or more non-investment based variable rates) may be capped at the third segment rate. If this approach is used, the third segment rate cap would have to satisfy the rules that apply to the use of the third segment rate as an interest crediting rate. Thus, the cap could be any of the third segment rates that may be used as an interest crediting rate and the cap would have to use a permissible lookback month and stability period. Note, however, that if any noncompliant composite rate is limited so that it does not exceed a third segment rate cap, that limit would also apply with respect to any annual fixed minimum rate that is part of the noncompliant composite rate. Therefore, the annual interest crediting rate (taking into account the cap) could be lower than the otherwise applicable fixed minimum rate.[3]

A special rule has been added to the regulations to clarify that an amendment to correct a noncompliant feature that provides for a greater interest crediting rate than the specific amendment set forth in the regulations also does not violate section 411(d)(6). Thus, for example, in any case in which it is permissible to address a noncompliant rate by capping the rate at the third segment rate, it would also be permissible to address the noncompliant rate simply by switching to the third segment rate. Similarly, an amendment to switch to the third segment rate together with a permitted fixed minimum rate would be permissible.

These final regulations also provide flexibility with respect to noncompliant investment-based rates. In particular, if a plan credits interest using a noncompliant investment-based rate and there is no permitted investment-based rate with similar risk and return characteristics as the plan's impermissible rate, then, as an alternative to the specified corrective amendment that was in the proposed regulations, an amendment to switch to the third segment rate with a 4 percent fixed minimum rate is permitted. The regulations also clarify the specified corrective amendment that was in the proposed regulations by providing that it is permissible in such a case to switch to a permitted investment-based rate that is otherwise similar to the plan's impermissible investment-based rate but without the risk and return characteristics of the impermissible rate that caused it to be impermissible (generally requiring the use of a rate that is less volatile than the plan's impermissible investment-based rate but is otherwise similar to that rate).

The preamble to the 2014 final hybrid plan regulations contained a discussion of statutory hybrid plans that permit participants to choose from among a menu of hypothetical investment options. Because of the significant concerns relating to the use of these plan designs, the Treasury Department and the IRS continue to study the issues raised in the preamble to the 2014 final hybrid plan regulations related to these plans, and it is possible that the Treasury Department and the IRS will conclude that such plan designs are not permitted. Nevertheless, the Treasury Department and the IRS understand that some of these plans contain one or more hypothetical investment options that provide for a rate of return that is not permitted under the final hybrid plan regulations. A special rule is included in these regulations in order to address the noncompliance that results from the availability of at least one hypothetical investment option that provides for an impermissible rate of return. This special rule provides that the rules of these final regulations may be applied separately to correct each impermissible hypothetical investment option. Alternatively, with respect to such a plan that permitted a participant to choose an interest crediting rate from among a menu of hypothetical investment options on September 18, 2014, pursuant to plan provisions that were adopted on or before September 18, 2014, this special rule provides that the entire menu of investment options may be treated as an impermissible investment-based rate for which there is no permitted investment-based rate with similar risk and return characteristics (so that the rule of § 1.411(b)(5)–1(e)(3)(vi)(C)(*7*) does not apply). As a result, plans described in the preceding sentence may be amended to eliminate a participant's ability to choose an interest crediting rate from among a menu of hypothetical investment options in accordance with § 1.411(b)(5)–1(e)(3)(vi)(C)(*9*). The inclusion of this special rule with respect to plan designs that permit participant direction of interest crediting rates is merely intended to address the noncompliance that results from the availability of a hypothetical investment option that provides for an impermissible rate of return, and should not be construed to create any inference as to the permissibility of these plan designs in general.

The preamble to the 2014 proposed regulations specifically requested comments as to an amendment to bring a plan into compliance if the plan credits interest using a composite rate that is an investment-based rate of return with an impermissible annual (or more frequent) fixed or variable rate. Many commenters requested flexibility to choose among options in such a case because there is no single correction that is the best correction for all cases. The Treasury Department and the IRS agree that, for this type of interest crediting rate, no single correction method is the most appropriate method for all cases. Therefore, the final regulations provide that it is permissible either to eliminate the fixed minimum rate (or any variable non-investment based rate) and eliminate any reduction to the investment-based rate, or to switch to the third segment rate (preserving any fixed minimum rate to the maximum extent permitted).

In response to comments inquiring about the treatment of plans that provide for a cumulative floor (such as, for example, in order to comply with section 411(d)(6) in connection with a prior amendment to change the plan's interest crediting rate on accrued pay credits), the regulations provide for a special rule that applies with respect to a participant under a plan that takes into account a minimum rate of return that applies less frequently than annually or that determines the participant's benefit as of the annuity

[3] This limitation on an otherwise applicable minimum rate may have implications for plans that require an annual minimum rate in order to satisfy the anti-backloading rules of section 411(b)(1).

starting date as the benefit provided by the greatest of two or more account balances and that minimum rate or benefit based on two or more account balances does not satisfy the market rate of return rules. If this rule applies, the plan must be amended to provide that the benefit for a participant is based solely on the benefit (and the associated interest crediting rate with respect to that benefit) that is greatest for that participant as of the applicable amendment date for the amendment adopted pursuant to these regulations. In addition, the plan must be further amended pursuant to the other rules in these regulations if the remaining interest crediting rate does not satisfy the market rate of return rules.

In response to comments as to the permissibility of rounding interest crediting rates and the need for the regulations to provide section 411(d)(6) relief for plans that use an impermissible rounding rule, the regulations provide for a rounding rule and also provide for section 411(d)(6) relief for transitional amendments to comply with this rounding rule. Under the rounding rule, a plan is not treated as failing to meet the requirement that a plan not credit interest at a rate that exceeds a market rate of return merely because the plan determines interest credits for an interest crediting period by rounding the calculated interest rate or rate of return. Under this rule, an annual rate may be rounded to the nearest multiple of 25 basis points (or a smaller rounding interval). If a plan provides for the crediting of interest more frequently than annually, then the rounding interval must not exceed a pro-rata portion of 25 basis points. Notwithstanding the preceding sentence, a plan is permitted to round to the nearest basis point regardless of the length of the interest crediting period.

Several commenters identified the need for section 411(d)(6) relief for plans that provide for rules that apply upon plan termination that do not comply with the plan termination rules in the final hybrid plan regulations. In response to these comments, the regulations provide for section 411(d)(6) relief for transitional amendments made to enable a plan to comply with the plan termination rules in the final hybrid plan regulations.

In response to the comment request included in the 2014 proposed regulations with respect to all aspects of those proposed rules, the Department of Treasury and the IRS received a number of comments with respect to provisions of the 2014 final hybrid plan regulations instead of the 2014 proposed regulations. These final regulations delay the applicability date of certain provisions in the 2014 final hybrid plan regulations (and provide for a special delayed applicability date for collectively bargained plans), but do not otherwise address comments on provisions of the 2014 final hybrid plan regulations.[4]

Effective/Applicability Dates

These regulations generally apply to plan amendments made on or after September 18, 2014 (or an earlier date as elected by the taxpayer), and they do not apply for amendments made on or after the first day of the first plan year that begins on or after January 1, 2017. However, for collectively bargained plans, these regulations continue to apply for amendments made before the first day of the first plan year that begins on or after January 1, 2019, unless the last collective bargaining agreement ratified on or before November 13, 2015 expires before January 1, 2019, in which case these regulations cease to apply to amendments made on or after the first day of the first plan year that begins on or after the later of the date on which the last applicable collective bargaining agreement expires or January 1, 2017.

Special Analyses

Certain IRS regulations, including this one, are exempt from the requirements of Executive Order 12866, as supplemented and reaffirmed by Executive Order 13563. Therefore, a regulatory impact assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations, and because these regulations do not impose a collection of information on small entities, the Regulatory Flexibility Act (5 U.S.C. chapter 6) does not apply. Pursuant to section 7805(f) of the Code, the notice of proposed rulemaking preceding these regulations was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Drafting Information

The principal authors of these regulations are Neil S. Sandhu and Linda S.F. Marshall, Office of Associate Chief Counsel (Tax Exempt and Government Entities). However, other personnel from the IRS and the Treasury Department participated in the development of these regulations.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

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

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

§ 1.411(a)(13)–1 [Amended]

■ **Par. 2.** For each entry listed in the ''Location'' column, remove the language in the ''Remove'' column and add the language in the ''Add'' column in its place.

Location	Remove	Add
§ 1.411(a)(13)–1(d)(3)(i), third sentence.	for plan years that begin on or after January 1, 2016	for plan years described in paragraph (e)(2)(ii)(A) or (e)(2)(ii)(B) of this section, as applicable.
§ 1.411(a)(13)–1(d)(3)(i), fifth and sixth sentences.	for plan years that begin on or after January 1, 2016	for plan years described in paragraph (e)(2)(ii)(A) or (e)(2)(ii)(B) of this section (as applicable).
§ 1.411(a)(13)–1(d)(4)(ii)(A), second sentence.	for plan years that begin on or after January 1, 2016	for plan years described in paragraph (e)(2)(ii)(A) or (e)(2)(ii)(B) of this section (as applicable).
§ 1.411(a)(13)–1(d)(4)(ii)(C), second sentence.	For plan years that begin on or after January 1, 2016 ..	For plan years described in paragraph (e)(2)(ii)(A) or (e)(2)(ii)(B) of this section (as applicable).

[4] Proposed regulations (REG–132554–08) under sections 411(a)(13), 411(b)(1), and 411(b)(5) (2010 proposed hybrid plan regulations) were published by the Treasury Department and the IRS in the **Federal Register** on October 19, 2010 (75 FR 64197). The Treasury Department and the IRS received written comments on the 2010 proposed hybrid plan regulations, and a public hearing was held on January 26, 2011. The 2014 final hybrid plan regulations, which finalized the 2010 proposed hybrid plan regulations, took into account the comments received prior to publication of the 2014 final hybrid plan regulations.

■ **Par. 3.** Section 1.411(a)(13)–1 is amended by revising paragraph (e)(2)(ii) to read as follows:

§ 1.411(a)(13)–1 Statutory hybrid plans.

* * * * *

(e) * * *

(2) * * *

(ii) *Special effective date*—(A) *In general.* Except as otherwise provided in this paragraph (e)(2)(ii), paragraphs (b)(2), (3), and (4) of this section apply to plan years that begin on or after January 1, 2017.

(B) *Collectively bargained plans.* In the case of a plan maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers ratified on or before November 13, 2015, that constitutes a collectively bargained plan under the rules of § 1.436–1(a)(5)(ii)(B), paragraphs (b)(2), (3), and (4) of this section apply to plan years that begin on or after the later of—

(*1*) January 1, 2017; and

(*2*) The earlier of—

(*i*) January 1, 2019; and

(*ii*) The date on which the last of those collective bargaining agreements terminates (determined without regard to any extension thereof on or after November 13, 2015).

* * * * *

§ 1.411(b)(5)–1 [Amended]

■ **Par. 4.** For each entry listed in the ''Location'' column, remove the language in the ''Remove'' column and add the language in the ''Add'' column in its place.

Location	Remove	Add
§ 1.411(b)(5)–1(b)(1)(ii)(F) ...	For plan years that begin on or after January 1, 2016 ..	For plan years described in paragraph (f)(2)(i)(B)(*1*) or (f)(2)(i)(B)(*3*) of this section (as applicable).
§ 1.411(b)(5)–1(b)(1)(iii), third sentence.	for plan years that begin on or after January 1, 2016	for plan years described in paragraph (f)(2)(i)(B)(*1*) or (f)(2)(i)(B)(*3*) of this section (as applicable).
§ 1.411(b)(5)–1(b)(2)(i), third sentence.	for plan years that begin on or after January 1, 2016	for plan years described in paragraph (f)(2)(i)(B)(*1*) or (f)(2)(i)(B)(*3*) of this section, as applicable.
§ 1.411(b)(5)–1(e)(2)(ii)(B)(*1*), second sentence.	the first plan year that begins on or after January 1, 2016.	the first plan year described in paragraph (f)(2)(i)(B)(*1*) or (f)(2)(i)(B)(*3*) of this section (as applicable).
§ 1.411(b)(5)–1(e)(3)(ii)(D) ...	For plan years that begin on or after January 1, 2016 ..	For plan years described in paragraph (f)(2)(i)(B)(*1*) or (f)(2)(i)(B)(*3*) of this section (as applicable).

■ **Par. 5.** Section 1.411(b)(5)–1 is amended by:

■ 1. Adding a new sentence between the second and third sentences of paragraph (d)(1)(iv)(A);

■ 2. Adding paragraph (d)(1)(iv)(E);

■ 3. Adding paragraphs (e)(3)(vi) and (vii); and

■ 4. Revising paragraph (f)(2)(i)(B).

The additions and revisions read as follows:

§ 1.411(b)(5)–1 Reduction in rate of benefit accrual under a defined benefit plan.

* * * * *

(d) * * *

(1) * * *

(iv) * * *

(A) * * * In addition, a plan is permitted to round the calculated interest rate or rate of return in accordance with paragraph (d)(1)(iv)(E) of this section.

* * * * *

(E) *Rounding of interest crediting rate.* A plan is not treated as failing to meet the requirements of this paragraph (d) merely because the plan determines interest credits for an interest crediting period by rounding the calculated interest rate or rate of return in accordance with this paragraph (d)(1)(iv)(E). An annual rate may be rounded to the nearest multiple of 25 basis points (or a smaller rounding interval). If a plan provides for the crediting of interest more frequently than annually, then the rounding interval must not exceed a pro-rata portion of 25 basis points. Notwithstanding the preceding sentence, a plan is permitted to round to the nearest basis point regardless of the length of the interest crediting period.

* * * * *

(e) * * *

(3) * * *

(vi) *Transitional amendments needed to satisfy the market rate of return rules*—(A) *In general.* Notwithstanding the requirements of section 411(d)(6), if the requirements set forth in this paragraph (e)(3)(vi) are satisfied, a plan may be amended to change its interest crediting rate with respect to benefits that have already accrued in order to comply with the requirements of section 411(b)(5)(B)(i) and paragraph (d) of this section. A plan amendment is eligible for the treatment provided under this paragraph (e)(3)(vi)(A) to the extent that the amendment modifies an interest crediting rate that does not satisfy the requirements of section 411(b)(5)(B)(i) and paragraph (d) of this section in the manner specified in paragraph (e)(3)(vi)(C) of this section.

(B) *Rules of application*—(*1*) *Multiple noncompliant features.* If a plan's interest crediting rate has more than one noncompliant feature as described in paragraph (e)(3)(vi)(C) of this section, then each noncompliant feature must be addressed separately in the manner specified in paragraph (e)(3)(vi)(C) of this section.

(*2*) *Definition of investment-based rate.* The application of the rules of paragraph (e)(3)(vi)(C) of this section to an interest crediting rate depends on whether the interest crediting rate is an investment-based rate. For purposes of this paragraph (e)(3)(vi), an investment-based rate is a rate based on either a rate of return provided by actual investments (taking into account the return attributable to any change in the value of the underlying investments) or a rate of return for an index that measures the change in the value of investments. A rate is an investment-based rate even if it is based only in part on a rate described in the preceding sentence.

(*3*) *Timing rules for permitted amendments.* The rules under this paragraph (e)(3)(vi) apply only to a plan amendment that is adopted prior to and effective no later than the first day of the first plan year described in paragraph (f)(2)(i)(B)(*1*) or (f)(2)(i)(B)(*3*) of this section, as applicable. In addition, the rules under this paragraph (e)(3)(vi) apply to a plan amendment only with respect to interest credits that are credited for interest crediting periods that begin on or after the applicable amendment date (within the meaning of § 1.411(d)–3(g)(4)).

(*4*) *Amendments that provide for greater interest crediting rates.* If a plan is amended in accordance with paragraphs (e)(3)(vi)(C)(*1*) through (*10*) of this section to switch from a noncompliant rate to a compliant rate and is subsequently amended to switch to a second compliant rate that can

never be less than the first compliant rate, then the second amendment does not violate section 411(d)(6). If, instead, the plan is amended to switch from the noncompliant rate to the second compliant rate in a single amendment, that amendment also does not violate section 411(d)(6). For example, if it is permitted under paragraph (e)(3)(vi)(C) of this section to first amend the plan to credit interest using the lesser of the current rate and a rate described in paragraph (d)(3) of this section, it is then permissible to amend the plan to credit interest using that rate described in paragraph (d)(3) of this section. In such a case, it is also permissible to amend the plan to switch from the current rate to a rate described in paragraph (d)(3) of this section in a single amendment.

(*5*) *Cumulative floors, including floors resulting from a prior change in rates with section 411(d)(6) protection.* This paragraph (e)(3)(vi)(B)(*5*) applies to a plan that takes into account a minimum rate of return that applies less frequently than annually. This paragraph (e)(3)(vi)(B)(*5*) also applies to a plan that determines the participant's benefit as of the annuity starting date as the benefit provided by the greatest of two or more account balances (for example, in order to comply with section 411(d)(6) in connection with a prior amendment to change the plan's interest crediting rate). In either case, this paragraph (e)(3)(vi)(B)(*5*) applies with respect to a participant only if the requirements of paragraph (d)(6) of this section are not satisfied with respect to that participant. If this paragraph (e)(3)(vi)(B)(*5*) applies with respect to a participant, the plan must be amended to provide that the benefit for the participant is based solely on the benefit (and the associated interest crediting rate with respect to that benefit) that is greatest for that participant as of the applicable amendment date for the amendment made pursuant to this paragraph (e)(3)(vi). In addition, the plan must be further amended pursuant to the other rules in this paragraph (e)(3)(vi) if the remaining interest crediting rate does not satisfy the requirements of paragraph (d) of this section.

(*6*) *Plans that permit participant direction of interest crediting rates.* This paragraph (e)(3)(vi)(B)(*6*) applies in the case in which a plan permits a participant to choose an interest crediting rate from among a menu of hypothetical investment options and at least one of those hypothetical investment options provides for an interest crediting rate that is not permitted under paragraph (d) of this section (so that the plan fails to satisfy the requirements of paragraph (d) of this section). In such a case, the rules of this paragraph (e)(3)(vi) may be applied separately to correct each impermissible investment option. Alternatively, with respect to such a plan that permitted a participant to choose an interest crediting rate from among a menu of hypothetical investment options on September 18, 2014, pursuant to plan provisions that were adopted on or before September 18, 2014, the entire menu of investment options may be treated as an impermissible investment-based rate for which there is no permitted investment-based rate with similar risk and return characteristics (so that the rule of paragraph (e)(3)(vi)(C)(*7*) of this section does not apply). As a result, plans described in the preceding sentence may be amended to eliminate a participant's ability to choose an interest crediting rate from among a menu of hypothetical investment options in accordance with paragraph (e)(3)(vi)(C)(*9*) of this section.

(C) *Noncompliant feature and amendment to bring plan into compliance*—(*1*) *Timing or other rules related to determining interest credits not satisfied.* If a plan has an underlying interest rate that generally satisfies the rules of paragraph (d) of this section but that does not satisfy the rules relating to how interest credits are determined and credited as set forth in paragraph (d)(1)(iv) of this section, then the plan must be amended either—

(*i*) To correct the aspect of the plan's interest crediting rate that fails to comply with the rules of paragraph (d)(1)(iv) of this section with respect to its underlying interest crediting rate; or

(*ii*) If the plan's interest crediting rate is a variable rate that is not an investment-based rate of return, to provide that the plan's interest crediting rate is the lesser of that variable rate and a rate described in paragraph (d)(3) of this section that satisfies the rules of paragraph (d)(1)(iv) of this section.

(*2*) *Fixed rate in excess of 6 percent.* If a plan's interest crediting rate is a fixed rate in excess of the rate described in paragraph (d)(4)(v) of this section, then the plan must be amended to reduce the interest crediting rate to an annual interest crediting rate of 6 percent.

(*3*) *Bond-based rate with margin exceeding maximum permitted margin.* If a plan's interest crediting rate is a noncompliant rate that consists of an underlying rate described in paragraph (d)(3) or (d)(4) of this section except that the plan applies a margin that exceeds the maximum permitted margin under paragraph (d)(3) or (d)(4) of this section to the underlying rate, then the plan must be amended either—

(*i*) To reduce the margin to the maximum permitted margin for the underlying rate used by the plan; or

(*ii*) To provide that the plan's interest crediting rate is the lesser of the plan's noncompliant rate and a rate described in paragraph (d)(3) of this section (together with any fixed minimum rate that was part of the noncompliant rate, reduced to the extent necessary to comply with paragraph (d)(6)(ii) of this section).

(*4*) *Bond-based rate with fixed minimum rate applied on an annual or more frequent basis in excess of the highest permitted fixed minimum rate.* If a plan's interest crediting rate is a composite rate that consists of a variable rate described in paragraph (d)(3) or (d)(4) of this section in combination with a fixed minimum rate in excess of the highest permitted fixed minimum rate under paragraph (d)(6)(ii)(A)(*2*) or (B)(*2*) of this section (as applicable), then the plan must be amended in one of the following manners:

(*i*) To reduce the fixed minimum rate to the highest permitted fixed minimum rate that may be used in combination with the plan's variable rate;

(*ii*) To credit interest using an annual interest crediting rate of 6 percent; or

(*iii*) To provide that the plan's interest crediting rate is the lesser of the plan's noncompliant composite rate and a rate described in paragraph (d)(3) of this section (together with a fixed minimum rate of 4 percent).

(*5*) *Greatest of two or more variable bond-based rates.* If a plan's interest crediting rate is a composite rate that is the greatest of two or more variable rates described in paragraph (d)(3) or (d)(4) of this section, then the plan must be amended to provide for an interest crediting rate that is the lesser of the composite rate and a rate described in paragraph (d)(3) of this section.

(*6*) *Other impermissible bond-based rates.* If, after application of the rules of paragraphs (e)(3)(vi)(C)(*1*) through (*5*) of this section, a plan's interest crediting rate is a variable rate that is not an investment-based rate of return and is not described in paragraph (d)(3) or (d)(4) of this section, then the plan must be amended either—

(*i*) To provide for an interest crediting rate based on a variable rate described in paragraph (d)(3) or (d)(4) of this section that has similar duration and quality characteristics as the plan's variable rate, if such a rate can be selected; or

(*ii*) To provide for an interest crediting rate that is the lesser of the plan's

variable rate and a rate described in paragraph (d)(3) of this section.

(*7*) *Impermissible investment-based rate that can be replaced with a permissible rate that has similar risk and return characteristics.* If a plan's interest crediting rate is an investment-based rate of return that is not described in paragraph (d)(5) of this section and a permitted investment-based rate described in paragraph (d)(5)(ii)(A), (d)(5)(ii)(B), or (d)(5)(iv) of this section that has similar risk and return characteristics as the plan's impermissible investment-based rate can be selected, then the plan must be amended to provide for an interest crediting rate based on such a permitted investment-based rate.

(*8*) *Investment-based rate with an annual or more frequent minimum rate that is either a fixed rate or a non-investment based variable rate.* If a plan's interest crediting rate is an investment-based rate of return that would be described in paragraph (d)(5) of this section except that the plan uses an annual or more frequent minimum rate that is either a fixed rate or a non-investment based variable rate in conjunction with the investment-based rate, then the plan must be amended either—

(*i*) To credit interest using that investment-based rate of return described in paragraph (d)(5) of this section without the minimum rate and eliminating any reduction (or other adjustment) to the investment-based rate; or

(*ii*) To provide that the plan's interest crediting rate is a rate described in paragraph (d)(3) of this section (together with any fixed minimum rate, reduced to the extent necessary to comply with paragraph (d)(6)(ii) of this section).

(*9*) *Other impermissible investment-based rates.* If, after application of the rules of paragraphs (e)(3)(vi)(C)(*1*), (*7*), and (*8*) of this section, a plan's interest crediting rate is an investment-based rate that is not described in paragraph (d)(5) of this section, then the plan must be amended either—

(*i*) To provide for an interest crediting rate that is an investment-based rate that is described in paragraph (d)(5) of this section and that is otherwise similar to the plan's impermissible investment-based rate but without the risk and return characteristics of the impermissible investment-based rate that caused it to be impermissible (generally requiring the use of a rate that is less volatile than the plan's impermissible investment-based rate but is otherwise similar to that rate); or

(*ii*) To provide that the plan's interest crediting rate is a rate described in paragraph (d)(3) of this section with a fixed minimum rate of 4 percent.

(D) *Examples.* The following examples illustrate the application of the rules of this paragraph (e)(3)(vi). Each plan has a plan year that is the calendar year, and all amendments are adopted on October 1, 2016, and become effective for interest crediting periods beginning on or after January 1, 2017. Except as otherwise provided, the interest crediting rate under the plan satisfies the timing and other rules related to crediting interest under paragraph (d)(1)(iv) of this section.

Example 1. (i) *Facts.* A plan determines interest credits for a plan year using the average yield on 30-year Treasury Constant Maturities for the last week of the preceding plan year (which is an impermissible lookback period for this purpose pursuant to paragraph (d)(1)(iv)(B) of this section because it is not a month).

(ii) *Conclusion.* Pursuant to paragraph (e)(3)(vi)(C)(*1*) of this section, the plan must be amended in one of two manners. It may be amended to determine interest credits for a plan year using the average yield on 30-year Treasury Constant Maturities for a lookback month that complies with the requirements of paragraph (d)(1)(iv)(B) of this section. Alternatively, the plan may be amended to cap the existing rate so that it cannot exceed a third segment rate described in paragraph (d)(3) of this section for a period that complies with the requirements of paragraph (d)(1)(iv)(B) of this section.

Example 2. (i) *Facts.* A plan determines interest credits for a plan year using the average yield on 30-year Treasury Constant Maturities for the last week of the preceding plan year, plus 50 basis points.

(ii) *Conclusion.* Pursuant to paragraph (e)(3)(vi)(B)(*1*) of this section, the plan must be amended to correct both the impermissible lookback period and the excess margin. Accordingly, pursuant to paragraph (e)(3)(vi)(C)(*1*) and (*3*) of this section, the plan may be amended to determine interest credits for a plan year using the average yield on 30-year Treasury Constant Maturities (with no margin) for a period that complies with the requirements of paragraph (d)(1)(iv)(B) of this section. Alternatively, the plan may be amended to cap the existing rate so that it cannot exceed a third segment rate described in paragraph (d)(3) of this section for a period that complies with the requirements of paragraph (d)(1)(iv)(B) of this section.

Example 3. (i) *Facts.* A plan credits interest for a plan year using the rate of return on plan assets for the preceding plan year.

(ii) *Conclusion.* Pursuant to paragraph (e)(3)(vi)(C)(*1*) of this section, the plan must be amended to determine interest credits for each plan year using the rate of return on plan assets for that plan year.

Example 4. (i) *Facts.* A plan credits interest using the average yield on 30-year Treasury Constant Maturities for December of the preceding plan year with a minimum rate of 5.5 percent per year.

(ii) *Conclusion.* Pursuant to paragraph (e)(3)(vi)(C)(*4*) of this section, the plan must be amended to change the plan's interest crediting rate. The new interest crediting rate under the plan may be the average yield on 30-year Treasury Constant Maturities for December of the preceding plan year with a minimum rate of 5 percent per year. Alternatively, the new interest crediting rate under the plan may be an annual interest crediting rate of 6 percent. As another alternative, the existing noncompliant composite rate may be capped so that it cannot exceed a third segment rate described in paragraph (d)(3) of this section, with a minimum rate of 4 percent as a floor on the entire resulting rate.

Example 5. (i) *Facts.* A plan credits interest using the greater of the unadjusted yield on 30-year Treasury Constant Maturities and the yield on 1-year Treasury Constant Maturities plus 100 basis points.

(ii) *Conclusion.* Pursuant to paragraph (e)(3)(vi)(C)(*5*) of this section, the plan must be amended to cap the existing composite ''greater-of'' rate so that the composite rate cannot exceed a third segment rate described in paragraph (d)(3) of this section.

Example 6. (i) *Facts.* A plan credits interest using a broad-based index that measures the yield to maturity on a group of intermediate-term investment grade corporate bonds.

(ii) *Conclusion.* Pursuant to paragraph (e)(3)(vi)(C)(*6*) of this section, the plan must be amended in one of two manners. The plan may be amended to credit interest using a second segment rate described in paragraph (d)(4)(iv) of this section. Alternatively, the plan may be amended to cap the existing rate so that it cannot exceed a third segment rate described in paragraph (d)(3) of this section.

Example 7. (i) *Facts.* A plan credits interest using the rate of return for a broad-based index that measures the yield to maturity on a group of short-term non-investment grade corporate bonds.

(ii) *Conclusion.* Pursuant to paragraph (e)(3)(vi)(C)(*6*)(*ii*) of this section, the plan must be amended to cap the existing rate so that it cannot exceed a third segment rate described in paragraph (d)(3) of this section.

Example 8. (i) *Facts.* A plan credits interest using the rate of return for the S&P 500 index. To bring the plan into compliance with the market rate of return rules, the plan sponsor amends the plan to credit interest based on the rate of return on a RIC that is designed to track the rate of return on the S&P 500 index.

(ii) *Conclusion.* The amendment satisfies the rule of paragraph (e)(3)(vi)(C)(*7*) of this section.

Example 9. (i) *Facts.* A plan credits interest based on the rate of return on a collective trust that holds a portfolio of equity investments, which provides a rate of return that is reasonably expected to be not significantly more volatile than the broad U.S. equities market or a similarly broad international equities market. To bring the plan into compliance with the market rate of return rules, the plan sponsor amends the plan to credit interest based on the actual rate of return on the assets within a specified subset of the plan's assets that is invested in the collective trust and that satisfies the requirements of paragraph (d)(5)(ii)(B) of this section.

(ii) *Conclusion.* The amendment satisfies the rule of paragraph (e)(3)(vi)(C)(*7*) of this section.

Example 10. (i) *Facts.* A plan credits interest for a plan year using the rate of return on a RIC that has most of its investments concentrated in the semiconductor industry.

(ii) *Conclusion.* Pursuant to paragraph (e)(3)(vi)(C)(*9*) of this section, the plan must be amended in one of two manners. The plan may be amended to provide for an interest crediting rate that is an investment-based rate that is described in paragraph (d)(5) of this section and that is similar to the plan's impermissible investment-based rate except to the extent that the risk and return characteristics of the impermissible investment-based rate caused it to be impermissible. Thus, the plan may be amended to provide for an interest crediting rate based on the rate of return on a RIC that is invested in a broader sector of the market than the semiconductor industry (such as the overall technology sector of the market), provided that the sector in which the RIC is invested is broad enough that the volatility requirements of paragraph (d)(5)(iv) of this section are satisfied. Alternatively, the plan may be amended to provide that the plan's interest crediting rate is a third segment rate described in paragraph (d)(3) of this section with a fixed minimum rate of 4 percent.

Example 11. (i) *Facts.* A plan was amended in 2014 to change its interest crediting rate for all interest crediting periods after the applicable amendment date of the amendment. The amendment changed the rate from the yield on 30-year Treasury Constant Maturities to the rate of return on aggregate plan assets under paragraph (d)(5)(ii)(A) of this section. The amendment also provided for section 411(d)(6) protection with respect to the account balance as of the applicable amendment date (by providing that the account balance after the applicable amendment date will never be smaller than the account balance as of the applicable amendment date credited with interest using the yield on 30-year Treasury Constant Maturities).

(ii) *Conclusions.* (A) *Participants benefiting under the plan.* With respect to those participants who were benefiting under the plan as of the applicable amendment date of the amendment described in paragraph (i) of this *Example 11,* the requirements of paragraph (e)(3)(iii) of this section (which provides a special market rate of return rule to permit certain changes in rates for participants benefiting under the plan) are satisfied. Accordingly, no amendment is required under this paragraph (e)(3)(vi) with respect to those participants.

(B) *Participants not benefiting under the plan.* With respect to those participants who were not benefiting under the plan as of the applicable amendment date of the amendment described in paragraph (i) of this *Example 11,* the requirements of paragraph (e)(3)(iii) of this section are not satisfied and, accordingly, the ''greater-of'' rate resulting from the section 411(d)(6) protection does not satisfy the requirements of paragraph (d)(6) of this section. As a result, pursuant to paragraph (e)(3)(vi)(B)(*5*) of this section, it must be determined on a participant-by-participant basis which account balance provides the benefit that is greater as of the applicable amendment date for the amendment made pursuant to this paragraph (e)(3)(iv) (the transitional amendment). If, as of the applicable amendment date for the transitional amendment, the account balance credited with interest after the change in rates using the yield on 30-year Treasury Constant Maturities is greater, then the plan must be amended to provide that the participant's benefit is based solely on that account balance credited with interest using the yield on 30-year Treasury Constant Maturities. On the other hand, if, as of the applicable amendment date for the transitional amendment, the account balance using the rate of return on aggregate plan assets is greater, then the plan must be amended to provide that the participant's benefit is based solely on that account balance credited with interest at the rate of return on aggregate plan assets.

(vii) *Plan termination amendments.* A plan amendment with an applicable amendment date on or before the first day of the first plan year described in paragraph (f)(2)(i)(B)(*1*) or (*3*) of this section (as applicable) is not treated as reducing accrued benefits in violation of section 411(d)(6) merely because the amendment changes the rules that apply upon plan termination in order to satisfy the requirements of paragraph (e)(2) of this section.

* * * * *

(f) * * *

(2) * * *

(i) * * *

(B) *Special effective date*—(*1*) *In general.* Except as otherwise provided in this paragraph (f)(2)(i)(B), paragraphs (d)(1)(iii), (d)(1)(iv)(D) and (E), (d)(1)(vi), (d)(2)(ii) and (v), (d)(5)(ii)(B), (d)(5)(iv), (d)(6), (e)(2), (e)(3)(iii), (iv) and (v), and (e)(4) of this section apply to plan years that begin on or after January 1, 2017 (or an earlier date as elected by the taxpayer).

(*2*) *Transitional amendments.* Paragraphs (e)(3)(vi) and (vii) of this section apply to plan amendments made on or after September 18, 2014 (or an earlier date as elected by the taxpayer).

(*3*) *Collectively bargained plans.* In the case of a plan maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers ratified on or before November 13, 2015, that constitutes a collectively bargained plan under the rules of § 1.436–1(a)(5)(ii)(B), the paragraphs referenced in paragraph (f)(2)(i)(B)(*1*) of this section apply to plan years that begin on or after the later of—

(*i*) January 1, 2017; and

(*ii*) The earlier of January 1, 2019; and the date on which the last of those collective bargaining agreements terminates (determined without regard to any extension thereof on or after November 13, 2015).

* * * * *

John Dalrymple,

Deputy Commissioner for Services and Enforcement.

Approved: November 3, 2015.

Mark J. Mazur,

Assistant Secretary of the Treasury (Tax Policy).

[FR Doc. 2015–28915 Filed 11–13–15; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG–2015–0994]

RIN 1625–AA00

Safety Zone; Unknown Substance in the Vicinity of Kelley's Island Shoal, Lake Erie; Kelley's Island, OH

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone in the waters of the Lake Erie in the vicinity of Kelley's Island Shoal, OH. This zone is intended to restrict vessels from a portion of Lake Erie due to the presence of an unknown substance emanating from an unknown vessel. This temporary safety zone is necessary to protect people and vessels from the hazards associated with this event.

DATES: This rule is effective without actual notice from November 16, 2015 until 8 p.m. November 24, 2015. For the purposes of enforcement, actual notice will be used from 2 p.m. October 25, 2015, until November 16, 2015.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG–2015–0994 and are available online by going to *www.regulations.gov,* type the docket number in the ''SEARCH'' box and click ''SEARCH.'' Click on Open Docket Folder on the line associated with this rulemaking. They are also available for inspection or copying at the 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, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary final rule, contact or email LT Jennifer Disco, U.S. Coast Guard Marine Safety Unit Toledo, telephone (419) 418–6000, email *Jennifer.M.Disco@USCG.MIL.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

COTP Captain of the Port
DHS Department of Homeland Security
E.O. Executive Order
NAD 83 North American Datum of 1983

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency, for good cause, finds that those procedures are ''impracticable, unnecessary, or contrary to the public interest.'' Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because doing so would be impracticable. The Coast Guard received notification of the unknown substance emanating from an unknown vessel on the evening of October 23, 2015. Thus, waiting for a notice and comment period to run would inhibit the Coast Guard from protecting the public and vessels from the possible hazards associated with this unknown substance.

Under 5 U.S.C. 553(d)(3), The Coast Guard finds that good cause exists for making this temporary rule effective less than 30 days after publication in the **Federal Register**. For the same reasons discussed in the preceding paragraph, waiting for a 30 day notice period to run would be impracticable and contrary to the public interest.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1231, 33 CFR 1.05–1 and 160.5; and Department of Homeland Security Delegation No. 0170.1. The Captain of the Port Detroit (COTP) has determined that a temporary safety zone is necessary to ensure the safety of vessels from the unknown hazards associated with this substance. Such hazards include the possibility of an inhalation hazard that may cause death or serious bodily harm.

Establishing a safety zone to control vessel movements around the location of the unknown substance will help ensure the safety of persons and property during assessment and response activities and help minimize the associated risks. Therefore, this rule will remain in place for the time stated herein but will be canceled if response activities cease before 24 November 2015.

IV. Discussion of Rule

This rule establishes a safety zone from 2 p.m. on October 25, 2015 until 8 p.m. on November 24, 2015. The safety zone will encompass all U.S. navigable waters of Lake Erie within a 1000 foot radius of 41°38′21″ N., 82°29′35″ W. (NAD 83).

Entry into, transiting, or anchoring within the safety zone is prohibited unless authorized by the COTP or a designated representative. Vessel operators must contact the COTP or his on-scene representative to obtain permission to transit through this safety zone. The COTP or his on-scene representative may be contacted via VHF Channel 16.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on these statutes and executive orders.

A. Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of E.O. 12866, Regulatory Planning and Review, as supplemented by E.O. 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of E.O. 12866 or under section 1 of E.O. 13563. The Office of Management and Budget has not reviewed it under those Orders.

We conclude that this rule is not a significant regulatory action because we anticipate that it will have minimal impact on the economy, will not interfere with other agencies, will not adversely alter the budget of any grant or loan recipients, and will not raise any novel legal or policy issues. The safety zone created by this rule will be relatively small and enforced for a relatively short duration, and it is designed to minimize the impact on navigation. Moreover, under certain conditions, vessels may still transit through the safety zone when permitted by the COTP.

B. Impact on Small Entities

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

This rule will affect the following entities, some of which might be small entities: The owners or operators of vessels intending to transit or anchor in designated portions of Lake Erie from 2 p.m. on October 25, 2015 until 8 p.m. on November 24, 2015.

This safety zone will not have a significant economic impact on a substantial number of small entities for the reasons cited in the *Regulatory Planning and Review* section. Additionally, before the enforcement of the zone, Coast Guard Sector Detroit will issue a local Broadcast Notice to Mariners so vessel owners and operators can plan accordingly.

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

C. Collection of Information

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

D. Federalism and Tribal Implications

A rule has implications for federalism under E.O. 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and determined that this rule does not have implications for federalism.

Also, this rule does not have tribal implications under E.O. 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct

effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

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

F. Environment

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

G. Protest Activities

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

H. Taking of Private Property

This rule will not cause a taking of private property or otherwise have taking implications under E.O. 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

I. Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of E.O. 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

J. Protection of Children

We have analyzed this rule under E.O. 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

K. Energy Effects

This action is not a ''significant energy action'' under E.O. 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.

List of Subjects in 33 CFR Part 165

Harbors, Marine Safety, Navigation (water), Reporting and record keeping requirements, Security measures, Waterways.

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

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

■ 2. Add § 165.T09–0994 to read as follows:

§ 165.T09–0994 Safety Zone; Unknown Substance in the Vicinity of Kelley's Island Shoal, Lake Erie; Kelley's Island, OH.

(a) *Location.* The following area is a temporary safety zone: Unknown substance from an unknown vessel in the vicinity of Kelley's Island Shoal, Lake Erie; Kelley's Island, OH. The safety zone will encompass all U.S. navigable waters of Lake Erie within a 1000 foot radius of 41°38′21″ N, 82°29′35″ W. All coordinates are North American Datum 1983 (NAD 83).

(b) *Enforcement period.* The safety zone described in paragraph (a) of this section will be enforced from 2 p.m. on October 25, 2015 until 8 p.m. on November 24, 2015.

(c) *Regulations.* (1) In accordance with the general regulations in § 165.23, entry into, transiting, or anchoring within these safety zone is prohibited unless authorized by the Captain of the Port, Sector Detroit (COTP) or his designated on-scene representative.

(2) The safety zone is closed to all vessel traffic, except as may be permitted by the COTP, via the Command Center, or his designated on-scene representative.

(3) The ''on-scene representative'' of the COTP is any Coast Guard commissioned, warrant or petty officer or a Federal, State, or local law enforcement officer designated by or assisting the COTP to act on his behalf.

(4) Vessel operators must contact the COTP via the Command Center to obtain permission to enter or operate within the safety zone. The COTP may be contacted via VHF Channel 16 or at 313–568–9560. Vessel operators given permission to enter or operate in the safety zone must comply with all directions given to them by the COTP, via the Sector Command Center or his on-scene representative.

Dated: October 25, 2015.

Scott B. Lemasters,

Captain, U.S. Coast Guard, Captain of the Port Detroit.

[FR Doc. 2015–29171 Filed 11–13–15; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2014–0256; FRL–9936–77–Region 9]

Approval and Promulgation of Implementation Plans; Arizona; Phased Discontinuation of Stage II Vapor Recovery Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking final action to approve a state implementation plan (SIP) revision from the Arizona Department of Environmental Quality related to the removal of ''Stage II'' vapor recovery equipment at gasoline dispensing facilities in the Phoenix-Mesa area. Specifically, the EPA is approving a SIP revision that eliminates the requirement to install and operate such equipment at new gasoline dispensing facilities, and that provides for the phased removal of such equipment at existing gasoline dispensing facilities from October 2016 through September 2018. The EPA has

previously determined that onboard refueling vapor recovery is in widespread use nationally and waived the stage II vapor recovery requirement. The EPA is approving this SIP revision because the resultant short-term incremental increase in emissions would not interfere with attainment or maintenance of the national ambient air quality standards or any other requirement of the Clean Air Act and because it would avoid longer-term increases in emissions due to the incompatibilities between onboard refueling vapor recovery equipment on motor vehicles and the predominant type of stage II vapor recovery equipment installed at existing gasoline dispensing facilities in the Phoenix-Mesa area.

DATES: This final rule is effective on December 16, 2015.

ADDRESSES: The EPA has established docket number EPA–R09–OAR–2014–0256 for this action. The index to the docket is available electronically at *www.regulations.gov* and in hard copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (*e.g.,* copyrighted material), and some may not be publicly available in either location (*e.g.,* Confidential Business Information). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed in the **FOR FURTHER INFORMATION CONTACT** section.

FOR FURTHER INFORMATION CONTACT: Jeffrey Buss, Office of Air Planning, U.S. Environmental Protection Agency, Region 9, (415) 947–4152, email: *buss.jeffrey@epa.gov.*

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

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I. Background for Final Rule

On September 2, 2015 (80 FR 53086), we proposed this action and provided for a 30-day comment period. On that same date, we issued a direct final rule (80 FR 53001) taking final action effective November 2, 2015 but indicated that, if we received adverse comments by the end of the comment period, we would publish a withdrawal of the direct final rule in the **Federal Register** prior to the effective date informing the public that the direct final rule will not take effect.

We received timely adverse comments, and on October 27, 2015 (80 FR 65660), we withdrew the direct final rule. In today's action, we provide our responses to the public comments and take final action based on the proposal published on September 2, 2015.

II. Summary of Proposed Action

In our September 2, 2015 proposed rule (80 FR 53086), we directed commenters to the direct final rule for a detailed rationale for the proposed approval of the SIP revision. As such, the following paragraphs summarize the background information and evaluation included in the direct final rule also published on September 2, 2015 (80 FR 53001).

Under the Clean Air Act (CAA or ''Act''), the EPA has promulgated national ambient air quality standards (NAAQS or ''standards'') for certain pervasive air pollutants. The NAAQS are concentration levels the attainment and maintenance of which EPA has determined to be requisite to protect public health (*i.e.,* the ''primary'' NAAQS) and welfare (*i.e.,* the ''secondary'' NAAQS). Under the CAA, states are required to develop and submit plans, referred to as state implementation plans (SIPs) to implement, maintain, and enforce the NAAQS.[1]

Ozone is one of the air pollutants for which the EPA has established NAAQS.[2] The original NAAQS for ozone was 0.12 parts per million (ppm), 1-hour average (''1-hour ozone standard'').[3] In 1997, we revised the ozone NAAQS, setting it at 0.08 ppm averaged over an 8-hour timeframe (referred to herein as the ''1997 8-hour ozone standard'') (62 FR 33856, July 18, 1997), and in 2008, we lowered the 8-hour ozone standard to 0.075 ppm (''2008 8-hour ozone standard'') (73 FR 16436, March 27, 2008). The 1-hour ozone standard and the 1997 8-hour ozone standard have now been revoked. See 69 FR 23951 (April 30, 2004) and 80 FR 12264 (March 6, 2015). Since publication of the direct final rule, the EPA has lowered the ozone standard further, to a level of 0.070 ppm, eight-hour average (''2015 8-hour ozone standard''). 80 FR 65292 (October 26, 2015).

Under the CAA, the EPA is also responsible for designating areas of the country as attainment, nonattainment, or unclassifiable for the various NAAQS. We classified the ''Phoenix metropolitan area,'' defined by the Maricopa Association of Governments' (MAGs') urban planning area boundary (but later revised to exclude the Gila River Indian Community, as a ''Moderate,'' and later ''Serious,'' nonattainment area for the 1-hour ozone standard. We have designated a larger geographic area, referred to as the ''Phoenix-Mesa'' area,[4] as a ''Marginal'' nonattainment area for the 1997 8-hour ozone standard and 2008 8-hour ozone standard. While we have redesignated the Phoenix metropolitan area, and the Phoenix-Mesa area as ''attainment,'' for the 1-hour and 1997 8-hour ozone standards, respectively, the Phoenix-Mesa area remains ''Marginal'' nonattainment for the 2008 ozone standard. More recently, we proposed to reclassify the Phoenix-Mesa area as ''Moderate'' ozone nonattainment for the 2008 8-hour ozone standard based on ambient data showing that the area did not attain the standard by the applicable attainment date (*i.e.,* July 20, 2015) for such areas. 80 FR 51992 (August 27, 2015). The EPA has not yet issued area designations for the 2015 8-hour ozone standard.

States with ''nonattainment'' areas are required to submit revisions to their SIPs that include a control strategy necessary to demonstrate how the area will attain the NAAQS. As ''Moderate,'' and later ''Serious,'' nonattainment for the 1-hour ozone standard, the State of Arizona was required under CAA section 182(b)(3) to submit a SIP revision that requires the use of ''Stage II'' vapor recovery systems at gasoline dispensing facilities (GDFs) located within the Phoenix metropolitan area.[5]

[1] Under Arizona law, the Arizona Department of Environmental Quality (ADEQ) is responsible for adopting and submitting the Arizona SIP and SIP revisions. Within the Maricopa County portion of the Phoenix-Mesa area, the Maricopa Association of Governments (MAG) is responsible for developing regional ozone air quality plans.

[2] Ground-level ozone is an oxidant that is formed from photochemical reactions in the atmosphere between volatile organic compounds (VOC) and oxides of nitrogen (NO_X) in the presence of sunlight. These two pollutants, referred to as ozone precursors, are emitted by many types of pollution sources including on-road motor vehicles (cars, trucks, and buses), nonroad vehicles and engines, power plants and industrial facilities, and smaller area sources such as lawn and garden equipment and paints.

[3] See 44 FR 8202 (February 8, 1979).

[4] The Phoenix-Mesa 1997 8-hour ozone nonattainment area covers a much larger portion of Maricopa County than the Phoenix metropolitan 1-hour ozone area and also includes the Apache Junction portion of Pinal County. The precise boundaries of the Phoenix-Mesa 1997 8-hour ozone nonattainment area and the Phoenix metropolitan 1-hour ozone nonattainment are found in 40 CFR 81.303.

[5] Gasoline dispensing pump vapor control devices, commonly referred to as ''Stage II'' vapor recovery, are systems that control VOC vapor

In response to this requirement, the State of Arizona promulgated and submitted certain statutes and regulations that require use of Stage II vapor recovery systems in the Phoenix metropolitan area, and later extended the requirements to a larger geographic area referred to as ''Area A.'' [6] The EPA approved the state's Stage-II-related statutes and regulations as a revision to the Arizona SIP. See 59 FR 54521 (November 1, 1994) and 77 FR 35279 (June 13, 2012).

The 1990 amended CAA anticipates that, over time, Stage II vapor recovery requirements at GDFs would be replaced by ''onboard refueling vapor recovery'' (ORVR) systems that the EPA was to establish for new motor vehicles under CAA section 202(a)(6). ORVR consists of an activated carbon canister installed in a motor vehicle. The carbon canister captures gasoline vapors during refueling. There the vapors are captured by the activated carbon in the canister. When the engine is started, the vapors are drawn off of the activated carbon and into the engine where they are burned as fuel. In 1994, the EPA promulgated its ORVR standards,[7] with a minimum 95% vapor capture efficiency, which fully applied to all new light duty vehicles by 2000. The ORVR requirements were phased in to apply to heavier classes of vehicles as well—reaching full effect for all new vehicles with a gross vehicle weight rating of up to 10,000 pounds by 2006.

Recognizing that, over time, the number of vehicles with ORVR as a percentage of the overall motor vehicle fleet would increase with the turnover of older models not equipped with ORVR with newer models equipped with ORVR, CAA section 202(a)(6) permits the EPA to promulgate a determination that ORVR is in ''widespread use'' throughout the motor vehicle fleet and to revise or waive Stage II vapor recovery requirements for Serious, Severe and Extreme ozone nonattainment areas. The EPA made the determination that ORVR systems are in ''widespread use'' in the nation's motor vehicle fleet in 2012. 77 FR 28772, May 16, 2012; and 40 CFR 51.126. In the wake of the EPA's ''widespread use'' determination, states, such as Arizona, that were required to implement Stage II vapor recovery programs under CAA section 182(b)(3) are now permitted to remove the requirement from their SIPs under certain circumstances.

On August 7, 2012, the EPA released its ''Guidance on Removing Stage II Gasoline Vapor Control Programs from State Implementation Plans and Assessing Comparable Measures'' [8] (''Stage II Guidance'') to aid in the development of SIP revisions to remove Stage II controls from GDFs. The EPA's Stage II Guidance projects that, by 2015, over 84% of all the gasoline dispensed in the nation will be dispensed to ORVR-equipped motor vehicles.[9] As such, Stage II and ORVR have become largely redundant technologies, and Stage II control systems are achieving an ever-declining emissions benefit as more ORVR-equipped vehicle continue to enter the on-road motor vehicle fleet. In addition, the EPA's Stage II Guidance recognizes that, in areas where certain types of vacuum-assist Stage II control systems are used, the limited compatibility between ORVR and some configurations of this Stage II hardware may ultimately result in an area-wide emissions disbenefit. The disbenefit can result when the Stage II controls pull air into the underground tank instead of gasoline vapors when both vacuum-assist Stage II controls and ORVR are active during refueling. This increases the pressure in the underground tank and can cause venting of excess emissions into the air. The Phoenix-Mesa ozone nonattainment area is an area where the vast majority of Stage II systems that have been installed use vacuum assist technologies.[10]

In light of EPA's national ''widespread use'' determination allowing states to revise their SIPs to remove Stage II vapor recovery requirements and the potential for a disbenefit from continuation of the Stage II vapor recovery program, MAG developed emissions estimates based on information from the EPA's Stage II guidance and based on Phoenix-area-specific motor vehicle fleet data to determine the impact of continuation of the program and the impact of the phased removal of Stage II vapor recovery in the Phoenix-Mesa area. The emissions estimates demonstrated that the emissions reduction benefit from the Stage II vapor recovery program would continue to provide marginal but diminishing emissions reductions through 2017 and that the disbenefit from continuation of the Stage II vapor recovery program would begin in 2018 and increase in the years thereafter. See table 1 on page 53005 of the direct final rule.

In response to these findings, the Arizona Legislature adopted changes in the specific statutory provisions establishing the Stage II vapor recovery program to eliminate the requirement to install Stage II equipment at new GDFs and to provide for a phased decommissioning process to remove Stage II equipment at existing GDFs beginning in October 2016 and ending in September 2018.[11]

Subsequent to legislative action, on September 2, 2014, ADEQ submitted a SIP revision, titled ''MAG State Implementation Plan Revision for the Removal of Stage II Vapor Recovery Controls in the Maricopa Eight-Hour Ozone Nonattainment Area'' (''Stage II Vapor Recovery SIP Revision'' or ''SIP Revision''), including the statutory revisions and related emissions impact documentation.

After review of the SIP Revision, on September 2, 2015 (80 FR 53086), the EPA proposed approval based on the following conclusions:

- ADEQ has met the procedural requirements for SIP revisions under section 110(l);
- Pursuant to the EPA's determination of ''widespread use'' (of ORVR systems in the motor vehicle fleet), states are allowed to rescind Stage II vapor recovery control requirements in their SIPs if doing so is consistent with the general SIP revision requirements of CAA section 110(l) and section 193;
- CAA section 193 does not apply to this particular SIP revision because the Stage II vapor recovery controls were not in effect prior to the 1990 CAA Amendments;
- MAG's year-by-year estimates of areawide VOC emissions with and

releases during the refueling of motor vehicles. This process takes the vapors normally emitted directly into the atmosphere when pumping gas and recycles them back into the underground fuel storage tank, preventing them from polluting the air.

[6] ''Area A'' is defined in Arizona Revised Statutes (ARS) section 49–541, and it includes all of the Phoenix metropolitan 1-hour ozone nonattainment area plus additional areas in Maricopa County to the north, east, and west, as well as small portions of Yavapai County and Pinal County. Area A roughly approximates the boundaries of the Phoenix-Mesa area designated by the EPA for the 1997 8-hour ozone standard.

[7] See 59 FR 16262 (April 6, 1994).

[8] ''Guidance on Removing Stage II Gasoline Vapor Control Programs from State Implementation Plans and Assessing Comparable Measures,'' EPA Office of Air Quality Planning and Standards, August 7, 2012.

[9] See Table A–1 of the Stage II Guidance.

[10] Table A–6 of the EPA's Stage II Guidance cites the percentages of State/Area GDF using vacuum assist Stage II technology. The listed percentage for the Phoenix-Mesa area is 85%.

[11] Effective for State law purposes upon the Governor's signature (*i.e.,* on April 22, 2014), House Bill (HB) 2128 (in relevant part) amends Arizona Revised Statutes (ARS) sections 41–2131 (''Definitions''), 41–2132 (''Stage I vapor recovery systems''), 41–2133 (''Compliance schedules''), and adds new section 41–2135 (''Stage II vapor recovery systems''). The new section ARS 41–2135 retains the existing Stage II control requirements for existing GDFs and establishes a phased decommissioning process to remove Stage II controls beginning October 1, 2016 and ending September 30, 2018.

without the SIP Revision reflect reasonable methods and assumptions, and provide a reasonable basis upon which to evaluate the ozone impacts of the SIP Revision;

• MAG's emissions estimates conclude that the temporary emissions increases due to the SIP Revision (relative to the scenario in which Stage II requirements remain fully implemented) will occur during years 2014 through 2017 and will range from 0.015 metric tons per day (mtpd) to 0.031 mtpd, and that beginning in 2018 and increasing in magnitude thereafter, the SIP Revision will result in fewer VOC emissions than would otherwise have occurred if Stage II requirements were to remain fully implemented in the Phoenix-Mesa area (due to the incompatibility of ORVR-equipped vehicles and vacuum-assist Stage II technologies);

• The temporary increases in VOC emissions during years 2014 through 2017 due to the SIP Revision would represent an approximate 0.002 percent to 0.005 percent increase in the overall VOC emissions inventory in the Phoenix-Mesa area; [12] and

• The SIP Revision would not interfere with reasonable further progress or attainment of the ozone NAAQS for the purposes of CAA section 110(l) because: (1) The increases in VOC emissions from 2014 through 2017 would have negligible impacts on ozone concentrations in the area; (2) the schedule for the phase-out of Stage II controls under the SIP Revision will maintain most of the emissions reductions benefits associated with Stage II control through 2017; (3) the scheduled phase-out will reduce the emissions increase (due to ORVR and Stage II incompatibilities) that would otherwise be expected in 2018 but would not entirely avoid an emissions increase in that year because some existing GDFs will not yet have removed Stage II controls by the beginning of the 2018 ozone season; and (4) the phase-out of Stage II controls by the end of the 2018 ozone season will support longer-term regional efforts to attain or maintain the ozone standards in the Phoenix-Mesa area.

For further information about the SIP Revision and our corresponding evaluation, please see the direct final rule (80 FR 53001, September 2, 2015).

[12] The EPA-approved MAG Eight-Hour Ozone Maintenance Plan anticipates VOC emissions between 653.9 mtpd (June ozone episode, 2005) and 659.0 mtpd (June ozone episode, 2015) during the relevant period. See our proposed approval of the maintenance plan and redesignation request at 79 FR 16734, at 16744 (March 26, 2014).

III. Public Comments and EPA Responses

In response to September 2, 2015 proposed rule, we received four comments. In the following paragraphs, we provide our responses to these comments.

Comment #1: While supportive of our proposed action, a commenter suggests that the EPA eliminate the Arizona vehicle inspection and maintenance (VEI) program as well.

Response #1: The State of Arizona's VEI program is an approved element of the Arizona SIP. A state may submit revisions to its SIP, but such revisions do not become effective until the EPA approves them under section 110(k) of the CAA. No VEI SIP revision submittal is pending at this time. If the State of Arizona were to submit a revision to the SIP-approved VEI program, or rescission of the program, the EPA is authorized to approve such a revision only if such revision were consistent with all CAA requirements such as section 110(l), which prohibits the EPA from approving a SIP revision if the revision would interfere with any applicable requirement concerning reasonable further progress towards, and attainment of, the NAAQS.

Comment #2: A commenter was not opposed to the removal of Stage II vapor recovery equipment at GDFs so long as the fuel pump dispensing nozzle is properly covered to capture vapors during refueling.

Response #2: We disagree that such covers are necessary to capture vapors during refueling with ORVR-equipped motor vehicles. While Stage II vapor recovery systems rely upon a rubber boot around the nozzle to create a seal between the nozzle and the vehicle, ORVR prevents vapors from escaping during refueling by employing a seal in the fill pipe. In most instances, these seals are created by the incoming gasoline backing slightly near the bottom of the fill pipe. When the engine is started, the vapors are purged from the activated carbon canister and into the engine where they are burned as fuel. See 77 FR 28772 at 28774 (May 16, 2012). Because ORVR uses a seal within the fill pipe of the vehicle, a rubber boot or cover is not required to prevent vapors from escaping during refueling.

Comment #3: A commenter objects to our proposal, and asks the EPA to reconsider its proposed approval of the SIP revision, contending that the revision will cause adverse effects particularly in the summer months. This commenter also questions whether there would be any benefit from the revision and asks the EPA to identify to whom the revision applies.

Response #3: We recognize that the Stage II vapor recovery controls have provided significant reductions of VOC emissions in the Phoenix-Mesa area since they were implemented in the mid-1990s. These controls have done so by taking the vapors normally emitted directly into the atmosphere when pumping gas and recycling them back into the underground fuel storage tank, preventing them from polluting the air. However, as discussed in more detail in the direct final rule at 80 FR 53002 and 52003 (September 2, 2015), the 1990 amended CAA anticipated that, over time, Stage II vapor recovery requirements at gasoline stations would be replaced by ORVR systems installed on motor vehicles, and authorized the EPA to revise or waive Stage II vapor recovery requirements for ozone nonattainment areas, including such areas as the Phoenix-Mesa area, once the EPA determines that ORVR is in ''widespread use'' throughout the motor vehicle fleet. The EPA published its ''widespread use'' determination in 2012 at 77 FR 28772 (May 16, 2012), and as a result, the Stage II vapor recovery controls are no longer required in ozone nonattainment areas.

Moreover, as described further in our direct final rule at 53004, with certain types of vacuum-assist Stage II control systems, the limited compatibility between ORVR and some configurations of this Stage II hardware may ultimately result in an area-wide emissions disbenefit. This is because the Stage II controls pull air into the underground tank instead of gasoline vapors when both vacuum-assist Stage II control and ORVR are active during refueling, increasing the pressure in the underground tank and causing venting of excess emission into the air. The Phoenix-Mesa ozone nonattainament area is an area where the vast majority of Stage II systems that have been installed use vacuum assist technologies, and MAG has estimated that 2018 is the first year in which the disbenefit from implementation of Stage II controls would occur if Stage II control requirements were to remain in place given the motor vehicle fleet in the Phoenix-Mesa area. The disbenefit (*i.e.,* the increase in emissions if Stage II control were to be retained) grows quickly after that year as shown in table 1 of our direct final rule at 53005.

Thus, from the perspective of summertime ozone conditions in the Phoenix-Mesa area, the issue is not whether to remove the Stage II vapor recovery equipment but when and how. The state has submitted a SIP revision

that eliminates the requirement for installation of Stage II vapor recovery equipment at new GDFs, and that establishes a phased decommissioning process to remove Stage II controls at existing GDFs over a two-year period beginning October 1, 2016 and ending September 30, 2018. As explained on page 53003 of the direct final rule, the two-year period for decommissioning is based on the expectation of the Arizona Department of Weights and Measures of the time necessary to safely decommission Stage II controls at the over 1,000 existing GDFs in the Phoenix-Mesa area. Decommissioning is expected to be spread evenly over each of the 24 months from October 2016 through September 2018 and to occur for existing GDFs during the month when the annual scheduled Stage II control test would have occurred.

We believe that the two-year decommissioning process established by the state minimizes the temporary adverse effect of increased VOC emissions (*i.e.,* from foregone emissions reductions from elimination of the Stage II requirement at new GDFs and the phase-out of Stage II equipment at existing GDFs) while avoiding the longer-term adverse impact due to the disbenefit associated with retaining the Stage II vapor recovery controls. As noted on page 53005 of the direct final rule, the temporary adverse effect during years 2014 through 2017 would represent an approximate 0.002 percent to 0.005 percent increase in the overall VOC emission inventory in the Phoenix-Mesa area. Based on the small magnitude of this impact, its temporary nature, and the avoidance of the long-term disbenefit, we have concluded that the SIP revision would not interfere with attainment or maintenance of the ozone NAAQS in the Phoenix-Mesa area.

Comment #4: A commenter objects to our proposal, stating that it does not take into account those individuals who are chemically sensitive to vapors and would be harmed if the SIP revision were to be approved. This commenter also noted that there are communities where most of the drivers operate older vehicles and that those living in such areas would be at higher risk than those in areas where the vehicle models are newer, and suggested that the EPA defer the approval of the Stage II vapor recovery phase-out for a couple of years to allow for a greater percentage of ORVR-equipped vehicles to replace the older vehicles without ORVR.

Response #4: The commenter is correct that, in reviewing the Stage II SIP Revision, the EPA did not take into account the particular sensitivities of individuals to gasoline vapors or the percentage of ORVR-equipped vehicles refueling at individual GDFs in the Phoenix-Mesa area. Our role in a reviewing SIP revision is to approve state choices, provided that they meet the criteria of the CAA. None of the applicable CAA criteria calls for evaluating the sensitivities of individuals to gasoline vapors nor do the criteria require a GDF-specific ORVR evaluation.

Rather, as described on pages 53004 and 53004 of the direct final rule, we evaluated the SIP revision for compliance with CAA section 110(l), which prohibits the EPA from approving a SIP revision if that revision would interfere with any applicable requirement concerning reasonable further progress towards, or attainment of, any of the NAAQS, or any applicable requirement of the CAA. In this instance, because the Stage II SIP revision would affect VOC emissions, and because VOC is a precursor to ozone, we focused on ozone NAAQS impacts. Ozone is a regional pollutant and thus our evaluation of the SIP revision is appropriately based on area-wide VOC emissions estimates and considers those emissions in the context of regional, not local, ozone concentrations.

Lastly, deferral by the EPA of action on the Stage II SIP revision is not appropriate because CAA section 110(k)(2) establishes a deadline of at most 18 months from the date a SIP revision is submitted for the EPA to take final action. Moreover, we have concluded that the two-year decommissioning process established by the state would minimize the temporary adverse impact on regional VOC emissions while avoiding the longer term disbenefit associated with implementation of Stage II vapor recovery controls at GDFs in the Phoenix-Mesa area. Deferral by the state of the two-year decommissioning process would be less advantageous from a regional ozone perspective because it would only serve to lengthen the period in which the area would experience the disbenefit from Stage II vapor recovery due to the increasing percentage of motor vehicles with ORVR and accompanying incompatibilities with the Stage II vapor recovery equipment.

IV. Final Action

Under CAA section 110(k) and for the reasons set forth in our September 2, 2015 direct final rule and summarized above, the EPA is taking final action to approve the Stage II Vapor Recovery SIP Revision submitted by ADEQ on September 2, 2014 to provide for the phased removal of ''Stage II'' vapor recovery equipment at GDFs in the Phoenix-Mesa area. Specifically, the EPA is approving a SIP revision that eliminates the requirement to install and operate such equipment at new GDFs, and that provides for the phased removal of such equipment at existing GDFs from October 2016 through September 2018.

The EPA is approving this SIP revision because Stage II vapor recovery controls are no longer a SIP requirement under CAA section 182(b)(3) due to EPA's ''widespread use determination'' for ORVR. Additionally, we are approving this SIP revision because the temporary incremental increase in VOC emissions from 2014 through 2017 would not interfere with reasonable further progress toward, or attainment of, any of the NAAQS, and because this SIP revision avoids the longer-term VOC emissions increases associated with continued implementation of Stage II controls in the Phoenix-Mesa area. As part of this final action, the EPA is approving the specific statutory provisions that provide for the phase-out of Stage II controls in Area A, *i.e.,* sections 5 through 8, and 10 through 12 of House Bill 2128, amending ARS sections 41–2131, 41–2132, 41–2133 and adding section 41–2135.[13]

V. Incorporation by Reference

In this rule, the EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is finalizing the incorporation by reference of certain sections of House Bill 2128 amending various sections of the Arizona Revised Statutes related to stage II vapor recovery systems in Area A, effective April 22, 2014, as described in the amendments to 40 CFR part 52 set forth below. The EPA has made, and will continue to make, these documents generally available electronically through *www.regulations.gov* and/or in hard copy at the appropriate EPA office (see the **ADDRESSES** section of this preamble for more information).

[13] Approval of these statutory provisions as revisions to the Arizona SIP supersedes the following existing SIP provisions in the Arizona SIP: ARS section 41–2131, as approved at 77 FR 35279 (June 13, 2012); ARS section 41–2132, as approved at 77 FR 35279 (June 13, 2012); and ARS section 41–2133, as approved at 77 FR 35279 (June 13, 2012). As noted previously, ''Area A'' is roughly the same geographic area as the Phoenix-Mesa 8-hour ozone nonattainment area.

VI. Statutory and Executive Order Reviews

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

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 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, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

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

Under section 307(b)(1) of the Clean Air Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 15, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements (see section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Dated: October 28, 2015.

Jared Blumenfeld,

Regional Administrator, Region IX.

Chapter I, title 40 of the Code of Federal Regulations is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

Subpart D—Arizona

■ 2. Section 52.120 is amended by adding paragraph (c)(171) to read as follows:

§ 52.120 Identification of plan.

* * * * *

(c) * * *

(171) The following plan was submitted on September 2, 2014 by the Governor's designee.

(i) Incorporation by reference.

(A) Arizona Department of Environmental Quality.

(*1*) House Bill 2128, effective April 22, 2014, excluding sections 1 through 4, and 9 (including the text that appears in all capital letters and excluding the text that appears in strikethrough).

(ii) Additional materials.

(A) Arizona Department of Environmental Quality.

(*1*) *MAG 2014 State Implementation Plan Revision for the Removal of Stage II Vapor Recovery Controls in the Maricopa Eight-Hour Ozone Nonattainment Area* (August 2014), adopted by the Regional Council of the Maricopa Association of Governments on August 27, 2014, excluding appendix A, exhibit 2 (''Arizona Revised Statutes Listed in Table 1–1'').

* * * * *

[FR Doc. 2015–28909 Filed 11–13–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[EPA–R05–OAR–2015–0701; FRL–9936–96–Region 5]

Air Plan Approval; Michigan; Sewage Sludge Incinerators State Plan and Small Municipal Waste Combustors Negative Declaration for Designated Facilities and Pollutants

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving Michigan's State Plan to control air pollutants from ''Sewage Sludge Incinerators'' (SSI). The Michigan Department of Environmental Quality (MDEQ) submitted the State Plan on September 21, 2015. The State Plan is consistent with the Emission Guidelines (EGs) promulgated by EPA on March 21, 2011. This approval means that EPA finds that the State Plan meets applicable Clean Air Act (Act) requirements for subject SSI units. Once effective, this approval also makes the State Plan Federally enforceable. EPA is also notifying the public that we have received from Michigan a negative declaration for Small Municipal Waste Combustors (SMWC). The MDEQ submitted its negative declaration on

July 27, 2015. MDEQ notified EPA in its negative declaration letter that there are no SMWC units subject to the requirements of the Act currently operating in Michigan.

DATES: This direct final rule will be effective January 15, 2016, unless EPA receives adverse comments by December 16, 2015. If adverse comments are received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect, and will respond to all comments in a final action based upon the associated proposal.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2015–0701, by one of the following methods:

1. *www.regulations.gov:* Follow the on-line instructions for submitting comments.
2. *Email: nwia.jacqueline@epa.gov.*
3. *Fax:* (312) 692–2566.
4. *Mail:* Jacqueline Nwia, Acting Chief, Toxics and Global Atmosphere Section, Air Toxics and Assessment Branch (AT–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.
5. *Hand Delivery:* Jacqueline Nwia, Acting Chief, Toxics and Global Atmosphere Section, Air Toxics and Assessment Branch (AT–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m. excluding Federal holidays.

Instructions: Direct your comments to Docket ID No. EPA–R05–OAR–2015–0701. 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 not contain special characters or any form of encryption, and should be free of any defects or viruses.

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI or other information whose disclosure is restricted by statute. Certain other 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 hard copy at the Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. We recommend that you telephone Margaret Sieffert, Environmental Engineer, at (312) 353–1151 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT: Margaret Sieffert, Environmental Engineer, Environmental Protection Agency, Region 5, 77 West Jackson Boulevard (AT–18J), Chicago, Illinois 60604, (312) 353–1151, *sieffert.margaret@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we mean EPA. This **SUPPLEMENTARY INFORMATION** section is arranged as follows:

I. Background
II. What does the State Plan contain?
III. Does the state plan meet the EPA requirements?
IV. What action is EPA taking?
V. Statutory and Executive Order Reviews

I. Background

Section 111(d) of the Act requires that EPA develop regulations providing that states must submit to EPA plans establishing standards of performance for certain existing sources of pollutants when a standard of performance would apply to the existing source if it were a new source, and if the pollutants are noncriteria pollutants (*i.e.,* pollutants for which there is no national ambient air quality standard) and are not on a list published under section 108 of the Act or emitted from a source category regulated under section 112 of the Act. Section 129 of the Act and 40 CFR part 60, subpart B apply the section 111(d) requirements to existing solid waste combustors, including SSIs and SMWCs, and provide that EPA should include, as part of the performance standards, emissions guidelines (EGs) that include the plan elements required by section 129.

EPA promulgated new source performance standards and EGs for SMWCs on December 6, 2000, (64 FR 76349, 65 FR 76377). The standards and EGs are codified at 40 CFR part 60, subparts AAAA and BBBB, respectively. Thus, states were required to develop plans for existing SMWCs, pursuant to sections 111(d) and 129 of the Act and 40 CFR part 60, subpart B.

EPA promulgated new source performance standards and EGs for SSIs on March 21, 2011, (76 FR 15372). The standards and EGs are codified at 40 CFR part 60, subparts LLLL and MMMM, respectively. Thus, states were required to develop plans for existing SSIs, pursuant to sections 111(d) and 129 of the Act and 40 CFR part 60, subpart B.

A SMWC unit is defined in 40 CFR 60.1550, as any device that has the capacity to combust at least 35 tons per day of municipal solid waste but no more than 250 tons per day of municipal solid waste or refuse derived fuel. The designated facilities to which the EGs apply are existing SMWC units that commenced construction on or before August 30, 1999.

A SSI unit is defined in 40 CFR 60.5250 as any device that combusts sewage sludge for the purpose of reducing the volume of the sewage sludge by removing combustible matter. The designated facilities to which the EGs apply are existing SSI units that commenced construction on or before October 14, 2010. 40 CFR 60.5060.

Under section 129(b)(2) of the Act and the EGs at 40 CFR part 60, subpart MMMM, States with SSIs must submit to EPA plans that implement the EGs. The plans, which must be at least as protective as the EGs, become Federally enforceable when EPA approves them. 42 U.S.C. 7411(d)(2). If the state fails to submit a satisfactory plan, the Administrator must promulgate a Federal plan for implementation and enforcement. *Id.*

40 CFR part 60, subpart B contains general provisions applicable to the adoption and submittal of state plans for

subject facilities under sections 111(d) and 129 (111(d)/129 plan). 40 CFR part 62, subpart A provides the procedural framework for the submission of the plans. However, 40 CFR 60.23(b) and 62.06 provide that, if there are no existing sources of the designated pollutant in a state, the state may submit a letter of certification to that effect (*i.e.,* a negative declaration) in lieu of a plan. The negative declaration exempts the state from the provisions of 40 CFR part 60, subpart B that require the submittal of a 111(d)/129 plan.

On September 21, 2015, MDEQ submitted its SSI State Plan. The State's final rule became effective on May 20, 2015. The public hearing for the State Plan was on August 19, 2015. The plan includes State rule R 336.1972, ''Emission standards for existing sewage sludge incineration units,'' and R 336.1902 ''Adoption of standards by reference,'' which contain emission standards for existing SSI.

On July 27, 2015, MDEQ submitted its SMWC negative declaration, in which it certifies that there are no SMWC units currently operating in Michigan.

II. What does the state plan contain?

The State SSI plan submittal is based on the Federal SSI EGs. As set forth in section 129 of the Act and in 40 CFR part 60, subparts B and MMMM, the State Plan addresses the nine minimum required elements, as follows:

1. An inventory of affected SSI units, including those that have ceased operation but have not been dismantled. Michigan has provided this along with the shutdown notices for four facilities and the operating permits for the remaining three affected facilities in Michigan.

2. An inventory of the emissions from affected SSI units. Michigan has provided this.

3. Compliance schedules for each affected SSI unit. Michigan has provided a compliance schedule with a compliance date of March 21, 2016.

4. Emission limits, emission standards, operator training and qualification requirements and operating limits for affected SSI units that are at least as protective as the EGs. Michigan has provided this.

5. Performance testing, recordkeeping and reporting and requirements. Michigan has provided this.

6. Certification that the hearing on the state plan was held, a list of witnesses and their organizational affiliations, if any, appearing at the hearing, and a brief written summary of each presentation or written submission. Michigan has provided the required certification and other information, including a summary of the one comment it received.

7. A provision for State progress reports to EPA. Michigan has stated that it will submit an annual report that will include updates to the inventory, removing sources that have shut down, adding any new sources, and identifying any sources that have met increments of progress. The annual report will also include any enforcement activities initiated against designated facilities and submission of technical reports on all performance testing on designated facilities, including updated emissions inventories.

8. Identification of enforceable state mechanisms that the State selected for implementing the EGs. Michigan has provided a detailed list which identified the enforceable mechanisms.

9. A demonstration of the State's legal authority to carry out the SSI State Plan. Michigan has provided a detailed list which demonstrated that it has such legal authority. This includes the legal authority to incorporate by reference federal emission guidelines provisions, as confirmed by a Michigan Attorney General's Opinion letter dated May 27, 2015.

III. Does the State Plan meet the EPA requirements?

EPA evaluated the SSI State Plan and related information submitted by Michigan for consistency with the Act, EPA regulations and policy. For the reasons discussed above, EPA has determined that the State Plan meets all applicable requirements and, therefore, is approvable.

IV. What action is EPA taking?

EPA is approving the State Plan which Michigan submitted on September 21, 2015, for the control of emissions from existing SSI sources in the State. EPA is also providing the public with notice of, and amending 40 CFR part 62 to reflect, EPA's receipt of Michigan's negative declaration for SMWC facilities.

The EPA Administrator continues to retain authority for several tasks, as provided in 40 CFR 60.5050 and as stated in the cover letter of the State Plan.

EPA is publishing this approval action without prior proposal because the Agency views this as a non-controversial action and anticipates no adverse comments. However, in the proposed rules section of this **Federal Register** publication, EPA is publishing a separate document that will serve as the proposal to approve the State Plan in the event adverse written comments are filed. This rule will be effective January 15, 2016 without further notice unless we receive relevant adverse written comments by December 16, 2015. If we receive such comments, we will withdraw this action before the effective date by publishing a subsequent document that will withdraw the final action. We will then address all public comments received in a subsequent final rule based on the proposed action. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule, and if that provision can be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. If we do not receive any comments, this action will be effective January 15, 2016.

V. Statutory and Executive Order Reviews

A. General Requirements

This action is not a ''significant regulatory action'' under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993) and therefore is not subject to review by the Office of Management and Budget under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011). For this reason, this action is also not subject to Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001). This action merely approves state law as meeting Federal requirements and merely notifies the public of EPA receipt of a negative declaration from an air pollution control agency without any existing SMWC units in its state. This action imposes no requirements beyond those imposed by the state. Accordingly, the Administrator certifies that this rule will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*). Because this rule approves pre-existing requirements under state law and does not impose any additional enforceable duty beyond that required by state law, it 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). This rule 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). This action also does not have Federalism implications because it does not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government, as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). This action merely approves a state rule implementing a Federal requirement, and does not alter the relationship or the distribution of power and responsibilities established in the Act. This rule also is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because it approves a state rule implementing a Federal standard.

In reviewing section 111(d)/129 plan submissions, EPA's role is to approve State choices, provided that they meet the criteria of the Act. With regard to negative declarations for designated facilities received by EPA from states, EPA's role is to notify the public of the receipt of such negative declarations and revise 40 CFR part 62 accordingly. In this context, in the absence of a prior existing requirement for the State to use voluntary consensus standards (VCS), EPA has no authority to disapprove a section 111(d)/129 plan submission or negative declaration for failure to use VCS. It would thus be inconsistent with applicable law for EPA, when it reviews a section 111(d)/129 plan or negative declaration submission, to use VCS in place of a section 111(d)/129 plan or negative declaration submission that otherwise satisfies the provisions of the Act. Thus, the requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) do not apply. This rule does not impose an information collection burden under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

B. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. 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**. This rule is not a ''major rule'' as defined by 5 U.S.C. 804(2).

C. Petitions for Judicial Review

Under Section 307(b)(1) of the Act, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by January 15, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action approving Michigan's section 111(d)/129 plan for SSI sources or negative declaration for SMWC units may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2)).

List of Subjects in 40 CFR Part 62

Environmental protection, Administrative practice and procedure, Air pollution control, Intergovernmental relations, Reporting and recordkeeping requirements, Sewage sludge incinerators, Small municipal waste combustors.

Dated: October 29, 2015.

Susan Hedman,

Regional Administrator, Region 5.

40 CFR part 62 is amended as follows:

PART 62—APPROVAL AND PROMULGATION OF STATE PLANS FOR DESIGNATED FACILITIES AND POLLUTANTS

■ 1. The authority citation for part 62 continues to read as follows:

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

Subpart X—Michigan

■ 2. Add two undesignated center headings and §§ 62.5620, 62.5621, 62.5622, and 62.5630 to subpart X to read as follows:

Control of Air Emissions From Sewage Sludge Incinerators

§ 62.5620 Identification of plan.

On September 21, 2015, Michigan submitted a State Plan for implementing the emission guidelines for Sewage Sludge Incinerators (SSI). The enforceable mechanism for this State Plan is a State rule codified in R 336.1972, ''Emission standards for existing sewage sludge incineration units,'' and R 336.1902 ''Adoption of standards by reference.'' The State's final rule became effective on May 20, 2015.

§ 62.5621 Identification of sources.

The Michigan State Plan for existing Sewage Sludge Incinerators (SSI) applies to all SSIs for which construction commenced on or before October 14, 2010 or for which a modification was commenced on or before September 21, 2011 primarily to comply with this rule.

§ 62.5622 Effective date.

The Federal effective date of the Michigan State Plan for existing Sewage Sludge Incinerators is January 15, 2016.

Control of Air Emissions From Small Municipal Waste Combustors

§ 62.5630 Identification of plan—negative declaration.

On July 27,2015, the Michigan Department of Environmental Quality submitted a negative declaration letter to EPA certifying that there are no existing Small Municipal Waste Combustors (SMWC) units in the State of Michigan subject to the emissions guidelines at 40 CFR part 60, subpart BBBB.

[FR Doc. 2015–28911 Filed 11–13–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2015–0421; FRL–9936–25]

Tamarind Seed Gum, 2-Hydroxypropyl Ether Polymer; Tolerance Exemption

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of tamarind seed gum, 2-hydroxypropyl ether polymer (CAS Reg. No. 68551–04–2) when used as an inert ingredient in a pesticide chemical formulation. Lamberti USA, Incorporated submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of tamarind seed gum, 2-hydroxypropyl ether polymer on food or feed commodities.

DATES: This regulation is effective November 16, 2015. Objections and requests for hearings must be received on or before January 15, 2016, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2015–0421, is available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. Can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2015–0421 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before January 15, 2016. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2015–0421, by one of the following methods.

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Background and Statutory Findings

In the **Federal Register** of August 26, 2015 (80 FR 51759) (FRL–9931–74), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the receipt of a pesticide petition (PP IN–10807) filed by Lamberti USA, Incorporated, 161 Washington Street Eight Tower Bridge, Suite 1000 Conshohocken, PA 19428. The petition requested that 40 CFR 180.960 be amended by establishing an exemption from the requirement of a tolerance for residues of tamarind seed gum, 2-hydroxypropyl ether polymers (CAS Reg. No. 68551–04–2). That document included a summary of the petition prepared by the petitioner and solicited comments on the petitioner's request. The Agency did not receive any comments.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is ''safe.'' Section 408(c)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and use in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing an exemption from the requirement of a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue . . .'' and specifies factors EPA is to consider in establishing an exemption.

III. Risk Assessment and Statutory Findings

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be shown that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this

action and considered its validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. In the case of certain chemical substances that are defined as polymers, the Agency has established a set of criteria to identify categories of polymers expected to present minimal or no risk. The definition of a polymer is given in 40 CFR 723.250(b) and the exclusion criteria for identifying these low-risk polymers are described in 40 CFR 723.250(d). Tamarind seed gum, 2-hydroxypropyl ether polymers conforms to the definition of a polymer given in 40 CFR 723.250(b) and meets the following criteria that are used to identify low-risk polymers.

1. The polymer is not a cationic polymer nor is it reasonably anticipated to become a cationic polymer in a natural aquatic environment.

2. The polymer does contain as an integral part of its composition the atomic elements carbon, hydrogen, and oxygen.

3. The polymer does not contain as an integral part of its composition, except as impurities, any element other than those listed in 40 CFR 723.250(d)(2)(ii).

4. The polymer is neither designed nor can it be reasonably anticipated to substantially degrade, decompose, or depolymerize.

5. The polymer is manufactured or imported from monomers and/or reactants that are already included on the TSCA Chemical Substance Inventory or manufactured under an applicable TSCA section 5 exemption.

6. The polymer is not a water absorbing polymer with a number average molecular weight (MW) greater than or equal to 10,000 daltons.

7. The polymer does not contain certain perfluoroalkyl moieties consisting of a CF3- or longer chain length as specified in 40 CFR 723.250(d)(6).

Additionally, the polymer also meets as required the following exemption criteria specified in 40 CFR 723.250(e).

8. The polymer's minimum number average MW is greater than or equal to 10,000 daltons. The polymer contains less than 2% oligomeric material below MW 500 and less than 5% oligomeric material below MW 1,000.

Thus, tamarind seed gum, 2-hydroxypropyl ether polymer meets the criteria for a polymer to be considered low risk under 40 CFR 723.250. Based on its conformance to the criteria in this unit, no mammalian toxicity is anticipated from dietary, inhalation, or dermal exposure to tamarind seed gum, 2-hydroxypropyl ether polymer.

IV. Aggregate Exposures

For the purposes of assessing potential exposure under this exemption, EPA considered that tamarind seed gum, 2-hydroxypropyl ether polymer could be present in all raw and processed agricultural commodities and drinking water, and that non-occupational non-dietary exposure was possible. The number average MW of tamarind seed gum, 2-hydroxypropyl ether polymer is 10,000 daltons. Generally, a polymer of this size would be poorly absorbed through the intact gastrointestinal tract or through intact human skin. Since tamarind seed gum, 2-hydroxypropyl ether polymer conform to the criteria that identify a low-risk polymer, there are no concerns for risks associated with any potential exposure scenarios that are reasonably foreseeable. The Agency has determined that a tolerance is not necessary to protect the public health.

V. Cumulative Effects From Substances With a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

EPA has not found tamarind seed gum, 2-hydroxypropyl ether polymer to share a common mechanism of toxicity with any other substances, and tamarind seed gum, 2-hydroxypropyl ether polymer does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that tamarind seed gum, 2-hydroxypropyl ether polymer does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's Web site at *http://www.epa.gov/pesticides/cumulative.*

VI. Additional Safety Factor for the Protection of Infants and Children

Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base unless EPA concludes that a different margin of safety will be safe for infants and children. Due to the expected low toxicity of tamarind seed gum, 2-hydroxypropyl ether polymer, EPA has not used a safety factor analysis to assess the risk. For the same reasons the additional tenfold safety factor is unnecessary.

VII. Determination of Safety

Based on the conformance to the criteria used to identify a low-risk polymer, EPA concludes that there is a reasonable certainty of no harm to the U.S. population, including infants and children, from aggregate exposure to residues of tamarind seed gum, 2-hydroxypropyl ether polymer.

VIII. Other Considerations

A. Existing Exemptions From a Tolerance

There are no existing tolerance exemptions for tamarind seed gum, 2-hydroxypropyl ether polymer.

B. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

C. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for tamarind seed gum, 2-hydroxypropyl ether polymer.

IX. Conclusion

Accordingly, EPA finds that exempting residues of tamarind seed gum, 2-hydroxypropyl ether polymer from the requirement of a tolerance will be safe.

X. Statutory and Executive Order Reviews

This action establishes a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

XI. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), 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**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: November 5, 2015.

G. Jeffrey Herndon,

Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.960, add alphabetically the polymer in the table to read as follows:

§ 180.960 Polymers; exemptions from the requirement of a tolerance.

* * * * *

Polymer	CAS No.
* * * * *	
Tamarind seed gum, 2-hydroxypropyl ether polymer, minimum number average molecular weight (in amu), 10,000	68551–04–2
* * * * *	

[FR Doc. 2015–29169 Filed 11–13–15; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R5–ES–2014–0021; FXES11130900000; 4500030113]

RIN 1018–AY83

Endangered and Threatened Wildlife and Plants; Removal of the Delmarva Peninsula Fox Squirrel From the List of Endangered and Threatened Wildlife

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: The best available scientific and commercial data indicate that the Delmarva Peninsula fox squirrel (*Sciurus niger cinereus*) has recovered. Therefore, under the authority of the Endangered Species Act of 1973, as amended (Act), we, the U.S. Fish and Wildlife Service (Service), remove the Delmarva Peninsula fox squirrel (commonly called the Delmarva fox squirrel) from the Federal List of Endangered and Threatened Wildlife (List). This determination is based on a thorough review of all available information, which indicates that the subspecies is now sufficiently abundant and well distributed to withstand foreseeable threats and no longer meets the definition of an endangered or threatened species under the Act.

This rule removes the Delmarva fox squirrel from the List throughout its range, including the experimental population designated for Assawoman Wildlife Management Area in Delaware. It also announces the availability of a post-delisting monitoring plan for the subspecies.

DATES: This rule is effective December 16, 2015.

ADDRESSES: This final rule and the post-delisting monitoring plan are available on the Internet at *http://www.regulations.gov* under Docket No. FWS–R5–ES–2014–0021. Comments and materials received, as well as supporting documentation used in rule preparation, will be available for public inspection, by appointment, during normal business hours at: U.S. Fish and Wildlife Service, Chesapeake Bay Field Office, 177 Admiral Cochrane Drive, Annapolis, MD 21401; and on the Chesapeake Bay Field Office Web site at: *http://www.fws.gov/chesapeakebay/.*

FOR FURTHER INFORMATION CONTACT: Field Office Supervisor, Genevieve LaRouche, by telephone at 410–573–4573; or Cherry Keller, Wildlife Biologist, at 410–573–4532, or by email

at *cherry_keller@fws.gov.* Written questions or requests for additional information may also be directed to: Delmarva fox squirrel QUESTIONS, at the street address listed under **ADDRESSES.** Individuals who are hearing-impaired or speech-impaired may call the Federal Relay Service at 1–800–877–8337 for TTY assistance.

SUPPLEMENTARY INFORMATION:

Background

Previous Federal Action

On September 23, 2014, the Service published a proposed rule (79 FR 56686) to remove the Delmarva Peninsula fox squirrel, commonly called and hereafter referred to as the Delmarva fox squirrel (DFS), from the List of Endangered and Threatened Wildlife (List). In the proposed rule, we solicited information and comments from the public and scientific experts for 60 days, ending November 24, 2014. Later in this document, we discuss comments we received. For more information on previous Federal actions concerning the Delmarva fox squirrel, refer to the proposed rule available at *http://www.regulations.gov* under Docket No. FWS–R5–ES–2014–0021.

Species Information

The Delmarva fox squirrel (*Sciurus niger cinereus*), a subspecies of the eastern fox squirrel (*Sciurus niger*) found only on the Delmarva Peninsula, is located between the Chesapeake Bay and the Atlantic Ocean in portions of Maryland, Delaware, and Virginia. The DFS is a large, silver-gray tree squirrel with white underparts and a wide tail. It inhabits mature forests of mixed hardwoods and pines within the agricultural landscapes of the Delmarva Peninsula and is not typically found in suburban settings. The DFS is also associated with forests that have a relatively open understory (Dueser et al. 1988, entire; Dueser 2000, entire) or where understory shrubs are clumped, leaving other open spaces (Morris 2006, p. 37). While these squirrels need mature forest for both feeding and denning, they can travel and forage in other areas, including clearcuts, young forests, and agricultural fields.

As a member of the Order Rodentia, the DFS has a life history with good potential for population increase. For example, females breed at 1 year of age, litter sizes range from two to four young, some females have potential for two litters in 1 year, and lifespans can reach 6 to 7 years in the wild. Den sites are frequently found in tree cavities, but leaf nests may also be used. Home ranges of the DFS vary considerably but are typically 12 to 16 hectares (ha) (30 to 40 acres (ac)), and individual home ranges overlap (Flyger and Smith 1980; entire, Paglione 1996; entire, Pednault-Willett 2002, p. 109). Densities range from 0.36 to 1.29 DFS per ha (0.15 to 0.5 DFS per ac), averaging 0.82 DFS per ha (0.33 DFS per ac) (Paglione 1996, p. 28; Pednault-Willett 2002, pp. 85–104).

Historically, this subspecies had a patchy distribution throughout most of the Delmarva Peninsula and into southern Pennsylvania, but by the time of its listing in 1967 (32 FR 4001; March 11, 1967), remnant populations occurred in only four Maryland counties (Taylor 1976, entire); this range contraction was most likely caused by land use changes and hunting. When the subspecies was listed, its distribution had been reduced to only 10 percent of the Delmarva Peninsula. After listing, the hunting season for this subspecies was closed, and recovery efforts focused on expanding the squirrel's distribution through translocations. In addition, new populations have been discovered since the time of listing (particularly since more intensive search efforts were initiated), and there are now many more areas of forest known to be occupied by the DFS.

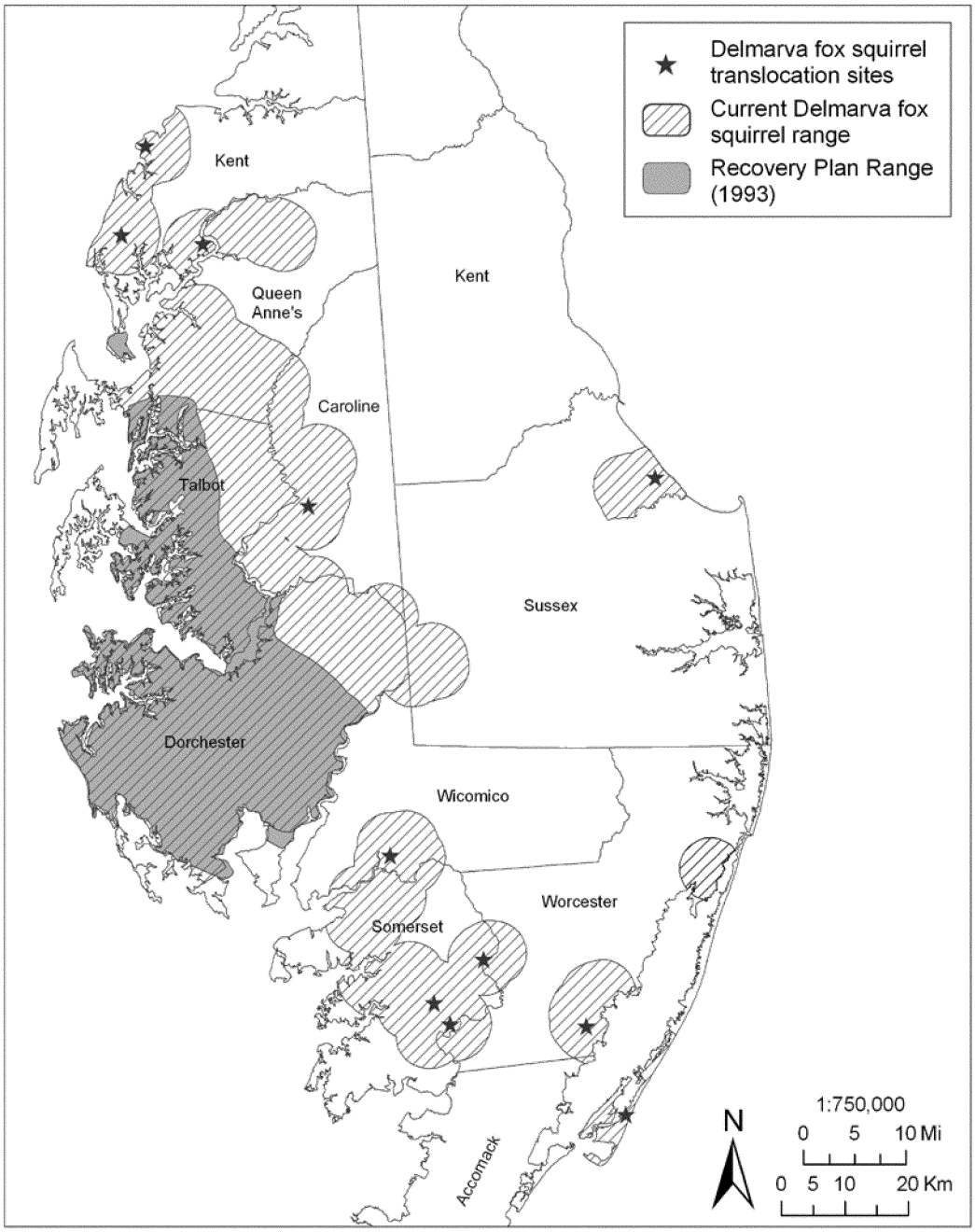
The squirrel's current occupied range is defined as the area within 4.8 kilometers (km) (3 miles (mi)) of credible DFS sightings. As of the 2012 status review for the DFS, this covered 28 percent of the Delmarva Peninsula, including 10 of the 14 peninsular counties (8 counties in Maryland and 1 each in Delaware and Virginia) and 54,543 ha (134,778 ac) of occupied forest (USFWS 2012, based on 2010 data). Since that time, new sightings have continued to occur and an updated overview of its range as of 2013 is provided below in Table 1. An additional population discovered in Worcester County, Maryland, is the first population found there that was not a result of a translocation. Figure 1 shows range changes between the time of the 1993 recovery plan and the present decade.

TABLE 1—KNOWN OCCUPIED RANGE OF THE DFS, 1970 TO 2013

Occupied range	Year				
	~ 1970	1990	2005	2010	2013
Number of counties in the range (without translocations).	3	3	6	6	7.
Number of counties in the range (with translocations).	4	10	10	10	10.
Total acres of occupied forest rangewide	N/A	103,311	128,434	134,778	137,363.
Percent of historical range occupied	10		27	28	28.
Source	*Taylor and Flyger 1974.*	*USFWS 1993, recovery plan.*	*USFWS 2007, 5-yr review.*	*USFWS 2012, 5-yr review.*	*USFWS 2013 data.*

BILLING CODE 4333–15–P

Figure 1. Changes in the range of DFS, 1993 to the present, including successful translocation sites.



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Summary of Changes From the Proposed Rule

We have not made any substantive changes in this final rule based on the comments that we received during the public comment period on the September 23, 2014, proposed rule (79 FR 56686), but we have added or corrected text to clarify the information that was presented. This information and other clarifications have been incorporated into this final rule as discussed below in Summary of Comments and Recommendations.

Summary of Comments and Recommendations

In the proposed rule published on September 23, 2014 (79 FR 56686), we requested that all interested parties submit written comments on the proposal by November 24, 2014. We also solicited peer review of the scientific basis for the proposal (see *Peer Review Comments,* below), and contacted appropriate Federal and State agencies, scientific experts and organizations, and other interested parties and invited them to comment on the proposal. Newspaper notices inviting general public comment were published in the Baltimore Sun, placed on Service Web sites, and advertised by other online media outlets (*e.g., http://www.wboc.com/story/26574688/*

maryland-state-officials-set-to-discuss-delmarva-peninsula-fox-squirrel). We did not receive any requests for a public hearing.

During the public comment period for the proposed rule, we received a total of 129 comment letters. Of these, 74 provided substantive comments that we address below, including one letter from the State of Maryland and comments from two peer reviewers. Both peer reviewers asked for additional detail on the life history of this subspecies, which we have provided in the supplemental documents that can be found at *http://www.regulations.gov* under Docket No. FWS–R5–ES–2014–0021. All substantive information provided during the review period either has been incorporated directly into this final determination or into the supplemental documents, or is addressed below.

Comments From States

(1) Comment: The State of Maryland's Department of Natural Resources (DNR) was supportive of the proposed rule and concurred with our findings. The DNR added that it would continue to provide protection to the DFS under the authority of Maryland's Nongame and Endangered Species Conservation Act, although likely not at the endangered level. The DNR also stated that the post-delisting monitoring plan proposed by the Service was adequate to document expansion or contraction of the range of the DFS and that the agency would participate in the monitoring effort.

Our Response: We are in agreement with the DNR and appreciate its commitment to continued conservation.

Public Comments

(2) Comment: Several commenters expressed concern that the DFS would be hunted after delisting, and that populations would then decline and might require relisting.

Our Response: As explained in the proposed rule and supplementary documents (see Post-delisting Monitoring Plan, appendices D through F), after delisting, the State of Maryland intends to keep the DFS on the State list of endangered and threatened species as a Species of Conservation Concern; this status does not allow a hunting season. This intention is reinforced by the State of Maryland's comment letter reiterating that the subspecies will remain State-listed as described above.

The State of Delaware also intends to keep this subspecies on its State list of endangered and threatened species, and no hunting of the DFS will be allowed after delisting. The State has written a management plan for the DFS (DNREC 2014) that calls for adding two additional DFS populations in the State, likely through translocations.

In the State of Virginia, all DFSs are currently on the Chincoteague National Wildlife Refuge, where they will not be hunted. The State has evaluated locations for potential translocations of DFSs in the future, but any future translocated populations are not expected to be subject to hunting. Enhancement of DFS populations in Virginia would be primarily aimed at restoring the native fauna of Virginia.

(3) Comment: Several commenters stated that the occupancy of 28 percent of the historical range was insufficient to warrant delisting.

Our Response: The Act is legislation intended to prevent extinction of native species and does not describe recovery in terms of the proportion of a historical range that is occupied by a species. We do take into account in our listing and delisting determinations the effects that loss of historical range may have on the current and future viability of a species. As explained in our significant portion of the range (SPR) final policy (79 FR 37578; July 1, 2014), we have concluded that this consideration is sufficient to account for the effects of loss of historical range when evaluating the current status of a species. The purposes of the Act, stated in section 2, are to provide a means to conserve the ecosystems upon which endangered species and threatened species depend and to provide a program for the conservation of endangered species and threatened species. The Act itself does not contain the phrase ''historical range,'' nor does it ever allude to restoration throughout the entire historical range as a conservation purpose.

Some concerns about the current range of the DFS likely stem from a frequently quoted reason for listing, ''the species was listed because it declined to 10 percent of its historical range'' (USFWS 1993, p. 1). However, the substantial population decline as evidenced by that range decline is the actual reason for the listing. In 1944, the DFS was found in seven counties (Dozier and Hall 1944), but by 1967, it was known to occur in only four counties; thus, the decline would have been apparent and reasonably concerning to many biologists at the time of listing.

(4) Comment: Several commenters stated that the total number of animals in the rangewide population did not appear to be large enough to warrant delisting and expressed a concern that the population would decline again after delisting.

Our Response: As described in the proposed rule, the best estimate of the rangewide number of the DFS at the time of the 2012 status review was 22,368 (USFWS 2012, p. 20), which we can approximate as 20,000. However, the critical question with regard to the listing status of the subspecies is not a specified number of individuals; rather, it is the level of extinction risk, indicating whether the subspecies meets the definition of endangered or threatened. To address this question, we conducted a population viability analysis (PVA) for the DFS (Hilderbrand et al. 2007, entire), which enabled us to evaluate how the foreseeable threats may affect the probability of extinction of DFS subpopulations (USFWS 2012, pp. 18–21, 23–44).

The Hilderbrand et al. (2007) PVA model indicates that a population of 130 animals would have a 95 percent chance of persisting for 100 years. This threshold, also called a minimum viable population (MVP), provides a useful benchmark of extinction risk. It should not be mistaken for a recovery goal but is, rather, a population size with an associated extinction risk based on the life history of the DFS before assessing additional threats. This PVA includes variations in adult and juvenile survival, the number of young produced per year, and variability in environmental effects.

Using this model, we estimate that the known occupied forest within the range of the DFS contains a total population that is 171 times the MVP and that, even under the worst-case scenarios for threats, including inundation of areas up to 0.6 meters (m) (2 feet (ft)) above sea level due to sea level rise, we would still have a total population that is 145 times the MVP. Further, our analysis indicates that the rangewide population would comprise at least 15 subpopulations broadly distributed across the Delmarva Peninsula. After considering the conservation imperatives of habitat availability, habitat connectivity, population resiliency and redundancy, and genetic and/or ecological representation, we concluded that the risk of extinction is low, even under a worst-case scenario, and that the current population is sufficiently abundant and well distributed to withstand foreseeable threats.

(5) Comment: Several commenters stated that sea level rise was a great concern, and that threats from climate change and sea level rise have not been eliminated.

Our Response: We agree that climate change and sea level rise trends are continuing; nonetheless, the pertinent

question is whether these factors are likely to threaten the DFS with extinction or with endangerment in the foreseeable future. We analyzed the impact of sea level rise and associated habitat loss on the DFS using a worst-case scenario of 0.6 m (2 ft) of inundation within 40 years. As stated in our response to Comment 4, we evaluated this factor along with a number of other factors with the potential to affect the long-term viability of DFS subpopulations (noting that various conditions can occur on the landscape and threaten some species and not others depending on the abundance, distribution, and life history of the species). After considering habitat availability and connectivity, as well as population resiliency, redundancy, and representation, we conclude that the risk of extinction is low even under the worst-case sea level rise scenario (see Summary of Factors Affecting the Species, *Factor A*), given projected population levels and distribution, and the ability of the DFS to colonize unoccupied habitat as described in the September 23, 2014, proposed rule (79 FR 56686) and 2012 status review (USFWS 2012).

(6) Comment: One commenter expressed two concerns regarding DFS movements in response to sea-level rise: First, during sea level rise, individual animals would not be able to move inland because DFSs prefer moving on the ground and would be unable to move across habitat that became flooded. Second, with the occurrence of sea-level rise and the associated loss of habitat, populations would not be able to shift inland over time.

Our Response: DFSs have always been abundant in southern Dorchester County, where forests are frequently flooded in the spring and are often exposed to high tidal surges. Further, DFSs have been observed moving across marshlands to other woodlands (L. Miranda 2010 and C. Keller pers. comm. 2009) and moving through flooded woodlands on logs and hummocks as well as through the trees (C. Bocetti pers. comm. 2015). In these same areas, marked animals have been documented to move 4 km (2.5 mi) and return within a season, despite intervening streams and associated marshlands 100 m (328 ft) wide or greater (C. Bocetti pers. comm. 2015). Typical home ranges are about 16.2 ha (40 ac) in size and generally include forested wetlands, indicating that DFSs already inhabit forests that experience periodic flooding.

Sea level rise is likely to result in more frequent flooding and storm and tidal surges, with gradual deterioration of habitat at the shoreline edges. It is therefore likely that individual animals will need to shift their home range inland and that the overall population will shift inland as well. The ability of DFSs to shift their home ranges in response to habitat change has already been demonstrated as individual animals moved to new areas following clearcuts in portions of their home ranges (Paglione 1996); we note that clearcutting is a more rapid and dramatic habitat alteration than would be expected from flooding or storm surges.

In terms of available habitat for the DFS to move into following storm events and/or sea level rise, we evaluated the rangewide availability and connectivity of forest patches in the 2012 status review (USFWS 2012) by mapping the connectivity of forest patches relative to dispersal of DFS subpopulations (USFWS 2012, figures 9 and 10). After quantitative analysis of habitat that could be lost due to sea level rise and development (USFWS 2012, table 7), we concluded that even if all potentially affected habitat was lost immediately, remaining DFS populations would still be sufficiently abundant and well distributed to alleviate the risk of extinction.

With regard to the connectivity needed to allow DFSs to move to more upland habitats, we recognize that sea-level rise can widen rivers and increase obstacles to DFS movement, especially from west to east in southern Dorchester County. However, even with maximum projected inundation, DFSs could disperse from southern Dorchester without crossing streams. In addition, southern Dorchester County would still contain about 2,400 to 3,200 ha (6,000 to 8,000 ac) of suitable occupied habitat, supporting at least six times the MVP. Given this, we predict long-term population viability in these areas of Dorchester County.

(7) Comment: One commenter stated that the DFS should not be delisted because it has not met all of the recovery criteria contained in the most recent DFS recovery plan (USFWS 1993). In particular, the commenter contended that our analysis of recovery criterion 6 does not adequately support our conclusion that this criterion has been met.

Our Response: We will respond first to the issue of whether recovery criteria must be met in order to delist a species, and second to the issue of whether criterion 6 has been met.

Notwithstanding our conclusion that the recovery criteria for the DFS, as required under section 4(f) of the Act, have been met, this is not the requisite analysis for determining the appropriate listing status of the species. Rather, listing determinations must be made in accordance with sections 4(a)(1) and 4(b) of the Act. Section 4(a)(1) requires that the Secretary determine whether a species is endangered or threatened because of one or more of five threat factors, while section 4(b) requires that the determination be made ''solely on the basis of the best scientific and commercial data available.'' Thus, any determination to delist a species must be based on the best information available at the time of the determination and the results of the five-factor analysis, notwithstanding any information in the recovery plan.

Although meeting recovery criteria is not essential for determining a species' listing status, our most recent status review (USFWS 2012) led us to the conclusion that all recovery criteria for the DFS, including criterion 6, have been met. Criterion 6 states that ''mechanisms that ensure perpetuation of suitable habitat at a level sufficient to allow for desired distribution [must be] in place and implemented within all counties in which the species occurs.'' Our analysis showed that there are many State and Federal laws and land protection programs in place that actively protect land at the present time and will continue to do so into the future. A detailed table and map of the land protected by these programs in each county is provided for each county in the 2012 status review (USFWS 2012, table 5 and figure 7). These protective mechanisms are also presented in our analysis of Factor D (USFWS 2012, pp. 38–39), with a detailed description of each program provided in appendix D of the same document. These data clearly portray the adequacy of these regulatory mechanisms.

(8) Comment: One commenter stated we had not adequately addressed the future of the translocated population of the DFS at Chincoteague National Wildlife Refuge (NWR) due to the projections in sea level rise.

Our Response: We agree with the commenter that this coastal population of the DFS, inhabiting Assateague Island, a barrier island, is vulnerable to reduced habitat and isolation from sea level rise, and we discussed this situation in the September 23, 2014, proposed rule (79 FR 56686). We also discuss it below, under Factor A: *Loss of forest habitat from sea level rise,* where we note that although the island's beaches, marshes, and shorelines are vulnerable to sea level rise, most of the forest habitat occupied by the DFS is above the 0.6 m (2 ft) inundation worst-case scenario. Even so, Refuge managers

are aware of the risks of sea level rise and are actively exploring management responses to this factor. As stated in the proposed rule: ''Sea level rise is expected to cause severe losses to beach and tidal flat habitat but currently upland habitat would only be reduced by 4 to 8 percent (National Wildlife Federation 2008, p. 69). [Chincoteague's] Comprehensive Conservation Plan [CCP] commits to continued forest management to maintain suitable habitat for Delmarva fox squirrels and continued monitoring of Delmarva fox squirrel populations.'' The draft CCP is available at: *http://www.fws.gov/nwrs/threecolumn.aspx?id=2147550165.*

We consider it highly likely that a DFS population will persist on Chincoteague NWR for the foreseeable future, although there may be a shift in the habitats that are occupied. Nonetheless, even if the Chincoteague population were to be lost, this would not cause a rangewide risk of extinction (USFWS 2012, table 7).

(9) Comment: One commenter stated, ''In its 2007 and 2012 status reviews, the Service concluded that these recovery criteria were not based on the best available science and did not represent the most up-to-date information on the biology of the DFS. And the Service also concluded in these status reviews that the recovery criteria did not specifically address all of the five threat-based listing factors.''

Our Response: The commenter may be referring to sections 2.2.2.1 and 2.2.2.2 of the referenced status reviews (USFWS 2007, p. 3; USFWS 2012, p. 5):

''*2.2.2.1 Do the recovery criteria reflect the best available and most up-to-date information on the biology of the species and its habitat?* No. More recent information on the squirrel's distribution, subpopulation delineation, and population persistence is not reflected in the 1993 recovery criteria. Nonetheless, these criteria continue to act as generally appropriate measures of recovery.

2.2.2.2 Are all of the relevant listing factors addressed in the recovery criteria? No. None of the recovery criteria specifically addresses any of the five listing factors, although habitat-related threats are alluded to. The criteria evaluate the biological status of the species.''

These statements are intended to convey that although new information had become available since 1993, the recovery criteria were still considered adequate for assessing DFS recovery progress. With regard to criteria addressing the five listing factors, the lack of specific threats-based criteria is typical of recovery plans at that time and does not preclude a separate five-factor analysis (see Comment 7, above). Significantly, since the two status reviews analyze both the recovery criteria and the five listing factors, each review constitutes a complete assessment of the status of the species (USFWS 2007; USFWS 2012). Overall, the two status reviews and the September 23, 2014, proposed rule (79 FR 56686) are based on the best available information on the biology of the DFS and the threats to its long-term viability.

(10) Comment: One commenter noted that the population data in the 2012 status review were the same as those in the 2007 review and suggested that this showed there was no increase in the population or range between those two time periods. The commenter further suggested that there was a decrease in DFS-occupied forest between 2007 and 2012. The commenter stated that despite the information for the two status reviews being essentially the same, different conclusions were reached.

Our Response: It is not clear how the commenter's interpretation of the data in the two reviews was made. Both the September 23, 2014, proposed rule (79 FR 56686 Table 1) and the 2012 status review (Chart 2) clearly show an increase in the area of occupied forest from 51,975 ha (128,434 ac) in 2005, to 54,543 ha (134,778 ac) by 2010; a map illustrating the changes in the range between the two reviews is also provided (USFWS 2012, figure 3). Since 2010, we have continued to document new areas of occupied forest and provide an updated number of 55,589 ha (137,363 ac) as of 2013 (79 FR 56686, September 23, 2014, Table 1).

The rangewide population estimates in the 2007 and 2012 reviews differ only slightly (19,265 versus 22,368 animals, respectively), but as described in the 2012 review, the two estimates were based on different survey methods. Light detection and ranging (LiDAR) data, which allow us to distinguish between mature forests and other forested areas, were not available for the 2007 status review. We were able to use a more refined and conservative approach in the 2012 review and estimated the rangewide population using only occupied mature forest. Both estimates are intended to provide a general measure of the rangewide population size (USFWS 2007, p. 8; USFWS 2012 p. 20).

It should also be noted that in the 2007 review, we concluded that DFS recovery was imminent. We indicated that a final listing recommendation was pending while we obtained and analyzed LiDAR data, and that, if new information continued to support our finding that DFS habitat availability and connectivity were likely to persist over the foreseeable future, we would recommend initiation of delisting when the LiDAR analysis was completed (USFWS 2007, p. 27).

(11) Comment: One commenter was concerned because 9 of 22 subpopulations (40 percent) appear to be vulnerable to extirpation.

Our Response: This concern does not take into account the relative size of these subpopulations. As described in the 2012 status review (USFWS 2012, p. 42, figure 5 and table 7), there is a higher vulnerability to extirpation for 9 smaller subpopulations, but the vast majority (95 percent) of DFSs occurs in 11 large, secure subpopulations. This provides a solid indication of continued persistence and growth of the rangewide population. Most of the smaller populations originated as translocations, which have become well established and have contributed to the expanded distribution of the subspecies. Further, as shown by the 2007 population viability analysis (Hilderbrand et. al 2007), if one or more small populations blink out, the rangewide population is still not vulnerable to extinction; even accounting for all projected losses from sea level rise and development, the rangewide population will still be 145 times the MVP, indicating long-term viability.

Peer Review Comments

In accordance with our peer review policy published on July 1, 1994 (59 FR 34270), we solicited expert opinion from five independent scientists with expertise that included familiarity with the DFS and its habitat, biological needs, and threats. We received responses from two of the peer reviewers.

We reviewed comments received from the peer reviewers for substantive issues and new information regarding the status of the DFS. The peer reviewers generally concurred with our methods and conclusions and considered the scientific information to be correct and the analyses to be sound. However, both reviewers identified parts of the document that could be strengthened. Peer reviewer comments are addressed below and incorporated as appropriate into the final rule or supplemental documents, available at *http://www.regulations.gov* under Docket No. FWS–R5–ES–2014–0021.

(12) Peer Review Comment: Both reviewers asked for more detail to be provided on life history of the subspecies.

Our Response: We have added more life-history information in a supplemental document for the final rule, particularly life history related to reproduction, litter size, and survival. The supplemental document is available at *http://www.regulations.gov* under Docket No. FWS–R5–ES–2014–0021.

(13) Peer Review Comment: One reviewer asked for clarification on the length of time that agreements preventing development on private lands would continue.

Our Response: The private lands we consider protected from development have easements that extend in perpetuity, and this has been added to the text of this rule.

(14) Peer Review Comment: Both reviewers thought that the rate of future development might be underestimated and suggested possibly using zoning or projected road development as additional sources of information.

Our Response: We consider the analysis of future development conducted by the Maryland Department of Planning to be the best available source of information on development trends insofar as this office has both the responsibility for tracking such information and the requisite expertise to make trend projections. The September 23, 2014, proposed rule (79 FR 56686) and 2012 status review (USFWS 2012) used data from Maryland's 2008 planning report (Maryland Department of Planning 2008a), as this was the most current information at the time; the same trends and areas of expected development are also mapped in a more recent planning document (Maryland Department of Planning 2011a). The data continue to show that the eastern shore of Maryland is far more rural, with less development and more protected lands, than elsewhere in Maryland. Thus, the most recent information continues to support the past and future trends used in our previous analysis.

Consideration of zoning was not included in our analysis specifically because zoning restrictions can be changed, making projections based on this source of information less certain. Further, we took a cautious approach in considering future development by projecting complete loss of any DFS-occupied habitat within a ''Smart Growth'' area that was not otherwise protected. (''Smart Growth'' is a theory of land development that concentrates new development and redevelopment in areas that have existing or planned infrastructure to avoid sprawl.) Currently, DFSs inhabit blocks of forest within the Smart Growth areas of both Cambridge and Easton in Maryland. Although limited monitoring shows that DFSs have been persisting in these woodlands over many years and may be able to continue doing so in the future, our analysis assumes loss based on lack of ensured habitat protection.

(15) Peer Review Comment: One peer review comment referred to the possibility of residential development causing problems because of the presence of free-ranging dogs that may pursue the DFS.

Our Response: We agree that this can be a problem in some situations, and although all counties within the current range of the DFS have regulations that require dogs to be on a leash, at heel, or directly beside the owner, enforcing these regulations can be difficult. Further, as noted in the status review (USFWS 2012, p. 27), the presence of dogs may be one reason DFSs do not inhabit residential developments. Despite these concerns, we do not consider free-roaming dogs to be a threat that would result in population-level effects, either individually or in combination with other possible risks, to this subspecies, as effects are highly localized and regulations do exist to enable management of this issue.

(16) Peer Review Comment: Both peer reviewers raised a concern regarding the commitment to monitoring of the DFS after delisting and questioned whether there would be long-term funds, time, and available personnel to carry out the monitoring work described in the post-delisting monitoring plan.

Our Response: We agree that sustaining monitoring efforts can be challenging and subject to competing priorities. Nonetheless, we have designed the post-delisting monitoring strategy to fit into current work plans and are seeking additional ways in which this effort can be incorporated into other monitoring work conducted by the States. For example, the hunt clubs leasing the Maryland State Chesapeake Forest lands are now asked to report sightings or camera shots which have already provided DFS records, and we are working with the States on other opportunities to invite hunters to report DFS sightings. We also anticipate that DFS-occupied sites managed by conservation groups will be monitored as part of their management efforts; sightings of DFSs are often reported by those who live or work on these properties. Overall, recording these sightings will enhance our ability to conduct widespread monitoring of the DFS.

Recovery

Section 4(f) of the Act directs us to develop and implement recovery plans for the conservation and survival of endangered and threatened species unless we determine that such a plan will not promote the conservation of the species. Recovery plans are not regulatory documents and are instead intended to establish goals for long-term conservation of a listed species; define criteria that are designed to indicate when the threats facing a species have been removed or reduced to such an extent that the species may no longer need the protections of the Act; and provide guidance to our Federal, State, and other governmental and nongovernmental partners on methods to minimize threats to listed species. There are many paths to accomplishing recovery of a species, and recovery may be achieved without all criteria being fully met. For example, one or more criteria may have been exceeded while other criteria may not have been accomplished, yet the Service may judge that, overall, the threats have been minimized sufficiently, and that the species is robust enough to reclassify or delist the species. In other cases, recovery opportunities may have been recognized that were not known at the time the recovery plan was finalized. These opportunities may be used instead of methods identified in the recovery plan.

Likewise, information on the species that was not known at the time of the recovery plan may become available. The new information may change the extent that criteria need to be met for recognizing recovery of the species. Recovery of species is a dynamic process requiring adaptive management that may, or may not, fully follow the guidance provided in a recovery plan.

Despite the guidance provided by recovery plans, determinations to remove species from the List must be made in accordance with sections 4(a)(1) and 4(b) of the Act. Section 4(a)(1) requires that the Secretary determine if a species is endangered or threatened because of one or more of five threat factors. Section 4(b) of the Act requires that the determination be made ''solely on the basis of the best scientific and commercial data available.''

Although recovery criteria, as mentioned above, help guide recovery efforts and should always be consulted when considering a change in the status of a listed species, the ultimate determination of whether to reclassify or delist a species must be made in accordance with statutory standards, and recovery criteria can neither substitute for nor pre-empt section 4(a)(1) requirements. Ultimately, a decision to remove a species from the

List is made when the best available data show that the species is no longer an endangered species or a threatened species, regardless of how closely this information conforms to the information and criteria in the recovery plan.

The most recent DFS recovery plan was approved by the Service on June 8, 1993 (USFWS 1993, entire), and updated on October 31, 2003 (USFWS 2003, entire). The plan states that ''the long-range objective of the DFS recovery program is to restore this endangered species to a secure status within its former range.'' The plan provides three criteria for reclassifying the DFS from endangered to threatened status. It then provides four additional criteria to be considered in conjunction with the first three for delisting the DFS.

Recovery Criteria

A discussion of the extent to which each recovery criterion has been met is provided in the proposed rule (79 FR 56686; September 23, 2014). This discussion is summarized below.

Criterion 1: Ecological requirements and distribution within the remaining natural range are understood sufficiently to permit effective management. A considerable body of new information has been amassed regarding the DFS' distribution and ecological requirements, and we thus conclude that this recovery criterion has been met. The six key contributions to our understanding of the DFS are summarized below.

(1) DFS range and distribution: The geographic information system (GIS) maintained for the DFS documents a significant increase in the area occupied by the DFS since the 1993 recovery plan was issued (see Figure 1, above). Records of DFS sightings by knowledgeable observers and, in particular, the use of trap and camera surveys have greatly improved our ability to determine which forest tracts are occupied by the DFS and monitor continued presence.

(2) Population persistence: Persistence of DFS populations over the recovery period has been evaluated through comparison of occupancy over time, including a survey conducted in 1971 and repeated in 2001, and a second analysis comparing occupancy from 1990 through 2010 (Table 2). These studies are summarized in the proposed rule (79 FR 56686; September 23, 2014) and status review (USFWS 2012, pp. 15–17).

TABLE 2—DFS OCCUPANCY OF 275 FORESTED TRACTS (41,733 ha or 103,125 ac) IN MARYLAND, 1990 COMPARED TO 2010

Occupancy change from 1990 to 2010	Area of forest	Number of forest tracts	Percent of the original 41,733 ha (103,125 ac) in each occupancy status
Persistence	38,130 ha (94,221 ac)	181	91
Extirpations	499 ha (1,233 ac)	7	1
Uncertain	3,104 ha (7,671 ac)	87	8
Discoveries or colonizations	13,042 ha (32,227 ac)	250	

As indicated in Table 2, DFSs continued to persist in the vast majority of woodlots where they were known to occur in 1990, and their presence was newly documented in an additional 13,042 ha (32,227 ac) in all three States through 2010 (USFWS 2012, p. 8). Although some of these discoveries are likely to be occurrences that were previously present but undetected, anecdotal information indicates that several new localities represent true range expansion (see, for example, USFWS 2012, figure 4). Using the 2010 figures for occupied forest in all three States, as well as maps of mature forest and density estimates of the DFS available from various studies, we estimate that the total population of the DFS is now about 20,000 animals across an expanded range (USFWS 2012, p. 21).

(3) Population viability: A DFS population viability analysis (PVA) developed by Hilderbrand et al. (2007, entire) modeled the extinction probabilities of different-sized populations and determined that a population with 65 females, or 130 animals total, had a 95 percent chance of persisting for 100 years. This value, also called a minimum viable population (MVP), was used to gauge extinction risk by projecting how many populations of this size are likely to remain present in a given portion of the current DFS range (USFWS 2012, pp. 18–20; also see *Public Comments,* above).

The PVA also estimated that 75 percent of a given DFS population would have the ability to disperse to areas within 4 km (2.5 mi) (Hilderbrand et al. 2007, p. 73), and thus animals in forested tracts within this distance would be likely to interbreed; these interbreeding groups are defined as subpopulations. The analysis indicated that approximately 85 percent of DFSs are found in four large, narrowly separated subpopulations that could expand to become even more connected. Each of these subpopulations contains populations estimated to be several times the MVP minimum and have a high likelihood of population persistence. Overall, the rangewide population, estimated at between 17,000 and 20,000 animals, contains more than 100 times the MVP.

(4) Effects of timber harvest: Two major studies of the effects of timber harvest on the DFS (Paglione 1996, entire; Bocetti and Pattee 2003, entire) suggest that the subspecies is fairly tolerant of timber harvest, although specific impacts depend on the size, location, and landscape context of the harvest. Small clearcuts within a surrounding forest showed relatively little impact on the DFS, with individual squirrels shifting their home ranges into adjacent habitat, whereas harvest of more isolated forest peninsulas forced DFSs to move greater distances (Paglione 1996). Findings from the long-term Bocetti and Pattee (2003) study lead to the general conclusion that the DFS can tolerate timber harvests and can continue to occupy forested mosaics of mature and regenerating stands. In addition, both studies suggest that the DFS has high site fidelity and tends to shift home ranges rather than abandon a site in response to disturbance.

(5) Habitat availability: An analysis of LiDAR data provided by the State of Maryland enabled an inventory of mature forest suitable for the DFS throughout most of the squirrel's range (USFWS 2012, Appendix E). As of 2004, LiDAR mapping had identified 175,656

ha (434,056 ac) of mature forest in the eight Maryland counties occupied by DFSs (55 percent of all forest was considered mature), with 17 percent currently occupied and thus over 80 percent of mature forest available for expansion (USFWS 2012, table 4).

Although the amount and location of mature forest will change over time with timber harvest and forest growth, these data provide good baseline information about the availability and distribution of suitable habitat. Mature forest is often found in riparian zones (USFWS 2012, figure 8) that can provide connected habitat for DFS dispersal and colonization of new areas. LiDAR mapping also showed large tracts of mature forest distributed in upland areas throughout the Maryland portion of the subspecies' range. Given that most DFS populations occur in Maryland and, further, that unoccupied but suitable habitat is found both along the coast and inland elsewhere on the Delmarva Peninsula, we can infer from this habitat inventory that there is ample unoccupied mature forest to enable further expansion of the DFS' rangewide population.

(6) Habitat connectivity: Lookingbill et al. (2010, entire) conducted a GIS analysis of the connectivity between 400-ha (175-ac) forest patches on the Delmarva Peninsula (although the DFS is not a forest interior obligate and does not require forest blocks this large). Study results show high connectivity of forest blocks in the southern Maryland portion of the squirrel's range, indicating few obstacles to DFS dispersal throughout this area. Two major forest corridors were identified for DFS dispersal out of Dorchester County, Maryland, one of which is already occupied by the DFS (a third dispersal corridor not identified by the model is also DFS-occupied). Observations of DFS movement through a wide range of habitats, in conjunction with the results of this connectivity model and the map of LiDAR-defined mature forests, indicate that there is sufficient habitat availability and connectivity for further DFS range expansion.

Criterion 2: Benchmark populations are shown to be stable or expanding based on at least 5 years of data. Criterion 2 was intended to measure overall DFS population trends using monitoring data from seven benchmark populations. Although a slightly different set of eight benchmark sites was ultimately monitored, analysis of the resulting data (Dueser 1999, entire) showed that the benchmark sites were stable over a 5- to 7-year period, and benchmark monitoring was concluded.

We also have collected data to better understand rangewide population trends. The distribution data that document an expanded range and population persistence within that range as described under criterion 1, above, are much better indicators of DFS recovery. Although DFS populations in isolated areas (such as on small islands) are vulnerable to extirpation, all available population data for the DFS indicate that the range has expanded and populations are persisting within the range, and that this recovery criterion has been met.

Criterion 3: Ten translocated colonies are successfully established throughout the historical range. This criterion requires that at least 10 new DFS colonies must show evidence of presence for at least 5 to 8 years after release, demonstrating the ability of the DFS to colonize new sites, whether naturally or through management.

Post-release trapping results (Therres and Willey 2002, entire), along with more recent trapping and camera surveys, indicate continued presence of 11 of 16 translocated colonies (69 percent) for more than 20 years (USFWS 2012, table 1, p. 83). Further, in several of these areas, DFSs have dispersed well beyond the initial release site.

This success rate is higher than is typically found for similar translocation efforts for other endangered species (see Fischer and Lindenmayer 2000, p. 5), although the success rate is generally higher for mammals and wild source populations (Wolf et al. 1996, p. 1146). Further, despite some initial concerns about the genetic diversity of the translocated populations, subsequent analysis indicated that their genetic diversity was comparable to that of their source populations (Lance et al. 2003, entire). These data indicate that this criterion has been met.

Criterion 4: Five additional (post-1990) colonies are established outside of the remaining natural range. Criterion 4 requires discovery or establishment of colonies outside the range known at the time of the 1993 recovery plan, thus addressing the threat of range contraction and providing for additional population redundancy as one component of long-term species viability.

By 2007, eight new populations had been identified that did not result from translocations (USFWS 2007, figure 2), expanding the range toward the east. Notably, a colony discovered in Sussex County, Delaware, represents the first population found in that State since the time of listing that was not a result of a translocation. Since 2007, additional occupied forest has been discovered between some of these new populations, thus improving their long-term likelihood of survival (USFWS 2012, figure 3). We therefore conclude that this recovery criterion has been met.

Criterion 5: Periodic monitoring shows that translocated populations have persisted over the recovery period. Criterion 5 requires the continued presence of at least 80 percent of translocated populations, with at least 75 percent of these populations shown to be stable or improving. All successfully established translocated populations have persisted over the full period of recovery and have either become more abundant on their release sites or have expanded or shifted into new areas, as shown by trapping efforts (Therres and Willey 2002, entire), and, more recently, both trapping and/or camera surveys (USFWS 2012, table 1). Overall, the continued presence and growth of DFS populations at translocation sites show that this recovery criterion has been met.

Criterion 6: Mechanisms that ensure perpetuation of suitable habitat at a level sufficient to allow for desired distribution are in place and implemented within all counties in which the species occurs. Several well-established programs protect DFS habitat from development in perpetuity (Rural Legacy, Maryland Environmental Trust, Maryland Agricultural Programs, etc.). These programs, along with State and Federal ownership, protect an estimated 15,994 ha (39,524 ac; 29 percent) of DFS-occupied forest throughout the subspecies' current range (USFWS 2012, table 3). In addition, several State laws and regulatory programs will continue to protect forest habitat (USFWS 2012, appendix D). In Delaware and Virginia, the DFS occurs primarily on Federal and State land; the sole Virginia population was established on Chincoteague NWR and is completely protected from residential development or commercial timber harvest. Overall, we conclude that this recovery criterion has been met.

Criterion 7: Mechanisms are in place and implemented to ensure protection of new populations, to allow for expansion, and to provide inter-population corridors to permit gene flow among populations. As discussed under recovery criterion 1, LiDAR data indicate that mature forest blocks connected by riparian corridors are scattered throughout the Delmarva Peninsula. Further, Lookingbill et al. (2010, entire) indicate that these connected blocks constitute a good network of forest to allow for dispersing DFSs. Given ample opportunities for

dispersal, and the fact that many of these corridors are protected by State regulatory mechanisms (as discussed under *The Inadequacy of Existing Regulatory Mechanisms,* below), we conclude this recovery criterion has been met.

Summary of Factors Affecting the Species

Overview

Section 4 of the Act and its implementing regulations (50 CFR part 424) set forth the procedures for listing species, reclassifying species, or removing species from listed status. ''Species'' is defined in section 3 of the Act as any species or subspecies of fish or wildlife or plants, and any distinct vertebrate population segment of fish or wildlife that interbreeds when mature (16 U.S.C. 1532(16)). A species may be determined to be an endangered or threatened species based on one or more factors described in section 4(a)(1) of the Act: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence.

We must consider these same factors in delisting a species, and we must show that the best available scientific and commercial data indicate that the species is neither endangered nor threatened because: (1) It is extinct; (2) it has recovered and is no longer endangered or threatened (as is the case with the DFS); and/or (3) the original scientific data used at the time of listing classification were in error (50 CFR 424.11(d)). Determining whether a species is recovered requires evaluation of both the threats currently facing the species and the threats that are reasonably likely to affect the species in the foreseeable future following delisting and removal or reduction of the Act's protections.

A species is endangered for purposes of the Act if it is in danger of extinction throughout all or a significant portion of its range (SPR) and is threatened if it is likely to become endangered within the foreseeable future throughout all or a significant portion of its range. The word ''range'' in these definitions refers to the range in which the species currently exists. Although the term ''foreseeable future'' is left undefined, for the purposes of this rule, we regard foreseeable future as the extent to which, given available data, we can reasonably anticipate events or effects, or extrapolate threat trends, such that reliable predictions can be made concerning the future status of the DFS. In conducting this analysis, our general approach was to review past threat trends and the DFS' response, followed by a prediction of future trends. With some exceptions, we used a time frame of approximately 40 years for both past and future trend analyses; this time period also allowed use of available data to make more reliable projections despite the inherent uncertainties attached to predicting the future.

In the following five-factor analysis, we evaluate the status of the DFS throughout its entire range. We then address the question of whether the DFS is endangered or threatened in any significant portion of its range. Note that information discussed in detail in the September 23, 2014, proposed rule (79 FR 56686) and/or the 2012 status review (USFWS 2012, pp. 26–44) is summarized for each factor below.

Factor A. The Present or Threatened Destruction, Modification, or Curtailment of Its Habitat or Range

Here we considered habitat changes caused by residential development, sea level rise, and commercial timber harvest, as well as the habitat-related effects on DFS population and rangewide viability, with the exception of development or timber harvest effects on the population on Chincoteague NWR, as it is completely protected from these activities; we did, however, address the impact of sea level rise on this population.

Habitat Loss Due to Development

The Delmarva Peninsula is basically a rural landscape, but the human population has increased since the DFS was listed, as shown by Maryland Department of Planning data discussed in the September 23, 2014, proposed rule (79 FR 56686) (see Maryland Department of Planning 2008a, 2008b, and 2011b). Despite the past—and continuing—growth, the majority of the Delmarva Peninsula's land base remains rural, with approximately 47 percent agricultural land, 36 percent forest, 9 percent wetlands, and only 7 percent developed land (USFWS 2012, table 2).

Further, since listing, a variety of State laws and programs have been put in place to counteract the rate of development across the State (USFWS 2012, appendix D), including the Maryland Forest Conservation Act and Maryland Critical Area Law. In addition, the Maryland Environmental Trust, Maryland Agricultural Land Protection Fund, and Maryland Rural Legacy Program used easements to permanently protect about 3,642 ha per year (9,000 ac per year) of private lands between 2000 and 2008, enhancing protection of DFS habitat (USFWS 2012, chart 4).

Overall, approximately 30 percent of DFS-occupied forest lands, widely distributed across the subspecies' range, is protected from development (USFWS 2012, table 5). Additional acres of protected forest outside the current range of the DFS provide areas for further expansion (USFWS 2012, figure 7). Overall, the 15,995 ha (39,524 ac) of occupied forest protected from development could support a DFS population 45 times the MVP (based on Hilderbrand et al. 2007, entire). However, because 70 percent of DFS-occupied forest occurs on private land that remains legally unprotected from development, future losses from development are likely.

We assessed the potential threat of DFS habitat loss stemming from future development by overlaying the acres of existing occupied forest with areas projected to be lost to development, including: (1) Smart Growth areas (excluding the acres that are protected by easement), (2) areas where development projects are already planned, and (3) areas that are projected to be lost by 2030 if Smart Growth policies are not implemented (USFWS 2012, figure 11). Overall, 3 percent (2,283 ha or 5,643 ac) of the forest area currently occupied by the DFS is anticipated to be lost to development by 2030. This relatively low rate of projected loss can be attributed to the likelihood that most future development on the Delmarva Peninsula will occur outside the current range of the DFS. Future development within the current range is expected to primarily affect two small, isolated DFS subpopulations where extirpation is already probable. Together these subpopulations constitute less than 0.5 percent of the total viable population; thus, their loss would have a negligible effect on the rangewide extinction risk for the DFS. Although information on development projections past 2030 is not available at this time, we consider it likely that development on the Delmarva Peninsula will continue to be concentrated near large towns outside the range of the DFS, with some scattered development within the subspecies' range.

Conversely, we also anticipate continued expansion of DFS populations, including expansion onto Chesapeake Forest lands (which are now owned and managed by the State of Maryland), noting that some occupancy on these lands has already

occurred. The anticipated discovery of additional occupied forest areas may further offset projected loss of occupied forest due to development, resulting in little change to the overall area of the distribution. Discovery of additional occupied forest has occurred at the rate of 763 ha per year (1,887 ac per year) over the past 10 years. Even if we discover new occupied forest at half that rate, the anticipated net loss of occupied habitat from development would be offset by known occupied habitat in 6 years. With the continued protection of forest lands provided by State laws and programs, we do not expect habitat loss from development to substantially elevate the risk of the DFS' extinction.

Loss of Forest Habitat From Sea Level Rise

The Delmarva Peninsula is a low-lying landform, and sea level rise in the Chesapeake Bay can flood and kill shoreline forests that provide habitat for the DFS. However, the DFS does not occur exclusively in coastal habitats, which moderates its vulnerability to this threat, and GIS analysis indicates that over 80 percent of the current range would remain even after a projected inundation of coastal areas by 0.61 m (2 ft); see the discussion below.

Regarding sea level rise in the past, the forces of land subsidence and sea level rise have resulted in a long history of island loss and formation in the Chesapeake Bay. In the last century, these forces combined to produce a relative sea level rise in the Chesapeake Bay region of approximately 0.3 m (1 ft) per 100 years (National Wildlife Federation 2008, p. 2).

Loss of some forest areas in southern Dorchester County, Maryland, is already apparent at the lowest elevations where trees have been killed by saltwater intrusion from recent hurricanes. Although we cannot precisely estimate how much occupied habitat has been lost in the past 40 years, LiDAR analysis of forest height and canopy cover has identified at least 68 ha (170 ac) at the edge of coastal marshes that are now standing dead trees.

Hurricanes contribute to forest loss as sea levels rise, with saltwater moving farther into forested areas during associated storm surges. However, hurricanes and intense storms have always been part of the weather in this region, and there is no evidence that they pose a problem *per se* for the DFS. For instance, in October 2012, cameras placed in woods to monitor DFSs near the Atlantic coast recorded DFSs onsite after superstorm Sandy passed through, indicating survival through the storm. Although direct loss of trees used by the DFS may have occurred in the past, the major effect of hurricanes has been the additional push of saltwater into more upland areas, killing coastal forest trees.

In terms of future effects of sea level rise and climate change, sea level rise in the Chesapeake Bay is certain to continue, and the rate of change is likely to be even higher than in the past (National Wildlife Federation 2008, pp. 16–17; Sallenger et al. 2012, entire; Boesch et al. 2013, entire). To determine the extent of DFS-occupied forest that may be lost through the combined effects of sea level rise and subsidence (*i.e.,* relative sea level rise), we used a 0.61-m (2-ft) inundation scenario. A rise in sea level of this magnitude is predicted to occur by about 2050 under a worst-case scenario (Boesch et al. 2013, p. 15).

Our GIS analysis, in which we overlaid this inundation scenario with DFS-occupied forest, indicated that the most severe effects of sea level rise on the DFS by 2050 will be seen in the southwestern portion of Dorchester County, Maryland (USFWS 2012, figure 12). Here, 9,332 ha (23,060 ac) of currently occupied forest would either be lost or remain only on isolated islands (USFWS 2012, figure 12). In addition, 4,409 ha (10,897 ac) of habitat along the remaining southern edge of the county would eventually deteriorate, causing DFSs to move inland. The ability of DFSs to move into connected habitat likely reduces the effects on this subspecies due to forest losses at the coastal marsh fringe; we nonetheless recognize this as habitat loss. Other projected forest losses include scattered patches throughout the range, including some losses in the range of the Chincoteague population (USFWS 2012, figure 12).

Even if the predicted habitat losses from sea level rise in southwestern Dorchester County were to occur immediately, the area's remaining 23,632 ha (58,398 ac) of occupied habitat would continue to support a highly abundant DFS population with a negligible risk of extinction. Moreover, the habitat in the northeastern portion of this area is connected to existing occupied forest farther inland (USFWS 2012, figure 9) into which DFSs could move. In particular, a large tract of State-owned forest that will soon become sufficiently mature to allow for DFS expansion connects the Dorchester DFS subpopulation to forest tracts in Caroline and Sussex Counties (USFWS 2012, figure 10). Although sea level rise may cause streams and rivers to widen and pose more of a barrier in the future, forested corridors will still be available to provide DFSs with access to habitat in the inland portions of Dorchester County.

Given our current understanding of DFS habitat use, dispersal, and population dynamics, the expected DFS response to deterioration of coastal woodlands from sea level rise is the gradual movement of some DFSs to more inland areas. The DFS is known to travel across areas of marsh and can move at least 40 to 50 m (131 to 164 ft) between forested islands and may also move across frozen marsh in the winter. We acknowledge that despite the squirrel's ability to move, isolation and loss of some individuals is likely to occur. Nonetheless, we conclude that habitat loss due to sea level rise will not be a limiting factor to the future viability of this subspecies.

The 0.61-m (2-ft) inundation scenario does not play out the same in parts of the range outside southwestern Dorchester County. In the series of small peninsulas in northwestern Dorchester County called the ''neck region,'' this scenario results in shrinkage of available habitat but does not create islands, and leaves habitat for the DFS to move into (USFWS 2012, figure 12). This is also the case in other portions of the squirrel's range near the Chesapeake Bay and the Atlantic Coast. Some additional small areas of occupied habitat may be lost, but the gradual loss can be accommodated by shifts in DFS home ranges to adjacent but currently unoccupied habitat.

The most coastal population of the DFS is a translocated population introduced in 1968 to Chincoteague NWR, a barrier island in Virginia that could be severely affected by sea level rise (National Wildlife Federation 2008, p. 69). The refuge's draft Comprehensive Conservation Plan (available at *http://www.fws.gov/nwrs/threecolumn.aspx?id=2147550165*) addresses this issue, and the refuge may consider future land acquisitions on the Delmarva Peninsula mainland. Chincoteague NWR will continue to manage for the DFS into the future whether or not the subspecies remains listed. In addition, translocations of DFSs to areas outside refuge boundaries at some point in the future are possible.

It is not clear how climate change effects may alter the nature of the forests of the Delmarva Peninsula. However, as the DFS occurs in pine, hardwood, and mixed hardwood forests, with a preference for mixed forests with diverse tree species, any effects on the species composition of these forests are unlikely to become a significant threat for the squirrel.

Overall, DFS distribution has increased in the past 40 years even with

some sea level rise occurring. In the next 40 years under a worst-case scenario, we predict some deterioration of forests in certain areas along the Chesapeake Bay and the Atlantic Coast (USFWS 2012, figure 12), but we also anticipate population expansion and shifts in DFS home ranges into suitable but currently unoccupied habitat available in the interior of the Delmarva Peninsula. Although some concern has been expressed about the likelihood of such expansion (*e.g.,* by the Center for Biological Diversity 2013), the analysis of habitat suitability, connectivity, and the range expansion documented in the last 15 years provides a rational basis for this expectation. Thus, available data indicate that loss of habitat due to climate change and sea level rise does not pose an extinction risk to the DFS.

Combined Effects of Development and Sea Level Rise

Having determined that neither development nor sea level alone threatens the DFS with rangewide extinction, we conducted a spatial analysis to examine how these most pervasive stressors might interact (USFWS 2012, figure 5 and table 7).

As of 2010, 54,429 ha (134,496 ac) of habitat supported 22 DFS subpopulations, (USFWS 2012, table 7), and 95 percent of the occupied forest contains the 11 largest subpopulations, which are highly likely to remain demographically viable. Even with projected losses from both development and sea level rise, and not accounting for potential discovery of additional occupied habitat, over 95 percent of the DFS-occupied forest would continue to support these most viable subpopulations. Thus, the combined effects of these threats do not pose an extinction risk to the DFS.

Loss of Mature Forest From Timber Harvest

Unlike development and sea level rise, timber harvest does not result in permanent loss of habitat. Further, as noted under *Recovery Criteria,* above, DFSs are resilient to timber harvests when there is adjacent habitat into which they can move. Thus, the major habitat concerns related to timber harvests are (1) the prevalence of short-rotation timber harvests, where trees are harvested before they mature enough to become DFS habitat; and (2) harvest rates that exceed growth rates and result in a continual decline of mature forest.

Short-rotation pine forestry involves harvesting stands at approximately 25 years of age for pulp and other fiber products, precluding their suitability as DFS habitat. In the past, two large corporations managed for short-rotation pine on the Delmarva Peninsula; however, these industries have effectively left the Peninsula. In 1999, the State of Maryland acquired 23,471 ha (58,000 ac) of these lands, collectively administered as the Chesapeake Forest Lands and comprising scattered parcels throughout the southern four Maryland counties (USFWS 2012, figure 13). Another 4,202 ha (10,384 ac) of forest land previously owned and managed for short-rotation pine are now owned by the State of Delaware. All these lands will now be protected from development and managed for sustainable sawtimber harvest and wildlife habitat objectives. Moreover, DFS management has been integrated into the Sustainable Forest Management Plan for Chesapeake Forest Lands prepared by Maryland's Department of Natural Resources (Maryland DNR 2013, pp. 92–96), which identifies a total of 17,618 ha (43,535 ac) as DFS Core Areas and DFS Future Core Areas. Overall, these land acquisitions represent a future of protected forest areas managed for sawtimber where the DFS can survive and grow in numbers, substantially removing the threat posed by short-rotation pine management on the lower Delmarva Peninsula.

Harvest rate estimates for both the 2007 and 2012 status review (USFWS 2007, pp. 17–20; USFWS 2012, table 6) indicated that harvests in more recent years have been substantially less than in previous years (generally prior to 2005) (USFWS 2012, table 6). For instance, in the four southern Maryland counties, the average annual harvest dropped from approximately 1,050 ha (2,594 ac) prior to 2005, to approximately 303 ha (749 ac) since then. The average size of harvested stands in these counties has also decreased, from an average of 22 ha (54 ac) to an average of 15 ha (36 ac). This is also the case in Delaware; in Sussex County, the annual harvest rate in the last 4 years was half of what was generally harvested between 1998 and 2005, with the same holding true for the size of individual harvest areas.

Among other reasons for these reductions, economic pressures have resulted in the closure of several sawmills on the Delmarva Peninsula. The market for timber has declined dramatically, with low prices acting as a disincentive to harvesting. As discussed below, reduced harvest levels are likely to continue in the future.

Although it is very difficult to predict future market forces, trends in fragmentation and parcelization in the Chesapeake Bay region (Sprague et al. 2006, pp. 22–24) suggest that future timber harvests might remain smaller in size and occur less frequently. Parcelization is the subdivision of large blocks of land into multiple ownerships, with a consequent tendency to shift from forest management to management for aesthetics and wildlife values. In Maryland, 45 percent of woodland owners own less than 20 ha (50 ac) of woods (U.S. Department of Agriculture, 2012). Given general sizes of timber harvests, these woodlands may be too small for future harvests and are more likely to be managed for aesthetics and wildlife.

This ownership pattern also reflects the gentrification of the eastern shore of Maryland, with landowners becoming less likely to be farmers or foresters and more likely to be commuters or retirees who do not use their properties for income. This trend is expected to continue into the future (see *http://www.mdp.state.md.us/msdc/S3_Projection.shtml*), with a concomitant reduction in total acres harvested.

Overall, the forest land transfers in Maryland and Delaware, in conjunction with available data on harvest rates across the range of the squirrel, suggest that timber harvest does not pose an extinction risk for the DFS.

Factor A Summary

The current range of the DFS spans coastal and interior areas of the Delmarva Peninsula where DFSs inhabit diverse wetland and upland forest types, suggesting that DFS populations will continue to remain resilient to a variety of habitat-related effects. Further, the distribution of these habitats provides for redundancy of populations, which reduces the risk of catastrophic loss. We recognize that habitat losses may occur in some areas, primarily from residential development and sea level rise, but we expect the DFS population to remain at or above recovered levels, and, moreover, we do not expect such habitat losses to prevent overall expansion of the range in the future.

Factor B. Overutilization for Commercial, Recreational, Scientific, or Educational Purposes

Overhunting has been posited as a factor in the original decline of this subspecies. Squirrel hunting was common in the early and middle decades of the 20th century, and hunting of the DFS in small, isolated woodlots or narrow riparian corridors could have resulted in local extirpations. Taylor (1976, p. 51) noted that the DFS remained present on large agricultural estates where hunting was not allowed, suggesting that these areas

may have provided a network of refugia for the DFS.

By 1972, hunting of DFS was banned through state regulations. Removal of hunting pressure may have been one factor in the renewed population growth and expansion of the squirrel's range to its current extent. Coincidentally, squirrel hunting has declined in popularity in recent decades; nationwide, squirrel hunting declined by about 40 percent between 1991 and 2001, and by an additional 20% between 2001 and 2011 (DOI 1991 p. 70; DOI 2001, p. 57; DOI 2011, p. 60). Recent records of squirrel hunters specifically are not available for Maryland but the number of small game hunters in Maryland (pursuing squirrels, rabbits and/or quail) declined from 64,000 to 35,000 between 1991 and 2011 (DOI 1991, p. 113; DOI 2011, p. 102). Hunting gray squirrels will continue to some extent, and though some hunters may mistake DFS for gray squirrels, this is likely a rare situation that has not prevented the DFS from expanding over the last 40 years.

Regarding hunting in the future, discussions with our State partners indicate that DFS management after delisting would be conducted very cautiously and that a hunting season would not be initiated in the immediate future. We recognize that a restricted hunt could be conducted at sites where DFSs are abundant without causing a population decline, and that State management agencies have the capability to implement careful hunting restrictions and population management; the reopening of the black bear (*Ursus americanus*) hunt in Maryland is a good example of a carefully and successfully managed hunt (Maryland Department of Natural Resources 2012, entire).

We nonetheless foresee only limited individual interest in reinitiating a DFS hunt, coupled with strong public attitudes against hunting DFSs and, more generally, recreational hunting (Duda and Jones 2008, p. 183). Given public sentiment, the declining interest in squirrel hunting, and the restrictions that we expect would be imposed on a renewed hunting program, hunting is highly unlikely to pose an extinction risk to the DFS in the foreseeable future.

Factor C. Disease or Predation

Each of these types of threat is summarized below.

Disease

Reports of disease in the DFS are uncommon. Although other subspecies of eastern fox squirrels are known to carry diseases such as mange and rabies, there is no documentation of these diseases in the DFS, and there is no evidence or suspicion of disease-related declines in any local population (USFWS 2012, pp. 37–38).

Although the advent of white-nose syndrome affecting bats (Blehert et al. 2009, entire) and chytrid fungus affecting amphibians (Daszak et al. 1999, entire) demonstrates the uncertainty surrounding novel disease events, the life-history traits of the DFS tend to make them less susceptible to these types of epizootics. Delmarva fox squirrels do not congregate in large numbers where disease can easily spread through a population. Further, the DFS is patchily distributed across its range, which makes it more difficult for disease to spread across populations, and DFSs are not migratory and do not inhabit the types of environment (as with aquatic species) where pathogens can readily disperse.

Overall, there currently is no evidence of disease-related declines or any indication that DFSs are particularly susceptible to disease outbreaks, and we conclude that disease is neither a current nor a future extinction risk for this subspecies.

Predation

Predators of the DFS include the red fox (*Vulpes vulpes*), gray fox (*Urocyon cinereoargenteus*), red-tailed hawk (*Buteo jamaicensis*), bald eagle (*Haliaeetus leucocephalus*), and possibly domestic pets and feral animals.

Changes in numbers of certain predators may cause some fluctuations in DFS numbers at a site (for instance, a DFS population may decline when red fox numbers increase), but these types of events are sporadic and localized. Conversely, although bald eagle numbers have dramatically increased in the Chesapeake Bay region over the past 40 years and eagles have been known to take DFSs, they still prey primarily on fish. And while feral dogs and cats may occasionally take DFSs, such predation is not a rangewide threat. The DFS population has increased over the last 40 years despite ongoing predation, and we conclude that predation at these levels is not a current or future extinction risk for this subspecies.

Factor D. The Inadequacy of Existing Regulatory Mechanisms

Several laws established in Maryland over the past 40 years provide substantial protections for DFS habitat (USFWS 2012, appendix D). The Maryland Critical Areas Act of 1984 designates all areas within 304.8 m (1,000 ft) of high tide as Critical Areas and, as amended, prohibits development and forest clearing within 60.96 m (200 ft) of streams and the Chesapeake Bay. These areas serve as both breeding habitat and dispersal corridors for DFSs. The Maryland Forest Conservation Act of 1991 requires that when a forested area is cleared and converted to other land uses, other forest areas must be protected in perpetuity or, alternatively, replanted to offset these losses. Additionally, the State-implemented portions of the Clean Water Act (33 U.S.C. 1251 *et seq.*) provide rangewide protection to the many forested wetlands where DFSs occur.

Several State programs in Maryland, including its Agricultural Land Protection Fund, Environmental Trust, and Rural Legacy Program, encourage voluntary conservation easements that protect lands from development. Collectively, these programs now protect 79,066 ha (195,377 ac) of private lands within the DFS' range. Similar programs in Delaware protect an additional 12,677 ha (31,327 ac) in Sussex County (USFWS 2012, table 3).

Although in Delaware and Virginia the DFS occurs primarily on Federal and State lands, regulatory protections affecting private lands allow for continued DFS range expansion. For example, Delaware's Agricultural Land Protection Program and Forest Legacy Program now protect more than 12,677 ha (31,327 ac) in Sussex County, much of which is or could be occupied by the DFS. The Virginia DFS population is completely protected on Chincoteague NWR. If needed, State-owned lands or private lands, or both, protected by land trusts would provide suitable habitat for future translocations.

Overall, many State laws and programs that protect the DFS and its habitat have been enacted or strengthened in the last 40 years, and it is likely that this State protection will continue. Currently, these regulatory mechanisms, together with other factors that address population and habitat trends, have substantially reduced threats to the DFS. We thus conclude that existing regulatory mechanisms are adequate in terms of reducing extinction risks for the DFS.

Factor E. Other Natural or Manmade Factors Affecting Its Continued Existence

The level of risk posed by each of the following factors is assessed below.

Forest Pest Infestations

Forest pest infestations can affect forest health and its ability to provide suitable habitat for the DFS. Gypsy moth

(*Lymantria dispar*) outbreaks can decimate mature forest stands, although the affected stands will eventually regenerate. Monitoring outbreaks and spraying for gypsy moth control appear to have reduced this threat within the current range of the DFS, as infestations in the last several years have diminished in acreage (Maryland Department of Agriculture Forest Health Highlights 2007, 2008, 2009; entire).

Southern pine bark beetle (*Dendroctonus frontalis*) infestations can also decimate mature forest stands within the range of the DFS. Although beetle outbreaks necessitated salvage cuts for a total of 809 ha (2,000 ac) scattered across the southern counties in Maryland in the early 1990s, monitoring and control efforts appear to have reduced this threat as well.

Overall, an analysis of forest pests in the Chesapeake Bay watershed found that most areas on the Eastern Shore where DFSs occur have a relatively low likelihood of insect infestations, with 3.8 to 10 percent of this area considered to be at risk (Sprague et al. 2006, p. 87). Although emergence of new forest pests is to be expected, Maryland's Forest Health Monitoring Program conducts surveys to map and report forest pest problems (Maryland Department of Agriculture, Forest Pest Management, 2012, entire). Forest pest outbreaks are likely to recur and may increase if the climate warms as projected; however, this threat appears to be localized and sporadic and, with existing programs to monitor and treat forest pest outbreaks, we conclude that this is not an extinction risk factor for the DFS.

Vehicle Strikes

Vehicle strikes are a relatively common source of DFS mortality. Similarly to other species, the probability of DFSs being hit by vehicles is dependent on the DFS' density and proximity of roads to habitat. Vehicle strikes of DFSs tend to be reported more frequently in areas where DFSs are abundant, even if traffic levels are relatively low (*e.g.,* Dorchester County). The conscientious reporting and collecting of DFSs killed on roads at the Blackwater and Chincoteague NWRs, where the DFS is very abundant, likely results in a more complete count of vehicle strikes than elsewhere. Vehicle strikes occur regularly at both refuges, yet DFSs remain abundant in both places and have expanded their occupancy at Chincoteague NWR.

Overall, most DFS populations across the subspecies' range continue to remain stable or are increasing in numbers despite these localized events, and we conclude that vehicle strikes alone are not a pervasive threat or extinction factor for this subspecies.

Overall Summary of Factors A Through E

A summary of the five-factor analysis discussed above is provided in Table 3. Based on our analysis, we conclude that no single factor or combination of factors poses a risk of extinction to the DFS now or in the foreseeable future.

TABLE 3—SUMMARY OF FIVE-FACTOR ANALYSIS UNDER THE ACT FOR DFS

Factor	Past trends	Foreseeable trends	Does factor pose an extinction risk?
Habitat loss from development.	In the past 40 years, development increased from 3 to 8 percent of the land area in the Maryland range of the DFS; development also increased in Sussex County, Delaware. Some habitat has been lost, but most development occurs near existing towns where DFSs are not as prevalent, and development often occurs on agricultural rather than forest land.	Development is projected to increase to 14 percent of the land area in the Maryland and Delaware portions of DFS' range. Although most development will occur near urban areas where DFSs do not occur, 3 to 4 percent of total DFS occupied habitat is expected to be affected. While these losses may cause some small subpopulations to disappear, most occupied habitat will remain available. Despite the projected development, DFS distribution is expected to continue to expand.	No.
Habitat loss from sea level rise.	In the past, loss of occupied habitat due to inundation and saltwater intrusion has occurred in southern Dorchester County, although the acreage is not known. Sea level rise has occurred in the past at the rate of 3.5 millimeters (mm) per year (about 1 ft per 100 years).	Under an extreme scenario of 0.61-m (2-ft) inundation in 40 years, considerable acreage will be lost or isolated in southwestern Dorchester County. However, even if this loss were to occur immediately, the Dorchester County subpopulation would remain over 70 times larger than the MVP. It would thus continue to be the largest subpopulation, and given a 40-year time frame for reaching this level of inundation, is very likely to remain viable over the long term.	No.
Habitat loss from timber harvest.	Sawtimber harvest has occurred throughout the Delmarva Peninsula. Past harvest rates appear to have been sustainable, as DFSs have remained present across the range.	Recent declines in timber harvests, along with mill closings, may reduce the harvest rate for some time. Increasing parcelization of land will further reduce opportunities for large-scale timber production. Gentrification of the Eastern Shore is shifting public values for forest management from timber production to management for aesthetics and wildlife. Thus, future timber harvest rates are not expected to exceed past harvest rates.	No.

TABLE 3—SUMMARY OF FIVE-FACTOR ANALYSIS UNDER THE ACT FOR DFS—Continued

Factor	Past trends	Foreseeable trends	Does factor pose an extinction risk?
Habitat loss from short-rotation pine management.	In the past, short-rotation pine harvests occurred on approximately 68,000 ac of the forest lands in the Maryland and Delaware portions of the DFS' range. These acres were typically harvested before they were mature enough to become DFS habitat.	Since 1999, these lands have been acquired by the States of Maryland and Delaware and are now managed for sawtimber, which will provide suitable DFS habitat. Thus, 58,000 ac of land in Maryland and 10,000 ac in Delaware are protected from development and managed for sawtimber, enabling future use by the DFS that was previously precluded.	No.
Overutilization	Hunting seasons have been closed since 1972 ...	Hunting seasons are likely to remain closed into the foreseeable future. If opened, DFS hunts would be limited and carefully managed. Interest in squirrel hunting has declined significantly, and public attitudes toward hunting have changed to primarily support hunting of those species viewed as needing population management, such as deer.	No.
Disease or predation	Disease and predation have not been significant threats for this subspecies in the past 40 years.	These threats are not expected to increase, and the expanding distribution of the DFS lessens the potential impacts that disease and predation could have on this subspecies.	No.
Inadequacy of regulatory mechanisms.	Several new Maryland laws have appeared in the last 40 years to help conserve forest areas that support the DFS. DFS occurrences in Delaware and Virginia are almost exclusively on protected lands.	In the next 40 years, forest conservation measures are expected to continue, and the programs that have begun in Maryland are expected to continue or increase as they have in the past. Easement programs that protect private lands from development have begun in Delaware and Virginia and are expected to increase in the future as well.	No.
Other natural or man-made factors.	Forest pests and vehicle strikes have occurred in the past 40 years to some extent but have not limited the expansion of the DFS' distribution.	Forest pests and vehicle strikes are likely to continue to some extent, but neither factor has limited growth of the subpopulations in the past, nor are they expected to do so in the future. As DFS populations increase in density, vehicle strikes could increase, as the probability of a strike is primarily a function of animal abundance.	No.

Determination

We have carefully assessed the best scientific and commercial information available regarding past, present, and future threats to the long-term viability of the DFS. The current range of the DFS spans the northern and southern portions of the Delmarva Peninsula, comprising all three States, and extends from coastal areas to the interior of the Delmarva Peninsula. The DFS inhabits a variety of forest types, from hardwood-dominated to pine-dominated forests and from wetland to upland forests, indicating an underlying genetic variability or behavioral plasticity that should enhance the subspecies' ability to adapt to changing environmental conditions. Its relatively wide distribution also provides redundancy of occupied forest across the landscape, which further reduces extinction risk, and its continued occupancy of woodlots over the past 20 to 30 years and the success of translocation efforts indicate considerable resilience to stochastic events. We thus expect the rangewide population of the DFS not only to remain at recovery levels but to grow and continue to occupy the full complement of landscapes and forest types on the Delmarva Peninsula.

The Act defines ''endangered species'' as any species that is ''in danger of extinction throughout all or a significant portion of its range,'' and ''threatened species'' as any species that is ''likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.'' The term ''species'' includes ''any subspecies of fish or wildlife or plants, and any distinct population segment [DPS] of any species of vertebrate fish or wildlife which interbreeds when mature.'' As a subspecies, the DFS has both met the recovery criteria we consider for delisting, and the analysis of existing and potential risks shows that the range and distribution of the subspecies is sufficient to withstand all foreseeable threats to its long-term viability. Thus, after assessing the best available information, we have determined that the DFS is no longer in danger of extinction throughout all of its range, nor is it likely to become threatened with endangerment in the foreseeable future.

Significant Portion of the Range Analysis

Overview

Having determined the status of the DFS throughout all of its range, we next examine whether the subspecies is in danger of extinction in a significant portion of its range. Under the Act and our implementing regulations, a species may warrant listing if it is in danger of extinction or likely to become so throughout all or a significant portion of its range, as stated above. We published a final policy interpreting the phrase ''significant portion of its range'' (79 FR 37578; July 1, 2014). This policy states that: (1) If a species is found to be endangered or threatened throughout a significant portion of its range, the entire species is listed as an endangered species or a threatened species,

respectively, and the Act's protections apply to all individuals of the species wherever found; (2) a portion of the range of a species is ''significant'' if the species is not currently endangered or threatened throughout all of its range, but the portion's contribution to the viability of the species is so important that, without the members in that portion, the species would be in danger of extinction or likely to become so in the foreseeable future throughout all of its range; (3) the range of a species is considered to be the general geographical area within which that species can be found at the time we make any particular status determination; and (4) if a vertebrate species is endangered or threatened throughout an SPR, and if it can also be shown the population in that significant portion is a valid DPS, we will list the DPS rather than the entire taxonomic species or subspecies.

The SPR policy is applied to all status determinations, including analyses for the purposes of making listing, delisting, and reclassification determinations. The procedure for analyzing whether any portion is an SPR is similar, regardless of the type of status determination we are making. The first step in our analysis of the status of a species is to determine its status throughout all of its range. If we determine that the species is in danger of extinction, or likely to become so in the foreseeable future, throughout all of its range, we list the species as an endangered (or threatened) species and no SPR analysis will be required. If the species is neither in danger of extinction, nor likely to become so, throughout all of its range, we determine whether the species is in danger of extinction or likely to become so throughout a significant portion of its range. If it is, we list the species as an endangered species or a threatened species, respectively; if it is not, we conclude that listing of the species is not warranted.

When we conduct an SPR analysis, we first identify any portions of the species' range that warrant further consideration. The range of a species can theoretically be divided into portions in an infinite number of ways. However, there is no purpose to analyzing portions of the range that are not reasonably likely to be both significant and endangered or threatened. To identify only those portions that warrant further consideration, we determine whether there is substantial information indicating that (1) the portions may be significant and (2) the species may be in danger of extinction in those portions or likely to become so within the foreseeable future. We emphasize that answering these questions in the affirmative is not a determination that the species is endangered or threatened throughout a significant portion of its range—rather, it is a step in determining whether a more detailed analysis of the issue is required. In practice, a key part of this analysis is whether the threats are geographically concentrated in some way. If the threats to the species are affecting it uniformly throughout its range, no portion is likely to warrant further consideration. Moreover, if any concentration of threats apply only to portions of the range that clearly do not meet the biologically based definition of ''significant'' (*i.e.,* the loss of that portion clearly would not be expected to increase the vulnerability to extinction of the entire species), those portions will not warrant further consideration.

If we identify any portions that may be both (1) significant and (2) endangered or threatened, we engage in a more detailed analysis to determine whether these standards are indeed met. The identification of an SPR does not create a presumption, prejudgment, or other determination as to whether the species in that identified SPR is endangered or threatened. We must go through a separate analysis to determine whether the species is endangered or threatened in the SPR. To determine whether a species is endangered or threatened throughout an SPR, we will use the same standards and methodology that we use to determine if a species is endangered or threatened throughout its range.

Depending on the biology of the species, its range, and the threats it faces, it may be more efficient to address the ''significant'' question first, or the status question first. Thus, if we determine that a portion of the range is not ''significant,'' we do not need to determine whether the species is endangered or threatened there. Conversely, if we determine that the species is not endangered or threatened in a portion of its range, we do not need to determine if that portion is ''significant.''

SPR Analysis for DFS

Having determined that the DFS does not meet the definition of endangered or threatened throughout its range, we considered whether there are any significant portions of its range in which it is in danger of extinction or likely to become so. The full discussion regarding this analysis, summarized here, is provided in the September 23, 2014, proposed rule (79 FR 56686).

Applying the process described above, we evaluated the range of the DFS to determine if any area could be considered a significant portion of its range. Based on examination of the relevant information on the biology and life history of the DFS, we determined that there are no separate areas of the range that are significantly different from others or that are likely to be of greater biological or conservation importance than any other areas. We next examined whether any threats are geographically concentrated in some way that would indicate the subspecies could be in danger of extinction, or likely to become so, in that area. Through our review of threats to the subspecies, we identified some areas where DFSs are likely to be extirpated, including areas in Queen Anne's County, Maryland, where DFS distribution is scattered and relatively isolated by roads and water, and where future development is anticipated. We thus considered whether this area in the northern portion of the range may warrant further consideration as a significant portion of its range.

The forest area currently occupied by DFSs that is projected to be lost to development by 2030 would affect two small populations in Queen Anne's County that together constitute less than 0.5 percent of the rangewide population; however, five large DFS subpopulations are expected to remain viable across the northern portion of the current range. Additionally, Queen Anne's County's landscape does not represent a unique habitat type or ecological setting for the subspecies. Thus, the areas expected to be lost due to development would not appreciably reduce the long-term viability of the subpopulation in the northern portion of the range, much less imperil the DFS in the remainder of its range. Therefore, we have determined that this portion of the DFS' range does not meet the definition of SPR under the 2014 policy.

We also anticipate loss of DFS-occupied forests from sea level rise in Dorchester County, Maryland, on the southwestern periphery of the habitat supporting the largest subpopulation of DFS. However, these losses do not threaten either the subpopulation or the subspecies with a risk of extinction, as there is ample unoccupied and sufficiently connected habitat for displaced squirrels to colonize; this is bolstered by their ability to readily colonize new areas evidenced by successful expansion of DFS translocations. In addition, we anticipate the continued presence of mixed pine/hardwood forests adjacent to marsh and open water in Dorchester

County and do not anticipate losses of any unique habitats. Therefore, losses due to sea level rise in this portion of the range would not appreciably reduce the long-term viability of the subpopulation, much less cause the subspecies in the remainder of its range to be in danger of extinction or likely to become so. We thus conclude the portion of the range that is expected to be lost from sea level rise does not meet the policy's definition of an SPR.

These are the only two portions of the range that we identified as meriting analysis as to their significance and level of endangerment in conformance with the 2014 SPR policy. Finding that the potential losses in small areas of Queen Anne's County would not cause cascading vulnerability and do not constitute unique areas that are not represented elsewhere in the subspecies' range, and finding that loss of areas in Dorchester County to sea level rise would not diminish the continued viability of the Dorchester subpopulation or cause the remainder of the subspecies to be in danger of extinction or likely to become so, we do not consider this subspecies to be endangered or threatened in any significant portion of its range. Further, having not found the basis for an SPR determination on grounds of either significance or threat, we also find that a DPS analysis is not warranted.

Summary

The subspecies' current and projected resiliency, redundancy, and representation should enable it to remain at recovered population levels throughout all of its range, and even expand its range, over the foreseeable future. Having assessed the best scientific and commercial data available and determined that the DFS is no longer endangered or threatened throughout all or a significant portion of its range and is not it likely to become so in the foreseeable future, we are removing this subspecies from the List under the Act.

Future Conservation Measures

Section 4(g)(1) of the Act requires us, in cooperation with the States, to implement a monitoring program for not less than 5 years for all species that have been recovered and delisted. The purpose of post-delisting monitoring (PDM) is to verify that a species remains secure from risk of extinction after the protections of the Act are removed by developing a program that detects the failure of any delisted species to sustain itself. If, at any time during the monitoring period, data indicate that protective status under the Act should be reinstated, we can initiate listing procedures, including, if appropriate, emergency listing under section 4(b)(7) of the Act.

This rule announces availability of the final PDM plan for the DFS. Public and peer review comments on the draft PDM plan have been addressed in the body of the plan and are summarized in the plan's appendix. The plan can be accessed at: *http://www.regulations.gov* under Docket No. FWS–R5–ES–2014–0021. It is also posted on the Service's national Web site (*http://endangered.fws.gov*) and the Chesapeake Bay Field Office's Web site (*http://www.fws.gov/chesapeakebay*). A summary of the PDM plan is provided below.

Post-Delisting Monitoring Plan Overview

The PDM plan for the DFS builds upon and continues the research conducted while the DFS was listed. In general, the plan directs the Service and State natural resource agencies to (1) continue to map all DFS sightings and occupied forest to delineate the distribution and range, and (2) assess the occupancy of DFS in a sample of forest tracts to estimate the relative persistence of DFS populations versus extirpations across the range.

The PDM plan identifies measurable management thresholds and responses for detecting and reacting to significant changes in the DFS's protected habitat, distribution, and ability to remain at recovered population levels. If declines are detected equaling or exceeding these thresholds, the Service, along with other post-delisting monitoring participants, will investigate causes, including consideration of habitat changes, stochastic events, or any other significant evidence. Results will be used to determine if the DFS warrants expanded monitoring, additional research, additional habitat protection, or resumption of Federal protection under the Act.

Effects of This Rule

This final rule revises 50 CFR 17.11(h) to remove the Delmarva Peninsula fox squirrel from the List of Endangered and Threatened Wildlife (List). It also revises 50 CFR 17.11(h) and 50 CFR 17.84(a) to remove the listing and regulations, respectively, for the nonessential experimental population of Delmarva Peninsula fox squirrels at Assawoman Wildlife Management Area in Sussex County, Delaware. The prohibitions and conservation measures provided by the Act, particularly through sections 7 and 9, no longer apply to this subspecies. Federal agencies are no longer required to consult with the Service under section 7 of the Act in the event that activities they authorize, fund, or carry out may affect the DFS. The take exceptions identified in 50 CFR 17.84(a)(2) for the experimental population of the DFS are also removed. There is no critical habitat designated for the DFS.

Required Determinations

National Environmental Policy Act

We have determined that environmental assessments and environmental impact statements, as defined under the authority of the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), need not be prepared in connection with regulations pursuant to section 4(a) of the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994, ''Government-to-Government Relations with Native American Tribal Governments'' (59 FR 22951), Executive Order 13175, and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our tribal trust responsibilities. We have determined that there are no tribal lands affected by this rule.

References Cited

A complete list of all references cited in this final rule is available at *http://www.regulations.gov,* or upon request from the Chesapeake Bay Field Office (see **ADDRESSES**).

Authors

The primary authors of this final rule are staff members of the Chesapeake Bay Field Office (see **ADDRESSES**).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Regulation Promulgation

Accordingly, we amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; 4201–4245, unless otherwise noted.

§ 17.11—[Amended]

■ 2. Amend § 17.11(h) by removing both entries for ''Squirrel, Delmarva Peninsula fox'' under MAMMALS from the List of Endangered and Threatened Wildlife.

§ 17.84—[Amended]

■ 3. Amend § 17.84 by removing and reserving paragraph (a).

Dated: October 23, 2015.

James W. Kurth,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. 2015–28742 Filed 11–13–15; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 141021887–5172–02]

RIN 0648–XE312

Fisheries of the Exclusive Economic Zone Off Alaska; Yellowfin Sole for Vessels Participating in the BSAI Trawl Limited Access Fishery in the Bering Sea and Aleutian Islands Management Area

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

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for yellowfin sole in the Bering Sea and Aleutian Islands management area (BSAI) for vessels participating in the BSAI trawl limited access fishery. This action is necessary to prevent exceeding the 2015 allocation of yellowfin sole total allowable catch for vessels participating in the BSAI trawl limited access fishery in the BSAI.

DATES: Effective 1200 hrs, Alaska local time (A.l.t.), November 11, 2015, through 2400 hrs, A.l.t., December 31, 2015.

FOR FURTHER INFORMATION CONTACT: Steve Whitney, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the BSAI according to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The 2015 allocation of yellowfin sole total allowable catch for vessels participating in the BSAI trawl limited access fishery in the BSAI is 16,165 metric tons (mt) as established by the final 2015 and 2016 harvest specifications for groundfish in the BSAI (80 FR 11919, March 5, 2015). In accordance with § 679.20(d)(1)(i), the Administrator, Alaska Region, NMFS (Regional Administrator), has determined that the 2015 allocation of yellowfin sole total allowable catch for vessels participating in the BSAI trawl limited access fishery in the BSAI will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 16,065 mt, and is setting aside the remaining 100 mt as incidental catch. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for yellowfin sole for vessels participating in the BSAI trawl limited access fishery in the BSAI.

After the effective date of this closure the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

This action responds to the best available information recently obtained from the fishery. The Assistant Administrator for Fisheries, NOAA (AA), finds good cause to waive the requirement to provide prior notice and opportunity for public comment pursuant to the authority set forth at 5 U.S.C. 553(b)(B) as such requirement is impracticable and contrary to the public interest. This requirement is impracticable and contrary to the public interest as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion and would delay the closure of directed fishing for yellowfin sole by vessels fishing in the BSAI trawl limited access fishery in the BSAI. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of November 9, 2015.

The AA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

This action is required by § 679.20 and is exempt from review under Executive Order 12866.

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

Dated: November 9, 2015.

Emily H. Menashes,

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

[FR Doc. 2015–29168 Filed 11–10–15; 4:15 pm]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 80, No. 220
Monday, November 16, 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

Animal and Plant Health Inspection Service

9 CFR Parts 54 and 79

[Docket No. APHIS–2007–0127]

Scrapie in Sheep and Goats

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Proposed rule; reopening of comment period.

SUMMARY: We are reopening the comment period for our proposed rule that would revise completely the scrapie regulations, which concern the risk groups and categories established for individual animals and for flocks, the use of genetic testing as a means of assigning risk levels to animals, movement restrictions for animals found to be genetically less susceptible or resistant to scrapie, and recordkeeping requirements. This action will allow interested persons additional time to prepare and submit comments.

DATES: The comment period for the proposed rule published on September 10, 2015 (80 FR 54660–54692) is reopened. We will consider all comments that we receive on or before December 9, 2015.

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

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov/#!docketDetail;D=APHIS-2007-0127.*
- *Postal Mail/Commercial Delivery:* Send your comment to Docket No. APHIS–2007–0127, Regulatory Analysis and Development, PPD, APHIS, Station 3A–03.8, 4700 River Road Unit 118, Riverdale, MD 20737–1238.

Supporting documents and any comments we receive on this docket may be viewed at *http://www.regulations.gov/#!docketDetail;D=APHIS-2007-0127* or in our reading room, which is located in Room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799–7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Diane Sutton, National Scrapie Program Coordinator, Sheep, Goat, Cervid & Equine Health Center, Surveillance, Preparedness and Response Services, VS, APHIS, 4700 River Road, Unit 43, Riverdale, MD 20737–1235; (301) 851–3509.

SUPPLEMENTARY INFORMATION: On September 10, 2015, we published in the **Federal Register** (80 FR 54660–54692, Docket No. APHIS–2007–0127) a proposal to revise completely the scrapie regulations in 9 CFR parts 54 and 79, which concern the risk groups and categories established for individual animals and for flocks, the use of genetic testing as a means of assigning risk levels to animals, movement restrictions for animals found to be genetically less susceptible or resistant to scrapie, and recordkeeping requirements.

Comments on the proposed rule were required to be received on or before November 9, 2015. We are reopening the comment period on Docket No. APHIS–2007–0127 for an additional 30 days until December 9, 2015. We will also consider all comments received between November 9, 2015, and the date of this notice. This action will allow interested persons additional time to prepare and submit comments.

Authority: 7 U.S.C. 8301–8317; 7 CFR 2.22, 2.80, and 371.4.

Done in Washington, DC, this 9th day of November 2015.

Kevin Shea,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 2015–29179 Filed 11–13–15; 8:45 am]

BILLING CODE 3410–34–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R10–OAR–2015–0398: FRL–9937–11–Region 10]

Approval of Regional Haze BART Alternative Measure: Washington

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a Best Available Retrofit Technology (BART) alternative measure for the BP Cherry Point Refinery located near Ferndale, Washington. The BART alternative measure increases the oxides of nitrogen (NO_X) emission limit from the R–1 HC Reactor Heater (R–1 Heater), a BART-eligible source currently subject to BART emission limits on NO_X. To offset the increase in NO_X emissions from this emission unit, the NO_X emission limits on the 1st Stage Hydrocracker Fractionator Reboiler (R–1 Reboiler), also a BART-eligible source subject to BART emission limits on NO_X, will be reduced. The net effect of these changes is a decrease of 10.4 tons per year (tpy) of allowable NO_X emissions from sources subject to BART at the BP Cherry Point Refinery.

DATES: Comments must be received on or before December 16, 2015.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R10–OAR–2015–0398, by one of the following methods:

- *www.regulations.gov:* Follow the on-line instructions for submitting comments.
- *Email: R10-Public_Comments@epa.gov.*
- *Mail:* Steve Body, EPA Region 10, Office of Air, Waste and Toxics (AWT–150), 1200 Sixth Avenue, Suite 900, Seattle, WA 98101.
- *Hand Delivery/Courier:* EPA Region 10, 1200 Sixth Avenue, Suite 900, Seattle, WA 98101. Attention: Steve Body, Office of Air, Waste and Toxics, AWT–150. Such deliveries are only accepted during normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA–R10–OAR–2015–

0398. The 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 the disclosure of which 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 the 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 the 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, the 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 the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *e.g.,* CBI 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 hard copy. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy during normal business hours at the Office of Air, Waste and Toxics, EPA Region 10, 1200 Sixth Avenue, Seattle WA, 98101.

FOR FURTHER INFORMATION CONTACT: Steve Body at (206) 553–0782, *body.steve@epa.gov,* or the above EPA, Region 10 address.

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

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I. Background

In the Clean Air Act (CAA) Amendments of 1977, Congress established a program to protect and improve visibility in the Nation's national parks and wilderness areas. See CAA section 169A. Congress amended the visibility provisions in the CAA in 1990 to focus attention on the problem of regional haze. See CAA section 169B. The EPA promulgated regional haze regulations (RHR) in 1999 to implement sections 169A and 169B of the CAA. These regulations require states to develop and implement plans to ensure reasonable progress toward improving visibility in mandatory Class I Federal areas 1 [1] (Class I areas). See 64 FR 35714 (July 1, 1999); sec also 70 FR 39104 (July 6, 2005) and 71 FR 60612 (October 13, 2006).

Regional haze is impairment of visual range or colorization caused by air pollution, principally fine particulate, produced by numerous sources and activities, located across a broad regional area. The sources include but are not limited to, major and minor stationary sources, mobile sources, and area sources including non-anthropogenic sources. These sources and activities may emit fine particles ($PM_{2.5}$) (*e.g.,* sulfates, nitrates, organic carbon, elemental carbon, and soil dust), and their precursors (*e.g.,* sulfur dioxide (SO_2), NO_X, and in some cases, ammonia and volatile organic compounds). Fine particulate can also cause serious health effects and mortality in humans, and contributes to environmental effects such as acid deposition and eutrophication. See 64 FR at 35715. Data from the existing visibility monitoring network, the ''Interagency Monitoring of Protected Visual Environments'' (IMPROVE) monitoring network, show that visibility impairment caused by air pollution occurs virtually all the time in most national parks and wilderness areas. The average visual range in many Class I areas in the western United States is 100–150 kilometers, or about one-half to two-thirds the visual range that would exist without manmade air pollution.[2] Visibility impairment also varies day-to-day and by season depending on variations in meteorology and emission rates. The deciview (dv) is the metric by which visibility is measured in the regional haze program. A change of 1 dv is generally considered the change in visual range that the human eye can perceive.

The RHR requires each state's regional haze implementation plan to contain emission limitations representing BART and schedules for compliance with BART for each source subject to BART, unless the state demonstrates that an emissions trading program or other alternative measure will achieve greater reasonable progress toward natural visibility conditions.

II. Regional Haze Rule Provisions for BART Alternative Measures

The RHR contains provisions whereby a state may choose to implement an alternative measure as an alternative to BART if the state can demonstrate that the alternative measure achieves greater reasonable progress toward achieving natural visibility conditions than would be achieved through the installation, operation and maintenance of BART. The requirements for alternative measures are established at 40 CFR 51.308(e)(2). As explained in the RHR, the state must demonstrate that all necessary emission reductions will take place during the first long term strategy period (*i.e.,* by 2018) and that the emissions reductions resulting from the alternative measure will be surplus to those reductions resulting from measures adopted to meet requirements of the CAA as of the baseline date of the SIP. See 40 CFR 51.308(e)(2)(iii) and (iv). Sources subject to BART must be in compliance with the BART emission limitations as expeditiously as practical but no later than 5 years after EPA approves the implementation plan revision. See 40 CFR 51.308(e)(1)(iv).

III. Washington's State Implementation Plan Revision Submittal

On December 22, 2010, Washington submitted to the EPA for approval a

[1] Areas designated as mandatory Class I Federal areas consist of national parks exceeding 6000 acres, wilderness areas and national memorial parks exceeding 5000 acres, and all international parks that were in existence on August 7, 1977. 42 U.S.C. 7472(a). In accordance with section 169A of the CAA, the EPA, in consultation with the Department of Interior, promulgated a list of 156 areas where visibility is identified as an important value. 44 FR 69122 (November 30, 1979). The extent of a mandatory Class I area includes subsequent changes in boundaries, such as park expansions. 42 U.S.C. 7472(a). Although states and tribes may designate as Class I additional areas which they consider to have visibility as an important value, the requirements of the visibility program set forth in section 169A of the CAA apply only to ''mandatory Class I Federal areas.'' Each mandatory Class I Federal area is the responsibility of a ''Federal Land Manager.'' 42 U.S.C. 7602(i). When we use the term ''Class I area'' in this action, we mean a ''mandatory Class I Federal area.''

[2] 64 FR at 35715.

Regional Haze State Implementation Plan (2010 RH SIP) to meet the requirements of 40 CFR 51.308. The SIP submittal covers the planning period of 2008 through 2018 and, among the other required elements, includes a BART determination for the BP Cherry Point Refinery located near Ferndale Washington. On June 11, 2014, the EPA approved certain BART-related provisions of Washington's 2010 RH SIP, including the final BART determination for the BP Cherry Point Refinery. See 79 FR 33438. That approval incorporated by reference specified conditions of Administrative Order No. 7836 issued by Washington to BP Cherry Point Refinery on July 7, 2010 (Original BART Order). See 40 CFR 52.2470(d).

On May 8, 2015, the State submitted a revision to the 2010 RH SIP that includes a BART alternative measure for the BP Cherry Point Refinery. This BART alternative measure is contained in Administrative Order 7836, Revision 2-Inclusion of BART Alternative, dated May 13, 2015 (Revision 2). The BART alternative measure would revise the BART emission limits in Conditions 2.6.1.2 and 2.7.1 of the original BART Order that apply to the R1-Heater and R1-Boiler, respectively, and are currently incorporated by reference into the Federally-approved SIP for Washington. The current Federally-approved Condition 2.6.1.2 limits NO_X emissions from the R1-Heater to 3.6 pounds per hour (lb/hr) based on a 24-hour rolling average. Condition 2.5.1.2 of Revision 2 increases the NO_X emission limit on the R1-Heater to 4.9 lb/hr based on a 24-hour rolling average.

To offset the NO_X emissions increase at the R1-Heater, Revision 2 contains a BART alternative measure. Revision 2 decreases the NO_X emission limits for the R1-Boiler associated with the hydrocracker to reflect the installation of ultra-low NO_X burners that were installed after Washington's submission of the 2010 RH SIP. Condition 2.7.1 of the original BART Order currently approved in the SIP limits NO_X emissions from the R1-Boiler to 0.07 pounds per million British thermal units (lb/MMBtu) and 56.2 tpy. Condition 2.6.2 of Revision 2 reduces these limits to 0.05 lb/MMBtu and 9.9 lb/hr.

Revision 2 also: (1) Adds language clarifying that when an emission unit subject to BART is decommissioned and permanently taken out of service, the BART emission limits no longer apply to that unit and, (2) allows the State to revise the monitoring, recordkeeping, and reporting requirements through issuance of a regulatory order, rather than through a revision of the BART order, provided the revised monitoring, recordkeeping, and reporting provide equal or better information on the compliance status of the emission unit in question.[3]

IV. The EPA's Evaluation of SIP Revision Submittal

A. BART Alternative Measure

The EPA evaluated the emission reductions associated with the BART alternative measure. The BART alternative measure revises the 24-hour maximum mass emission limit for the R–1 Heater, but does not revise the concentration limit for this unit. The concentration limit remains 26 parts per million by volume, dry basis, corrected to 7 percent oxygen, based on a 24-hour rolling average. However, Washington requests approval to revise the Federally-approved NO_X BART mass emission limit on the R1–Heater from 3.6 lb/hr to 4.9 lb/hr of NO_X, reflecting an increase in operation of the burners from 88 mmBTU/hr to 120 mmBTU/hr. This change results in an increase in the hourly average mass emission limit from the R–1 Heater of 1.3 lb/hr of NO_X. The increase in annual emissions is 5.7 tons of NO_X per year.

The increase in the allowable mass NO_X emissions from the R–1 Heater is offset by a decrease in the emission limit for the R–1 Reboiler. This decrease results from the installation of ultra-low NO_X burners on the R–1 Reboiler. The emission limit is reduced from the current 0.07 lb/MMBtu and 12.8 lb/hr to 0.05 lb/MMBtu and 9.9 lb/hr. The net emission reduction in allowable NO_X emissions as a result of the BART alternative measure is 1.6 lb/hr, on a 24-hour rolling average. These emission reductions are not otherwise required by the CAA as of the baseline date of Washington's regional haze SIP and thus may be considered surplus.

These are emission reductions that are achieved at the same location and for the same visibility impairing pollutant, NO_X. Thus, because the BART alternative measure in Washington's submission results in a greater emissions reduction than BART, the BART alternative measure is deemed to achieve greater reasonable progress. See 40 CFR 51.308(e)(3). With reduced NO_X emissions, reduced visibility impairment from the formation of secondary nitrate would be expected.

The EPA believes the BART alternative measure submitted by Washington as a SIP revision meets the requirements of 40 CFR 51.308(e)(2) and proposes to approve it.

B. Decommissioned BART Units

Condition 9 of Revision 2 is a new provision that states the BART requirements for an emission unit specifically listed in Revision 2 do not apply after the BP Cherry Point Refinery has certified in writing to Washington and the local air pollution authority that the named BART emission unit ''has been permanently taken out of service and dismantled.'' The State explains in its submittal that any replacement unit would be subject to new source review and would not be subject to BART. Ecology's SIP meets the requirements for new source review under 40 CFR 51.307 and will ensure that new subject sources will not have an adverse impact on visibility and will be consistent with making reasonable further progress towards the national visibility goal, as applicable. See WAC 173–400–117.

Although not a BART requirement on the BP Cherry Point Refinery, this condition results in a clear statement that BART requirements no longer apply to an emission unit once subject to BART that has been permanently taken out of service and dismantled. The EPA therefore proposes to approve Condition 9.

C. Revisions to Monitoring, Recordkeeping, and Reporting

As discussed above, Revision 2 includes a provision authorizing the State to revise the monitoring, recordkeeping, and reporting requirements in Revision 2 in a regulatory order. See Revision 2, Condition 10. Washington explains that any revised monitoring, recordkeeping, and reporting requirements approved by the State under Condition 10 will need to be submitted to, and approved by, the EPA as a SIP revision in order to become the applicable federally-enforceable monitoring, recordkeeping, and reporting requirements. Thus, in the interim, both sets of monitoring, recordkeeping, and reporting requirements apply to the source and must be included in the Title V permit. The EPA agrees with this assessment.

[3] Between issuing the original BART Order that was incorporated into the SIP and submission of BART Order Revision 2, Washington issued BP a BART Order Revision 1 in May 2013 (Revision 1). Revision 1 removed from the Original BART Order the conditions for Boilers #6 and #7, two units that were not BART-eligible. Boilers #6 and #7 replaced Boilers #1 and #3 that were subject to BART. This action resulted in a renumbering of conditions in the order. The original BART Order required that Boilers #1 and #3 be decommissioned by no later than March 27, 2010. Boilers #6 and #7 were subject to New Source Review and are not subject to BART. The Conditions in the Original BART Order applicable to Boilers #6 and #7 were not incorporated into the SIP, see 79 FR 33440, and Revision 1 was not submitted by Washington to the EPA as a SIP revision.

The EPA has a longstanding interpretation of the CAA that prohibits ''director's discretion'' provisions in SIPs if they provide unbounded discretion to allow what would amount to a case-specific revision of the SIP without meeting the statutory requirements of the CAA for SIP revisions. See 80 FR 33840, 22874–75 (June 12, 2015); see also 40 CFR 52.2476 (specifically providing that any change of a provision to the Washington SIP must be submitted by the State for approval by the EPA in accordance with 40 CFR 51.104). Accordingly, the EPA is proposing to not approve Condition 10.

V. The EPA's Proposed Action

The EPA proposes to approve the BART alternative measure for the BP Cherry Point Refinery located near Ferndale, Washington by incorporating by reference the conditions of Revision 2 identified below. The EPA proposes to remove the BP Cherry Point Refinery, BART Compliance Order No. 7836 currently in the Federally approved SIP at 40 CFR 52.2470(d) and replace it with provisions of the BP Cherry Point Refinery, BART Compliance Order No. 7836 Revision 2. The EPA is also proposing to approve new Condition 9 of the BART Compliance Order 7836 Revision 2 relating to decommissioned units. The conditions of the BP BART Compliance Order Revision 2 that are proposed for incorporation by reference are:

Condition 1: 1.1, 1.1.1, 1.2, 1.2.1, 1.2.2;

Condition 2: 2.1, 2.1.1, 2.1.2, 2.1.3, 2.1.4, 2.1.5, 2.2, 2.2.1, 2.2.2, 2.3, 2.3.1, 2.3.2, 2.4, 2.4.1, 2.4.2, 2.4.2.1, 2.5, 2.5.1, 2.5.1.1, 2.5.1.2, 2.5.2, 2.5.3, 2.5.4, 2.6, 2.6.1, 2.6.2, 2.6.3, 2.7, 2.7.1, 2.7.2, 2.7.3, 2.7.4, 2.8, 2.8.1, 2.8.2, 2.8.3, 2.8.4, 2.8.5, 2.8.6;

Condition 3, 3.1, 3.1.1, 3.1.2, 3.2, 3.2.1, 3.2.2, 3.2.3, 3.2.4;

Condition 4, 4.1, 4.1.1, 4.1.1.1, 4.1.1.2, 4.1.1.3, 4.1.1.4;

Condition 5, 5.1, 5.2;

Condition 6, 6.1, 6.2, 6.3;

Condition 7; and

Condition 9.

VI. Incorporation by Reference

In accordance with requirements of 1 CFR 51.5, the EPA is proposing to revise our incorporation by reference located in 40 CFR 52.2470(d)—''EPA-Approved State Source-Specific Requirements—Washington'' to reflect the proposed approval of the BART alternative measure for the BP Cherry Point Refinery and the provision relating to decommissioned units. Due to the fact that the conditions in the original BART Order were renumbered in Revision 1, which was not submitted as a SIP revision, the EPA is proposing to remove the original IBR entry for ''BP Cherry Point Refinery'' in its entirety and incorporate in its place the specified conditions of Revision 2 included in the docket for this action. The end result is that all of the conditions in the Original BART order remain in the SIP (but with different numbers) except as discussed above with respect to the BART alternative measure and the addition of Condition 9. The EPA has made, and will continue to make, these documents generally available electronically through *www.regulations.gov* and/or in hard copy at the appropriate EPA office (see the **ADDRESSES** section of this preamble for more information).

VII. Statutory and Executive Order Reviews

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

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 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, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the Clean Air Act; and
- does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

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

List of Subjects in 40 CFR Part 52

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

Dated: November 3, 2015.

Dennis J. McLerran,

Regional Administrator.

[FR Doc. 2015–29175 Filed 11–13–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2015–0710; FRL–9937–09–Region 7]

Approval of Air Quality State Implementation Plans (SIP); State of Nebraska; Infrastructure SIP Requirements for the 2008 Ozone National Ambient Air Quality Standard in Regards to Section 110(a)(2)(D)(i)(I)—Prongs 1 and 2

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve elements of a State Implementation Plan (SIP) submission from the State of Nebraska addressing the applicable requirements of Clean Air Act (CAA) section 110 for the 2008 National Ambient Air Quality Standards (NAAQS) for Ozone (O_3). CAA section 110 requires that each state adopt and submit a SIP to support implementation, maintenance, and enforcement of each

new or revised NAAQS promulgated by EPA. These SIPs are commonly referred to as ''infrastructure'' SIPs. The infrastructure requirements are designed to ensure that the structural components of each state's air quality management program are adequate to meet the state's responsibilities under the CAA.

Specifically, EPA is proposing to approve Nebraska's SIP as it relates to section 110 (a)(2)(D)(i)(I) prongs 1 and 2, for the 2008 O_3 NAAQS.

DATES: Comments must be received on or before December 16, 2015.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R07–OAR–2015–0710, to *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from Regulations.gov. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.*, on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

Publicly available docket materials are available either electronically in *www.regulations.gov* or at the Environmental Protection Agency, Air Planning and Development Branch, 11201 Renner Boulevard, Lenexa, Kansas 66219. The Regional Office's official hours of business are Monday through Friday, 8:00 a.m. to 4:30 p.m., excluding legal holidays. The interested persons wanting to examine these documents should make an appointment with the office at least 24 hours in advance.

FOR FURTHER INFORMATION CONTACT: Mr. Gregory Crable, Air Planning and Development Branch, U.S. Environmental Protection Agency, Region 7, 11201 Renner Boulevard, Lenexa, KS 66219; *telephone number:* (913) 551–7391; *fax number:* (913) 551–7065; *email address: crable.gregory@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document whenever ''we,'' ''us,'' or ''our'' is used, we refer to EPA. This section provides additional information by addressing the following questions:

I. What is a section 110(a)(1) and (2) infrastructure SIP?
II. What are the applicable elements under sections 110(a)(1) and (2)?
III. What is EPA's approach to the review of infrastructure SIP submissions?
IV. What is EPA's evaluation of how the state addressed the relevant elements of sections 110(a)(1) and (2)?
V. What action is EPA proposing?
VI. Statutory and Executive Order Review

I. What is a section 110(a)(1) and (2) infrastructure SIP?

Section 110(a)(1) of the CAA requires, in part, that states make a SIP submission to EPA to implement, maintain and enforce each of the NAAQS promulgated by EPA after reasonable notice and public hearings. Section 110(a)(2) includes a list of specific elements that such infrastructure SIP submissions must address. SIPs meeting the requirements of sections 110(a)(1) and (2) are to be submitted by states within three years after promulgation of a new or revised NAAQS. These SIP submissions are commonly referred to as ''infrastructure'' SIPs.

II. What are the applicable elements under sections 110(a)(1) and (2)?

On March 12, 2008, EPA promulgated a revised NAAQS for ozone based on 8-hour average concentrations. The level of the 2008 8-hour ozone NAAQS (hereafter the 2008 O_3 NAAQS) was revised from 0.08 parts per million (ppm) to 0.075 ppm (73 FR 16436).

For the 2008 O_3 NAAQS, states typically have met many of the basic program elements required in section 110(a)(2) through provisions adopted in earlier SIP submissions in connection with previous NAAQS. Nevertheless, pursuant to section 110(a)(1), states must review and revise, as appropriate, their existing SIPs to ensure that the SIPs are adequate to address the 2008 O_3 NAAQS. To assist states in meeting this statutory requirement, EPA issued guidance on September 13, 2013 (2013 Guidance), addressing the infrastructure SIP elements required to be addressed under section 110 (a)(1) and (2) for the 2008 O_3 NAAQS.[1] In a previous final rulemaking (80 FR 55266, September 15, 2015) EPA addressed elements (A through C), (D)(i)(II), and (E through M). As discussed in that notice, EPA planned to take separate action on section 110(a)(2)(D)(i)(I)—prongs 1 and 2 on a timeline consistent with a deadline agreed to by the parties and entered by the court in *Sierra Club* v. *McCarthy* 4:14–cv–05091–YGR (N.D. Cal. May 15, 2015). In this action, EPA proposes action that, if finalized, fulfills that commitment to take final action as to Nebraska's SIP submission addressing section 110(a)(2)(D)(i)(I).

[1] Stephen D. Page, Director, Air Quality Policy Division, Office of Air Quality Planning and Standards, ''Guidance on Infrastructure State Implementation Plan (SIP) Elements Under Clean Air Act Sections 110(a)(1) and 110(a)(2),'' Memorandum to EPA Regional Air Division Directors, Regions I–X, September 13, 2013.

III. What is EPA's approach to the review of infrastructure SIP submissions?

EPA is acting upon the February 11, 2013, SIP submission from Nebraska that addresses the infrastructure requirements of CAA sections 110(a)(1) and 110(a)(2) for the 2008 O_3 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 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.[2] 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.

The following examples of ambiguities illustrate the need for EPA to interpret some section 110(a)(1) and section 110(a)(2) requirements with respect to infrastructure SIP submissions for a given new or revised NAAQS. One example of ambiguity is that section 110(a)(2) requires that ''each'' SIP submission must meet the list of requirements therein, while EPA has long noted that this literal reading of the statute is internally inconsistent and would create a conflict with the nonattainment provisions in part D of title I of the Act, which specifically address nonattainment SIP requirements.[3] Section 110(a)(2)(I) pertains to nonattainment SIP requirements and part D addresses when attainment plan SIP submissions to address nonattainment area requirements are due. For example, section 172(b) requires EPA to establish a schedule for submission of such plans for certain pollutants when the Administrator promulgates the designation of an area as nonattainment, and section 107(d)(1)(B) allows up to two years, or in some cases three years, for such designations to be promulgated.[4] This ambiguity illustrates that rather than apply all the stated requirements of section 110(a)(2) in a strict literal sense, EPA must determine which provisions of section 110(a)(2) are applicable for a particular infrastructure SIP submission.

Another example of ambiguity within sections 110(a)(1) and 110(a)(2) with respect to infrastructure SIPs pertains to whether states must meet all of the infrastructure SIP requirements in a single SIP submission, and whether EPA must act upon such SIP submission in a single action. Although section 110(a)(1) directs states to submit ''a plan'' to meet these requirements, EPA interprets the CAA to allow states to make multiple SIP submissions separately addressing infrastructure SIP elements for the same NAAQS. If states elect to make such multiple SIP submissions to meet the infrastructure SIP requirements, EPA can elect to act on such submissions either individually or in a larger combined action.[5] Similarly, EPA interprets the CAA to allow it to take action on the individual parts of one larger, comprehensive infrastructure SIP submission for a given NAAQS without concurrent action on the entire submission. For example, EPA has sometimes elected to act at different times on various elements and sub-elements of the same infrastructure SIP submission.[6]

Ambiguities within sections 110(a)(1) and 110(a)(2) may also arise with respect to infrastructure SIP submission requirements for different NAAQS. Thus, EPA notes that not every element of section 110(a)(2) would be relevant, or as relevant, or relevant in the same way, for each new or revised NAAQS. The states' attendant infrastructure SIP submissions for each NAAQS therefore could be different. For example, the monitoring requirements that a state might need to meet in its infrastructure SIP submission for purposes of section 110(a)(2)(B) could be very different for different pollutants, for example, because the content and scope of a state's infrastructure SIP submission to meet this element might be very different for an entirely new NAAQS than for a minor revision to an existing NAAQS.[7]

EPA notes that interpretation of section 110(a)(2) is also necessary when EPA reviews other types of SIP submissions required under the CAA. Therefore, as with infrastructure SIP submissions, EPA also has to identify and interpret the relevant elements of section 110(a)(2) that logically apply to these other types of SIP submissions. For example, section 172(c)(7) requires that attainment plan SIP submissions required by part D have to meet the ''applicable requirements'' of section 110(a)(2). Thus, for example, attainment plan SIP submissions must meet the requirements of section 110(a)(2)(A) regarding enforceable emission limits and control measures and section 110(a)(2)(E)(i) regarding air agency resources and authority. By contrast, it is clear that attainment plan SIP submissions required by part D would not need to meet the portion of section 110(a)(2)(C) that pertains to the PSD program required in part C of title I of the CAA, because PSD does not apply to a pollutant for which an area is designated nonattainment and thus subject to part D planning requirements. As this example illustrates, each type of SIP submission may implicate some elements of section 110(a)(2) but not others.

Given the potential for ambiguity in some of the statutory language of section 110(a)(1) and section 110(a)(2), EPA believes that it is appropriate to interpret the ambiguous portions of section 110(a)(1) and section 110(a)(2) in the context of acting on a particular SIP submission. In other words, EPA assumes that Congress could not have

[2] 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.

[3] See, *e.g.,* ''Rule To Reduce Interstate Transport of Fine Particulate Matter and Ozone (Clean Air Interstate Rule); Revisions to Acid Rain Program; Revisions to the NO_X SIP Call; Final Rule,'' 70 FR 25162, at 25163–65 (May 12, 2005) (explaining relationship between timing requirement of section 110(a)(2)(D) versus section 110(a)(2)(I)).

[4] EPA notes that this ambiguity within section 110(a)(2) is heightened by the fact that various subparts of part D set specific dates for submission of certain types of SIP submissions in designated nonattainment areas for various pollutants. Note, *e.g.*, that section 182(a)(1) provides specific dates for submission of emissions inventories for the ozone NAAQS. Some of these specific dates are necessarily later than three years after promulgation of the new or revised NAAQS.

[5] See, *e.g.,* ''Approval and Promulgation of Implementation Plans; New Mexico; Revisions to the New Source Review (NSR) State Implementation Plan (SIP); Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NNSR) Permitting,'' 78 FR 4339 (January 22, 2013) (EPA's final action approving the structural PSD elements of the New Mexico SIP submitted by the State separately to meet the requirements of EPA's 2008 $PM_{2.5}$ NSR rule), and ''Approval and Promulgation of Air Quality Implementation Plans; New Mexico; Infrastructure and Interstate Transport Requirements for the 2006 $PM_{2.5}$ NAAQS,'' (78 FR 4337) (January 22, 2013) (EPA's final action on the infrastructure SIP for the 2006 $PM_{2.5}$ NAAQS).

[6] On December 14, 2007, the State of Tennessee, through the Tennessee Department of Environment and Conservation, made a SIP revision to EPA demonstrating that the State meets the requirements of sections 110(a)(1) and (2). EPA proposed action for infrastructure SIP elements (C) and (J) on January 23, 2012 (77 FR 3213) and took final action on March 14, 2012 (77 FR 14976). On April 16, 2012 (77 FR 22533) and July 23, 2012 (77 FR 42997), EPA took separate proposed and final actions on all other section 110(a)(2) infrastructure SIP elements of Tennessee's December 14, 2007, submittal.

[7] For example, implementation of the 1997 $PM_{2.5}$ NAAQS required the deployment of a system of new monitors to measure ambient levels of that new indicator species for the new NAAQS.

intended that each and every SIP submission, regardless of the NAAQS in question or the history of SIP development for the relevant pollutant, would meet each of the requirements, or meet each of them in the same way. Therefore, EPA has adopted an approach under which it reviews infrastructure SIP submissions against the list of elements in section 110(a)(2), but only to the extent each element applies for that particular NAAQS.

Historically, EPA has elected to use guidance documents to make recommendations to states for infrastructure SIPs, in some cases conveying needed interpretations on newly arising issues and in some cases conveying interpretations that have already been developed and applied to individual SIP submissions for particular elements.[8] EPA most recently issued guidance for infrastructure SIPs on September 13, 2013 (2013 Guidance).[9] EPA developed the 2013 Guidance document to provide states with up-to-date guidance for infrastructure SIPs for any new or revised NAAQS. Within the 2013 guidance, EPA describes the duty of states to make infrastructure SIP submissions to meet basic structural SIP requirements within three years of promulgation of a new or revised NAAQS. EPA also made recommendations about many specific subsections of section 110(a)(2) that are relevant in the context of infrastructure SIP submissions.[10] The guidance also discusses the substantively important issues that are germane to certain subsections of section 110(a)(2). Significantly, EPA interprets sections 110(a)(1) and 110(a)(2) such that infrastructure SIP submissions need to address certain issues and need not address others. Accordingly, EPA reviews each infrastructure SIP submission for compliance with the applicable statutory provisions of section 110(a)(2), as appropriate.

As an example, section 110(a)(2)(E)(ii) is a required element of section 110(a)(2) for infrastructure SIP submissions. Under this element, a state must meet the substantive requirements of section 128, which pertain to state boards that approve permits or enforcement orders and heads of executive agencies with similar powers. Thus, EPA reviews infrastructure SIP submissions to ensure that the state's SIP appropriately addresses the requirements of section 110(a)(2)(E)(ii) and section 128. The 2013 Guidance explains EPA's interpretation that there may be a variety of ways by which states can appropriately address these substantive statutory requirements, depending on the structure of an individual state's permitting or enforcement program (*e.g.*, whether permits and enforcement orders are approved by a multi-member board or by a head of an executive agency). However they are addressed by the state, the substantive requirements of section 128 are necessarily included in EPA's evaluation of infrastructure SIP submissions because section 110(a)(2)(E)(ii) explicitly requires that the state satisfy the provisions of section 128.

As another example, EPA's review of infrastructure SIP submissions with respect to the PSD program requirements in sections 110(a)(2)(C), (D)(i)(II), and (J) focuses upon the structural PSD program requirements contained in part C and EPA's PSD regulations. Structural PSD program requirements include provisions necessary for the PSD program to address all regulated sources and New Source Review (NSR) pollutants, including greenhouse gases (GHGs). By contrast, structural PSD program requirements do not include provisions that are not required under EPA's regulations at 40 CFR 51.166 but are merely available as an option for the state, such as the option to provide grandfathering of complete permit applications with respect to the 2012 $PM_{2.5}$ NAAQS. Accordingly, the latter optional provisions are types of provisions EPA considers irrelevant in the context of an infrastructure SIP action.

For other section 110(a)(2) elements, however, EPA's review of a state's infrastructure SIP submission focuses on assuring that the state's SIP meets basic structural requirements. For example, section 110(a)(2)(C) includes, *inter alia*, the requirement that states have a program to regulate minor new sources. Thus, EPA evaluates whether the state has an EPA-approved minor NSR program and whether the program addresses the pollutants relevant to that NAAQS. In the context of acting on an infrastructure SIP submission, however, EPA does not think it is necessary to conduct a review of each and every provision of a state's existing minor source program (*i.e.*, already in the existing SIP) for compliance with the requirements of the CAA and EPA's regulations that pertain to such programs.

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 that may be contrary to the CAA and EPA's policies addressing such excess emissions (''SSM''); (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 PSD programs that may be inconsistent with current requirements of EPA's ''Final NSR Improvement Rule,'' 67 FR 80186 (December 31, 2002), as amended by 72 FR 32526 (June 13, 2007) (''NSR Reform''). Thus, EPA believes it may approve an infrastructure SIP submission without scrutinizing the totality of the existing SIP for such potentially deficient provisions and may approve the submission even if it is aware of such existing provisions.[11] It is important to note that EPA's approval of a state's infrastructure SIP submission should not be construed as explicit or implicit re-approval of any existing potentially deficient provisions that relate to the three specific issues just described.

EPA's approach to review of infrastructure SIP submissions is to identify the CAA requirements that are

[8] EPA notes, however, that nothing in the CAA requires EPA to provide guidance or to promulgate regulations for infrastructure SIP submissions. The CAA directly applies to states and requires the submission of infrastructure SIP submissions, regardless of whether or not EPA provides guidance or regulations pertaining to such submissions. EPA elects to issue such guidance in order to assist states, as appropriate.

[9] ''Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act Sections 110(a)(1) and 110(a)(2),'' Memorandum from Stephen D. Page, September 13, 2013.

[10] EPA's September 13, 2013, guidance did not make recommendations with respect to infrastructure SIP submissions to address section 110(a)(2)(D)(i)(I). EPA issued the guidance shortly after the U.S. Supreme Court agreed to review the D.C. Circuit decision in *EME Homer City*, 696 F.3d 7 (D.C. Cir. 2012) which had interpreted the requirements of section 110(a)(2)(D)(i)(I). In light of the uncertainty created by this litigation (which culminated in the Supreme Court's April 29, 2014 decision at 134 SCt. 1584), EPA elected not to provide additional guidance on the requirements of section 110(a)(2)(D)(i)(I) at that time. As the guidance is neither binding nor required by statute, whether EPA elects to provide guidance on a particular section has no impact on a state's CAA obligations.

[11] By contrast, EPA notes that if a state were to include a new provision in an infrastructure SIP submission that contained a legal deficiency, such as a new exemption for excess emissions during SSM events, then EPA would need to evaluate that provision for compliance against the rubric of applicable CAA requirements in the context of the action on the infrastructure SIP.

logically applicable to that submission. EPA believes that this approach to the review of a particular infrastructure SIP submission is appropriate, because it would not be reasonable to read the general requirements of section 110(a)(1) and the list of elements in section 110(a)(2) as requiring review of each and every provision of a state's existing SIP against all requirements in the CAA and EPA regulations merely for purposes of assuring that the state in question has the basic structural elements for a functioning SIP for a new or revised NAAQS. Because SIPs have grown by accretion over the decades as statutory and regulatory requirements under the CAA have evolved, they may include some outmoded provisions and historical artifacts. These provisions, while not fully up to date, nevertheless may not pose a significant problem for the purposes of ''implementation, maintenance, and enforcement'' of a new or revised NAAQS when EPA evaluates adequacy of the infrastructure SIP submission. EPA believes that a better approach is for states and EPA to focus attention on those elements of section 110(a)(2) of the CAA most likely to warrant a specific SIP revision due to the promulgation of a new or revised NAAQS or other factors.

For example, EPA's 2013 Guidance gives simpler recommendations with respect to carbon monoxide than other NAAQS pollutants to meet the visibility requirements of section 110(a)(2)(D)(i)(II), because carbon monoxide does not affect visibility. As a result, an infrastructure SIP submission for any future new or revised NAAQS for carbon monoxide need only state this fact in order to address the visibility prong of section 110(a)(2)(D)(i)(II).

Finally, EPA believes that its approach with respect to infrastructure SIP requirements is based on a reasonable reading of sections 110(a)(1) and 110(a)(2) because the CAA provides other avenues and mechanisms to address specific substantive deficiencies in existing SIPs. These other statutory tools allow EPA to take appropriately tailored action, depending upon the nature and severity of the alleged SIP deficiency. Section 110(k)(5) authorizes EPA to issue a ''SIP call'' whenever the Agency determines that a state's SIP is substantially inadequate to attain or maintain the NAAQS, to mitigate interstate transport, or to otherwise comply with the CAA.[12] Section 110(k)(6) authorizes EPA to correct errors in past actions, such as past approvals of SIP submissions.[13] Significantly, EPA's determination that an action on a state's infrastructure SIP submission is not the appropriate time and place to address all potential existing SIP deficiencies does not preclude EPA's subsequent reliance on provisions in section 110(a)(2) as part of the basis for action to correct those deficiencies at a later time. For example, although it may not be appropriate to require a state to eliminate all existing inappropriate director's discretion provisions in the course of acting on an infrastructure SIP submission, EPA believes that section 110(a)(2)(A) may be among the statutory bases that EPA relies upon in the course of addressing such deficiency in a subsequent action.[14]

IV. What is EPA's evaluation of how the state addressed the relevant elements of sections 110(a)(1) and (2)?

EPA Region 7 received Nebraska's infrastructure SIP submission for the 2008 O_3 standard on February 11, 2013. The SIP submission became complete as a matter of law on August 11, 2013. EPA has reviewed Nebraska's infrastructure SIP submission and the applicable statutory and regulatory authorities and provisions referenced in those submissions or referenced in Nebraska's SIP. EPA has previously approved sections 110(a)(2)(A), (B), (C), (D)(i)(II)— prong 3, (D)(ii), (E), (F), (G), (H), (J), (K), (L), and (M); did not propose any action on section 110(a)(2)(I)— Nonattainment Area Plan or Plan Revisions under part D; and disapproved 110(a)(2)(D)(i)(II)— prong 4, as it relates to the protection of visibility (80 FR 55266, September 15, 2015). EPA also stated that it would take action on section 110(a)(2)(D)(i)(I)— prongs 1 and 2 at a later time (80 FR 35290). A discussion of that action follows.

On March 12, 2008, the EPA revised 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). The CAA requires states to submit, within three years after promulgation of a new or revised standard, SIPs meeting the applicable ''infrastructure'' elements of sections 110(a)(1) and (2). One of these applicable infrastructure elements, CAA section 110(a)(2)(D)(i), requires SIPs to contain ''good neighbor'' provisions to prohibit certain adverse air quality effects on neighboring states due to interstate transport of pollution. There are four sub-elements (or prongs) within CAA section 110(a)(2)(D)(i). This action addresses the first two sub-elements of the good neighbor provisions, at CAA section 110(a)(2)(D)(i)(I). These sub-elements require that each SIP for a new or revised standard contain adequate provisions to prohibit any source or other type of emissions activity within the state from emitting air pollutants that will ''contribute significantly to nonattainment'' or ''interfere with maintenance'' of the applicable air quality standard in any other state. We note that the EPA has addressed the interstate transport requirements of CAA section 110(a)(2)(D)(i)(I) for the eastern portion of the United States in several past regulatory actions.[15] We most recently promulgated the Cross-State Air Pollution Rule (CSAPR), which addressed CAA section 110(a)(2)(D)(i)(I) in the eastern portion of the United States.[16] CSAPR addressed multiple national ambient air quality standards, but did not address the 2008 8-hour ozone standard.[17]

In CSAPR, the EPA used detailed air quality analyses to determine whether an eastern state's contribution to downwind air quality problems was at or above specific thresholds. If a state's contribution did not exceed the specified air quality screening threshold, the state was not considered ''linked'' to identified downwind nonattainment and maintenance receptors and was therefore not considered to significantly contribute or interfere with maintenance of the standard in those downwind areas. If a state exceeded that threshold, the state's

[12] For example, EPA issued a SIP call to Utah to address specific existing SIP deficiencies related to the treatment of excess emissions during SSM events. See ''Finding of Substantial Inadequacy of Implementation Plan; Call for Utah State Implementation Plan Revisions,'' 74 FR 21639 (April 18, 2011).

[13] EPA has used this authority to correct errors in past actions on SIP submissions related to PSD programs. See ''Limitation of Approval of Prevention of Significant Deterioration Provisions Concerning Greenhouse Gas Emitting-Sources in State Implementation Plans; Final Rule,'' 75 FR 82536 (December 30, 2010). EPA has previously used its authority under CAA section 110(k)(6) to remove numerous other SIP provisions that the Agency determined it had approved in error. See, *e.g.*, 61 FR 38664 (July 25, 1996) and 62 FR 34641 (June 27, 1997) (corrections to American Samoa, Arizona, California, Hawaii, and Nevada SIPs); 69 FR 67062 (November 16, 2004) (corrections to California SIP); and 74 FR 57051 (November 3, 2009) (corrections to Arizona and Nevada SIPs).

[14] See, *e.g.*, EPA's disapproval of a SIP submission from Colorado on the grounds that it would have included a director's discretion provision inconsistent with CAA requirements, including section 110(a)(2)(A). See, *e.g.*, 75 FR 42342 at 42344 (July 21, 2010) (proposed disapproval of director's discretion provisions); 76 FR 4540 (January 26, 2011) (final disapproval of such provisions).

[15] NO_X SIP Call, 63 FR 57371 (October 27, 1998); Clean Air Interstate Rule (CAIR), 70 FR 25172 (May 12, 2005); Cross-State Air Pollution Rule (CSAPR), 76 FR 48208 (August 8, 2011).

[16] 76 FR 48208.

[17] CSAPR addressed the 1997 8-hour ozone, and the 1997 and 2006 fine particulate matter NAAQS.

emissions were further evaluated, taking into account both air quality and cost considerations, to determine what, if any, emissions reductions might be necessary. For the reasons stated below, we believe it is appropriate to use the same approach we used in CSAPR to establish an air quality screening threshold for the evaluation of interstate transport requirements for the 2008 ozone standard.

In CSAPR, the EPA proposed an air quality screening threshold of one percent of the applicable NAAQS and requested comment on whether one percent was appropriate.[18] The EPA evaluated the comments received and ultimately determined that one percent was an appropriately low threshold because there were important, even if relatively small, contributions to identified nonattainment and maintenance receptors from multiple upwind states. In response to commenters who advocated a higher or lower threshold than one percent, the EPA compiled the contribution modeling results for CSAPR to analyze the impact of different possible thresholds for the eastern United States. The EPA's analysis showed that the one-percent threshold captures a high percentage of the total pollution transport affecting downwind states, while the use of higher thresholds would exclude increasingly larger percentages of total transport. For example, at a five percent threshold, the majority of interstate pollution transport affecting downwind receptors would be excluded.[19] In addition, the EPA determined that it was important to use a relatively lower one-percent threshold because there are adverse health impacts associated with ambient ozone even at low levels.[20] The EPA also determined that a lower threshold such as 0.5 percent would result in relatively modest increases in the overall percentages of fine particulate matter and ozone pollution transport captured relative to the amounts captured at the one-percent level. The EPA determined that a ''0.5 percent threshold could lead to emission reduction responsibilities in additional states that individually have a very small impact on those receptors—an indicator that emission controls in those states are likely to have a smaller air quality impact at the downwind receptor. We are not convinced that selecting a threshold below one percent is necessary or desirable.'' [21]

In the final CSAPR, the EPA determined that one percent was a reasonable choice considering the combined downwind impact of multiple upwind states in the eastern United States, the health effects of low levels of fine particulate matter and ozone pollution, and the EPA's previous use of a one-percent threshold in CAIR. The EPA used a single ''bright line'' air quality threshold equal to one percent of the 1997 8-hour ozone standard, or 0.08 ppm.[22] The projected contribution from each state was averaged over multiple days with projected high modeled ozone, and then compared to the one-percent threshold. We concluded that this approach for setting and applying the air quality threshold for ozone was appropriate because it provided a robust metric, was consistent with the approach for fine particulate matter used in CSAPR, and because it took into account, and would be applicable to, any future ozone standards below 0.08 ppm.[23]

On August 4, 2015, the EPA issued a Notice of Data Availability (NODA) containing air quality modeling data that applies the CSAPR approach to contribution projections for the year 2017 for the 2008 8-hour ozone NAAQS.[24] The moderate area attainment date for the 2008 ozone standard is July 11, 2018. In order to demonstrate attainment by this attainment deadline, states will use 2015 through 2017 ambient ozone data. Therefore, 2017 is an appropriate future year to model for the purpose of examining interstate transport for the 2008 ozone NAAQS. The EPA used photochemical air quality modeling to project ozone concentrations at air quality monitoring sites to 2017 and estimated state-by-state ozone contributions to those 2017 concentrations. This modeling used the Comprehensive Air Quality Model with Extensions (CAMx version 6.11) to model the 2011 base year, and the 2017 future base case emissions scenarios to identify projected nonattainment and maintenance sites with respect to the 2008 ozone NAAQS in 2017. The EPA used nationwide state-level ozone source apportionment modeling (CAMx Ozone Source Apportionment Technology/Anthropogenic Precursor Culpability Analysis technique) to quantify the contribution of 2017 base case NO_X and VOC emissions from all sources in each state to the 2017 projected receptors. The air quality model runs were performed for a modeling domain that covers the 48 contiguous United States and adjacent portions of Canada and Mexico. The NODA and the supporting technical support documents have been included in the docket for this SIP action.

The modeling data released in the NODA on July 23, 2015, is the most up-to-date information the EPA has developed to inform our analysis of upwind state linkages to downwind air quality problems. For purposes of evaluating Nebraska's interstate transport SIP with respect to the 2008 8-hour ozone standard, the EPA is proposing that states whose contributions are less than one percent to downwind nonattainment and maintenance receptors are considered non-significant. The modeling indicates that Nebraska's largest contribution to any projected downwind nonattainment site is 0.51 ppb and Nebraska's largest contribution to any projected downwind maintenance-only site is 0.36 ppb. 80 FR 46271.[25] These values are below the one percent screening threshold of 0.75 ppb, and therefore there are no identified linkages between Nebraska and 2017 downwind projected nonattainment and maintenance sites. Note that the EPA has not done an assessment to determine the applicability for the use of the one percent screening threshold for western states that contribute above the one percent threshold. There may be additional considerations that may impact regulatory decisions regarding ''potential'' linkages in the West identified by the modeling.

The State of Nebraska submitted a SIP on February 11, 2013. The SIP states that Nebraska does not contribute significantly to nonattainment in, or interfere with maintenance by, any other state with regards to the 2008 O_3 NAAQS. To support this conclusion, Nebraska cited modeling that EPA conducted for purposes of evaluating upwind contributions to downwind air quality in the CSAPR rulemaking. *See* 76 FR 48244 (Federal Implementation Plans: Interstate Transport of Fine Particulate Matter and Ozone and Correction of SIP Approvals; Final Rule). Nebraska noted EPA's statement in that action, that states ''which

[18] CSAPR proposal, 75 FR 45210, 45237 (August 2, 2010).

[19] *See also* Air Quality Modeling Final Rule Technical Support Document, Appendix F, Analysis of Contribution Thresholds, Docket ID #EPA–HQ–OAR–2009–0491–4140.

[20] CSAPR, 76 FR 48208, 48236–37 (August 8, 2011).

[21] *Id.*

[22] *Id.*

[23] *Id.*

[24] *See* 80 FR 46271 (August 4, 2015) (Notice of Availability of the Environmental protection Agency's Updated Ozone Transport Modeling Data for the 2008 Ozone National Ambient Air Quality Standard (NAAQS)).

[25] Largest Ozone Contributions From Each State to Downwind 2017 Projected Nonattainment and to 2017 Projected Maintenance-only sites, specific to the state of Nebraska are found in Table 3 at 80 FR 46277.

contribute 0.8 ppb or more to 8-hour ozone nonattainment or maintenance in another state are identified as states with contributions to downwind attainment and maintenance sites large enough to warrant further analysis.'' Nebraska noted that 0.8 ppb cutoff equates to a one percent threshold, which was the threshold EPA used in that rulemaking for the previous 1997 ozone NAAQS. According to Nebraska, the rule stands for the proposition that ''states whose contributions are below these thresholds do not significantly contribute or interfere with maintenance of the relevant NAAQS.'' Nebraska noted that, pursuant to the modeling discussed in that rule (76 FR 48245), Nebraska's largest downwind contribution to any identified nonattainment or maintenance receptors for ozone was 0.2 ppb. Nebraska concluded that because this modeling contribution represents far less than one percent of the 2008 ozone NAAQS at issue here, it ''does not have any obligations'' to reduce emissions to address interstate transport as to that standard.

The EPA notes that the modeling Nebraska relies upon was conducted by EPA in 2011, for purposes of evaluating upwind state contributions and downwind air quality problems as to a prior, less-stringent ozone NAAQS, and that the modeling evaluated a 2012 compliance year. Accordingly, the fact that this modeling showed downwind contribution less than one percent of the 2008 ozone NAAQS is not necessarily dispositive of Nebraska's obligations under section 110(a)(2)(D)(i)(I).[26] However, as discussed above, the EPA has conducted more updated modeling subsequent to the state's SIP submission that confirms the underlying conclusion of our 2011 modeling, and of Nebraska's SIP submission.

Based on the modeling data and the information and analysis provided in Nebraska's SIP, EPA is proposing to approve Nebraska's interstate transport SIP for purposes of meeting the CAA section 110(a)(2)(D)(i)(I) requirements as to the 2008 ozone standard. The EPA's modeling confirms the results of the State's analysis: Nebraska does not significantly contribute to nonattainment or interfere with maintenance of the 2008 ozone standard in any other state.

V. What action is EPA proposing?

Based upon review of the state's infrastructure SIP submission for the 2008 O_3 NAAQS, with respect to the requirements of section 110(a)(2)(D(i)(I)—prongs 1 and 2, and relevant statutory and regulatory authorities and provisions referenced in these submissions or referenced in Nebraska's SIP, EPA is proposing to approve this element of the February 11, 2013 SIP submission.

We are hereby soliciting comment on this proposed action. Final rulemaking will occur after consideration of any comments.

VI. Statutory and Executive Order Review

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

- Is not a ''significant regulatory action'' under the terms of Executive Order 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under Executive Orders 12866 and 13563 (76 FR 3821, January 21, 2011).
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

The SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications 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).

Statutory Authority

The statutory authority for this action is provided by section 110 of the CAA, as amended (42 U.S.C. 7410).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements.

Dated: November 2, 2015.

Mark Hague,

Regional Administrator, Region 7.

[FR Doc. 2015–28908 Filed 11–13–15; 8:45 am]

BILLING CODE 6560–50–P

[26] Nebraska's SIP submission appears to rely on EPA's 2011 air quality modeling because at that time, the D.C. Circuit's decision in *EME Homer City Generation, L.P.* v. *EPA* held that EPA must first quantify each state's transport obligation before states had an obligation to make a SIP submission. *See* 696 F.3d 7 (D.C. Cir. 2012). Accordingly, Nebraska cites a November 19, 2012, memorandum from Assistant Administrator Gina McCarthy, which describes the D.C. Circuit's holding that ''a SIP cannot be deemed deficient for failing to meet the good neighbor obligation before the EPA quantifies that obligation.'' *See* Memo at 2, *available at http://www3.epa.gov/airtransport/pdfs/CSAPR_Memo_to_Regions.pdf.* The memorandum also communicated the Agency's intentions to ''act in accordance with the [D.C. Circuit] decision during the pendency of the appeal,'' *id.,* but on appeal the Supreme Court reversed that holding. *See EPA* v. *EME Homer City Gen.,* 134 S. Ct. 1584, 1609–10 (2014).

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 62

[EPA–R05–OAR–2015–0701; FRL–9936–95–Region 5]

Air Plan Approval; Michigan; Sewage Sludge Incinerators State Plan and Small Municipal Waste Combustors Negative Declaration for Designated Facilities and Pollutants

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve

Michigan's State Plan to control air pollutants from Sewage Sludge Incinerators (SSI). The Michigan Department of Environmental Quality submitted the State Plan on September 21, 2015, following the required public process. The State Plan is consistent with the Emission Guidelines promulgated by EPA on March 21, 2011. This approval means that EPA finds that the State Plan meets applicable Clean Air Act requirements for subject SSI units. Once effective, this approval also makes the State Plan Federally enforceable. EPA is also announcing that we have received from Michigan a negative declaration for Small Municipal Waste Combustors (SMWC). The Michigan Department of Environmental Quality submitted on July 27, 2015 a negative declaration certifying that there are no SMWC units currently operating in the state of Michigan.

DATES: Comments must be received on or before December 16, 2015.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2015–0071, by one of the following methods:

1. *www.regulations.gov:* Follow the on-line instructions for submitting comments.
2. *Email: nwia.jacqueline@epa.gov.*
3. *Fax:* (312) 692–2566.
4. *Mail:* Jacqueline Nwia, Acting Chief, Toxics and Global Atmosphere Section, Air Toxics and Assessment Branch (AT–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.
5. *Hand Delivery:* Jacqueline Nwia, Acting Chief, Toxics and Global Atmosphere Section, Air Toxics and Assessment Branch (AT–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m. excluding Federal holidays.

Please see the direct final rule which is located in the Rules section of this **Federal Register** for detailed instructions on how to submit comments.

FOR FURTHER INFORMATION CONTACT: Margaret Sieffert, Environmental Engineer, Environmental Protection Agency, Region 5, 77 West Jackson Boulevard (AT–18J), Chicago, Illinois 60604, (312) 353–1151, *sieffert.margaret@epa.gov.*

SUPPLEMENTARY INFORMATION: In the Rules section of this **Federal Register**, EPA is approving through a direct final rulemaking Michigan's State Plan for control of air pollutants from SSI sources, and is amending 40 CFR part 62 to reflect the State's submittal of the negative declaration as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this rule, no further activity is contemplated. If EPA receives adverse comments, we will withdraw the direct final rule and will address all public comments in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule, and if that provision can be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. For additional information, see the direct final rule which is located in the Rules section of this **Federal Register**.

Dated: October 29, 2015.

Susan Hedman,

Regional Administrator, Region 5.

[FR Doc. 2015–28910 Filed 11–13–15; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

45 CFR Part 1329

RIN 0985–AA10

Independent Living Services and Centers for Independent Living

AGENCY: Administration for Community Living, HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement the Workforce Innovation and Opportunity Act enacted on July 22, 2014 and reflects the transfer of Independent Living Services and Centers for Independent Living programs from the Department of Education to the Department of Health and Human Services. The previous regulations were issued by the Department of Education. This proposed rule will consolidate the Independent Living (IL) regulations into a single part, align the regulations with the current statute and HHS policies, and will provide guidance to IL grantees.

DATES: Comments are due on or before January 15, 2016.

ADDRESSES: You may submit comments in one of following ways (no duplicates, please): Written comments may be submitted through any of the methods specified below. Please do not submit duplicate comments.

- *Federal eRulemaking Portal:* You may (and we encourage you to) submit electronic comments on this regulation at *http://www.regulations.gov.* Follow the instructions under the ''submit a comment'' tab. Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.
- *Regular, Express, or Overnight Mail:* You may mail written comments to the following address ONLY: Administration for Community Living, Attention: IL NPRM, U.S. Department of Health and Human Services, Washington, DC 20201. Please allow sufficient time for mailed comments to be received before the close of the comment period.
- *Individuals with a Disability:* We will provide an appropriate accommodation, including alternative formats, upon request. To make such a request, please contact Marlina Moses-Gaither, (202) 357–3552 (Voice) or at *marlina.moses-gaither@acl.hhs.gov.*

FOR FURTHER INFORMATION CONTACT: Molly Burgdorf, Administration for Community Living, telephone (202) 357–3411 (Voice). This is not a toll-free number.

SUPPLEMENTARY INFORMATION:

I. Workforce Innovation and Opportunity Act of 2014

The Workforce Innovation and Opportunity Act (''WIOA,'' Pub. L. 113–128), signed into law on July 22, 2014, included significant changes to title VII of the Rehabilitation Act of 1973. WIOA transfers the Independent Living Services and Centers for Independent Living programs authorized under chapter 1, title VII of the Rehabilitation Act of 1973 (Rehabilitation Act or Act), as amended by WIOA (Pub. L. 113–128) from the Rehabilitation Services Administration (RSA), U.S. Department of Education (ED), to the Administration for Community Living (ACL), U.S. Department of Health and Human Services (HHS). WIOA also transferred the National Institute on Disability, Independent Living, and Rehabilitation Research, and the Assistive Technology Act programs to ACL.

Background

ACL was established as an Operating Division within HHS in 2012. ACL focuses on the shared interests of both older adults and people with disabilities, while acknowledging and continuing to address the unique needs and differences across the populations served. As an agency, we strive to ensure that all Americans, regardless of age or disability, can make their own choices and live, learn and work in their communities with the services and supports they need to be fully participating and contributing members of society. The transferred Independent Living (IL) programs make important contributions to the work of ACL in unique ways, and they also align with the mission of ACL to maximize the independence, well-being and health of individuals with disabilities across the lifespan, and their families and caregivers.

As part of the transfer, the Administrator of ACL (Administrator) is issuing new regulations for the programs that implement changes made by WIOA in accordance with section 12 of the Rehabilitation Act, as amended, 29 U.S.C. 709(e), and section 491(f) of WIOA, 42 U.S.C. 3515e(f). This notice of proposed rulemaking applies to the Independent Living programs. It proposes new regulations that implement the transition of the Independent Living programs, including the Independent Living Services and the Centers for Independent Living, to ACL. While the proposed regulations retain many of the provisions in the Department of Education regulations, they also include new provisions to implement changes made to the programs by WIOA and to replace references to Department of Education procedures and regulations with references to procedures and regulations applicable to Department of Health and Human Services programs. Existing Department of Education Independent Living program regulations found at 34 CFR parts 364, 365, and 366 remain in effect until such time as the proposed HHS regulations become final.

Programs Amended by WIOA

Overview of the Independent Living Program

Independent Living (IL) empowers individuals with disabilities to live independently in their communities assisted by two federal programs: Independent Living Services (ILS) and Centers for Independent Living (referred to as CILs or Centers).

Independent Living Services

Authorized under Title VII, chapter 1, part B of the Rehabilitation Act, as amended by WIOA, the Independent Living Services (ILS) Program provides formula grants, based primarily on population, to States for the purpose of funding, directly and/or through grant or contractual arrangements a number of activities. These activities include:

1. Supporting the operation of Statewide Independent Living Councils (SILCs);
2. Providing IL services to individuals with significant disabilities, particularly those in unserved areas of the State;
3. Demonstrating ways to expand and improve IL services;
4. Supporting the operation of CILs that comply with the standards and assurances of section 725;
5. Increasing the capacity of public or nonprofit organizations and other entities to develop comprehensive approaches or systems for providing IL services;
6. Conducting studies and analyses, developing model policies and procedures, and presenting information, approaches, strategies, findings, conclusions, and recommendations to federal, State and local policymakers to enhance IL services;
7. Training service providers and individuals with disabilities on the IL philosophy; and
8. Providing outreach to populations that are unserved or underserved by IL programs, including minority groups and urban and rural populations.

To be eligible for financial assistance, States are required to establish and maintain a SILC and to submit an approvable State Plan for Independent Living (SPIL) jointly developed by the chairperson of the SILC and the directors of the Centers for Independent Living, with input from individuals with disabilities and other stakeholders throughout the State. The SPIL must be signed by the SILC chairperson acting on behalf of and at the direction of the SILC, the director of the designated State entity (DSE), and not less than 51 percent of the directors of CILs in the State.

Centers for Independent Living

Authorized under title VII, chapter 1, part C of the Rehabilitation Act, as amended by WIOA, the Centers for Independent Living Program provides grants to consumer-controlled, community-based, cross-disability, nonresidential, private nonprofit agencies for the provision of an array of IL services to individuals with significant disabilities. At a minimum, Centers funded by the program are required to provide the following five IL core services:

1. Information and referral;
2. IL skills training;
3. Peer counseling;
4. Individual and systems advocacy; and
5. Services that facilitate transition from nursing homes and other institutions to home and community based residences with the necessary supports and services, provide assistance to those at risk of entering institutions, and facilitate transition of youth to postsecondary life.

Centers also may provide, among others: Services related to securing housing or shelter; personal assistance services; transportation, including referral and assistance, mobility training, rehabilitation technology; and other services consistent with 29 U.S.C. 705(18), including those necessary to improve the ability of individuals with significant disabilities to function independently in the family or community and/or to continue in employment. The Rehabilitation Act establishes a set of activities along with standards and assurances that must be met by the Centers. To continue receiving CIL program funding, eligible Centers must demonstrate minimum compliance with the following evaluation standards: Promotion of the IL philosophy; provision of IL services on a cross-disability basis; support for the development and achievement of IL goals chosen by the consumer; efforts to increase the availability of quality community options for IL; provision of IL core services; resource development activities to secure other funding sources; and community capacity-building activities. Centers' levels of compliance with the standards are assessed based on compliance indicators.

A population-based formula determines the total funding available for discretionary grants to Centers in each State. Subject to the availability of appropriations as required by statute, ACL provides continuation funding to existing Centers at the same level of funding they received the prior fiscal year, including a cost-of-living increase, as long as they meet the standards and assurances, or are taking appropriate action to address identified deficiencies though a corrective action plan. Funding for new Centers in a State is awarded on a competitive basis, based on the State's priority designation of unserved or underserved areas in the SPIL and the availability of sufficient additional funds within the State. There are currently 354 Centers for

Independent Living that receive direct grants from the federal government.[1]

Statewide Independent Living Councils

As discussed above, a State must establish and maintain a Statewide Independent Living Council (referred to as a SILC or Council) in order to be eligible for IL and CIL funding. Although SILCs are not funded directly by the federal government, they are an important partner in implementing the ILS and CIL programs in a State. The SILCs are composed of a majority of people with disabilities and include other independent living stakeholders. SILC members are generally appointed by the Governor of the State, except in the case of a State that, under State law, vests authority for the administration of the activities carried out under the IL programs in an entity other than the Governor (such as one or more houses of the State legislature or an independent board), the chief officer of that entity would appoint SILC members. The chairperson of the SILC, and the directors of the Centers for Independent Living in the State jointly develop the State Plan for Independent Living (referred to as SPIL or State plan) after receiving public input from individuals with disabilities and other stakeholders throughout the State. The SILC monitors, reviews and evaluates the implementation of the SPIL.

A SPIL has already been approved in each State through fiscal year 2016. The law remains unchanged that the SPIL continues to govern the provision of IL services in the State. Each State is expected to continue its support, including specified obligations, under the approved SPIL. Any amendments to the SPIL, reflecting either a change based on the WIOA amendments or any material change in State law, organization, policy or agency operations that affect the administration of the SPIL, must be developed and signed in accordance with section 704(a)(2) of the Rehabilitation Act, as amended. SPIL amendments must be submitted by the State to ACL for approval.

Indicators of Minimum Compliance

WIOA requires ACL to publish minimum compliance indicators for CILs and SILCs before July 22, 2015. (See section 706(b) of the Rehabilitation Act, 29 U.S.C. 796d–1(b), as amended.) Section 706(c) of the Rehabilitation Act continues to require compliance reviews of CILs funded under section 722 and reviews of State entities funded under section 723 of the Rehabilitation Act. Until the new minimum compliance indicators are published, the IL staff at ACL will continue to conduct compliance reviews and make final decisions on any proposed corrective actions and/or technical assistance related to compliance reviews, in accordance with current compliance indicators. Grantees must also continue to submit annual performance reports (referred to as the 704 Report). ACL is in the process of reviewing related instruments and instructions in light of changes under WIOA. Proposed changes and new indicators will be published in the **Federal Register** in accordance with the requirements of the Paperwork Reduction Act of 1995, 44 U.S.C. chapter 35.

Overview of Key Statutory Changes Made by WIOA

As previously discussed, WIOA transferred the Independent Living Programs to ACL and created a new Independent Living Administration within the agency, adding section 701A of the Rehabilitation Act, 29 U.S.C. 796–1. WIOA also made a number of other changes. WIOA amended section 702 of the Act, 29 U.S.C. 796a, to insert the definition of Administrator as the Administrator of the Administration for Community Living in the U.S. Department of Health and Human Services. The responsibilities of the Administrator are set forth in amended section 706, 29 U.S.C. 796d–1.

New section 702 of the Act also amended the definition of a CIL and requires that CILs provide, at a minimum, independent living core services for individuals with significant disabilities, regardless of age or income.

WIOA amended section 7(17) of the Act, to add a new fifth core service to the definition of independent living core services. Other relevant amendments to the definition section include the addition of a new section 7(42), definition of youth with a disability.

WIOA also amends section 704 of the Act, 42 U.S.C. 796c, which describes requirements for the State Plan. The law now requires that the SPIL be developed jointly by the chairperson of the Statewide Independent Living Council (SILC) and the directors of the Centers for Independent Living, after receiving public input from individuals with disabilities and other stakeholders throughout the State. The SPIL is to be signed by the SILC chairperson acting for and at the direction of the SILC, the director of the designated State entity (DSE), and not less than 51 percent of the CILs in the state. The law also requires that the SPIL address working relationships and collaboration between CILs and other entities performing similar work. Finally, the SPIL is required to describe strategies for providing independent living services on a statewide basis, to the greatest extent possible.

As part of the amendments to section 704 of the Act, the DSE is responsible to receive, account for and distribute funds based on the SPIL, provide administrative support for programs under Title VII B, maintain records, and provide information or assurances to the Administrator. Section 704(c)(5) adds a cap of 5 percent of the funds received by the State for any fiscal year under Independent Living Services that the DSE may retain to perform these services.

WIOA made several amendments to section 705 of the Act, 29 U.S.C. 796d, regarding the Statewide Independent Living Council. Amended section 705 (b)(2) requires that voting members of the SILC include, in a state in which one or more CILs are run by, or in conjunction with, the governing bodies of American Indian tribes located on Federal or State reservations, at least one representative of the director of such Centers. It also removes the term limit for a CIL director appointed to the SILC if there is only one CIL within the State. Amended section 705(c)(2) permits the SILC to engage in new activities in addition to the original duties outlined in section 705(c)(1). However, the amended section 705(c) also provides that the SILC may not provide independent living services directly to individuals with significant disabilities or manage such services. The SILC may work with CILs to coordinate services with public and private entities in order to improve services provided to individuals with disabilities, and may now also conduct resource development activities. SILCs must prepare a resource plan in conjunction with the designated State entity.

WIOA requires that between 1.8 percent and 2 percent of funds be set aside for technical assistance and training for SILCs. The law also amends section 713 of the Act, 29 U.S.C. 796e–2, to provide that States may not use more than 30 percent of the funds received under chapter 1, part B, of the Rehabilitation Act for the SILC resource plan unless the State plan specifies a greater percentage is needed.

Finally, WIOA modifies section 706(c) of the Act, 29 U.S.C. 796d–1(c) to eliminate the requirement that

[1] In many States there are additional CILs that receive State funding or federal IL funding administered by the State agencies.

compliance reviews of CILs be conducted randomly.

Overview of Regulatory Changes

U.S. Department of Education (ED) regulations governing the Independent Living Program are found at 34 CFR parts 364, 365, and 366. Part 364 sets forth regulations addressing State Independent Living Services and Centers for Independent Living: General Provisions; part 365 sets forth regulations addressing State Independent Living Services; and part 366 sets forth regulations addressing Centers for Independent Living. ACL proposes to consolidate the IL regulations into one new part, 45 CFR part 1329. We further propose to eliminate regulations applicable specifically to ED processes, as well as to eliminate duplicative language or language no longer applicable in the existing ED regulations. We propose to eliminate regulatory language that does not add further interpretation to the statutory language. Unless otherwise noted, the proposed changes in in this notice of proposed rulemaking represent changes to implement WIOA, including the transfer of the programs from ED to HHS.

45 CFR Part 1329

Subpart A

We propose to create a Subpart A of the new 45 CFR part 1329 that will address General Provisions for the IL programs.

Proposed § 1329.1 sets out the programs covered by the new Part. Proposed § 1329.2 sets out their purpose as defined in Section 701 of the Act, 29 U.S.C. 796.

In considering the purpose of the Act and the changes made under WIOA, we wish to highlight ACL's interpretation that the IL programs promote a philosophy of person-centeredness in keeping with the mission of ACL and with the policy of the Department of Health and Human Services. On June 6, 2014, HHS issued guidance on implementing Section 2402(a) of the Affordable Care Act. Section 2402(a) of the Affordable Care Act requires the Secretary to ensure all States receiving federal funds develop service systems that are responsive to the needs and choices of beneficiaries receiving home and community-based long-term services (HCBS), maximize independence and self-direction, provide support coordination to assist with a community-supported life, and achieve a more consistent and coordinated approach to the administration of policies and procedures across public programs providing HCBS. Because so much of the work done by IL programs involves these same principles, we believe it is important to clarify that the June 2014 guidance, including person-centered planning requirements,[2] applies to IL programs.

Proposed § 1329.3 replaces the ED regulations specified in 34 CFR 364.3 with references to other HHS regulations that govern the activities of the Independent Living programs.

Proposed § 1329.4 is the Definitions section.

Sec. 1329.4 Definitions

Proposed § 1329.4 defines terms used in the regulations. We propose to include statutory definitions when we believe the terms to be significant enough to warrant repetition in the regulations. We propose to incorporate some definitions from the existing ED regulations at 34 CFR 364.4. We propose modifications to other definitions to reflect WIOA changes or to modernize the terms.

a. Definition of Independent Living Core Services

ACL proposes to amend the existing regulatory definition of independent living core services by adding the new fifth core service to the previous definition. The four original core services are information and referral services; independent living skills training; peer counseling, including cross-disability peer counseling; individual and systems advocacy.

The new fifth core service has three components, each of which must be met to fulfill the fifth core service. It requires CILs to (1) facilitate the transition of individuals with significant disabilities from nursing homes and other institutions to home and community-based residences, with the requisite supports and services; (2) provide assistance to individuals with significant disabilities who are at risk of entering institutions so that the individuals remain in the community; and (3) facilitate the transition of youth who are individuals with significant disabilities, who were eligible for individualized education programs (IEPs) under Section 614(d) of the Individuals with Disabilities Education Act, and who have completed their secondary education or otherwise left school to postsecondary life.

We recognize that the fifth core service of promoting full access to community living and postsecondary life is an important addition to the core services. We acknowledge that through various Medicaid and State-specific programs, including partnerships with other programs administered by ACL, many CILs have experience and existing services consistent with one or more of the three components. To achieve the right balance between clarity and flexibility in implementing the new core service, ACL is considering the appropriate level of detail. We invite comment on whether the proposed language is sufficiently specific, or if more information is needed to successfully implement this new requirement. Under our proposed approach, we have chosen not to define the terms ''institution,'' ''home and community-based residences,'' and ''at risk of institutionalization'' at this time. We propose, however, to define ''youth with a significant disability'' and related terms around youth transition to postsecondary education.

In considering whether to define the term ''institution,'' we looked at a variety of existing Medicare and Medicaid definitions, including the definitions at Sections 1819(a) and 1862(e)(1) of the Social Security Act, and 42 CFR 416.201, 441.301(c)(5), and 441.710(a)(2). These definitions include hospitals, skilled nursing facilities, Medicaid nursing facilities, and Intermediate Care Facilities for Individuals with Intellectual Disabilities (ICF/IID) services. They also include a definition consistent with settings that are not ''community based'' for Section 1915(c) home and community based waivers and for Section 1915(i) State plan home and community based services. We are concerned, however, that defining ''institution'' based on the Medicare and Medicaid model may not be broad enough to encompass all institutions with which CILs may work, including juvenile detention centers, jails and prisons. We seek public comment on whether to include a definition and, if so, the suitability of applying Medicare and Medicaid definitions to the fifth core service.

We also considered definitions of ''home and community-based residences'' and ''at risk'' of institutionalization. We determined not to define these terms at this time, but

[2] Person-centered planning is a process directed by the person with long-term services and supports needs. The person-centered planning approach identifies the person's strengths, goals, preferences, needs (*e.g.* medical and home and community-based services), and desired outcomes. The role of agency workers (*e.g.,* options counselors, support brokers, social workers and others) in the process is to enable and assist people in identifying and accessing a unique mix of paid and unpaid services to meet their needs, and provide support during planning. Person-centered planning is consistent with the independent living philosophy, including consumer control and self-determination, in order to maximize independence.

request comment on whether and how ''home and community-based residences'' and ''at risk'' of institutionalization should be defined for purposes of the fifth core service. We are specifically interested in learning how CILs that are already transitioning individuals with disabilities to the community and/or doing work to avoid the institutionalization of people with significant disabilities currently define ''transition'' from institutions to the community, and people who are ''at risk of entering institutions.'' To maintain the consumer-directed purpose of the programs, ACL also invites comments on the effectiveness and limitations of including the issue of being ''at risk'' as a part of CIL consumers self-disclosing their needs in the intake process.

CILs that provide youth transition services to a broader group of youth with significant disabilities beyond the populations covered under the youth transition prong of the new fifth core service (in Section (17)(E)(iii) of the Act) have the option of continuing to do so, but such services would be included as IL services, rather than as ''core services'' for purposes of the 704 report, and provision of those services would not satisfy the core services requirement. ACL proposes to define a youth with a significant disability as an individual with a significant disability who (i) is not younger than 14 years of age; and (ii) is not older than 24 years of age. This definition is based on the definition of ''individual with a significant disability'' in Section 7(21), 29 U.S.C. 705(21) and ''youth with a disability'' in Section 7(42) of the Act, 29 U.S.C. 705(42).

We further propose to define the term ''completed their secondary education'' to mean that an eligible youth has received a diploma; has received a certificate of completion for high school or other equivalent document marking the completion of participation in high school; has reached age 18, even if he or she is still receiving services in accordance with an individualized education program developed under the IDEA; or has exceeded the age of eligibility for IDEA services.[3] Similarly, we propose a broad interpretation of ''otherwise left school.'' For example, ''otherwise left school'' could mean that the youth has dropped out of school; taken a leave of absence from secondary school for health or disciplinary reasons; or did not graduate but is no longer attending classes at a secondary school. We request comments on this interpretation.

b. Definition of Other Terms in Proposed § 1329.4

We propose a definition of ''*Administrative support services*'' provided by the designated State entity under Part B, to Part C CILs administered by the State under Section 723 of the Act, with some examples. We request comments on this definition.

We proposed to incorporate the definition of ''*Administrator*'' at Section 702(1) of the Act, 29 U.S.C. 796a(1).

We propose to define *''Advocacy*'' consistent with the definition in the existing regulations, 34 CFR 364.4. Individual and system advocacy remain integral elements of promoting independent living according to the purpose of the law. The term includes providing assistance and/or representation in obtaining access to benefits, rights, services, and programs to which a consumer or group of consumers may be entitled. We invite comment on the definition. Grantees should continue to present information in a balanced and non-partisan manner that is consistent with the principles of the Rehabilitation Act and in accordance with relevant federal and State laws and the restrictions and exceptions in the Uniform Guidance, including 2 CFR 200.450, and other applicable requirements.

We propose to incorporate the existing definition of ''*Attendant care services*'' in 34 CFR 364.4.

We propose to add to the existing definition of *''Center for independent living*'' in 34 CFR 364.4 that the array of independent living services provided includes, at a minimum, the independent living core services defined in Section 7(17) of the Act. A ''Center'' that receives assistance under the Act must meet all of the requirements of Section 725 (b) and (c) of the Act, 29 U.S.C. 796f–4(b) and (c), the standards and assurances for Centers for Independent Living.

We propose to add to the statutory definition of *''Consumer control*'' at Section 702 of the Act, 29 U.S.C. 796a(3), that control is vested in individuals with disabilities, including those who are or who have been recipients of IL services.

We propose to add to the existing definition of ''*Cross-disability*'' at 34 CFR 364.4 that the CIL provide services to individuals representing a range of significant disabilities, including individuals who are members of unserved or underserved populations.

We propose to define *''Designated State entity (DSE)*'' based on Section 704 of the Act, 29 U.S.C. 796c(c).

We propose to incorporate the statutory definition of ''*Eligible agency,*'' Section 726 of the Act, 29 U.S.C. 796f–5.

We propose to incorporate the statutory definition of ''*Independent living services,*'' from Section 7(18) of the Act, 29 U.S.C. 705(18).

We propose to define ''*Individual with a disability*'' using the language of 42 U.S.C. 12102 as specified in Section 7(20)(B) of the Act, 29 U.S.C. 705(20)(B).

We propose to incorporate the statutory definition of ''*Individual with a significant disability*'' in Section 7(21)(B) of the Act, 29 U.S.C. 705(21)(B).

We propose to add a definition of ''*Majority*'' to clarify that a majority means more than 50 percent. This definition applies to the SILC member and voting member qualifications, 29 U.S.C. 796d(4)(A)(iv) and (B), and the required assurances relating to the CIL Board & CIL staff, 29 U.S.C. 796f–4(C)(2) and (6), among other provisions. This addition is intended to help clarify statutory requirements, particularly those related to establishing consumer control.

We propose to define *''Minority group*'' to mean American Indian, Alaskan Native, Asian American, Black or African American (not of Hispanic origin), Hispanic or Latino (including persons of Mexican, Puerto Rican, Cuban, and Central or South American origin), and Native Hawaiian or other Pacific Islander, based on the Office of Management and Budget Standards for the Classification of Federal Data on Race and Ethnicity (62 FR 58782 (Oct. 30, 1997)), considered in conjunction with the definition for minority in National Science Foundation regulations, 34 CFR part 637 and with the Centers for Disease Control and Prevention's Office of Minority Health's definitions.

We propose to incorporate the existing definition of ''*Nonresidential*'' at 34 CFR 364.4.

We propose to incorporate the existing definition of ''*Peer relationships*'' at 34 CFR 364.4.

We propose to incorporate the existing definition of ''*Peer role models*'' at 34 CFR 364.4.

We propose to add to the statutory definition of ''*Personal assistance services*'' in Section 7(28) of the Act, 29 U.S.C. 705(28), examples of what might constitute personal assistance services. We also propose to add that such services may be paid or unpaid.

[3] The fifth core independent living service to facilitate the transition of youth who are individuals with significant disabilities requires that they ''. . . were eligible for individualized education programs under section 614(d) of the Individuals with Disabilities Education Act (20 U.S.C. 1414(d) . . .'' under Section 7 of the Act, 29 U.S.C. 705(17)(E)(iii).

We propose a definition of ''*Service provider*'' based on the existing definition in 34 CFR 364.4. We further propose to modify the definition to reflect the WIOA changes by removing references to a designated State unit and adding a designated State entity (DSE).

We propose to incorporate the statutory definition of ''*State*'' Section 7(34) of the Act, 29 U.S.C. 705(34).

We propose to define ''*State plan*'' by reference to Section 704 of the Act, 29 U.S.C. 796c.

We propose to define ''*Unserved and underserved*'' groups or populations to include populations such as individuals with significant disabilities who are from racial and ethnic minority backgrounds, disadvantaged individuals, individuals with limited English proficiency, and individuals from underserved geographic areas (rural or urban). This definition is based on the statutory requirement in Section 704(l) of the Act, 29 U.S.C. 796c(l), to provide outreach to ''populations that are unserved or underserved by programs . . . including minority groups and urban and rural populations.'' We further base the definition on the Congressional findings on traditionally underserved populations set forth in Section 21 of the Act, 29 U.S.C. 718. We recognize that unserved and underserved groups or populations will vary by service area. For example, in some service areas unserved and underserved groups may include people with disabilities from the gay, lesbian, bisexual and transgender communities.

We propose to define *''Youth with a significant disability*'' consistent with the definition of ''individual with a significant disability'' in Section 7(21)(B), 29 U.S.C. 705(21)(B) and ''youth with a disability'' in Section 7(42)(A), 29 U.S.C. 705(42)(A), and with the definition of ''*individual with a disability*'' in § 1329.4.

Sec. 1329.5 Indicators of Minimum Compliance

Section 706 of the Act, 29 U.S.C. 796d–1, discusses the responsibilities of the Administrator with regard to oversight of the IL programs. Specifically, WIOA requires the development and publication of indicators of minimum compliance for CILs, consistent with the standards set forth in Section 725 of the Act, 29 U.S.C. 796f-4, and indicators of minimum compliance for SILCs. WIOA did not amend Section 706(c), which requires annual compliance reviews of 15 percent of CILs and, to the extent necessary to determine compliance with the requirements of Section 723(f) and (g) of the Act, 29 U.S.C. 796f–2, one-third of designated State entities. WIOA deleted the requirement that the CILs and State entities reviewed be chosen on a random basis and we propose to amend the regulations accordingly. We invite comment on the criteria and selection process for compliance reviews going forward, given this change.

ACL proposes to require Centers to demonstrate minimum compliance consistent with Section 725, for the following: Promotion of the IL philosophy; provision of IL services on a cross-disability basis; support for the development and achievement of IL goals chosen by the consumer; efforts to increase the availability of quality community options for IL; provision of IL core services; resource development activities to secure other funding sources; and community capacity-building activities. ACL will continue to monitor programs based on the standards and indicators set forth in the statute as we re-evaluate and develop protocols that meet the requirements of the Act.

Sec. 1329.6 Reporting

In addition to compliance reviews, each CIL and State is required to file an annual performance report, known as the 704 Report, which describes its work and how the CIL or State is meeting the goals and requirements of the Act. This requirement is set forth in proposed § 1329.6. ACL is currently in the process of reviewing the 704 reports. However, for this year, CILs and States are expected to complete the 704 instrument that they have used in the past. We will issue guidance as to how the reports are to be filed. We are considering changes to the 704 Report for future years. The 704 Reports are subject to the Paperwork Reduction Act of 1995 (PRA), and interested stakeholders will have an opportunity to comment on any future revisions to the report through the PRA clearance process.

Sec. 1329.7 Enforcement and Appeals Process

The existing IL regulations at 34 CFR 366.39 through 366.46, include an enforcement and appeals process for the CILs funded under Part C of Chapter 1 of Title VII of the Rehabilitation Act. There is no corresponding process in the existing ED independent living regulations for the designated State entities administering Part B funds in accordance with the State Plan, as authorized by Part B of Chapter 1 of Title VII. In determining the appropriate approach for enforcement and appeals, ACL reviewed the existing Department of Education regulations and the regulations applicable to ACL programs funded under the Older Americans Act (OAA), 45 CFR part 1321, and the Developmental Disabilities and Bill of Rights Act (DD Act) regulations, 45 CFR part 1385. The NPRM proposes to utilize a version of the process from the existing IL regulations modified to account for the new administrative structure of the programs. This approach, intended to create a uniform, clear and relatively simple process, best meets the needs of the CILs, has the advantage of offering a procedure that is familiar to the programs, and is not as intricate, formal or lengthy as those in current ACL rules.

Under the proposed rule, if the Director of the Independent Living Administration (ILA) determines that a Center is not in compliance with the standards and assurances of a grant received from ACL, the Director notifies the Center that the Center is out of compliance and may be subject to enforcement action, including termination of funds. ACL will continue to make reasonable efforts to work with the Center to provide technical assistance in accordance with the procedures in the Notice of Award terms and conditions and any applicable subsequent guidance, to correct any deficiencies and to resolve compliance concerns before taking enforcement action. ACL also proposes a two-step preliminary appeals process where there is the imminent threat of termination or withholding of funds: First to the Director of the Independent Living Administration and then to the Administrator of ACL.

The proposed rule requires a Center found out of compliance to develop a corrective action plan. ACL could provide technical assistance in developing and implementing the corrective action plan and would monitor its implementation. If the Center fails to submit an approvable plan or ACL determines that the Center is otherwise out of compliance, even with the plan, the Administrator may take steps to enforce the corrective action plan or to terminate funding. If the determination by the Administrator is a type of determination described in 45 CFR part 16, Appendix A, Paragraph C, subparagraphs (a)(1)–(4), it would be subject to review by the Departmental Appeals Board (DAB).[4] These

[4] 45 CFR part 16 refers to Procedures of the Departmental Grant Appeals Board, which is currently known within the U.S. Dep't of Health and Human Services as the Departmental Appeals Board (DAB).

determinations are: (1) A disallowance or other determination denying payment of an amount claimed under an award, or requiring return or set-off of funds already received; (2) a termination for failure to comply with the terms of an award; (3) a denial of a noncompeting continuation award under the project period system of funding where the denial is for failure to comply with the terms of a previous award; and (4) a voiding (a decision that an award is invalid because it was not authorized by statute or regulation or because it was fraudulently obtained). Under 45 CFR 16.3, the Center would have 30 days from receipt of notice of that determination in which to file a notice of appeal with the DAB.

We include the enforcement and appeals process in the General Provisions part of these proposed regulations because we propose a parallel process for the Part B grants. We also propose a two-step preliminary appeals process for the Part B grants where there is the imminent threat of termination or withholding of funds, first to the Director of the ILA and then to the Administrator of ACL. We believe such a process is necessary because there may be situations in which a State is out of compliance with the requirements of its grant or of these regulations. For example, Section 704 of the Rehabilitation Act requires that, ''[t]o be eligible to receive financial assistance . . . , a State shall submit to the Administrator, and obtain approval of, a State plan developed and signed in accordance with [Section 704] . . . .'' WIOA added the requirement that the State plan (SPIL) must be signed by not less than 51 percent of the CILs in the State. If a State submits a SPIL that does not comply with the 51 percent signature requirement, ACL wants to ensure that a process exists whereby ACL can provide technical assistance to the State to help bring it into compliance.

As indicated above, ACL may not provide any funds to a State that does not have an approved plan. ACL will work with States to resolve issues that may result in the disallowance or denial of funding. However, should these efforts be unsuccessful, we believe the State should have an appeals process through which it may appeal a decision to disallow or deny funds that would otherwise be provided to a State in accordance with an approved plan.

Because we intend to create a uniform process for Part B and Part C grants, we also propose in these regulations to allow a State to file an appeal with the DAB concerning the four types of determinations set forth in 45 CFR part 16, appendix A, paragraph C, subparagraphs (a)(1) through (4). We further propose that the procedures in 45 CFR part 16 apply to appeals by a State.

We solicit comments about our proposed process and whether additional details need to be included in regulation. As indicated, we intend to utilize technical assistance to help resolve issues before they reach the appeals stage, and are interested in the role that other informal types of dispute resolution and mediation might play in compliance and enforcement, and how such dispute resolution and mediations might be conducted. We note that mediation is already included as an option for determinations that are appealed to the DAB, 45 CFR 16.18.

Because the processes we propose are new, particularly with regard to Part B funds, we are considering the issuance of sub-regulatory guidance to provide additional detail. Such an approach provides ACL and stakeholders with the opportunity to determine the processes that allow Centers and States to come into compliance quickly, while giving ACL the authority to take enforcement actions if the need arises.

Subpart B Independent Living Services

Proposed Subpart B of proposed 45 CFR part 1329 sets forth requirements for the designated State entity (DSE), the Statewide Independent Living Council (SILC), and the State Plan for Independent Living (SPIL). It incorporates some of the regulatory language from 34 CFR part 364 and Part 365. ACL proposes to simplify language and processes, to eliminate duplication of language specified in the Act, and to implement and clarify changes made by WIOA.

Proposed § 1329.10 discusses the authorized use of funds for independent living (IL) services as set forth in the Act. WIOA amended Section 713(b)(1) of the Act to add that a State may use funds to provide independent living services to individuals with significant disabilities, ''particularly those in unserved areas of the State.'' This section includes the new statutory requirement that that States may not use more than 30 percent of the funds received under Chapter 1, Part B, of the Rehabilitation Act for the SILC resource plan unless the approved State plan specifies a greater percentage is needed. This new requirement is also reflected in § 1329.15(c)(3). We propose to add the phrase ''particularly to those in unserved areas of the State'' to the previous regulatory language at 34 CFR part 365.

In proposed § 1329.11 we describe the designated State entity (DSE) as the entity identified by the State and named in the State plan. We propose that the DSE must submit to the Administrator and receive approval of a State plan in order to receive funding under the Act.

Proposed § 1329.12 defines the role of the DSE as those services identified in Sections 704(c)(1) through (5) of the Act. These services were unchanged by WIOA. However, WIOA added Section 704(c)(5), stipulating that the DSE may not retain ''more than five (5) percent of the funds received by the State for any fiscal year under Subpart 2 for the performance of the services outlined in paragraphs (1) through (4).'' We propose in § 1329.12 that the 5 percent administrative cap apply only to the Part B funds allocated to the State and to the State's required 10 percent Part B match. We further propose that the five (5) percent cap not apply to program income funds, including, but not limited to, payments provided to a State from the Social Security Administration for assisting Social Security beneficiaries and recipients to achieve employment outcomes.

In implementing the new requirement, the proposed language in the rule adopts an interpretation that the ''funds received by the State'' include the Part B and State matching funds only, rather than applying the 5 percent cap on administrative funds allocated to the DSE to all federal funds, and other program income, supporting the Independent Living Services program. The cap limits the funds a DSE can retain for administrative purposes in order to ensure that the Part B (State Independent Living) funds are primarily used to support the State's independent living programs and give the SILC sufficient resources to carry out required duties. We think it is consistent with the administrative cap requirement that the required State match be treated on an equal basis with the Part B funds received under this section. This creates consistency in accounting for funds that are inextricably linked to the funds provided under the Part B program, and should be treated the same way as the federal award of Part B funds. However, because program income funds are ''received by the State'' through means other than an appropriation under Part B, we believe those funds should be treated differently and should not be included in the administrative cap.

Proposed § 1329.13 references the allotment of funds for IL services in accordance with statutory provisions. It also proposes that if a State plan designates more than one entity to administer the State plan, including a

State agency or unit of a State agency to administer IL services to individuals who are blind, then it is up to the State to determine and specify how the State's allotment will be distributed between the multiple entities, consistent with the State plan. We ask for comments on the likelihood of a State continuing to or deciding to designate more than one entity to share in the allotment.

Proposed § 1329.13(d) implements new Section 711A of the Act, which was added by WIOA. WIOA requires the Administrator to reserve between 1.8 percent and 2 percent of Part B appropriated funds to provide for training and technical assistance to SILCs. The proposed regulation authorizes the technical assistance to be provided directly or through grants, contracts, or cooperative agreements in accordance with Section 711A. ACL intends to provide further information about SILC technical assistance and training in any funding vehicle which makes funds available under Section 711A.

Proposed § 1329.14 describes the requirements for the establishment and maintenance of a Statewide Independent Living Council (SILC). We propose that a State must establish a SILC that meets the requirements of Section 705 of the Act, including composition and appointment of members, in order to receive funding.

WIOA made a number of amendments to the composition of the SILC. WIOA removes the requirement for a director of a project carried out under Section 121 (the American Indian Vocational Rehabilitation Services Program) to be a required SILC member. WIOA added the requirement that, in States with one or more CILs run by or in conjunction with the governing bodies of American Indian tribes located on Federal or State reservations, at least one representative of the directors of such Centers serve as a voting member of the SILC. We ask for comments whether additional directions are needed to implement this provision consistent with the definition of a Center in Section 702 of the Act. For example, we seek information about what types of CIL-Tribal relationships currently exist that would meet this definition, and to what extent might the current CIL-Tribal relationships meet the requirement of CILs ''run by'' or ''run in conjunction with'' the governing bodies of American Indian tribes located on Federal or State reservations.

In proposed § 1329.14(b), ACL proposes to further strengthen the independence of the SILC by requiring that the SILC be independent of and autonomous from the DSE and all other State agencies.

Proposed § 1329.15 describes the duties of the SILC with reference to Section 705 of the Act and incorporates several changes made by WIOA. We propose to clarify in § 1329.15(b) that the SILC may provide contact information for the nearest appropriate CIL, and that sharing of such information does not constitute the direct provision of independent living services. WIOA amended Section 713 of the Act to add new language that limits the share of Part B funds that may be provided to the SILC resource plan. We propose in § 1329.15(c) to incorporate and clarify this change.

The resource plan, as required under Section 705(e) of the Act, is a document that is separate from the SPIL and that describes how resources necessary and sufficient to carry out the functions of the SILC, will be made available. The WIOA amendment to Section 713 provides that not more than 30 percent of the funds allocated to the State may be used for the resource plan, unless the SPIL specifies that a greater percentage is needed.

Because Section 713 refers to funds received under Part B, we propose to include the State's required 10 percent Part B match in calculating the 30 percent cap to provide the resources in its resource plan.[5] The cap on Part B funds being used for the resource plan ensures that there are sufficient financial resources remaining so that the State may achieve the goals and objectives for Part B funding identified in the SPIL. The State match of the Part B funds is included in the calculation of the 30 percent amount, because the Part B funds are not available in the absence of the State match. Treating the State match as part of the 30 percent also creates efficiency and consistency of accounting within the programs regarding treatment of the Part B State match. In addition, it aligns with current practice in other ACL-administered grants, such as the Alzheimer's Disease Supportive Services Program, which include the State match in calculating the caps for administrative costs and the set asides for services required under the Public Health Services Act.

The proposed regulation states that the percentage allocated to the resource plan in each State is based on the amount of Part B funds actually needed (*i.e.,* ''necessary and sufficient'') by each SILC to fulfill its statutory duties and authorities, rather than an expectation that 30 percent is automatically the baseline. Under WIOA, 30 percent is the ceiling, unless the SPIL explicitly authorizes additional funding, and SILCs are not guaranteed the 30 percent. The language authorizing up to 30 percent of Part B funds to be used for the SILC resource plan will not automatically result in a greater share to be allocated to the SILCs, though it may present an opportunity for an increase. The actual percentage received will result from negotiations among the SILC and DSEs as mandated under the law, and, as indicated, may exceed 30 percent if the State specifies that a greater percentage is needed in the approved SPIL. These changes in the law should allow States the flexibility to choose an approach that works best for the IL network in the State.

We have not defined what is meant by funds necessary and sufficient to carry out the functions of the SILC. We seek comments on whether a definition is necessary, including the process for making that determination.

Proposed § 1329.15(d) requires the SILC, as appropriate, to coordinate activities with other entities in the State that provide services similar to or complementary to independent living services. ACL recognizes that many SILCs, as well as many CILs, already coordinate activities with other entities, including Area Agencies on Aging, Protection and Advocacy programs, Long-Term Care Ombudsman Programs, Aging and Disability Resource Centers, and other organizations funded by ACL, other federal agencies, and States. Some SILCs may choose to coordinate with private entities providing similar services. We have chosen not to include a list of all such entities so as to provide SILCs with the maximum flexibility to work with entities in their state to serve individuals with significant disabilities.

Proposed § 1329.16 describes the authorities of the SILC to conduct discretionary activities as described in the State Plan. The proposed rule requires coordination with the CILs. Again, we have chosen not to define how a SILC should engage in coordination, recognizing that such efforts depend on the needs and requirements in each State.

Proposed § 1329.17 sets forth the requirements for the State Plan for

[5] The proposed regulation concerns the Part B funds, to which the ''30 percent'' specifically applies. Many SILCs receive Part B funds and/or Vocational Rehabilitation program Innovation and Expansion (I&E) funds, Social Security reimbursement funds, other federal funds, State matching funds or other public or private funds. Conversely, in several States SILCs receive no Part B funds at all, but are funded instead through I&E funds, primarily, and possibly other non-Part B federal and non-federal funds as well. Of the 32 states/territories that reported using I&E funds towards their SILC Resource Plan in the FY14–16 SPILs, 13 of these funded their SILC Resource Plan entirely with I&E.

Independent Living (SPIL). The SPIL is a plan that identifies activities to achieve the State's specified independent living objectives and reflects the State's commitment to comply with applicable statutory and regulatory requirements. Each State must have a SPIL approved by the Administrator in order to receive both CIL and ILS program funds under the Act, and each SPIL must be reviewed ''not less than once every three years,'' Under Sec. 704(a)(3) of the Act.[6] WIOA did not change the requirement that each SPIL be reviewed not less than once every three years. We propose that the State must submit the SPIL in the form, manner and time frame determined by the Administrator in accordance with Section 704.

WIOA changed the requirements for joint development of the State Plan, and we propose to implement the new requirements in the proposed regulations. Section 704(a)(2) of the Act, 29 U.S.C. 796c(a)(2), was amended to require that the State plan be developed jointly by the chairperson of the SILC and the directors of the Centers for Independent Living in the State, after receiving public input from individuals with disabilities and other stakeholders throughout the State. While WIOA eliminated the required role of the designated State entity (formerly the designated State unit) in development of the State plan, it does not preclude DSE input in the development of the SPIL in collaboration with the SILC and CILs, and ACL would encourage such input. Proposed § 1329.17(d) makes this change.

WIOA also amended Section 704(a)(2) to require that the SPIL be signed by the chairperson of the SILC acting on behalf of and at the direction of the Council; the director of the DSE; and by not less than 51 percent of the directors of the Centers for Independent Living in that State. We propose in § 1329.17(d)(2)(iii), and (iv) to define a CIL for purposes of signing the SPIL as any consumer-controlled, community-based, cross-disability, nonresidential, private nonprofit agency for individuals with significant disabilities, regardless of funding source, that is designed and operated within a local community by individuals with disabilities; and provides an array of IL services, including, at a minimum, independent living core services and complies with the standards set out in Section 725(b) and provides and complies with the assurances in Section 725(c) of the Act and § 1329.5 of these regulations. We seek comments on this approach.

[6] 29 U.S.C. 796c(a)(3).

On a related issue regarding what type of entity constitutes a CIL for SPIL signature purposes, proposed § 1329.17(d)(2)(iii) counts the ''legal entity'' that may receive more than one grant as the entity included in determining the 51 percent, rather than looking at individual grants. For example, an agency that receives multiple Part C grant awards serving different geographical locations and operated by one governing board and that has one director would constitute a single CIL for SPIL signature purposes, rather than labeling each Part C grant awarded to that agency a stand-alone Center for Independent Living. ACL's intent is that the proposed change will add clarity and simplify the signature process. We seek comments on this proposal as well, including whether this change should be implemented and the problems, if any, this interpretation would create. If the proposed language should be implemented in this instance, should it also be applied more broadly across the IL programs? What are the possible implications for the 704 Reporting process?

Additional proposed regulatory language related to the SPIL in proposed § 1329.17 primarily mirrors Section 704 of the Act and existing regulatory language in 34 CFR part 364, with technical changes, and requirements for effective communication and access for individuals with disabilities, as required under existing law, including Section 504 of the Rehabilitation Act and the Americans with Disabilities Act as amended.

Subpart C—Centers for Independent Living

Subpart C of part 1329 of the regulations concerns the Centers for Independent Living. The proposed regulations are derived from and consolidate existing regulations in 34 CFR part 366. ACL proposes to simplify language and processes and to eliminate duplication of language. We invite comment on the need for additional clarity in these regulatory sections.

Proposed § 1329.20 refers to the definition of a CIL and eligible agency in § 1329.4 of the regulations, and includes Rehabilitation Act citations regarding the Part C allotment to States and the funding formula to CILs.

Proposed § 1329.21 outlines the conditions CILs which currently receive Part C funds have to meet in order to receive continuation funding. It also addresses continuation funding requirements for States that receive Part C funds under Section 723 (currently, Minnesota and Massachusetts) and Section 724 (currently American Samoa) of the Act.

Proposed § 1329.22 discusses competitive awards to new Centers for Independent Living in accordance with the requirements of Sections 722(d) of the Act, 29 U.S.C. 796f–1, 796f–2. It stipulates that such awards are provided to the most qualified applicant based on the selection criteria established by the Administrator consistent with Section 722(d) of the Act; subject to the availability of funds; and in accordance with the order of priorities in Section 722(e) of the Act and the State Plan's design for statewide network of Centers.

Proposed § 1329.23 addresses the periodic reviews of CILs to verify compliance with the standards and assurances in Section 725(b) and (c) of the Act and the grant terms and conditions, in accordance with Sections 706(c), 722(g) and 723(g) of the Act and guidance set forth by the Administrator.

Proposed § 1329.24 sets forth the requirement that the Administrator reserve between 1.8 percent and 2 percent of appropriated funds to provide, either directly or through grants, contracts, or cooperative agreements, training and technical assistance to CILs. The proposed regulation states that the training and technical assistance shall be in accordance with Section 721(b) of the Act. ACL intends to provide further guidance in any funding opportunity announcement related to training and technical assistance for CILs.

II. Regulatory Impact Analysis

A. Executive Order 12866

Executive Order 12866 requires that regulations be drafted to ensure that they are consistent with the priorities and principles set forth in Executive Order 12866. The Department has determined that this rule is consistent with these priorities and principles. Executive Order 12866 encourages agencies, as appropriate, to provide the public with meaningful participation in the regulatory process. The rule implements the Workforce Innovation and Opportunity Act enacted on July 22, 2014. In developing the final rule, we will consider input received from the public, including stakeholders.

B. Regulatory Flexibility Analysis

The Secretary certifies under 5 U.S.C. 605(b), the Regulatory Flexibility Act (Pub. L. 96–354), that this regulation will not have a significant economic impact on a substantial number of small entities. The small entities that would be affected by these proposed regulations are States and Centers

receiving Federal funds under these programs. However, the regulations would not have a significant economic impact on States or Centers affected because the regulations would not impose excessive regulatory burdens or require unnecessary Federal supervision. The proposed regulations would implement statutory changes that impose new requirements to ensure the proper expenditure of program funds.

The ILS Program provides formula grants to States for the purpose of funding a number of activities, directly and/or through grant or contractual arrangements. To be eligible for financial assistance, States are required to establish a designated State entity, State Independent Living Council and to submit an approvable three-year State Plan for Independent Living (SPIL) jointly developed by the chairperson of the SILC and the directors of the CILs in the State and signed by the chairperson of the SILC, not less than 51 percent of the directors of the CILs in the state, and the director of the designated State entity (DSE). The signature requirement of not less than 51 percent of CIL directors is a new requirement under WIOA. While this requirement does increase the amount of time a State may need to prepare an approvable SPIL, the statute provides no flexibility in implementing the new requirement. We are not able to estimate the amount of additional time the 51 percent signatory requirement will add to the SPIL development and approval process at the State level given that this is a new requirement. We are soliciting comments from affected States on this issue.

The CILs program provides grants to consumer-controlled, community-based, cross-disability, nonresidential, private nonprofit agencies for the provision of IL services to individuals with significant disabilities. WIOA expanded the previous definition of core IL services, specified in Section 7(17) of the Act, to include a fifth core service. Specifically, Centers funded by the program must now provide services that facilitate transition from nursing homes and other institutions to the community, provide assistance to those at risk of entering institutions, and facilitate transition of youth to postsecondary life. Currently there are 354 CILs that receive federal funding under this program.

WIOA did not include any additional funding for the provision of this new fifth core service, but rather assumed that CILs would reallocate existing grant money to ensure the appropriate provision of all services required under Title VII of the Rehabilitation Act. Since successful transition is a process that requires sustained efforts and supports over a long-term period, and the CILs were aware of the changes under the law before officially tracking these efforts as core services, we do not currently have a clear picture of the impact of the changes under WIOA on the programs, though we are applying the closest applicable data to the estimates in this analysis. We hope to conduct a more throughout analysis when we are able to collect updated data and specifically request comments on the impact of the change.

Analysis of Fiscal Year (FY) 2014 data available in the required annual performance reports (704 Report) indicates that CILs are providing services that are same or similar to the new fifth core service to one or more consumers. For purposes of this analysis, we looked at three specific categories of data currently captured in the 704 Annual Performance Report that we believe most accurately match the three components of the fifth core service.[7] We believe that the ''Relocation from a Nursing Home or Institution'' category matches the first component of the new fifth core service: Facilitate transitions from nursing homes and other institutions to the community. We believe that the ''Community-Based Living'' category matches the second component of the new fifth core service: Provide assistance to those at risk of entering institutions. We believe the ''Youth/Transition Services'' category captures some relevant information for the third component of the new fifth core service: Facilitate transition of youth to postsecondary life. For FY 2014, 281 CILs report nursing home transition goals established for at least one consumer, 343 CILS report community-based living goals established for at least one consumer, and 224 CILs report youth transition services provided to at least one consumer under the ''Youth/Transition Services'' category of the 704 Annual Performance Report.

5th Core service	704 Annual performance report category	Percentage of CILs *	Number of CILS
Facilitate Transitions from Nursing Homes and Other Institutions to the Community.	Relocation from a Nursing Home or Institution	83	281
Provide Assistance to those at risk of entering institutions.	Community-Based Living	99	343
Facilitate Transition of Youth to Postsecondary Life	Youth/Transition Services	66	224

* Percentage of CILs reporting a goal set for at least one consumer. The Youth/Transition Services sub-category represents the percentage of CILs reporting service provision to at least one consumer.

Based on this analysis, we believe that many CILs currently have staff capable of providing the new fifth core service. However, due to the lack of additional funding, compliance with this statutory change may require CILs to re-examine their individual budgets, staffing plans, and consumer needs in order to reallocate funding to ensure the appropriate provisions of services as required by the Rehabilitation Act. We estimate that this analysis will require approximately 10–15 hours of time for each CIL director. We proposed to use the upper end of the time estimate (15 hours) for purposes of estimating the total impact of this statutory requirement. Therefore, we estimate the amount of compliance analysis time for CIL directors to total 5,310 hours.

To estimate the average hourly wage for a CIL director, we examined data compiled by the IL Net (a collaborative project of Independent Living Research Utilization (ILRU), the National Council on Independent Living (NCIL), and the Association of Programs for Rural Independent Living (APRIL)) and Bureau of Labor Statistics (BLS) data. According to a 2003 National Survey of Salaries and Work Experience of Center for Independent Living Directors, compiled by IL Net, the most common annual salary range for CIL directors in 2002 was between $41,000 and $45,000. This equates to an average hourly salary

[7] The current 704 Report was not designed to incorporate the fifth core service, so current data roughly corresponds with the categories.

range of $19.71 to $21.63. The Bureau of Labor Statistics (BLS) provided more recent salary information. According to 2012 BLS data, the average hourly wage for a social and community manager (a BLS occupational classification for managers who coordinate and supervise social service programs) was $28.83. We propose using the more recent BLS data to calculate the total estimated impact of this statutory requirement. In order to estimate the benefits and overhead associated with this hourly wage, we assume that these costs equal 100 percent of pre-tax wages, for a total hourly cost of $57.66. Therefore, we estimate the total dollar impact of this additional CIL director time to be $306,174.60.

As noted previously, we have interpreted recent 704 Reports as indicating that many CILs currently have staff capable of providing the new fifth core service. However, as shown in the table above, a substantial number of CILs do not yet provide the newly required services and therefore would potentially incur costs in order to comply with this proposed rule.[8] We would welcome comments from CILs as to their cost estimates of providing the statutorily-required fifth core service, so as to better inform our budgeting assumptions going forward.

WIOA continues to require annual onsite compliance reviews of at least 15 percent of CILs that receive funding under section 722 of the Act and at least one-third of designated state units that receive funds under section 723 of the Act. The only change made by WIOA was to eliminate the requirement that CILs subject to compliance reviews be selected randomly. ACL is not proposing any changes to the compliance review process in this regulation. We do not anticipate any additional burden on grantees as a result of the compliance and review process, including the development of additional corrective action plans in response to such reviews. While ACL is proposing to establish a new appeals process for States where there is the imminent threat of termination or withholding of funds, we anticipate that the process will be utilized infrequently based on past experience of the Independent Living Services programs. The process is designed to provide additional protection against the termination of funding. Therefore, we do not expect that funds will be terminated more or less frequently.

The allocation of 1.8 to 2 percent of Part B funds to training and technical assistance for SILCs is a new requirement under WIOA. We have limited available data regarding the impact on programs of this provision and therefore request comment on this aspect of the analysis.

The 5 percent administrative cap on the DSE and 30 percent ceiling on the SILC resource plan (absent a different amount with justification in the SPIL) are also new statutory requirements. The NPRM adopts a narrow interpretation of the 5 percent administrative cap, limiting its application to ''Part B'' funds only, rather than applying the 5 percent cap on administrative funds allocated to the DSE to all federal funds supporting the Independent Living Services. Additional funding sources include Social Security reimbursements, Vocational Rehabilitation program Innovation and Expansion (I&E) funds, and other public or private funds. The NPRM avoids a broader application of the cap in an attempt to avoid creating too great a disincentive to State agencies to serve as DSEs, given the more limited role of the DSEs in decision-making (as they no longer have a statutory role in the development of the SPIL). Our intent is to effectuate the limitation as required under the law, while helping ensure retention of DSEs for the Part B programs. We request comment on the impacts of this and other potential approaches.

C. Alternative Approaches

Although we believe that the approach of the proposed rule best serves the purposes of the law, we considered a regulatory scheme requiring an alternative treatment of the Part B State matching funds. In the proposed rule, funds used to meet the required 10 percent state match are treated the same as funds ''received by the State'' under Part B.

To better understand the implications of this decision, consider the five percent administrative cap on the DSE's use of Part B funds for administrative purposes in § 1329.12(a)(5), for example. The proposed regulatory language mandates that WIOA's 5 percent cap on funds for DSE administrative expenses applies only to the Part B funds allocated to the State and to the State's required 10 percent Part B match. It does not apply to other program funds, including, but not limited to, payments provided to a State from the Social Security Administration for assisting Social Security beneficiaries and recipients to achieve employment outcomes, any other federal funds, or to other funds allocated by the State for IL purposes. Treating the issue in this way makes more Part B funds available for IL services and SPIL activities, while retaining sufficient funds to permit the DSE to accomplish its responsibilities and oversight requirements for ILS program funds under the law. One key advantage of this approach is minimizing disruptions to the ILS program from potential DSE decisions to relinquish the program due to insufficient resources to fulfill the WIOA-related fiscal oversight/administrative support responsibilities. For context, on average, 10–15 percent of DSE funding was spent on administrative costs prior to WIOA, though this must be considered along with the more limited role the DSE now plays under the law as amended.

A narrower interpretation of this provision would be to apply it to Part B funds only, without the state match. Not only would this approach severely limit the funds available for fulfillment of DSE responsibilities under the law, it would also create some potential accounting burdens for programs, as State funds provided as a result of the ILS program's State matching requirement have traditionally been treated similarly to Federal Part B funds. It would also be inconsistent with prior accounting practices regarding the 10% State match for Part B funding, which existed prior to WIOA.

The broadest interpretation would include all federal funds supporting the ILS program, including Social Security reimbursements and Innovation and Expansion funds from the Title I (Vocational Rehabilitation) program in the cap, which would broaden the pot of monies allocated for administrative costs of the DSE, which on its face seems counter to the change in the law capping the available percentage for these purposes at a relatively low amount.

D. Paperwork Reduction Act of 1995

The Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.,* requires certain actions before an agency can adopt or revise a collection of information. Under the PRA, we are required to provide notice in the **Federal Register** and solicit public comment before an information collection request is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, Section

[8] Costs of new actions are included in a regulatory impact analysis even when budgets or grant amounts do not change. If CILs are reallocating grant funds to these newly required services, then they are doing some other worthwhile activity to a lesser extent, and the value of that alternative activity represents the opportunity cost of the new requirements.

3506(c)(2)(A) of the PRA requires that we solicit comments on new or revised information collections, which in the case of this rule, includes the new SPIL development requirements. The law is also intended to ensure that stakeholders can fully analyze the impact of the rule, which includes the associated reporting burden. We are not introducing any new information collections in this proposed rule however, it does revise process requirements. As discussed earlier, WIOA changed the requirements regarding SPIL development and who must sign the SPIL.

This NPRM makes no revisions to the 704 reporting instruments, the Section 704 Annual Performance Report (Parts I and II). ACL is currently convening workgroups to recommend and implement changes to the 704 reporting instruments. These changes will be subject to the public comment process under the PRA before they are finalized.

1. State Plans for Independent Living (SPIL)

The SPIL encompasses the activities planned by the State to achieve its specified independent living objectives and reflects the State's commitment to comply with all applicable statutory and regulatory requirements during the three years covered by the plan. A SPIL has already been approved in each State through fiscal year 2016. (State Plan for Independent Living and Center for Independent Living Programs, OMB Control Number 1820–0527.) The law remains unchanged that the SPIL continues to govern the provision of IL services in the State. Each State is expected to continue its support, including specified obligations, for an approved SPIL. Any amendments to the SPIL, reflecting either a change based on the WIOA amendments or any material change in State law, organization, policy, or agency operations that affect the administration of the SPIL, must be developed in accordance with Section 704(a)(2) of the Rehabilitation Act, as amended. SPIL amendments must be submitted by the State to ACL for approval.

WIOA changed the content of the SPIL to the extent that the SPIL must describe how the State will provide independent living services that promote full access to community life for individuals with significant disabilities and describe strategies for providing independent living services on a statewide basis, to the greatest extent possible. The SPIL must also include a justification for any funding allocation of Part B funds above 30% for the SILC's resource plan. We solicit comments on any information we should consider regarding the potential impact of these changes.

We anticipate that such changes may, on average, increase the amount of time to develop the SPIL by five (5) hours. There are 57 SPILs, one for each state, the District of Columbia, and the six territories. Assuming the same hourly cost of $57.66 discussed in the Regulatory Impact Analysis above, we therefore estimate the cost of the changes to be $16,433.1 (57 SPILs × $57.66/hour × 5 hours). We solicit comments on any information we should consider regarding the potential impact of these changes.

2. 704 Reporting Requirements

The Section 704 Annual Performance Report (Parts I and II) are the reporting instruments used to collect information required by the Act, as amended by WIOA, related to the use of Part B and Part C funds. Sections 704(m)(4)(D), 706(d), 704(c)(3) and (4), and 725(c) of the Rehabilitation Act, as amended, and these proposed regulations require CILs and DSEs to submit an annual performance report (704 report) to ACL to receive funding. This proposed regulation simply transfers the statutorily required annual reporting from the Department of Education Regulations to the Department of Health and Human Services (HHS) regulations. No additional reporting requirements are being added to the current OMB approved 704 report at this time. (Section 704 Annual Performance Report (Parts I and II), OMB Control Number 1820–0606).

Prior to WIOA, an effort was underway to make formal changes to the 704 reporting instruments. The passage of WIOA in July 2014 put those efforts on hold until late 2014. ACL is currently convening workgroups to recommend and implement changes to the 704 reporting instruments, and these changes will be subject to the public comment process under the PRA before they are finalized. Key steps in ACL's current and projected timeline on the process include an external workgroup webinar, held April 1, 2015, to share the status of 704 revision efforts and invite feedback on specific issues. It is ACL's goal to publish the revised reporting instruments for comment in **Federal Register** in April 2016. According to this projected timeline, in October 2017, programs will begin collecting information for the FY 18 reporting period using the new 704 reporting instruments. In December 2018, the FY18 704 reports reflecting the new reporting requirements will be due.

Updating the 704 reporting instruments (Parts I and II) will require changes to include the new fifth core service under WIOA. We propose definitions for some of the terms in the fifth core service in this NPRM, and request comments on other areas that need more detail, as well as the burdens on programs of implementing this required core service. Assuming revised 704 reports include reporting on the new fifth core service, we estimate that providing the information will take approximately 1 hour per 704 Report. We estimate the total number of 704 Reports filed annually to be 412.[9] Assuming the same hourly cost of $57.66 discussed in the regulatory impact analysis above, we estimate the cost of the changes to be $23,755.92. In summary, future proposed changes to the Section 704 Annual Performance Report (Parts I and II) will be published in the **Federal Register** in accordance with the requirements of the PRA. However, we seek comments now on these estimates.

Section 706 of the Rehabilitation Act continues to require reviews of CILs funded under Section 722 and reviews of state entities funded under Section 723 of the Rehabilitation Act. Therefore, ACL will continue to conduct compliance reviews and make final decisions on any proposed corrective actions and/or technical assistance related to compliance reviews of a CIL's grants.

In Section 706(b), 29 U.S.C. 796d–1(b), WIOA requires the Administrator to develop and publish in the **Federal Register** new indicators of minimum compliance for Statewide Independent Living Councils. The SILC Standards and Indicators of minimum compliance are currently under development. It is ACL's goal to share a draft for informal stakeholder review by January 2016. The CIL indicators of minimum compliance (consistent with the standards set forth in Section 725) are awaiting the addition of the fifth core service, which requires input in response to this proposed rule.

E. Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995 (Unfunded Mandates Act) requires that a covered agency prepare a budgetary impact statement before promulgating a rule that includes any Federal mandate that may result in expenditures by State, local, or Tribal governments, in the

[9] *See,* 79 FR 23960 (April 29, 2014); information collection approved June 4, 2014 through June 30, 2017. *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201404-1820-001.*

aggregate, or by the private sector, of $100 million, adjusted for inflation, or more in any one year.

If a covered agency must prepare a budgetary impact statement, Section 205 further requires that it select the most cost-effective and least burdensome alternatives that achieves the objectives of the rule and is consistent with the statutory requirements. In addition, Section 203 requires a plan for informing and advising any small government entities that may be significantly or uniquely impacted by a rule.

ACL has determined that this rulemaking does not result in the expenditure by State, local, and Tribal governments in the aggregate, or by the private sector of more than $100 million in any one year. The total FY 2015 budget for the Independent Living Services and Centers for Independent Living programs authorized under Chapter 1, Title VII of the Rehabilitation Act of 1973 (Rehabilitation Act or Act), as amended by WIOA (Pub. L. 113–128) is $101,183,000. We do not anticipate that the rule will impact the majority of the budget for these programs.

F. Congressional Review

This proposed rule is not a major rule as defined in 5 U.S.C. 804(2).

G. Assessment of Federal Regulations and Policies on Families

Section 654 of the Treasury and General Government Appropriations Act of 1999 requires Federal agencies to determine whether a policy or regulation may affect family well-being. If the agency's conclusion is affirmative, then the agency must prepare an impact assessment addressing seven criteria specified in the law. These proposed regulations do not have an impact on family well-being as defined in the legislation.

H. Executive Order 13132

Executive Order 13132 on ''federalism'' was signed August 4, 1999. The purposes of the Order are: ''. . . to guarantee the division of governmental responsibilities between the national government and the States that was intended by the Framers of the Constitution, to ensure that the principles of federalism established by the Framers guide the executive departments and agencies in the formulation and implementation of policies, and to further the policies of the Unfunded Mandates Reform Act . . .''

The Department certifies that this rule does not have a substantial direct effect on States, on the relationship between the Federal government and the States, or on the distribution of power and responsibilities among the various levels of government.

ACL is not aware of any specific State laws that would be preempted by the adoption of the regulation.

List of Subjects in 45 CFR 1329

Centers for independent living, Compliance, Enforcement and appeals, Independent living services, Persons with disabilities, Reporting.

Dated: June 24, 2015.

Kathy Greenlee,

Administrator, Administration for Community Living.

Approved: July 17, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

Regulatory Language

For the reasons discussed in the preamble, the Administration for Community Living, Department of Health and Human Services, proposes to add part 1329 to title 45, chapter XIII, subchapter C, of the Code of Federal Regulations to read as follows:

PART 1329—STATE INDEPENDENT LIVING SERVICES AND CENTERS FOR INDEPENDENT LIVING

Subpart A—General Provisions

Sec.

1329.1 Programs covered.
1329.2 Purpose.
1329.3 Applicability of other regulations.
1329.4 Definitions.
1329.5 Indicators of minimum compliance.
1329.6 Reporting.
1329.7 Enforcement and appeals procedures.

Subpart B—Independent Living Services

1329.10 Authorized use of funds for Independent Living Services.
1329.11 DSE eligibility and application.
1329.12 Role of the designated State entity.
1329.13 Allotment of Federal funds for State independent living (IL) services.
1329.14 Establishment of SILC.
1329.15 Duties of the SILC.
1329.16 Authorities of the SILC.
1329.17 General requirements for a State plan.

Subpart C—Centers for Independent Living Program

1329.20 Centers for Independent Living (CIL) program.
1329.21 Continuation awards to entities eligible for assistance under the CIL program.
1329.22 Competitive awards to new Centers for Independent Living.
1329.23 Compliance reviews.
1329.24 Training and technical assistance to Centers for Independent Living.

Authority: 29 U.S.C. 709; 42 U.S.C. 3515e.

Subpart A—General Provisions

§ 1329.1 Programs covered.

This part includes general requirements applicable to the conduct of the following programs authorized under title VII, chapter 1 of the Rehabilitation Act of 1973, as amended:

(a) Independent Living Services (ILS), title VII, chapter 1, part B (29 U.S.C. 796e to 796e–3).

(b) The Centers for Independent Living (CIL), title VII, chapter 1, part C (29 U.S.C. 796f to 796f–6).

§ 1329.2 Purpose.

The purpose of title VII of the Act is to promote a philosophy of independent living (IL), including a philosophy of consumer control, peer support, self-help, self-determination, equal access, and individual and system advocacy, in order to maximize the leadership, empowerment, independence, and productivity of individuals with disabilities, and to promote the integration and full inclusion of individuals with disabilities into the mainstream of American society by:

(a) Providing financial assistance to States for providing, expanding, and improving the provision of IL services;

(b) Providing financial assistance to develop and support statewide networks of Centers for Independent Living (Centers or CILs)

(c) Providing financial assistance to States, with the goal of improving the independence of individuals with disabilities, for improving working relationships among—

(1) State Independent Living Services;

(2) Centers for Independent Living;

(3) Statewide Independent Living Councils (SILCs or Councils) established under section 705 of the Act (29 U.S.C. 796d);

(4) State vocational rehabilitation (VR) programs receiving assistance under Title 1 of the Act;

(5) State programs of supported employment services receiving assistance under Title VI of the Act;

(6) Client assistance programs (CAPs) receiving assistance under section 112 of the Act (29 U.S.C. 732);

(7) Programs funded under other titles of the Act;

(8) Programs funded under other Federal laws; and

(9) Programs funded through non-Federal sources with the goal of improving the independence of individuals with disabilities.

§ 1329.3 Applicability of other regulations.

Several other regulations apply to all activities under this part. These include but are not limited to:

(a) 45 CFR part 16—Procedures of the Departmental Grant Appeals Board.

(b) 45 CFR part 46—Protection of Human Subjects.

(c) 45 CFR part 75—Uniform Administrative Requirements, Cost Principles, and Audit Requirements for HHS Award.

(d) 45 CFR part 80—Nondiscrimination under Programs Receiving Federal Assistance through the Department of Health and Human Services—Effectuation of title VI of the Civil Rights Act of 1964.

(e) 45 CFR part 81—Practice and Procedures—Practice and Procedure for Hearings under Part 80 of this title.

(f) 45 CFR part 84—Nondiscrimination on the Basis of Handicap in Programs and Activities Receiving Federal Financial Assistance.

(g) 45 CFR part 86—Nondiscrimination on the Basis of Sex in Education Programs and Activities Receiving or Benefiting from Federal Financial Assistance.

(h) 45 CFR part 91—Nondiscrimination on the Basis of Age in Programs or Activities Receiving Federal Financial Assistance from HHS.

(i) 45 CFR part 93—New restrictions on Lobbying.

(j) 2 CFR part 376—Nonprocurement Debarment and Suspension

(k) 2 CFR part 382—Requirements for Drug-Free Workplace (Financial Assistance)

§ 1329.4 Definitions.

For the purposes of this part, the following definitions apply:

Act means the Rehabilitation Act of 1973 (29 U.S.C. 701 *et seq.*), as amended. *Part B* refers to part B of chapter 1 of title VII of the Act (29 U.S.C. 796e to 7963–3). *Part C* refers to part C of chapter 1 of title VII, of the Act (29 U.S.C. 796f to 796f–6).

Administrative support services means services and supports provided by the designated State entity under Part B, and to Part C CILs administered by the State under section 723 of the Act in support of the goals, objectives and related activities under an approved State Plan for Independent Living (SPIL). Such support includes any costs associated with contracts and subgrants including fiscal and programmatic oversight, among other services.

Administrator means the Administrator of the Administration for Community Living (ACL) of the Department of Health and Human Services.

Advocacy means pleading an individual's cause or speaking or writing in support of an individual. To the extent permitted by State law or the rules of the agency before which an individual is appearing, a non-lawyer may engage in advocacy on behalf of another individual. Advocacy may—

(1) Involve representing an individual—

(i) Before private entities or organizations, government agencies (whether State, local, or Federal), or in a court of law (whether State or Federal); or

(ii) In negotiations or mediation, in formal or informal administrative proceedings before government agencies (whether State, local, or Federal), or in legal proceedings in a court of law; and

(2) Be on behalf of—

(i) A single individual, in which case it is individual advocacy;

(ii) A group or class of individuals, in which case it is *systems advocacy;* or

(iii) Oneself, in which case it is *self advocacy.*

Attendant care means a personal assistance service provided to an individual with significant disabilities in performing a variety of tasks required to meet essential personal needs in areas such as bathing, communicating, cooking, dressing, eating, homemaking, toileting, and transportation.

Center for independent living (''*Center*'') means a consumer-controlled, community-based, cross-disability, nonresidential, private nonprofit agency for individuals with significant disabilities (regardless of age or income) that—

(1) Is designed and operated within a local community by individuals with disabilities;

(2) Provides an array of IL services as defined in section 7(18) of the Act, including, at a minimum, independent living core services as defined in section 7(17); and

(3) Complies with the standards set out in Section 725(b) and provides and complies with the assurances in section 725(c) of the Act and § 1329.5 of these regulations.

Completed their secondary education means, with respect to the Independent Living Core Services that facilitate the transition of youth who are individuals with significant disabilities in section 7(17)(e)(iii) of the Act, that an eligible youth has received a diploma; has received a certificate of completion for high school or other equivalent document marking the completion of participation in high school; has reached age 18, even if he or she is still receiving services in accordance with an individualized education program developed under the IDEA; or has exceeded the age of eligibility for services under IDEA.

Consumer control means, with respect to a Center or eligible agency, that the Center or eligible agency vests power and authority in individuals with disabilities, including individuals who are or have been recipients of IL services, in terms of the management, staffing, decision making, operation, and provision of services.

Cross-disability means, with respect to services provided by a Center, that a Center provides services to individuals with all different types of significant disabilities, including individuals with significant disabilities who are members of unserved or underserved populations by programs under Title VII. Eligibility for services shall be determined by the Center, and shall not be based on the presence of any one or more specific significant disabilities.

Designated State entity (DSE) is the State agency designated in the State Plan for Independent Living (SPIL) that acts on behalf of the state to provide the functions described in title VII, chapter 1 of the Act.

Eligible agency means a consumer-controlled, community-based, cross-disability, nonresidential, private, nonprofit agency.

Independent living core services mean, for purposes of services that are supported under the ILS or CIL programs—

(1) Information and referral services;

(2) Independent Living skills training;

(3) Peer counseling, including cross-disability peer counseling;

(4) Individual and systems advocacy;

(5) Services that—

(i) Facilitate the transition of individuals with significant disabilities from nursing homes and other institutions to home and community-based residences, with the requisite supports and services;

(ii) Provide assistance to individuals with significant disabilities who are at risk of entering institutions so that the individuals may remain in the community; and

(iii) Facilitate the transition of youth who are individuals with significant disabilities, who were eligible for individualized education programs under section 614(d) of the Individuals with Disabilities Education Act (20 U.S.C. 1414(d)), and who have completed their secondary education or otherwise left school, to postsecondary life.

Independent living service includes the independent living core services and such other services as described in section 7(18) of the Act.

Individual with a disability means an individual who—

(1) Has a physical or mental impairment that substantially limits one or more major life activities of such individual;

(2) Has a record of such an impairment; or

(3) Is regarded as having such an impairment, as described in section 3(3) of the Americans with Disabilities Act of 1990 (42 U.S.C. 12102(3)).

Individual with a significant disability means an individual with a severe physical or mental impairment whose ability to function independently in the family or community or whose ability to obtain, maintain, or advance in employment is substantially limited and for whom the delivery of independent living services will improve the ability to function, continue functioning, or move toward functioning independently in the family or community or to continue in employment, respectively.

Majority means more than 50 percent.

Minority group means American Indian, Alaskan Native, Asian American, Black or African American (not of Hispanic origin), Hispanic or Latino (including persons of Mexican, Puerto Rican, Cuban, and Central or South American origin), and Native Hawaiian or other Pacific Islander.

Nonresidential means, with respect to a Center, that the Center does not operate or manage housing or shelter for individuals as an IL service on either a temporary or long-term basis unless the housing or shelter is—

(1) Incidental to the overall operation of the Center;

(2) Necessary so that the individual may receive an IL service; and

(3) Limited to a period not to exceed eight weeks during any six-month period.

Peer relationships mean relationships involving mutual support and assistance among individuals with significant disabilities who are actively pursuing IL goals.

Peer role models mean individuals with significant disabilities whose achievements can serve as a positive example for other individuals with significant disabilities.

Personal assistance services mean a range of services, paid or unpaid, provided by one or more persons, designed to assist an individual with a disability to perform daily living activities on or off the job that the individual would typically perform if the individual did not have a disability. These services must be designed to increase the individual's control in life and ability to perform everyday activities on or off the job and include but are not limited to: Getting up and ready for work or going out into the community (including bathing and dressing), cooking, cleaning or running errands.

Service provider means a Center for Independent Living that receives financial assistance under Part B or C of chapter 1 of title VII of the Act; a designated State entity (DSE) that directly provides IL services to individuals with significant disabilities; or any other entity or individual that provides IL services under a grant or contract from the DSE pursuant to section 704(f) of the Act.

State includes, in addition to each of the several States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

State plan means the State Plan for Independent Living (SPIL) required under Section 704 of the Act.

Unserved and underserved groups or populations include populations such as individuals from racial and ethnic minority backgrounds, disadvantaged individuals, individuals with limited English proficiency, and individuals from underserved geographic areas (rural or urban).

Youth with a significant disability means an individual with a significant disability who-

(1) Is not younger than 14 years of age; and

(2) Is not older than 24 years of age.

§ 1329.5 Indicators of minimum compliance.

To be eligible to receive funds under this part, a Center must comply with the standards in section 725(b) and assurances in section 725(c) of the Act, with the indicators of minimum compliance established by the Administrator in accordance with section 706 of the Act, and the requirements contained in the terms and conditions of the grant award.

§ 1329.6 Reporting.

(a) The Center must submit a performance report in a manner and at a time described by the Administrator, consistent with section 704(m)(4)(D) of the Act, 29 U.S.C. 796c(m)(4)(d).

(b) The DSE must submit a report in a manner and at a time described by the Administrator, consistent with section 704(c)(4) of the Act, 29 U.S.C. 796c(c)(4).

(c) The Administrator may require such other reports as deemed necessary to carry out the responsibilities set forth in section 706 of the Act, 29 U.S.C. 796d–1.

§ 1329.7 Enforcement and appeals procedures.

(a) *Process for Centers for Independent Living.* (1) If the Director of the Independent Living Administration (Director) determines that any Center receiving funds under this part, other than a Center that is provided Part C funding by the State under section 723 of the Act, is not in compliance with the standards and assurances in section 725 (b) and (c) of the Act and of this part, the Director must provide notice to the Center pursuant to guidance determined by the Administrator.

(2) The Director may offer technical assistance to the Center to develop a corrective action plan or to take such other steps as are necessary to come into comply with the standards and assurances.

(3) The Center may request a preliminary appeal to the Director in a form and manner determined by the Administrator. The Director shall review the appeal request and provide written notice of the determination within a timely manner.

(4) Where there is an imminent threat of termination or withholding of funds, the Center may appeal an unfavorable decision by the Director to the Administrator within a time and manner established by the Administrator. The Administrator shall review the appeal request and provide written notice of the determination within a timely manner.

(5) The Administrator may take steps to enforce a corrective action plan or to terminate funding if the Administrator determines that the Center remains out of compliance.

(6) Written notice of the determination by the Administrator shall constitute a final determination for purposes of 45 CFR part 16. A Center that receives such notice, which would result in termination or withholding of funds, may appeal to the Departmental Appeals Board pursuant to the provisions of 45 CFR part 16.

(7) A Center that is administered by the State under Section 723 of the Act must first exhaust any State process before going through the process described in paragraphs (a)(1) through (6) of this section.

(b) *Process for States.* (1) If the Director of the Independent Living Administration determines that a State is out of compliance with sections 704, 705, 713 or other pertinent sections of the Act, the Director must provide notice to the State pursuant to guidance determined by the Administrator.

(2) The Director may offer technical assistance to the State to develop a corrective action plan or to take such

other steps as are necessary to ensure that the State comes in to compliance.

(3) Where there is an imminent threat of termination or withholding of funds, the State may seek an appeal consistent with the steps set forth in paragraphs (a)(3) and (4) of this section.

(4) The Administrator may take steps to enforce statutory or regulatory requirements or to terminate funding if the Administrator determines that the State remains out of compliance.

(5) Written notice of the determination by the Administrator shall constitute a final determination for purposes of 45 CFR part 16 with regard to the types of determinations set forth in 45 CFR part 16, appendix A, section C, paragraphs (a)(1) through (4). A State that receives such notice that would result in termination or withholding of funds may appeal to the Departmental Appeals Board pursuant to the provisions of 45 CFR part 16.

Subpart B—Independent Living Services

§ 1329.10 Authorized use of funds for Independent Living Services.

(a) The State, after reserving funds under section 13(d) for SILC training and technical assistance:

(1) May use funds received under this part to support the SILC resource plan described in section 705(e) of the Act but may not use more than 30 percent of the funds unless an approved SPIL so specifies pursuant to § 1329.15(c);

(2) May retain funds under section 704(c)(5) of the Act; and

(3) Shall distribute the remainder of the funds received under this part in a manner consistent with the approved State plan for the activities described in paragraph (b) of this section.

(b) The State may use the remainder of the funds described in paragraph (a)(3) of this section to—

(1) Provide to individuals with significant disabilities the independent living (IL) services required by section 704(e) of the Act, particularly those in unserved areas of the State;

(2) Demonstrate ways to expand and improve IL services;

(3) Support the operation of Centers for Independent Living (Centers) that are in compliance with the standards and assurances in section 725 (b) and (c) of the Act;

(4) Support activities to increase the capacities of public or nonprofit agencies and organizations and other entities to develop comprehensive approaches or systems for providing IL services;

(5) Conduct studies and analyses, gather information, develop model policies and procedures, and present information, approaches, strategies, findings, conclusions, and recommendations to Federal, State, and local policy makers in order to enhance IL services for individuals with significant disabilities;

(6) Train individuals with disabilities and individuals providing services to individuals with disabilities, and other persons regarding the IL philosophy; and

(7) Provide outreach to populations that are unserved or underserved by programs under title VII of the Act, including minority groups and urban and rural populations.

§ 1329.11 DSE eligibility and application.

(a) Any designated State entity (DSE) identified by the State pursuant to section 704(c) is eligible to apply for assistance under this part in accordance with section 704 of the Act, 29 U.S.C. 796c.

(b) To receive financial assistance under Parts B and C of chapter 1 of title VII, a State shall submit to the Administrator and obtain approval of a State plan that meets the requirements of section 704 of the Act, 29 U.S.C. 796c.

(c) Allotments to states are determined in accordance with section 711 of the Act, 29 U.S.C. 796e.

§ 1329.12 Role of the designated State entity.

(a) A DSE that applies for and receives assistance must:

(1) Receive, account for, and disburse funds received by the State under Part B and Part C in a State under section 723 of the Act based on the state plan;

(2) Provide administrative support services for a program under Part B and for CILs under Part C when administered by the State under section 723 of the Act, 29 U.S.C. 796f–2;

(3) Keep such records and afford such access to such records as the Administrator finds to be necessary with respect to the programs;

(4) Submit such additional information or provide such assurances as the Administrator may require with respect to the programs; and

(5) Retain not more than 5 percent of the funds received by the State for any fiscal year under Part B, for the performance of the services outlined in paragraphs (a)(1) through (4) of this section. For purposes of these regulations, the 5 percent cap on funds for administrative expenses applies only to the Part B funds allocated to the State and to the State's required 10 percent Part B match. It does not apply to other program income funds, including, but not limited to, payments provided to a State from the Social Security Administration for assisting Social Security beneficiaries and recipients to achieve employment outcomes, any other federal funds, or to other funds allocated by the State for IL purposes.

(b) The DSE must also carry out its other responsibilities under the Act, including, but not limited to, arranging for the delivery of IL services under Part B of the Act, and for the necessary and sufficient resources needed by the SILC to fulfill its statutory duties and authorities, as authorized in the approved State Plan.

(c) Fiscal and accounting requirements: The DSE must adopt fiscal control and fund accounting procedures as may be necessary to ensure the proper disbursement of and accounting for federal funds provided to CILs, SILCs, and/or other services providers under the ILS program. The DSE must comply with all applicable federal and state laws and regulations, including those in 45 CFR parts 75.

§ 1329.13 Allotment of Federal funds for State independent living (IL) services.

(a) The allotment of Federal funds for State IL services for each State is computed in accordance with the requirements of section 711(a)(1) of the Act.

(b) Notwithstanding paragraph (a) of this section, the allotment of Federal funds for Guam, American Samoa, the United States Virgin Islands, and the Commonwealth of the Northern Mariana Islands is computed in accordance with section 711(a)(2) of the Act.

(c) If the State plan designates a State agency or unit of a State agency to administer the part of the plan under which State IL services are provided for individuals who are blind and a separate or different State agency or unit of a State agency to administer the rest of the plan, the division of the State's allotment between these two units is a matter for State determination, consistent with the State plan.

(d) The Administrator shall reserve between 1.8 percent and 2 percent of appropriated funds to provide, either directly or through grants, contracts, or cooperative agreements, training and technical assistance to SILCs. Training and technical assistance funds shall be administered in accordance with section 711A of the Act.

§ 1329.14 Establishment of a SILC.

(a) To be eligible to receive assistance under this part, each state shall establish and maintain a SILC that meets the requirements of section 705 of

the Act, including composition and appointment of members.

(b) The SILC shall not be established as an entity within a State agency, including the DSE. The SILC shall be independent of and autonomous from the DSE and all other State agencies.

§ 1329.15 Duties of the SILC.

(a) The duties of the SILC are those set forth in section 705(c), (d), and (e) of the Act.

(1) The SILC shall develop of the SPIL in accordance with guidelines developed by the Administrator.

(2) The SILC shall monitor, review and evaluate the implementation of the SPIL on a regular basis as determined by the SILC and set forth in the SPIL.

(3) The SILC shall meet regularly, and ensure that such meetings are open to the public and sufficient advance notice of such meetings is provided;

(4) The SILC shall submit to the Administrator such periodic reports as the Administrator may reasonably request, and keep such records, and afford such access to such records, as the Administrator finds necessary to verify the information in such reports; and

(5) The SILC shall, as appropriate, coordinate activities with other entities in the State that provide services similar to or complementary to independent living services, such as entities that facilitate the provision of or provide long-term community-based services and supports.

(b) In carrying out the duties under this section, the SILC may provide contact information for the nearest appropriate CIL. Sharing of such information shall not constitute the direct provision of independent living services as defined in section 705(c)(3) of the Act.

(c) The SILC, in conjunction with the DSE, shall prepare a plan for the provision of resources, including staff and personnel that are necessary and sufficient to carry out the functions of the SILC.

(1) The resource plan amount shall be commensurate, to the extent possible, with the estimated costs related to SILC fulfilment of its duties and authorities consistent with the approved State Plan.

(2) Such resources may consist of Part B funds, State matching funds, Innovation and Expansion (I & E) funds authorized by 29 U.S.C. 721(a)(18), and other public and private sources.

(3) In accordance with § 1329.10(a)(1), no more than 30 percent of the State's allocation of Part B and Part B State matching funds may be used to fund the resource plan, unless the approved SPIL provides that more than 30 percent is needed and justifies the greater percentage.

(4) No conditions or requirements may be included in the SILC's resource plan that may compromise the independence of the SILC.

(5) The SILC is responsible for the proper expenditure of funds and use of resources that it receives under the resource plan.

(6) A description of the SILC's resource plan must be included in the State plan.

(d) As appropriate, the SILC shall coordinate activities with other entities in the State that provide services similar to or complementary to independent living services, such as entities that facilitate the provision of or provide long-term community-based services and supports, to better serve individuals with significant disabilities and help achieve the purpose of section 701 of the Act.

(e) The SILC shall, consistent with State law, supervise and evaluate its staff and other personnel as may be necessary to carry out its functions under this section.

§ 1329.16 Authorities of the SILC.

(a) The SILC may conduct the following discretionary activities, as authorized and described in the approved State Plan:

(1) Work with Centers for Independent Living to coordinate services with public and private entities to improve services provided to individuals with disabilities;

(2) Conduct resource development activities to support the activities described in the approved SPIL and/or to support the provision of independent living services by Centers for Independent Living; and

(3) Perform such other functions, consistent with the purpose of this part and comparable to other functions described in section 705(c) of the Act, as the Council determines to be appropriate and authorized in the approved SPIL.

(b) In undertaking the foregoing duties and authorities, the SILC shall:

(1) Coordinate with the CILs in order to avoid conflicting or overlapping activities within the CILs' established service areas;

(2) Not engage in activities that constitute the direct provision of IL services to individuals, including the IL core services; and

(3) Comply with Federal prohibitions against lobbying.

§ 1329.17 General requirements for a State plan.

(a) The State may use funds received under Part B to support the Independent Living Services program and to meet its obligation under the Act, including the section 704(e) requirements that apply to the provision of independent living services. The State plan must stipulate that the State will provide IL services, directly and/or through grants and contracts, with Federal, State or other funds, and must describe how and to whom those funds will be disbursed for this purpose.

(b) In order to receive financial assistance under this part, a State shall submit to the Administrator a State plan for independent living.

(1) The State plan must contain, in the form prescribed by the Administrator, the information set forth in section 704 of the Act, including designation of an Agency to serve as the designated State entity, and such other information requested by the Administrator.

(2) The State plan must contain the assurances set forth in section 704(m) of the Act.

(3) The State plan must be signed in accordance with the provisions of this part.

(4) The State plan must be submitted 90 days before the completion date of the proceeding plan, and otherwise in the time frame and manner prescribed by the Administrator.

(5) The State plan must be approved by the Administrator.

(c) The State plan must cover a period of not more than three years and must be amended whenever necessary to reflect any material change in State law, organization, policy, or agency operations that affects the administration of the State plan.

(d) The State plan must be jointly—

(1) Developed by the chairperson of the SILC, and the directors of the CILs, after receiving public input from individuals with disabilities and other stakeholders throughout the State; and

(2) Signed by the—

(i) Chairperson of the SILC, acting on behalf of and at the direction of the SILC;

(ii) The director of the DSE; and

(iii) Not less than 51 percent of the directors of the CILs in the State. For purposes of this provision, if a legal entity that constitutes the ''CIL'' has multiple Part C grants considered as separate Centers for all other purposes, for SPIL signature purposes, it is only considered as one Center.

(e) In States where DSE duties are shared with a separate State agency authorized to administer vocational rehabilitation (VR) services for individuals who are blind, the State plan must be signed by the:

(1) Director of the DSE;

(2) Director of the separate State agency authorized to provide VR services for individuals who are blind;

(3) Chairperson of the SILC, acting on behalf of and at the direction of the SILC; and

(4) Not less than 51 percent of the directors of the CILs in the State.

(f) Periodic review and revision. The State plan must provide for the review and revision of the plan, not less than once every three years, to ensure the existence of appropriate planning, financial support and coordination, and other assistance to meet the requirements of section 704(a) of the Act.

(g) *Public input.* (1) The public, including people with disabilities and other stakeholders throughout the State, must have an opportunity to comment on the State plan prior to its submission to the Administrator and on any revisions to the approved State plan. Meeting this standard for public input from individuals with disabilities requires providing reasonable modifications in policies, practices, or procedures; effective communication and appropriate auxiliary aids and services for individuals with disabilities, which may include the provision of qualified interpreters and information in alternate formats, free of charge.

(2) The requirement in paragraph (g)(1) of this section may be met by holding public meetings before a preliminary draft State plan is prepared or by providing a preliminary draft State plan for comment at the public meetings, as appropriate.

(3) To meet the public input standard of paragraph (g) of this section, a public meeting requires:

(i) Accessible, appropriate and sufficient notice provided at least 30 days prior to the public meeting through various media available to the general public, such as Web sites, newspapers and public service announcements, and through specific contacts with appropriate constituency groups.

(ii) All notices, including notices published on a Web site, and other written materials provided at or prior to public meetings must be available upon request in accessible formats.

(h) The State plan must identify those provisions that are State-imposed requirements. For purposes of this section, a State-imposed requirement includes any State law, regulation, rule, or policy relating to the DSE's administration or operation of IL programs under Title VII of the Act, including any rule or policy implementing any Federal law, regulation, or guideline that is beyond what would be required to comply with the regulations in this part.

(i) The State plan must address how the specific requirements in the Act and in paragraph (g) of this section will be met.

Subpart C—Centers for Independent Living Program

§ 1329.20 Centers for Independent Living (CIL) program.

State allotments of Part C, funds shall be based on section 721(c) of the Act, and distributed to Centers within the State in accordance with the order of priorities in sections 722(e) and 723(e) of the Act.

§ 1329.21 Continuation awards to entities eligible for assistance under the CIL program.

(a) In any State in which the Administrator has approved the State plan required by section 704 of the Act, an eligible agency funded under Part C in fiscal year 2015 may receive a continuation award in FY 2016 or a succeeding fiscal year if the Center has—

(1) Complied during the previous project year with the standards and assurances in section 725 of the Act and the terms and conditions of its grant; and

(2) Submitted an approvable annual performance report demonstrating that the Center meets the indicators of minimum compliance referenced in in § 1329.5.

(b) If an eligible agency administers more than one Part C grant, each of the Center grants must meet the requirements of paragraph (a) of this section to receive a continuation award.

(c) A designated State entity (DSE) that operated a Center in accordance with section 724(a) of the Act in fiscal year (FY) 2015 is eligible to continue receiving assistance under this part in FY 2016 or a succeeding fiscal year if, for the fiscal year for which assistance is sought—

(1) No nonprofit private agency submits and obtains approval of an acceptable application under section 722 or 723 of the Act to operate a Center for that fiscal year before a date specified by the Administrator; or

(2) After funding all applications so submitted and approved, the Administrator determines that funds remain available to provide that assistance.

(d) A Center operated by the DSE under section 724(a) of the Act must comply with paragraphs (a), (b), and (c) of this section to receive continuation funding, except for the requirement that the Center be a private nonprofit agency.

(e) A designated State entity that administered Part C funds and awarded grants directly to Centers within the State under section 723 of the Act in fiscal year (FY) 2015 is eligible to continue receiving assistance under section 723 in FY 2016 or a succeeding fiscal year if the Administrator determines that the amount of State funding earmarked by the State to support the general operation of Centers during the preceding fiscal year equaled or exceeded the amount of federal funds allotted to the State under section 721(c) of the Act for that fiscal year.

(f) A DSE may apply to administer Part C funds under section 723 in the time and in the manner that the Administrator may require, consistent with section 723(a)(1)(A) of the Act.

(g) Grants awarded by the DSE under section 723 of the Act are subject to the requirements of paragraphs (a) and (b) of this section and the order of priorities in section 723(e) of the Act, unless the DSE and the SILC jointly agree on another order of priorities.

§ 1329.22 Competitive awards to new Centers for Independent Living.

(a) Subject to the availability of funds and in accordance with the order of priorities in section 722(e) of the Act and the State Plan's design for the statewide network of Centers, an eligible agency may receive Part C funding as a new Center for Independent Living in a State, if the eligible agency:

(1) Submits to the Administrator an application at the time and manner required in the funding opportunity announcement (FOA) issued by the Administrator which contains the information and meets the selection criteria established by the Administrator in accordance with section 722(d) of the Act;

(2) Proposes to serve a geographic area that has been designated as a priority unserved or underserved in the State Plan for Independent Living and that is not served by an existing Part C-funded Center; and

(3) Is determined by the Administrator to be the most qualified applicant to serve the designated priority area consistent with the State plan setting forth the design of the State for establishing a statewide network of Centers for independent living.

(b) An existing Part C-funded Center may apply to serve the designated unserved or underserved areas if it proposes the establishment of a separate and complete Center (except that the governing board of the existing center may serve as the governing board of the new Center) at a different geographical

location, consistent with the requirements in the FOA.

(c) An eligible agency located in a bordering State may be eligible for a new CIL award if the Administrator determines, based on the submitted application, that the agency:

(1) Is the most qualified applicant meeting the requirements in paragraphs (a) and (b) of this section; and

(2) Has the expertise and resources necessary to serve individuals with significant disabilities who reside in the bordering State, in accordance with the requirements of the Act and these regulations.

(d) If there are insufficient funds under the State's allotment to fund a new Center, the Administrator may—

(1) Use the excess funds in the State to assist existing Centers consistent with the State plan; or

(2) Reallot these funds in accordance with section 721(d) of the Act.

§ 1329.23 Compliance reviews.

(a) Centers receiving Part C funding shall be subject to periodic reviews, including on-site reviews, in accordance with sections 706(c), 722(g), and 723(g) of the Act and guidance set forth by the Administrator, to verify compliance with the standards and assurances in section 725(b) and (c) of the Act and the grant terms and conditions. The Administrator shall annually conduct reviews of at least 15 percent of the Centers.

(b) A copy of each review under this section shall be provided, in the case of section 723(g), by the director of the DSE to the Administrator and to the SILC, and in the case of section 722(g), by the Administrator to the SILC and the DSE.

§ 1329.24 Training and technical assistance to Centers for Independent Living.

The Administrator shall reserve between 1.8% and 2% of appropriated funds to provide training and technical assistance to Centers through grants, contracts or cooperative agreements, consistent with section 721(b) of the Act. The training and technical assistance funds shall be administered in accordance with section 721(b) of the Act.

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Notices

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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

Food Safety and Inspection Service

[Docket Number FSIS–2013–0029]

RIN 0583–AD39

Availability of FSIS Compliance Guidelines for Allergens and Ingredients of Public Health Concern: Identification, Prevention and Control, and Declaration Through Labeling

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of availability.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing the availability of an updated version of the Agency's compliance guidelines for controlling hazards posed by allergens and other ingredients of public health concern. The guidelines provide recommendations for identifying hazards when conducting a hazard analysis and for preventing and controlling hazards through a hazard analysis and critical control point (HACCP) plan or Sanitation standard operating procedures (SOPs) or other prerequisite programs with respect to these substances.

ADDRESSES: A downloadable version of the revised compliance guide is available to view and print at [*http://www.fsis.usda.gov/wps/wcm/connect/f9cbb0e9-6b4d-4132-ae27-53e0b52e840e/Allergens-Ingredients.pdf?MOD=AJPERES*]. No hard copies of the compliance guidelines have been published.

FOR FURTHER INFORMATION CONTACT: For further information contact Daniel Engeljohn, Assistant Administrator, Office of Policy and Program Development, FSIS, U.S. Department of Agriculture, 1400 Independence Avenue SW., Washington, DC 20250–3700, (202) 205–0495.

SUPPLEMENTARY INFORMATION:

Background

On April 21, 2014, FSIS published a **Federal Register** notice (79 FR 22083) announcing the availability of and opportunity to comment on Agency guidance on allergens and other ingredients of public health concern. FSIS explained that in recent years (2008-2012), there had been a sustained increase in the number of recalls of FSIS-regulated product that contained undeclared allergens, and that these recalls were preventable as many had been the result of ingredient changes, product changes, products in the wrong package, or products with misprinted labels. The Agency also explained that the consumption of meat and poultry products containing ingredients of public health concern, such as undeclared allergens, may result in adverse health outcomes for certain individuals.

The Agency explained that it was issuing the guidelines to provide meat and poultry establishments with recommendations on how to identify hazards with respect to allergens and other ingredients of public health concern when conducting their hazard analysis, how to prevent and control these hazards through HACCP plans, Sanitation SOPs, or other prerequisite programs, and how to properly declare allergens in product. The guidelines also provided information on proper procedures for processing, handling, storing, and labeling a product with an allergenic ingredient or ingredient of public health concern.

In addition, the Agency explained that the guidelines represent the best practice recommendations of FSIS, based on scientific and practical considerations, and that the recommendations are not requirements. FSIS said that by following the guidelines, establishments would be likely to ensure that product labels declare all ingredients, as required in the regulations, and that the product would not contain undeclared allergens or other undeclared ingredients. FSIS recommended that establishments consider incorporating the guidelines in their HACCP plan or Sanitation SOPs or other prerequisite programs.

Updated Guidelines:

FSIS has updated the guidelines to include numbered appendices for diagrams, checklists, and supplemental information to simplify locating these references. In response to the comments discussed below, FSIS updated the guidelines by:

- Clarifying, on pages 2 and 4, that the focus of the document is on FSIS-regulated establishments, state-regulated establishments, and operations where all or part of the premises meet the ''food processing plant'' definition, as defined in the Food and Drug Administration's (FDA) ''2013 Food Code'';
- clarifying, in Section 1.2, page 5, that sulfur-based preservatives (sulfites), lactose, FD&C Yellow 5 (Tartrazine), gluten, and monosodium glutamate (MSG) are ingredients of concern that may result in adverse reactions in certain susceptible individuals, yet they are not considered allergens;
- revising the ''What is a letter of guarantee (LOG)?'' box on page 8, and adding a paragraph on page 9 to clarify and describe a LOG, the difference between a LOG and a Certificate of Analysis (COA), and the communication and coordination between an establishment and its suppliers that FSIS recommends when an establishment relies on LOGs;
- adding ''Allergenic Ingredients and Foods,'' a listing of allergenic ingredients and foods that may contain allergenic ingredients, as a resource (Appendix 6);
- adding ''Tips for Avoiding Your Allergen,'' published by Food Allergy Research and Education (FARE) to the ''References and Resources'' section (Appendix 7); and
- adding FSIS Directive 8080.1, ''Recall of Meat and Poultry Products,'' to the ''References and Resources'' section (Appendix 7).

In addition, in Section 2.1, FSIS edited the text to emphasize the purpose of a hazard analysis and a hazard identification. Under Section 2.3, FSIS edited the third paragraph to delete that an establishment include storage in its HACCP system because that guidance is included in the first paragraph of this section. Also, in Section 2.3, FSIS added the recommendation that an establishment conduct simulations with inaccurate product labels to test system, checklists, and procedures as a step to prevent mislabeling during packing, labeling, and storage of the final product.

Comments and Responses

FSIS received a total of seven comments in response to the April 2014 **Federal Register** notice and guidelines. The commenters included consumer and trade organizations, individuals, and a professional organization. The comments and the Agency's responses are discussed below.

Comment: A professional organization recommended that FSIS modify the introductory sections of the document to clarify that the compliance guidelines were developed for a processing setting.

Response: FSIS has modified the introductory sections of the guidelines to clarify that the emphasis of the document is on FSIS-regulated establishments, state-regulated establishments, and operations where all or part of the premises meet the food processing plant definition as defined in the FDA ''2013 Food Code,'' available online at (*http://www.fda.gov/downloads/Food/GuidanceRegulation/RetailFoodProtection/FoodCode/UCM374510.pdf*).

Comment: An individual commented that Attachment 3 to FSIS Notice 29–13, ''Allergenic Ingredients and Foods,'' is very useful, especially to very small meat and poultry establishments, including those that are dual jurisdiction processing establishments, and that it should be included in the compliance guidelines.

Response: The attachment, entitled, ''Allergenic Ingredients and Foods,'' is based on ''Tips for Avoiding Your Allergen,'' published by Food Allergy Research and Education (FARE). FSIS Notice 29–13 was issued in April 2013 and is now expired. FSIS agrees that the attachment provides useful information and has included it in the guidelines as Appendix 7.

Comment: A consumer group recommended clarifying that some of the ingredients listed under Section 1.2 are not allergens, and that monosodium glutamate (MSG) should not be included because research has not confirmed that it causes adverse reactions.

Response: The list of ingredients in Section 1.2 has been modified to clarify that sulfur-based preservatives (sulfites), lactose, FD&C Yellow 5 (Tartrazine), gluten, and monosodium glutamate (MSG) are ingredients that may result in an adverse reaction in certain susceptible individuals, yet they are not considered allergens. FSIS is concerned about all foods or food ingredients that may cause adverse health effects. Therefore, MSG remains an ingredient of public health concern.

Comment: A trade group recommended that, to ensure that industry is aware of the recommendations in the compliance guide, FSIS provide outreach to the meat and poultry industry.

Response: FSIS intends to provide outreach to the meat and poultry industry on the compliance guidelines by conducting web-based (webinar) sessions for industry and announcing he compliance guide recommendations on the FSIS Small Plant News Web page at *http://www.fsis.usda.gov/wps/portal/fsis/newsroom/meetings/newsletters/small-plant-news/small-plant-news.*

Comment: One commenter requested that FSIS require the listing of all spices by name on product labels. The commenter stated that spice allergies are significant health concerns and that food labels need to specifically list all spices in the product. The commenter was specifically concerned with the labeling of garlic.

Response: The Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA) require the listing of the common or usual name of ingredients on product labels, except that spices and flavorings may be designated as ''spices'' and ''flavorings,'' without naming each ingredient. Therefore, FSIS does not have the legal authority to require the listing of each spice or flavoring. The term ''spice'' is defined in the FSIS labeling regulations (9 CFR 317.2(f)(1)(i)(A) and 381.118(c)(1)) to mean any aromatic vegetable substance in the whole, broken or ground form, with the exceptions of onions, garlic and celery, whose primary function in food is seasoning rather than nutritional, and from which no portion of any volatile oil or other flavoring principle has been removed. In addition, the terms ''natural flavor,'' ''natural flavoring,'' ''flavor,'' or ''flavoring'' may be used to designate spices as well as powdered garlic, powdered onion, or celery powder, specifically. If whole or broken garlic is used in the formulation of the product, it would need to be declared in the list of ingredients.

Comment: Two trade organizations commented that throughout the guidelines, the focus was on the ''Big Eight'' allergens with little discussion of the ingredients of concern that may cause adverse reactions in susceptible individuals. The commenters recommended that a list of ingredients of public health concern be created in collaboration with the National Institute of Allergy and Infectious Diseases or similarly informed entity.

Response: FSIS is concerned about all foods or food ingredients that may cause adverse health effects. These include the ''Big Eight'' ingredients as well as other ingredients of concern. As discussed above, FSIS has modified the list of ingredients in Section 1.2 to clarify that sulfur-based preservatives (sulfites), lactose, FD&C Yellow 5 (Tartrazine), gluten, and monosodium glutamate (MSG) are ingredients of concern that may cause adverse reactions in certain susceptible individuals. However, FSIS has not established a list of all ingredients to which consumers have reported adverse reactions. Establishments are required to be aware of the ingredients they are using in the production of their products and to determine whether the ingredients may trigger food sensitivities. They need to employ the necessary in-plant controls to prevent cross-contact and assure accurate label declarations.

In addition, FSIS Directive 8080.1, ''Recall of Meat and Poultry Products,'' lists factors considered by the FSIS Recall Committee when evaluating the public health significance of an undeclared ingredient in a meat or poultry product. The directive lists the questions and other factors that the Agency considers. Although the Directive provides instructions to FSIS personnel, the questions that the FSIS recall committee considers will be helpful to industry also. Therefore, the Directive has been added to the ''References and Resources'' section (Appendix 7).

Comment: A trade organization recommended that the list of undeclared allergen recalls include the corrective actions taken to ensure that allergens appear on the label.

Response: FSIS agrees that providing undeclared allergen corrective action scenarios could be a useful mechanism to ensure that allergens appear on the label. ''Allergen Scenarios and Possible Prevention Measures,'' Appendix 5 of the compliance guidelines, is based on historical recalls, giving some insight into the possible preventive measures that would have prevented the undeclared allergen.

Comment: Two trade organizations commented that requiring establishments to review ingredient lists on a continuous basis, especially when an establishment has changed suppliers, or the supplier has modified the ingredient formula, would create unjustified increases in manufacturing cost. They additionally commented that a review of letters of guarantee should not to be confused with certificates of analysis.

Response: FSIS has edited the ''What is a letter of guarantee (LOG)'' box on page 8 of the guidelines, as well as the description of recommendations on page 9 to clarify what are Letters of

Guarantee. As mentioned above, establishments are required to be aware of the ingredients they are using in the production of their products and to determine whether they have considered and employed the necessary in-plant controls to prevent cross-contact and assure accurate label declarations. LOGs are a means to prevent the possible inclusion in the product of an allergen that is not declared on the product label. If a LOG is only a general statement, the establishment should consider initiating a dialogue with its suppliers to ensure the establishment understands ingredient information or to recommend that more specific information be included in LOGs. However, these are guidelines, and FSIS is not establishing any new requirements.

Comment: Two trade organizations commented that if the Agency is suggesting that testing is the only way to meet the guidelines, the guidelines are regulatory requirements that should follow proper rulemaking procedures. The commenters stated that examples of cleaning controls and procedures of sanitation verification should be provided in the guidelines. They also recommended that testing ingredients should only be done in cooperation and knowledge of the supplier to ensure that related product is properly held.

Response: Because some FSIS-regulated establishments conduct testing for allergens in their products, page 12 of the guidelines includes information about the test kits and the use of reference laboratories. As stated in the guidelines, allergen testing may be considered to verify and document sanitation effectiveness. As also noted in the guidelines, testing is not the only way to demonstrate that allergens are not presented on a production line, on equipment, or in product, Section 2.2 specifically addresses sanitation. Therefore, testing is not required, and the guidelines do not represent regulatory requirements.

When establishments conduct allergen testing of ingredients, FSIS encourages communication with the supplier. Also, FSIS recommends that establishments hold or control product tested for allergens until they receive results, although doing so is not required. Establishments should design their food safety system within their available resources to take all necessary and practical steps to ensure that only safe product enters commerce.

Comment: Two trade organizations commented that proper labeling and packaging of products constitutes product separation. They stated that recommending unrealistic definitions of separation would be an unwarranted expense that would not effectively correct the cause of allergen recalls.

Response: Properly labeling and packaging products is essential and required by FSIS regulations and authorizing statues. As an additional preventive measure, as stated in the guidance, establishments should consider whether the identification and separation of products would effectively prevent employees from selecting the wrong ingredient during formulation, the wrong label, or the wrong product.

Comment: Two trade organizations commented that the compliance guideline establishes regulatory requirements. They recommended that the document more clearly state that the practices in the compliance guidelines are neither regulatory requirements nor the only way to control and prevent undeclared allergens in the production process.

Response: The compliance guidelines are intended to inform industry about effective and innovative methods to address the problem of undeclared allergens and ingredients of public health concern. The document does not establish any new requirements that industry must follow, but rather it is intended to assist establishments in meeting the existing FSIS labeling and HACCP regulations.

The compliance guidelines provide recommendations, not requirements, to establishments for identifying hazards when conducting a hazard analysis and for preventing and controlling hazards with respect to allergens and other ingredients of public health concern through the implementation of HACCP plans, sanitation SOPs, or other prerequisite programs. The guidelines were edited to clarify that the document consists of recommendations, not requirements.

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: November 9, 2015.

Alfred V. Almanza,

Acting Administrator.

[FR Doc. 2015–28935 Filed 11–13–15; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF AGRICULTURE

Forest Service

Yakutat Resource Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Yakutat Resource Advisory Committee (RAC) will meet in Yakutat, Alaska. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act. RAC information can be found at the following Web site *http://cloudapps-usda-gov.force.com/FSSRS/RAC_Page?id=001t0000002JcvkAAC.*

DATES: The meeting will be held December 10 & 11, 2015 from 6 p.m. to 8 p.m.

All RAC meetings are subject to cancellation. For status of meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**: Lee A. Benson, District Ranger and Designated Federal Official, Yakutat Ranger District, (907) 784–3359.

ADDRESSES: The meeting will be held at the Kwaan Conference Room, 712 Ocean Cape Drive, Yakutat, Alaska. Send written comments to Lee A. Benson, c/o Forest Service, USDA, P.O. Box 327, Yakutat, AK 99689, electronically to *labenson@fs.fed.us,* or via facsimile to 907–784–3457.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION**. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at the Yakutat Ranger District Office. Please call ahead to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Lee A. Benson, District Ranger by phone at (907) 784–3359 or via email at *labenson@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to: Review current and completed projects. We will also review proposals submitted for 2016 and 2017 project years.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by December 2, 2015 to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time to make oral comments must be sent to Lee A. Benson, District Ranger, P.O. Box 327, Yakutat, AK 99689 by email to *labenson@fs.fed.us,* or via facsimile to (907) 784–3457.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices or other reasonable accommodation for access to the facility or proceedings by contacting the person listed in the section titled **FOR FURTHER INFORMATION CONTACT**. All reasonable accommodation requests are managed on a case by case basis.

Dated: November 3, 2015.

Lee A. Benson,

District Ranger.

[FR Doc. 2015–28873 Filed 11–13–15; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF AGRICULTURE

Forest Service

Deschutes Provincial Advisory Committee

AGENCY: Forest Service, USDA.

ACTION: Notice of meeting.

SUMMARY: The Deschutes Provincial Advisory Committee (PAC) will meet in Bend, Oregon. The committee is authorized pursuant to the implementation of E–19 of the Record of Decision and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to provide advice and make recommendations to promote a better integration of forest management activities between Federal and non-Federal entities to ensure that such activities are complementary. PAC information can be found at the following Web site: *http://www.fs.usda.gov/detail/deschutes/workingtogether/advisorycommittees.*

DATES: The meeting will be held on December 15, 2015, from 9:00 a.m. to 3:00 p.m.

All PAC meetings are subject to cancellation. For status of meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

ADDRESSES: The meeting will be held at the Deschutes National Forest Headquarters Office, Ponderosa Conference Room, 63095 Deschutes Market Road, Bend, Oregon.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION**. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at Deschutes National Forest Headquarters Office. Please call ahead to facilitate entry into the building.

FOR FURTHER INFORMATION CONTACT: Beth Peer, PAC Coordinator, by phone at 541–383–4769 or via email at *bpeer@fs.fed.us.*

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The purpose of the meeting is to:

1. Review past work of sustainable recreation working group;
2. Determine primary elements of a sustainable recreation focus item;
3. Presentation of recent scientific findings concerning fire history in mixed conifer forests in central Oregon; and
4. Plan potential field trips for coming year.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by December 1, 2015, to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time to make oral comments must be sent to Beth Peer, Deschutes PAC Coordinator, 63095 Deschutes Market Road, Bend, Oregon, 97701; by email to *bpeer@fs.fed.us,* or via facsimile to 541–383–4755.

Meeting Accommodations: If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices or other reasonable accommodation for access to the facility or proceedings by

contacting the person listed in the section titled **FOR FURTHER INFORMATION CONTACT.** All reasonable accommodation requests are managed on a case by case basis.

John P. Allen,

Forest Supervisor, Deschutes National Forest.

[FR Doc. 2015–28926 Filed 11–13–15; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF COMMERCE

Census Bureau

Generic Clearance for Questionnaire Pretesting Research

AGENCY: U.S. Census Bureau, 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, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)).

DATES: To ensure consideration, written comments must be submitted on or before January 15, 2016.

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(s) and instructions should be directed to Jennifer Hunter Childs, U.S. Census Bureau, 4600 Silver Hill Road, Washington, DC 20233–9150, (202) 603–4827 (or via the Internet at *jennifer.hunter.childs@census.gov*).

SUPPLEMENTARY INFORMATION:

I. Abstract

The Census Bureau plans to request an extension of the current OMB approval to conduct a variety of small-scale questionnaire pretesting activities under this generic clearance. A block of hours will be dedicated to these activities for each of the next three years. OMB will be informed in writing of the purpose and scope of each of these activities, as well as the time frame and the number of burden hours used. The number of hours used will not exceed the number set aside for this purpose.

This research program will be used by the Census Bureau and survey sponsors to improve questionnaires and procedures, reduce respondent burden, and ultimately increase the quality of data collected in the Census Bureau censuses and surveys. The clearance will be used to conduct pretesting of decennial, demographic, and economic census and survey questionnaires prior to fielding them. Pretesting activities will involve one of the following methods for identifying measurement problems with the questionnaire or survey procedure: Cognitive interviews, focus groups, respondent debriefing, behavior coding of respondent/interviewer interaction, and split panel tests.

II. Method of Collection

Any of the following methods may be used: Mail, telephone, face-to-face; paper-and-pencil, CATI, CAPI, Internet, or IVR.

III. Data

OMB Control Number: 0607–0725.

Form Number: Various.

Type of Review: Regular submission.

Affected Public: Individuals or households, businesses or other for profit, farms.

Estimated Number of Respondents: 5,500 per year.

Estimated Time per Response: 1 hour.

Estimated Total Annual Burden Hours: 5,500 hours annually.

Estimated Total Annual Cost to Public: There is no cost to the respondent other than time to answer the information request.

Respondents Obligation: Voluntary.

Legal Authority: Data collection for this project is authorized under the authorizing legislation for the questionnaire being tested. This may be Title 13, Sections 131, 141, 161, 181, 182, 193, and 301 for Census Bureau-sponsored surveys, and Title 13 and 15 for surveys sponsored by other Federal agencies. We do not now know what other titles will be referenced, since we do not know what survey questionnaires will be pretested during the course of the clearance.

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: November 10, 2015.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2015–28929 Filed 11–13–15; 8:45 am]

BILLING CODE 3510–07–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–75–2015]

Foreign-Trade Zone (FTZ) 76—Bridgeport, Connecticut; Notification of Proposed Production Activity; MannKind Corporation (Inhalable Insulin); Danbury, Connecticut

MannKind Corporation (MannKind), an operator of FTZ 76, submitted a notification of proposed production activity to the FTZ Board for its facilities in Danbury, Connecticut, within FTZ 76. The notification conforming to the requirements of the regulations of the FTZ Board (15 CFR 400.22) was received on October 29, 2015.

A separate application for subzone designation at the MannKind facilities was submitted and will be processed under Section 400.31 of the FTZ Board's regulations (Doc. S–147–2015). The facilities are used for the production of inhalable insulin. Pursuant to 15 CFR 400.14(b), FTZ activity would be limited to the specific foreign-status material and specific finished product described in the submitted notification (as described below) and subsequently authorized by the FTZ Board.

Production under FTZ procedures could exempt MannKind from customs duty payments on the foreign-status ingredient used in export production. On its domestic sales, MannKind would be able to choose the duty rate during customs entry procedures that applies to inhalable insulin (duty-free) for the foreign-status ingredient, fumaryl diketopiperazone (duty rate—6.5%). Customs duties also could possibly be deferred or reduced on foreign-status production equipment.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary at the address below. The closing period for their receipt is December 28, 2015.

A copy of the notification will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the ''Reading Room'' section of the FTZ Board's Web site, which is accessible via *www.trade.gov/ftz.*

For further information, contact Diane Finver at *Diane.Finver@trade.gov* or (202) 482–1367.

Dated: November 9, 2015.

Elizabeth Whiteman,

Acting Executive Secretary.

[FR Doc. 2015–29241 Filed 11–13–15; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–45–2015]

Foreign-Trade Zone (FTZ) 277—Western Maricopa County, Arizona; Authorization of Production Activity; The Cookson Company, Inc. (Rolling Steel Doors); Goodyear, Arizona

On July 13, 2015, The Cookson Company, Inc. submitted a notification of proposed production activity to the Foreign-Trade Zones (FTZ) Board for its facility within FTZ 277—Site 11, in Goodyear, Arizona.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (80 FR 42789, July 20, 2015). The FTZ Board has determined that no further review of the activity is warranted at this time. The production activity described in the notification is authorized, subject to the FTZ Act and the FTZ Board's regulations, including Section 400.14.

Dated: November 10, 2015.

Elizabeth Whiteman,

Acting Executive Secretary.

[FR Doc. 2015–29250 Filed 11–13–15; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–151–2015]

Foreign-Trade Zone 119—Minneapolis/St. Paul, Minnesota; Application for Subzone; CNH Industrial America LLC; Benson, Minnesota

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the Greater Metropolitan Area Foreign Trade Zone Commission, grantee of FTZ 119, requesting subzone status for the facilities of CNH Industrial America LLC in Benson, Minnesota. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the FTZ Board (15 CFR part 400). It was formally docketed on November 9, 2015.

The proposed subzone would consist of the following sites: *Site 1* (25.26 acres)—Benson Plant, 260 Highway 12 SE., Benson; *Site 2* (4.01 acres)—Benson Plant Warehouse, 140 30th Avenue SE., Benson; and, *Site 3* (1.47 acres)—Benson Northstar, 2200 Tatges Avenue, Benson. The proposed subzone would be subject to the existing activation limit of FTZ 119. A notification of proposed production activity has been submitted and is being processed under 15 CFR 400.37 (Doc. B–61–2015).

In accordance with the FTZ Board's regulations, Camille Evans of the FTZ Staff is designated examiner to review the application and make recommendations to the Executive Secretary.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary at the address below. The closing period for their receipt is December 28, 2015. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to January 11, 2016.

A copy of the application will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the ''Reading Room'' section of the FTZ Board's Web site, which is accessible via *www.trade.gov/ftz.*

For further information, contact Camille Evans at *Camille.Evans@trade.gov* or (202) 482–2350.

Dated: November 9, 2015.

Elizabeth Whiteman,

Acting Executive Secretary.

[FR Doc. 2015–29237 Filed 11–13–15; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

[Docket No. 151022984–5984–01]

Impact of the Implementation of the Chemical Weapons Convention (CWC) on Legitimate Commercial Chemical, Biotechnology, and Pharmaceutical Activities Involving ''Schedule 1'' Chemicals (Including Schedule 1 Chemicals Produced as Intermediates) Through Calendar Year 2015

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Notice of inquiry.

SUMMARY: The Bureau of Industry and Security (BIS) is seeking public comments on the impact that implementation of the Chemical Weapons Convention (CWC), through the Chemical Weapons Convention Implementation Act (CWCIA) and the Chemical Weapons Convention Regulations (CWCR), has had on commercial activities involving ''Schedule 1'' chemicals during calendar year 2015. The purpose of this notice of inquiry is to collect information to assist BIS in its preparation of the annual certification to the Congress on whether the legitimate commercial activities and interests of chemical, biotechnology, and pharmaceutical firms are being harmed by such implementation. This certification is required under Condition 9 of Senate Resolution 75, April 24, 1997, in which the Senate gave its advice and consent to the ratification of the CWC.

DATES: Comments must be received by December 16, 2015.

ADDRESSES: You may submit comments by any of the following methods (please refer to RIN 0694–XC028 in all comments and in the subject line of email comments):

- *Federal rulemaking portal (http://www.regulations.gov)*—you can find this notice by searching on its regulations.gov docket number, which is BIS–2015–0039;
- *Email: willard.fisher@bis.doc.gov*—include the phrase ''Schedule 1 Notice of Inquiry'' in the subject line;
- *Fax:* (202) 482–3355 (Attn: Willard Fisher);
- By mail or delivery to Regulatory Policy Division, Bureau of Industry and

Security, U.S. Department of Commerce, Room 2099B, 14th Street and Pennsylvania Avenue NW., Washington, DC 20230.

FOR FURTHER INFORMATION CONTACT: For questions on the Chemical Weapons Convention requirements for ''Schedule 1'' chemicals, contact Douglas Brown, Treaty Compliance Division, Office of Nonproliferation and Treaty Compliance, Bureau of Industry and Security, U.S. Department of Commerce, Phone: (202) 482–1001. For questions on the submission of comments, contact Willard Fisher, Regulatory Policy Division, Office of Exporter Services, Bureau of Industry and Security, U.S. Department of Commerce, Phone: (202) 482–2440.

SUPPLEMENTARY INFORMATION:

Background

In providing its advice and consent to the ratification of the Convention on the Prohibition of the Development, Production, Stockpiling, and Use of Chemical Weapons and Their Destruction, commonly called the Chemical Weapons Convention (CWC or ''the Convention''), the Senate included, in Senate Resolution 75 (S. Res. 75, April 24, 1997), several conditions to its ratification. Condition 9, titled ''Protection of Advanced Biotechnology,'' calls for the President to certify to Congress on an annual basis that ''the legitimate commercial activities and interests of chemical, biotechnology, and pharmaceutical firms in the United States are not being significantly harmed by the limitations of the Convention on access to, and production of, those chemicals and toxins listed in Schedule 1.'' On July 8, 2004, President Bush, by Executive Order 13346, delegated his authority to make the annual certification to the Secretary of Commerce.

The CWC is an international arms control treaty that contains certain verification provisions. In order to implement these verification provisions, the CWC established the Organization for the Prohibition of Chemical Weapons (OPCW). The CWC imposes certain obligations on countries that have ratified the Convention (*i.e.*, States Parties), among which are the enactment of legislation to prohibit the production, storage, and use of chemical weapons, and the establishment of a National Authority to serve as the national focal point for effective liaison with the OPCW and other States Parties in order to achieve the object and purpose of the Convention and the implementation of its provisions. The CWC also requires each State Party to implement a comprehensive data declaration and inspection regime to provide transparency and to verify that both the public and private sectors of the State Party are not engaged in activities prohibited under the CWC.

''Schedule 1'' chemicals consist of those toxic chemicals and precursors set forth in the CWC ''Annex on Chemicals'' and in Supplement No. 1 to part 712 of the Chemical Weapons Convention Regulations (CWCR) (15 CFR parts 710–722). The CWC identified these toxic chemicals and precursors as posing a high risk to the object and purpose of the Convention.

The CWC (Part VI of the ''Verification Annex'') restricts the production of ''Schedule 1'' chemicals for protective purposes to two facilities per State Party: A single small-scale facility (SSSF) and a facility for production in quantities not exceeding 10 kg per year. The CWC Article-by-Article Analysis submitted to the Senate in Treaty Doc. 103–21 defined the term ''protective purposes'' to mean ''used for determining the adequacy of defense equipment and measures.'' Consistent with this definition and as authorized by Presidential Decision Directive (PDD) 70 (December 17, 1999), which specifies agency and departmental responsibilities as part of the U.S. implementation of the CWC, the Department of Defense (DOD) was assigned the responsibility to operate these two facilities. Although this assignment of responsibility to DOD under PDD–70 effectively precluded commercial production of ''Schedule 1'' chemicals for protective purposes in the United States, it did not establish any limitations on ''Schedule 1'' chemical activities that are not prohibited by the CWC. However, DOD does maintain strict controls on ''Schedule 1'' chemicals produced at its facilities in order to ensure accountability for such chemicals, as well as their proper use, consistent with the object and purpose of the Convention.

The provisions of the CWC that affect commercial activities involving ''Schedule 1'' chemicals are implemented in the CWCR (see 15 CFR 712) and in the Export Administration Regulations (EAR) (see 15 CFR 742.18 and 15 CFR 745), both of which are administered by the Bureau of Industry and Security (BIS). Pursuant to CWC requirements, the CWCR restrict commercial production of ''Schedule 1'' chemicals to research, medical, or pharmaceutical purposes (the CWCR prohibit commercial production of ''Schedule 1'' chemicals for ''protective purposes'' because such production is effectively precluded per PDD–70, as described above—see 15 CFR 712.2(a)). The CWCR also contain other requirements and prohibitions that apply to ''Schedule 1'' chemicals and/or ''Schedule 1'' facilities. Specifically, the CWCR:

(1) Prohibit the import of ''Schedule 1'' chemicals from States not Party to the Convention (15 CFR 712.2(b));

(2) Require annual declarations by certain facilities engaged in the production of ''Schedule 1'' chemicals in excess of 100 grams aggregate per calendar year (*i.e.*, declared ''Schedule 1'' facilities) for purposes not prohibited by the Convention (15 CFR 712.5(a)(1) and (a)(2));

(3) Provide for government approval of ''declared Schedule 1'' facilities (15 CFR 712.5(f));

(4) Provide that ''declared Schedule 1'' facilities are subject to initial and routine inspection by the Organization for the Prohibition of Chemical Weapons (15 CFR 712.5(e) and 716.1(b)(1));

(5) Require 200 days advance notification of establishment of new ''Schedule 1'' production facilities producing greater than 100 grams aggregate of ''Schedule 1'' chemicals per calendar year (15 CFR 712.4);

(6) Require advance notification and annual reporting of all imports and exports of ''Schedule 1'' chemicals to, or from, other States Parties to the Convention (15 CFR 712.6, 742.18(a)(1) and 745.1); and

(7) Prohibit the export of ''Schedule 1'' chemicals to States not Party to the Convention (15 CFR 742.18(a)(1) and (b)(1)(ii)).

For purposes of the CWCR (see 15 CFR 710.1), ''production of a Schedule 1 chemical'' means the formation of ''Schedule 1'' chemicals through chemical synthesis, as well as processing to extract and isolate ''Schedule 1'' chemicals produced biologically. Such production is understood, for CWCR declaration purposes, to include intermediates, by-products, or waste products that are produced and consumed within a defined chemical manufacturing sequence, where such intermediates, by-products, or waste products are chemically stable and therefore exist for a sufficient time to make isolation from the manufacturing stream possible, but where, under normal or design operating conditions, isolation does not occur.

Request for Comments

In order to assist in determining whether the legitimate commercial activities and interests of chemical, biotechnology, and pharmaceutical

firms in the United States are significantly harmed by the limitations of the Convention on access to, and production of, ''Schedule 1'' chemicals as described in this notice, BIS is seeking public comments on any effects that implementation of the Chemical Weapons Convention, through the Chemical Weapons Convention Implementation Act and the Chemical Weapons Convention Regulations, has had on commercial activities involving ''Schedule 1'' chemicals during calendar year 2015. To allow BIS to properly evaluate the significance of any harm to commercial activities involving ''Schedule 1'' chemicals, public comments submitted in response to this notice of inquiry should include both a quantitative and qualitative assessment of the impact of the CWC on such activities.

Submission of Comments

All comments must be submitted to one of the addresses indicated in this notice. The Department requires that all comments be submitted in written form.

The Department encourages interested persons who wish to comment to do so at the earliest possible time. The period for submission of comments will close on December 16, 2015. The Department will consider all comments received before the close of the comment period. Comments received after the end of the comment period will be considered if possible, but their consideration cannot be assured. The Department will not accept comments accompanied by a request that a part or all of the material be treated confidentially because of its business proprietary nature or for any other reason. The Department will return such comments and materials to the persons submitting the comments and will not consider them. All comments submitted in response to this notice will be a matter of public record and will be available for public inspection and copying.

The Office of Administration, Bureau of Industry and Security, U.S. Department of Commerce, displays public comments on the BIS Freedom of Information Act (FOIA) Web site at *http://www.bis.doc.gov/foia.* This office does not maintain a separate public inspection facility. If you have technical difficulties accessing this Web site, please call BIS's Office of Administration, at (202) 482–1093, for assistance.

Dated: November 6, 2015.

Kevin J. Wolf,

Assistant Secretary for Export Administration.

[FR Doc. 2015–29182 Filed 11–13–15; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF COMMERCE

International Trade Administration

President's Export Council; Meeting of the President's Export Council

AGENCY: International Trade Administration, U.S. Department of Commerce.

ACTION: Notice of an open meeting.

SUMMARY: The President's Export Council (Council) will hold a meeting to deliberate on recommendations related to promoting the expansion of U.S. exports. Topics may include: The Administration's trade agenda, Safe Harbor, infrastructure investment, workforce readiness, access to capital for microbusinesses and SMEs, and export control reform. The final agenda will be posted at least one week in advance of the meeting on the President's Export Council Web site at *http://trade.gov/pec.*

DATES: December 3, 2015 at 9:30 a.m. (ET).

ADDRESSES: The President's Export Council meeting will be broadcast via live webcast on the Internet at *http://whitehouse.gov/live.*

FOR FURTHER INFORMATION CONTACT: Tricia Van Orden, Executive Secretary, President's Export Council, Room 4043, 1401 Constitution Avenue NW., Washington, DC 20230, telephone: 202–482–5876, email: *tricia.vanorden@trade.gov.*

Press inquiries should be directed to the International Trade Administration's Office of Public Affairs, telephone: 202–482–3809.

SUPPLEMENTARY INFORMATION:

Background: The President's Export Council was first established by Executive Order on December 20, 1973 to advise the President on matters relating to U.S. export trade and to report to the President on its activities and recommendations for expanding U.S. exports. The President's Export Council was renewed most recently by Executive Order 13708 of September 30, 2015, for the two-year period ending September 30, 2017. This Committee is established in accordance with the provisions of the Federal Advisory Committee Act (FACA), as amended, 5 U.S.C. App.

Public Submissions: The public is invited to submit written statements to the President's Export Council. Statements must be received by 5:00 p.m. ET on December 1, 2015 by either of the following methods:

a. Electronic Submissions

Submit statements electronically to Tricia Van Orden, Executive Secretary, President's Export Council via email: *tricia.vanorden@trade.gov.*

b. Paper Submissions

Send paper statements to Tricia Van Orden, Executive Secretary, President's Export Council, Room 4043, 1401 Constitution Avenue NW., Washington, DC 20230.

Statements will be posted on the President's Export Council Web site (*http://trade.gov/pec*) without change, including any business or personal information provided such as names, addresses, email addresses, or telephone numbers. All statements received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. You should submit only information that you wish to make publicly available.

Meeting minutes: Copies of the Council's meeting minutes will be available within ninety (90) days of the meeting.

Dated: November 9, 2015.

Tricia Van Orden,

Executive Secretary. President's Export Council.

[FR Doc. 2015–28937 Filed 11–13–15; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–924]

Polyethylene Terephthalate Film, Sheet, and Strip From the People's Republic of China: Final Results of Administrative Review; 2013–2014

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

SUMMARY: On August 12, 2015, the Department of Commerce (the ''Department'') published the preliminary results and partial rescission of the 2013–2014 administrative review of the antidumping duty order on polyethylene terephthalate film, sheet, and strip (''PET film'') from the People's Republic of China (''PRC''), in accordance with section 751(a)(1)(B) of

the Tariff Act of 1930, as amended (''the Act'').[1] The period of review (''POR'') is November 1, 2013, through October 31, 2014. This review was initiated with respect to four companies. After rescinding the review with respect to three of the four companies, one company, Shaoxing Xiangyu Green Packing Co., Ltd. (''Green Packing''), remains under review. The Department invited interested parties to comment on the *Preliminary Results.* No parties commented. Our final results remain unchanged from the *Preliminary Results.*

DATES: *Effective Date:* November 16, 2015.

FOR FURTHER INFORMATION CONTACT: Jonathan Hill, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–3518.

SUPPLEMENTARY INFORMATION:

Background

On August 12, 2015, the Department published the *Preliminary Results.* We invited interested parties to submit comments on the *Preliminary Results,* but no comments were received.

Scope of the Order

The products covered by the order are all gauges of raw, pre-treated, or primed PET film, whether extruded or co-extruded. Excluded are metalized films and other finished films that have had at least one of their surfaces modified by the application of a performance-enhancing resinous or inorganic layer more than 0.00001 inches thick. Also excluded is roller transport cleaning film which has at least one of its surfaces modified by application of 0.5 micrometers of SBR latex. Tracing and drafting film is also excluded. PET film is classifiable under subheading 3920.62.00.90 of the Harmonized Tariff Schedule of the United States (''HTSUS''). While HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope of the order is dispositive.

Separate Rates

In the *Preliminary Results,* we determined that because Green Packing did not provide separate rate information, it did not establish its eligibility for separate rate status. Accordingly, the Department preliminarily determined that Green Packing is part of the PRC-wide entity, and determined a rate consistent with the Department's current practice regarding conditional review of the PRC-wide entity.[2]

No party commented on the *Preliminary Results.* For these final results, the Department continues to find that Green Packing is part of the PRC-wide entity.

Final Results of Review

The Department determines that Green Packing is part of the PRC-wide entity.

Assessment

The Department will determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review.[3] The Department intends to issue assessment instructions to CBP 15 days after the date of publication of these final results of review. The Department intends to instruct CBP to liquidate entries of subject merchandise from Green Packing at the PRC-wide rate of 76.72 percent.

Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the final results of this administrative review for all shipments of the subject merchandise 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 previously investigated or reviewed PRC and non-PRC exporters which are not under review in this segment of the proceeding but which have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recent period; (2) for all PRC exporters of subject merchandise that have not been found to be entitled to a separate rate, including Green Packing, the cash deposit rate will be the PRC-wide rate of 76.72 percent; and (3) 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(s) that supplied that non-PRC exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

Notification to Importers Regarding the Reimbursement of Duties

This notice serves as a final reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in the Department's presumption that reimbursement of antidumping duties has occurred and the subsequent assessment of doubled antidumping duties.

Notification to Interested Parties

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

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

Dated: November 9, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2015–29209 Filed 11–13–15; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Polyethylene Terephthalate Film, Sheet, and Strip From the People's Republic of China: Preliminary Results of Antidumping Administrative Review; 2013–2014,* 80 FR 48293 (August 12, 2015) (''*Preliminary Results*'').

[2] *See Preliminary Results* and accompanying Decision Memorandum at 4. *See also 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, 65970 (November 4, 2013). Under this practice, 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, the entity is not under review and the entity's rate is not subject to change.

[3] *See* 19 CFR 351.212(b)(1).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–028]

Hydrofluorocarbon Blends and Components Thereof From the People's Republic of China: Postponement of Preliminary Determination of Antidumping Duty Investigation

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

DATES: *Effective date:* November 16, 2015.

FOR FURTHER INFORMATION CONTACT: Dennis McClure or Elizabeth Eastwood at (202) 482–5973 and (202) 482–3874, respectively; AD/CVD Operations, Enforcement and Compliance, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230.

SUPPLEMENTARY INFORMATION:

Background

On July 22, 2015, the Department of Commerce (the Department) published a notice of initiation of antidumping duty investigation of hydrofluorocarbon blends and components thereof from the People's Republic of China.[1] The notice of initiation stated that the Department, in accordance with section 733(b)(1)(A) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.205(b)(1), would issue its preliminary determination for this investigation, unless postponed, no later than 140 days after the date of the initiation. The preliminary determination of this antidumping duty investigation is currently due no later than December 2, 2015.

Period of Investigation

The period of investigation is October 1, 2014, through March 31, 2015.

Postponement of Preliminary Determination

Section 733(c)(1)(A) of the Act permits the Department to postpone the time limit for the preliminary determination if it receives a timely request from the petitioner for postponement. The Department may postpone the preliminary determination under section 733(c)(1) of the Act no later than the 190th day after the date on which the administering authority initiates an investigation.

On October 28, 2015, American HFC Coalition and its individual members,[2] as well as District Lodge 154 of the International Association of Machinists and Aerospace Workers (collectively, the petitioners), made a timely request pursuant to section 733(c)(1) of the Act and 19 CFR 351.205(e) for postponement of the preliminary determination in this investigation. The petitioners requested a 50-day postponement of the preliminary determination in order to allow the petitioners additional time to review and comment on the questionnaire responses submitted in this case, as well as to consider the Department's recent inclusion of Mexico and Romania on the list of potential surrogate countries. The petitioners submitted a request for postponement of the preliminary determination more than 25 days before the scheduled date of the preliminary determination.[3]

Because the petitioners' request was timely and provided reasons for the request, and since the Department finds no compelling reasons to deny the request, the Department is postponing the deadline for the preliminary determination in accordance with section 733(c)(1)(A) of the Act and 19 CFR 351.205(b)(2) and (e) by 50 days to January 21, 2016. The deadline for the final determination will continue to be 75 days after the date of the preliminary determination unless postponed at a later date.

This notice is issued and published pursuant to section 733(c)(2) of the Act and 19 CFR 351.205(f)(1).

Dated: November 4, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2015–29172 Filed 11–13–15; 8:45 am]

BILLING CODE 3510–DS–P

[1] *See Hydrofluorocarbon Blends and Components Thereof From the People's Republic of China: Initiation of Less-Than-Fair-Value Investigation,* 80 FR 43387 (July 22, 2015).

[2] The individual members of the American HFC Coalition are: Amtrol Inc., Arkema Inc., The Chemours Company FC LLC, Honeywell International Inc., Hudson Technologies, Mexichem Fluor Inc., and Worthington Industries, Inc.

[3] *See* 19 CFR 351.205(e).

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–970]

Multilayered Wood Flooring From the People's Republic of China: Final Results of Changed Circumstances Review

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

SUMMARY: On September 24, 2015, the Department of Commerce (the ''Department'') published its preliminary results of a changed circumstances review [1] of the antidumping duty (''AD'') order on multilayered wood flooring (''MLWF'') from the People's Republic of China (''PRC'').[2] The Department preliminarily determined that Sino-Maple (JiangSu) Co., Ltd. (''Sino-Maple'') is the successor-in-interest to Jiafeng Wood (Suzhou) Co., Ltd. (''Jiafeng'') for purposes of the AD order on MLWF from the PRC and, as such, is entitled to Jiafeng's cash deposit rate with respect to entries of subject merchandise. We invited interested parties to comment on the *Preliminary Results.* As no parties submitted comments, and there is no other information or evidence on the record calling into question our *Preliminary Results,* the Department is making no changes to the *Preliminary Results.*

DATES: *Effective Date:* November 16, 2015.

FOR FURTHER INFORMATION CONTACT: Krisha Hill, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–4037.

SUPPLEMENTARY INFORMATION:

Background

On March 13, 2015, the Department of Commerce (the ''Department'') initiated a changed circumstance review to determine whether Sino-Maple, an exporter of subject merchandise to the United States, is the successor-in-interest to Jiafeng for purposes of the AD order on MLWF from the PRC.[3] On September 24, 2015, the Department made a preliminary finding that Sino-Maple is the successor-in-interest to Jiafeng, and is entitled to Jiafeng's cash deposit rate with respect to entries of merchandise subject to the AD order on MLWF from the PRC.[4] We also provided interested parties 30 days from the date of publication of the *Preliminary Results* to submit case briefs in accordance with 19 CFR 351.309(c)(1)(ii). No interested parties submitted case briefs or requested a hearing. On October 19, 2015, the Department issued to interested parties draft customs instructions and solicited comments.[5] No comments were received.

Scope of the Order

Multilayered wood flooring is composed of an assembly of two or

[1] *See Multilayered Wood Flooring From the People's Republic of China: Preliminary Results of the Changed Circumstances Review of Sino-Maple (JiangSu) Co., Ltd.,* 80 FR 57576 (September 24, 2015) (''*Preliminary Results*''), and accompanying Preliminary Decision Memorandum.

[2] *See Multilayered Wood Flooring From the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order,* 76 FR 76690 (December 8, 2011).

[3] *See Initiation of Antidumping Duty Changed Circumstances Review: Multilayered Wood Flooring From the People's Republic of China,* 80 FR 13328 (March 13, 2015) (''*Initiation Notice*'').

[4] *See Preliminary Results,* 80 FR at 57576.

[5] *See* Memorandum to the File from Krisha Hill, International Trade Compliance Analyst, regarding ''Changed Circumstances Review of Sino-Maple (JiangSu) Co., Ltd: Multilayered Wood Flooring from the People's Republic of China: Draft Customs Instructions,'' dated October 19, 2015.

more layers or plies of wood veneer(s) in combination with a core. The several layers, along with the core, are glued or otherwise bonded together to form a final assembled product. Multilayered wood flooring is often referred to by other terms, *e.g.,* ''engineered wood flooring'' or ''plywood flooring.'' Regardless of the particular terminology, all products that meet the description set forth herein are intended for inclusion within the definition of subject merchandise.

All multilayered wood flooring is included within the definition of subject merchandise, without regard to: Dimension (overall thickness, thickness of face ply, thickness of back ply, thickness of core, and thickness of inner plies; width; and length); wood species used for the face, back and inner veneers; core composition; and face grade. Multilayered wood flooring included within the definition of subject merchandise may be unfinished (*i.e.,* without a finally finished surface to protect the face veneer from wear and tear) or ''prefinished'' (*i.e.,* a coating applied to the face veneer, including, but not exclusively, oil or oil-modified or water-based polyurethanes, ultra-violet light cured polyurethanes, wax, epoxy-ester finishes, moisture-cured urethanes and acid-curing formaldehyde finishes). The veneers may be also soaked in an acrylic-impregnated finish. All multilayered wood flooring is included within the definition of subject merchandise regardless of whether the face (or back) of the product is smooth, wire brushed, distressed by any method or multiple methods, or hand-scraped. In addition, all multilayered wood flooring is included within the definition of subject merchandise regardless of whether or not it is manufactured with any interlocking or connecting mechanism (for example, tongue-and-groove construction or locking joints). All multilayered wood flooring is included within the definition of the subject merchandise regardless of whether the product meets a particular industry or similar standard.

The core of multilayered wood flooring may be composed of a range of materials, including but not limited to hardwood or softwood veneer, particleboard, medium-density fiberboard, high-density fiberboard (''HDF''), stone and/or plastic composite, or strips of lumber placed edge-to-edge.

Multilayered wood flooring products generally, but not exclusively, may be in the form of a strip, plank, or other geometrical patterns (*e.g.,* circular, hexagonal). All multilayered wood flooring products are included within this definition regardless of the actual or nominal dimensions or form of the product. Specifically excluded from the scope are cork flooring and bamboo flooring, regardless of whether any of the sub-surface layers of either flooring are made from wood. Also excluded is laminate flooring. Laminate flooring consists of a top wear layer sheet not made of wood, a decorative paper layer, a core-layer of HDF, and a stabilizing bottom layer.

Imports of the subject merchandise are provided for under the following subheadings of the Harmonized Tariff Schedule of the United States (''HTSUS''): 4412.31.0520; 4412.31.0540; 4412.31.0560; 4412.31.2510; 4412.31.2520; 4412.31.3175; 4412.31.4040; 4412.31.4050; 4412.31.4060; 4412.31.4070; 4412.31.4075; 4412.31.4080; 4412.31.5125; 4412.31.5135; 4412.31.5155; 4412.31.5165; 4412.31.5175; 4412.31.6000; 4412.31.9100; 4412.32.0520; 4412.32.0540; 4412.32.0560; 4412.32.0565; 4412.32.0570; 4412.32.2510; 4412.32.2520; 4412.32.2525; 4412.32.2530; 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; 4412.99.5105; 4412.99.5115; 4412.99.5710; 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.

While HTSUS subheadings are provided for convenience and customs purposes, the written description of the subject merchandise is dispositive.

Final Results of Changed Circumstances Review

Because no party submitted a case brief in response to the Department's *Preliminary Results,* and because the record contains no other information or evidence that calls into question the *Preliminary Results,* the Department continues to find that Sino-Maple is the successor-in-interest to Jiafeng, and is entitled to Jiafeng's cash deposit rate with respect to entries of merchandise subject to the AD order on MLWF from the PRC.[6]

Instructions to U.S. Customs and Border Protection

Based on these final results, we will instruct U.S. Customs and Border Protection to collect estimated ADs for all shipments of subject merchandise exported by Sino-Maple and entered, or withdrawn from warehouse, for consumption on or after the publication date of this notice in the **Federal Register** at the current AD cash deposit rate for Jiafeng (*i.e.,* 13.74 percent). This cash deposit requirement shall remain in effect until further notice.

Notification to Interested Parties

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

We are issuing and publishing this final results notice in accordance with sections 751(b) and 777(i) of the Tariff Act of 1930, as amended, and 19 CFR 351.216.

Dated: November 9, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2015–29199 Filed 11–13–15; 8:45 am]

BILLING CODE 3510–DS–P

[6] For a complete discussion of the Department's findings, which remain unchanged in these final results and which are herein incorporated by reference and adopted by this notice, *see generally* the Preliminary Decision Memorandum accompanying the *Preliminary Results.*

DEPARTMENT OF COMMERCE

International Trade Administration

[A–570–910]

Circular Welded Carbon Quality Steel Pipe From the People's Republic of China: Notice of Court Decision Not in Harmony With Final Determination and Amended Final Determination Under Section 129 of the Uruguay Round Agreements Act

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

SUMMARY: On October 22, 2015, the United States Court of International Trade (CIT or Court) issued final judgment in *Wheatland Tube Company* v. *United States,* Consol. Court No. 12–00296, affirming the Department of Commerce's (the Department) final results of redetermination pursuant to court remand. Consistent with the decision of the United States Court of Appeals for the Federal Circuit (CAFC) in *Timken Co.* v. *United States,* 893 F.2d 337 (Fed. Cir. 1990) (*Timken*), as clarified by *Diamond Sawblades Mfrs. Coalition* v. *United States,* 626 F.3d 1374 (Fed. Cir. 2010) (*Diamond Sawblades*), the Department is notifying the public that the final judgment in this case is not in harmony with the Department's implemented final determination in a proceeding conducted under section 129 of the Uruguay Round Agreements Act (Section 129) related to the Department's final affirmative determination in the antidumping duty (AD) investigation of circular welded carbon quality steel pipe (CWP) from the People's Republic of China (the PRC) for the period October 1, 2006, through March 31, 2007.[1] The Department is amending its implemented Final Section 129 Determination with regard to granting adjustments to the AD cash deposit rates.

DATES: *Effective Date:* November 2, 2015

FOR FURTHER INFORMATION CONTACT: Cara Lofaro, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–5720.

SUPPLEMENTARY INFORMATION:

Background

On July 22, 2008, the Department published AD and countervailing duty (CVD) orders on CWP imports from the PRC.[2] The Government of the People's Republic of China challenged the CWP orders and three other sets of simultaneously imposed AD and CVD orders before the Dispute Settlement Body of the World Trade Organization (WTO). The WTO Appellate Body, in March 2011, found that the United States had acted inconsistently with its international obligations in several respects, including the potential imposition of overlapping remedies, or so-called ''double remedies.'' [3] The U.S. Trade Representative then announced the United States' intention to comply with the WTO's rulings and recommendations, and the Department initiated a Section 129 proceeding.[4]

On July 31, 2012, the Department issued its Final Section 129 Determination. In that determination, the Department found that an adjustment was warranted to the AD rates on CWP imports from the PRC to account for remedies that overlap those imposed by the CVD order.[5] As a result, the Department reduced the applicable AD rate for separate rate companies from 69.2 percent to 45.35 percent and reduced the PRC-wide entity AD rate from 85.55 percent to 68.24 percent.[6] The Department published a notice implementing the Final Section 129 Determination on August 30, 2012.[7] Various parties challenged the Department's Final Section 129 Determination at the CIT.

Following the final disposition of litigation related to the Final Section 129 Determination regarding the CVD investigation of CWP from the PRC, in which the Department found no basis for making an adjustment to the companion AD rates under Section 777(A)(f) of the Tariff Act of 1930, as amended (the Act),[8] the CIT granted the Department's request for a voluntary remand in the litigation challenging the Final Section 129 Determination regarding the AD investigation of CWP from the PRC.[9] On October 8, 2015, the Department issued its Final Remand Redetermination regarding the AD investigation of CWP from the PRC, in which it amended its Final Section 129 Determination regarding the AD investigation and denied the adjustment to the AD cash deposit rates granted to respondents in the Final Section 129 Determination.[10] On October 22, 2015, the CIT sustained the Department's Final Remand Redetermination.[11]

Timken Notice

In its decision in *Timken,* 893 F.2d at 341, as clarified by *Diamond Sawblades,* the CAFC held that, pursuant to section 516A(e) of the Act, the Department must publish a notice of a court decision that is not ''in harmony'' with a Department determination and must suspend liquidation of entries pending a ''conclusive'' court decision. The CIT's October 22, 2015, judgment affirming the Final Remand Redetermination constitutes a final court decision that is not in harmony with the Department's Final Section 129 Determination. This notice is published in fulfillment of publication requirements of *Timken.*

Amended Final Determination

Because there is now a final court decision with respect to the Department's Final Section 129 Determination regarding the AD investigation of CWP from the PRC, the Department is amending the Final Section 129 Determination, as implemented, regarding an adjustment to the AD cash deposit rates. The revised AD cash deposit rates are as follows:

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[1] *See* Memorandum from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Antidumping and Countervailing Duty Operations, ''Final Determination: Section 129 Proceeding Pursuant to the WTO Appellate Body's Findings in WTO DS379 Regarding the Antidumping and Countervailing Duty Investigations of Circular Welded Carbon Quality Steel Pipe from the People's Republic of China,'' (July 31, 2012) (Final Section 129 Determination); *see* also *Implementation of Determinations Under Section 129 of the Uruguay Round Agreements Act: Certain New Pneumatic Off-the-Road Tires; Circular Welded Carbon Quality Steel Pipe; Laminated Woven Sacks; and Light-Walled Rectangular Pipe and Tube From the People's Republic of China,* 77 FR 52683 (August 30, 2012) (*Implementation Notice*).

[2] *See Notice of Antidumping Duty Order: Circular Welded Carbon Quality Steel Pipe from the People's Republic of China,* 73 FR 42547 (July 22, 2008); *see* also *Circular Welded Carbon Quality Steel Pipe from the People's Republic of China: Notice of Amended Final Affirmative Countervailing Duty Determination and Notice of Countervailing Duty Order,* 73 FR 42545 (July 22, 2008) (collectively, CWP orders).

[3] *See United States—Definitive Anti-Dumping and Countervailing Duties on Certain Products from China,* 611, WT/DS379/AB/R (Mar. 11, 2011).

[4] *See Implementation Notice.*

[5] *See* Final Section 129 Determination.

[6] *See Implementation Notice,* 77 FR at 52687.

[7] *Id.*

[8] *Wheatland Tube Co.* v. *United States,* Consol. Court No. 12–00298, Slip Op. 15–44 (Ct. Int'l Trade May 7, 2015).

[9] *See Wheatland Tube Co.* v. *United States,* Court No. 12–00296 (August 3, 2015).

[10] *See* ''Final Redetermination Pursuant to Court Remand, Wheatland Tube Co. v. United States, Consol. Court No. 12–00296,'' (October 8, 2015) (Final Remand Redetermination).

[11] *See Wheatland Tube Company* v. *United States,* Slip Op. 15–118, Consol. Court No. 12–00296 (CIT October 22, 2015).

Exporter	Producer	Revised AD cash deposit rate (percent)
BEIJING SAI LIN KE HARDWARE CO., LTD	XUZHOU GUANG HUAN STEEL TUBE PRODUCTS CO., LTD.	69.2
WUXI FASTUBE INDUSTRY CO., LTD	WUXI FASTUBE INDUSTRY CO., LTD	69.2
JIANGSU GUOQIANG ZINC-PLATING INDUSTRIAL COMPANY, LTD.	JIANGSU GUOQIANG ZINC-PLATING INDUSTRIAL COMPANY, LTD.	69.2
WUXI ERIC STEEL PIPE CO., LTD	WUXI ERIC STEEL PIPE CO., LTD	69.2
QINGDAO XIANGXING STEEL PIPE CO., LTD	QINGDAO XIANGXING STEEL PIPE CO., LTD	69.2
WAH CIT ENTERPRISES	GUANGDONG WALSALL STEEL PIPE INDUSTRIAL CO. LTD.	69.2
GUANGDONG WALSALL STEEL PIPE INDUSTRIAL CO. LTD	GUANGDONG WALSALL STEEL PIPE INDUSTRIAL CO. LTD.	69.2
HENGSHUI JINGHUA STEEL PIPE CO., LTD	HENGSHUI JINGHUA STEEL PIPE CO., LTD	69.2
ZHANGJIAGANG ZHONGYUAN PIPE-MAKING CO., LTD	ZHANGJIAGANG ZHONGYUAN PIPE-MAKING CO., LTD	69.2
WEIFANG EAST STEEL PIPE CO., LTD	WEIFANG EAST STEEL PIPE CO., LTD	69.2
SHIJIAZHUANG ZHONGQING IMP & EXP CO., LTD	BAZHOU ZHUOFA STEEL PIPE CO. LTD	69.2
TIANJIN BAOLAI INT'L TRADE CO., LTD	TIANJIN JINGHAI COUNTY BAOLAI BUSINESS AND INDUSTRY CO. LTD.	69.2
WAI MING (TIANJIN) INT'L TRADING CO., LTD	BAZHOU DONG SHENG HOT–DIPPED GALVANIZED STEEL PIPE CO., LTD.	69.2
KUNSHAN LETS WIN STEEL MACHINERY CO., LTD	KUNSHAN LETS WIN STEEL MACHINERY CO., LTD	69.2
SHENYANG BOYU M/E CO., LTD	BAZHOU DONG SHENG HOT–DIPPED GALVANIZED STEEL PIPE CO., LTD.	69.2
DALIAN BROLLO STEEL TUBES LTD	DALIAN BROLLO STEEL TUBES LTD	69.2
BENXI NORTHERN PIPES CO., LTD	BENXI NORTHERN PIPES CO., LTD	69.2
SHANGHAI METALS & MINERALS IMPORT & EXPORT CORP.	BENXI NORTHERN PIPES CO., LTD	69.2
HULUDAO STEEL PIPE INDUSTRIAL CO., LTD	HULUDAO STEEL PIPE INDUSTRIAL CO., LTD	69.2
TIANJIN XINGYUDA IMPORT AND EXPORT CO., LTD	TIANJIN LIFENGYUANDA STEEL GROUP CO. LTD	69.2
TIANJIN XINGYUDA IMPORT AND EXPORT CO., LTD	TIANJIN XINGYUNDA STEEL PIPE CO., LTD	69.2
TIANJIN XINGYUDA IMPORT AND EXPORT CO., LTD	TIANJIN LITUO STEEL PRODUCTS CO., LTD	69.2
TIANJIN XINGYUDA IMPORT AND EXPORT CO., LTD	TANGSHAN FENGNAN DISTRICT XINLIDA STEEL PIPE CO., LTD.	69.2
JIANGYIN JIANYE METAL PRODUCTS CO., LTD	JIANGYIN JIANYE METAL PRODUCTS CO., LTD	69.2
RIZHAO XINGYE IMPORT & EXPORT CO., LTD	SHANDONG XINYUAN GROUP CO., LTD	69.2
TIANJIN NO. 1 STEEL ROLLED CO., LTD	TIANJIN HEXING STEEL CO., LTD	69.2
TIANJIN NO. 1 STEEL ROLLED CO., LTD	TIANJIN RUITONG STEEL CO., LTD	69.2
TIANJIN NO. 1 STEEL ROLLED CO., LTD	TIANJIN YAYI INDUSTRIAL CO	69.2
KUNSHAN HONGYUAN MACHINERY MANUFACTURE CO., LTD.	KUNSHAN HONGYUAN MACHINERY MANUFACTURE CO., LTD.	69.2
QINGDAO YONGJIE IMPORT & EXPORT CO., LTD	SHANDONG XINYUANGROUP CO., LTD	69.2
PRC-WIDE ENTITY		85.55

Unless the applicable cash deposit rates have been superseded by cash deposit rates calculated in an intervening administrative review of the AD order on CWP from the PRC, the Department will instruct U.S. Customs and Border Protection to require a cash deposit for estimated AD duties at the rate noted above for each specified exporter and producer combination, for entries of subject merchandise, entered or withdrawn from warehouse, for consumption, on or after November 2, 2015.

This notice is issued and published in accordance with sections 516A(e) and 777(i)(1) of the Act and section 129(c)(2)(A) of the Uruguay Round Agreements Act.

Dated: November 5, 2015.

Paul Piquado,

Assistant Secretary for Enforcement and Compliance.

[FR Doc. 2015–29198 Filed 11–13–15; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC554

Marine Mammals; File No. 17952

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 a major amendment to Permit No. 17952–01 has been issued to Daniel P. Costa, Ph.D., Department of Biology and Institute of Marine Sciences, University of California, Santa Cruz, CA 95064.

ADDRESSES: The permit 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: Amy Sloan or Rosa L. González, (301) 427–8401.

SUPPLEMENTARY INFORMATION: On August 17, 2015, notice was published in the **Federal Register** (80 FR 49210) that a request for an amendment to Permit No. 17952–01 to conduct research on California sea lions (*Zalophus californianus*) had been submitted by the above-named applicant. The

requested permit amendment has been issued 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).

Permit No. 17952 authorized long-term research on California sea lions to study their foraging, diving, energetics, food habits, and at sea distribution through capture, sampling, and tagging California sea lions throughout their U.S. range (California, Oregon and Washington). The permit also authorized harassment of California sea lions, harbor seals (*Phoca vitulina*), and northern elephant seals (*Mirounga angustirostris*) incidental to research activities, unintentional mortalities of California sea lions, and import and export of pinniped samples. A minor amendment (Permit No. 17952–01) included attachment of cameras to instrumentation deployed on sea lions and intubation during gas anesthesia.

Permit No. 17952–02, issued on September 30, 2015, includes authorization to (1) add remote darting as an approved capture method with use of various sedative drugs for adult and juvenile California sea lions, (2) increase incidental harassment takes of non-target California sea lions, (3) include incidental harassment takes for the Eastern stock of Steller sea lions (*Eumetopias jubatus*), and (4) include takes for capture and disentanglement of California sea lions. The authorized takes are delineated in the amendment application and amended permit and are authorized for the duration of the permit. The permit expires June 7, 2018.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a final determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Dated: October 29, 2015.

Julia Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2015–28841 Filed 11–13–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XC014

Marine Mammals; File No. 17670

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 a major amendment to Permit No. 17670–02 has been issued to NMFS Northeast Fisheries Science Center, 166 Water Street, Woods Hole, MA 02543 (Responsible Party: William Karp, Ph.D.).

ADDRESSES: The permit 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: Amy Sloan or Rosa L. González, (301) 427–8401.

SUPPLEMENTARY INFORMATION: On July 10, 2015, notice was published in the **Federal Register** (80 FR 39749) that a request for an amendment Permit No. 17670–02 to conduct research on gray (*Halichoerus grypus*), harbor (*Phoca vitulina*), harp (*Pagophilus groenlandicus*), and hooded (*Cystophora cristata*) seals had been submitted by the above-named applicant. The requested permit amendment has been issued 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).

Permit No. 17670–00 authorized takes of gray, harbor, harp, and hooded seals in waters within or proximal to the U.S. EEZ from North Carolina northward to Maine, during conduct of stock assessment research, including estimation of distribution and abundance, determination of stock structure, habitat requirements, foraging ecology, health assessment and effects of natural and anthropogenic factors. Types of take include harassment during shipboard, skiff, and aircraft transect and photo-identification surveys, and scat collection; and, capture with tissue sampling and instrument or tag attachment. A limited number of research-related mortality is also allowed, as well as world-wide import and export of pinniped samples. A minor amendment (Permit No. 17670–01) authorized sampling of pinniped carcasses aboard commercial fishing vessels. An additional minor amendment (Permit No. 17670–02) authorized nail clipping and fecal loop sampling during permitted captures.

Permit No. 17670–03, issued September 28, 2015, includes authorization to increase the number and frequency of gray and harbor seal harassment and capture takes annually during research, add use of unmanned aircraft systems to survey seals, increase the number of biopsy samples taken (from one to two), increase the number of gray and harbor seal samples imported/exported annually, and allow euthanasia in the event sick or injured seals are inadvertently captured. The permit expires April 30, 2018.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a final determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Dated: October 29, 2015.

Julia Harrison,

Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2015–28838 Filed 11–13–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Telecommunications and Information Administration

Multistakeholder Process To Promote Collaboration on Vulnerability Research Disclosure

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 multistakeholder process concerning the collaboration between security researchers and software and system developers and owners to address security vulnerability disclosure on December 2, 2015.

DATES: The meeting will be held on December 2, 2015 from 10:30 a.m. to 4:30 p.m., Eastern Time. See Supplementary Information for details.

ADDRESSES: The meeting will be held at the 20 F Street NW Conference Center, 20 F Street NW., Washington, DC 20001.

FOR FURTHER INFORMATION CONTACT: Allan Friedman, National Telecommunications and Information Administration, U.S. Department of Commerce, 1401 Constitution Avenue NW., Room 4725, Washington, DC 20230; telephone (202) 482–4281; email; *afriedman@ntia.doc.gov*. Please direct media inquiries to NTIA's Office of Public Affairs, (202) 482–7002; email *press@ntia.doc.gov*.

SUPPLEMENTARY INFORMATION:

Background: On March 19, 2015, the National Telecommunications and Information Administration, working with the Department of Commerce's Internet Policy Task Force (IPTF), issued a Request for Comment to ''identify substantive cybersecurity issues that affect the digital ecosystem and digital economic growth where broad consensus, coordinated action, and the development of best practices could substantially improve security for organizations and consumers.'' [1] This Request built on earlier work from the Department, including the 2011 Green Paper *Cybersecurity, Innovation, and the Internet Economy,*[2] as well as comments the Department had received on related issues.[3] On July 9, 2015, after reviewing the comments, NTIA announced that the first issue to be addressed would be ''collaboration on vulnerability research disclosure,'' [4] and subsequently announced that the first meeting of a multistakeholder process on this topic would be held on September 29, 2015.[5]

Matters to Be Considered: The December 2, 2015 meeting is a continuation of a series of NTIA-convened multistakeholder discussions concerning collaboration on vulnerability disclosure. Stakeholders will engage in an open, transparent, consensus-driven process to develop voluntary principles guiding the collaboration between vendors and researchers about vulnerability information. The December 2, 2015 meeting will build on stakeholders' previous work. More information about stakeholders' work is available at: *http://www.ntia.doc.gov/other-publication/2015/multistakeholder-process-cybersecurity-vulnerabilities.*

Time and Date: NTIA will convene a meeting of the multistakeholder process to promote collaboration on vulnerability research disclosure on December 2, 2015, from 10:30 a.m. to 4:30 p.m., Eastern Time. The meeting date and time are subject to change. Please refer to NTIA's Web site, *http://www.ntia.doc.gov/other-publication/2015/multistakeholder-process-cybersecurity-vulnerabilities,* for the most current information.

Place: The meeting will be held at 20 F Street NW Conference Center, 20 F Street NW., Washington, DC 20001. The location of the meeting is subject to change. Please refer to NTIA's Web site, *http://www.ntia.doc.gov/other-publication/2015/multistakeholder-process-cybersecurity-vulnerabilities,* 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 Allan Friedman at (202) 482–4281 or *afriedman@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/2015/multistakeholder-process-cybersecurity-vulnerabilities,* for the most current information.

Dated: November 10, 2015.

Kathy D. Smith,

Chief Counsel, National Telecommunications and Information Administration.

[FR Doc. 2015–28933 Filed 11–13–15; 8:45 am]

BILLING CODE 3510–60–P

[1] U.S. Department of Commerce, Internet Policy Task Force, Request for Public Comment, Stakeholder Engagement on Cybersecurity in the Digital Ecosystem, 80 FR 14360, Docket No. 150312253–5253–01 (Mar. 19, 2015), *available at: http://www.ntia.doc.gov/files/ntia/publications/cybersecurity_rfc_03192015.pdf.*

[2] U.S. Department of Commerce, Internet Policy Task Force, *Cybersecurity, Innovation, and the Internet Economy* (June 2011) (Green Paper), *available at: http://www.nist.gov/itl/upload/Cybersecurity_Green-Paper_FinalVersion.pdf.*

[3] *See* Comments Received in Response to Federal Register Notice Developing a Framework for Improving Critical Infrastructure Cybersecurity, Docket No. 140721609–4609–01, *available at: http://csrc.nist.gov/cyberframework/rfi_comments_10_2014.html.*

[4] NTIA, *Enhancing the Digital Economy Through Collaboration on Vulnerability Research Disclosure* (July 9, 2015), *available at: http://www.ntia.doc.gov/blog/2015/enhancing-digital-economy-through-collaboration-vulnerability-research-disclosure.*

[5] NTIA, *Cybersecurity Vulnerabilities, http://www.ntia.doc.gov/other-publication/2015/multistakeholder-process-cybersecurity-vulnerabilities.*

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to the Procurement List.

SUMMARY: The Committee is proposing to add products to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

DATES: *Comments must be received on or before:* December 16, 2015.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov*.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 8503(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice will be required to procure the products listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

The following products are proposed for addition to the Procurement List for production by the nonprofit agencies listed:

Product Name(s)—NSN(s): Coat, Army Combat Uniform, Permethrin, Unisex, OCP 2015
8415–01–623–5052—XS–XXS
8415–01–623–5162—XS–XS
8415–01–623–5165—XS–S
8415–01–623–5166—XS–R
8415–01–623–5169—XS–L
8415–01–623–5170—XS–XL
8415–01–623–5172—S–XXS
8415–01–623–5174—S–XS
8415–01–623–5178—S–S
8415–01–623–5180—S–R
8415–01–623–5182—S–L
8415–01–623–5236—S–XL

8415–01–623–5237—M–XXS
8415–01–623–5525—M–XS
8415–01–623–5526—M–S
8415–01–623–5528—M–R
8415–01–623–5529—M–L
8415–01–623–5534—M–XL
8415–01–623–5537—M–XXL
8415–01–623–5541—L–XXS
8415–01–623–5542—L–XS
8415–01–623–5543—L–S
8415–01–623–5552—L–R
8415–01–623–5553—L–L
8415–01–623–5554—L–XL
8415–01–623–5557—L–XXL
8415–01–623–5740—XL–XXS
8415–01–623–5742—XL–XS
8415–01–623–5789—XL–S
8415–01–623–5790—XL–R
8415–01–623–5793—XL–L
8415–01–623–5795—XL–XL.
8415–01–623–5796—XL–XXL
8415–01–623–5797—XXL–R
8415–01–623–5801—XXL–L
8415–01–623–5803—XXL–XL
8415–01–623–5805—XXL–XXL

Mandatory Source(s) of Supply: Industries of the Blind, Inc., Greensboro, NC
Mississippi Industries for the Blind, Jackson, MS
San Antonio Lighthouse for the Blind, San Antonio, TX

Mandatory Purchase for: U.S. Army for up to 200,000 ACU Coats for a period of one year

Contracting Activity: Defense Logistics Agency Troop Support, Philadelphia, PA

Distribution: C-List

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2015–28922 Filed 11–13–15; 8:45 am]

BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Addition and Deletion

AGENCY: Committee for Purchase From People Who Are Blind or Severely Disabled.

ACTION: Addition to and deletion from the Procurement List.

SUMMARY: This action adds a service to the Procurement List that will be provided by nonprofit agency employing persons who are blind or have other severe disabilities, and deletes a service from the Procurement List previously furnished by such agency.

DATES: *Effective Date:* 12/16/2015.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, 1401 S. Clark Street, Suite 715, Arlington, Virginia 22202–4149.

FOR FURTHER INFORMATION CONTACT: Barry S. Lineback, Telephone: (703) 603–7740, Fax: (703) 603–0655, or email *CMTEFedReg@AbilityOne.gov.*

SUPPLEMENTARY INFORMATION:

Addition

On 10/2/2015 (80 FR 59740–59741), the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed addition to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agency to provide the service and impact of the additions on the current or most recent contractors, the Committee has determined that the service listed below is suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organization that will furnish the service to the Government.

2. The action will result in authorizing small entities to furnish the service to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the service proposed for addition to the Procurement List.

End of Certification

Accordingly, the following service is added to the Procurement List:

Service

Service Type: Landscaping Service
Service is Mandatory for: GSA PBS Region 1, John F. Kennedy Federal Building, 25 New Sudbury Street, Boston, MA
Mandatory Source of Supply: Work, Incorporated, Dorchester, MA
Contracting Activity: GSA/Public Buildings Service, Boston, MA

Deletion

On 10/2/2015 (80 FR 59740–59741), the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed deletion from the Procurement List.

After consideration of the relevant matter presented, the Committee has determined that the service listed below is no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.

Regulatory Flexibility Act Certification

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the service to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 8501–8506) in connection with the service deleted from the Procurement List.

End of Certification

Accordingly, the following service is deleted from the Procurement List:

Service

Service Type: Custodial Service
Service is Mandatory for: Isle Royale National Park & Ranger III Vessel, 800 East Lakeshore Drive, Houghton, MI
Mandatory Source of Supply: Goodwill Industries of Northern Wisconsin & Upper Michigan, Inc., Marinette, WI
Contracting Activity: National Park Service, MWR Regional Contracting, Omaha, NE

Barry S. Lineback,

Director, Business Operations.

[FR Doc. 2015–28923 Filed 11–13–15; 8:45 am]

BILLING CODE 6353–01–P

CONSUMER PRODUCT SAFETY COMMISSION

[Docket No. CPSC–2010–0038]

Agency Information Collection Activities; Proposed Collection; Comment Request; Third Party Testing of Children's Products

AGENCY: Consumer Product Safety Commission.

ACTION: Notice.

SUMMARY: As required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Consumer Product Safety Commission (''CPSC'' or ''Commission'') requests comments on a proposed extension of approval of a collection of information for Third Party Testing of Children's Products, approved previously under OMB Control No. 3041–0159. The Commission will consider all comments received in response to this notice before requesting an extension of this collection of information from the Office of Management and Budget (''OMB'').

DATES: Submit written or electronic comments on the collection of information by January 15, 2016.

ADDRESSES: You may submit comments, identified by Docket No. CPSC–2010–0038, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: *http://www.regulations.gov*. Follow the instructions for submitting comments. The Commission does not accept comments submitted by electronic mail (email), except through *www.regulations.gov*. The Commission encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Written Submissions: Submit written submissions by mail/hand delivery/courier to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7923.

Instructions: All submissions received must include the agency name and docket number for this notice. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to: *http://www.regulations.gov*. Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted in writing.

Docket: For access to the docket to read background documents or comments received, go to: *http://www.regulations.gov,* and insert the docket number CPSC–2010–0038, into the ''Search'' box, and follow the prompts.

FOR FURTHER INFORMATION CONTACT: Robert H. Squibb, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814; (301) 504–7815, or by email to: *rsquibb@cpsc.gov*.

SUPPLEMENTARY INFORMATION: CPSC seeks to renew the following currently approved collection of information:

Title: Third Party Testing of Children's Products.

OMB Number: 3041–0159.

Type of Review: Renewal of collection for third party testing of children's products and inclusion of the previously approved burden for marking and labeling of durable infant and toddler products into this collection of information.

General Description of Collection

Testing and Certification: On November 8, 2011, the Commission issued two rules for implementing third party testing and certification of children's products, as required by section 14 of the Consumer Product Safety Act (''CPSA''):

- *Testing and Labeling Pertaining to Product Certification* (76 FR 69482, codified at 16 CFR part 1107; ''the testing rule''); and
- *Conditions and Requirements for Relying on Component Part Testing or Certification, or Another Party's Finished Product Testing or Certification to Meet Testing and Certification Requirements* (76 FR 69547, codified at 16 CFR part 1109; ''the component part rule'').

The testing rule establishes requirements for manufacturers to conduct initial third party testing and certification of children's products, testing when there has been a material change in the product, continuing testing (periodic testing), and guarding against undue influence. A final rule on *Representative Samples for Periodic Testing of Children's Products* (77 FR 72205, Dec. 5, 2012) amended the testing rule to require that representative samples be selected for periodic testing of children's products.

The component part rule is a companion to the testing rule that is intended to reduce third party testing burdens by providing all parties involved in the required testing and certifying of children's products the flexibility to conduct or rely upon testing where it is the easiest and least expensive. Certification of a children's product can be based upon one or more of the following: (a) Component part testing; (b) component part certification; (c) another party's finished product testing; or (d) another party's finished product certification.

Records required by the testing rule and the rule on selecting representative samples appear in 16 CFR 1107.26. Required records include a certificate, and records documenting third party testing and related sampling plans. These requirements largely overlap the recordkeeping requirements in the component part rule, codified at 16 CFR 1109.5(g). Duplicate recordkeeping is not required; records need to be created and maintained only once to meet the applicable recordkeeping requirements. The component part rule also requires records that enable tracing a product or component back to the entity that had a product tested for compliance, and also requires attestations of due care to ensure test result integrity.

Section 104 Rules: The Commission has issued 14 rules for durable infant and toddler products under section 104 of the Consumer Product Safety Improvement Act of 2008 (''CPSIA'') (''section 104 rules''). Section 104 rules issued to date appear in Table 1. Each section 104 rule contains requirements for marking, labeling, and instructional literature:

- Each product and the shipping container must have a permanent label or marking that identifies the name and address (city, state, and zip code) of the manufacturer, distributor, or seller.
- A permanent code mark or other product identification shall be provided on the infant carrier and its package or shipping container, if multiple packaging is used. The code will identify the date (month and year) of manufacture and permit future identification of any given model.

Each standard also requires products to include easy-to-read and understand instructions regarding assembly, maintenance, cleaning, use, and adjustments, where applicable.

OMB has assigned control numbers for the estimated burden to comply with marking and labeling requirements in each section 104 rule. With this renewal, CPSC is moving the marking and labeling burden requirements for section 104 rules into the collection of information for Third Party Testing of Children's Products. The paperwork burdens associated with the section 104 rules are appropriately included in the collection for Third Party Testing of Children's Products because all of the section 104 products are also required to be third party tested. Having all of the burden hours under one collection for children's products provides one OMB control number and eases the administrative burden of renewing multiple collections. CPSC will discontinue using the OMB control numbers currently assigned to individual section 104 rules. The discontinued OMB control numbers are listed in Table 1.

Frequency of Response: On occasion.

Affected Public: Manufacturers and importers of children's products subject to a children's product safety rule.

Estimated Number of Respondents

Testing and Certification: CPSC reviewed every category in the NAICS and selected categories that included firms that could manufacture or sell any consumer product that could be covered by a consumer product safety rule. Using data from the U.S. Census Bureau, we determined that there were approximately 34,000 manufacturers, about 77,000 wholesalers, and about

133,000 retailers in these categories. However, these categories also include many non-children's products, which are not covered by any children's product safety rules. Therefore, these numbers would constitute an overestimate of the number of firms that are subject to the recordkeeping requirements.

Section 104 Rules: Table 1 summarizes the durable infant and toddler products subject to the marking and labeling requirements being moved into OMB control number 3041–0159.

TABLE 1—ESTIMATED BURDEN FOR MARKING AND LABELING IN SECTION 104 RULES

Discontinued OMB Control No.	16 CFR part	Description	Mfrs.	Models	Total respondent hours
3041–0145	1215	Safety Standard for Infant Bath Seats.	7	2	14
3041–0141	1216	Safety Standard for Infant Walkers ..	16	4	64
3041–0150	1217	Safety Standard for Toddler Beds ...	78	10	780
3041–0157	1218	Safety Standard for Bassinets and Cradles.	62	5	310
3041–0147	1219	Safety Standard for Full-Size Cribs	78	11	858
3041–0147	1220	Safety Standard for Non-Full-Size Cribs.	24	4	96
3041–0152	1221	Safety Standard for Play Yards	31	4	124
3041–0160	1222	Safety Standard for Infant Bedside Sleepers.	5	2	10
3041–0155	1223	Safety Standard for Swings	10	11	110
3041–0149	1224	Safety Standard for Portable Bedrails.	17	2	34
3041–0158	1225	Safety Standard for Hand-Held Infant Carriers.	71	2	142
3041–0162	1226	Safety Standard for Soft Infant and Toddler Carriers.	54	2	108
3041–0164	1227	Safety Standard for Carriages and Strollers.	85	8	680
3041–0166	1230	Safety Standard for Frame Child Carriers (not effective until 9/2016).	16	3	48
Total Burden Hours					3,378

Estimated Time per Response

Testing and Certification: Based on comments received during rulemaking for the testing rule, we estimate recordkeeping for approximately 300,000 non-apparel children's products per year, with an average of 5 hours of recordkeeping burden associated with each product. We also estimate recordkeeping for approximately 1.3 million children's apparel and footwear products per year, with an average of 3 hours of recordkeeping burden associated with each product. Manufacturers that are required to conduct periodic testing have an additional recordkeeping burden estimated at 4 hours per representative sampling plan.

Section 104 Rules: Each section 104 rule contains a similar analysis for marking and labeling that estimates the time to make any necessary changes to marking and labeling requirements at one hour per model.

Total Estimated Annual Burden

Testing and Certification: The total estimated annual burden for recordkeeping associated with the testing rule is 5.4 million hours (300,000 non-apparel children's products × 5 hours per non-apparel children's product + 1,300,000 children's apparel products × 3 hours per children's apparel product = 1.5 million hours + 3.9 million hours, or a total of 5.4 million hours).

Representative Sampling Plans for Periodic Testing: We estimate that if each product line averages 50 individual models or styles, then a total of 32,000 individual representative sampling plans (1.6 million children's products ÷ 50 models or styles) would need to be developed and documented. This would require 128,000 hours (32,000 plans × 4 hours per plan). If each product line averages 10 individual models or styles, then a total of 160,000 different representative sampling plans (1.6 million children's products ÷ 10 models or styles) would need to be documented. This would require 640,000 hours (160,000 plans × 4 hours per plan). Accordingly, the requirement to document the basis for selecting representative samples could increase the estimated annual burden by up to 640,000 hours.

Component Part Testing: The component part rule shifts some testing costs and some recordkeeping costs to component part and finished product suppliers because some testing will be performed by these parties rather than by the finished product certifiers (manufacturers and importers). Even if a finished product certifier can rely entirely on component part and finished product suppliers for all required testing, however, the finished product supplier will still have some recordkeeping burden to create and maintain a finished product certificate. Therefore, although the component part testing rule may reduce the total cost of the testing required by the testing and certification rule, the rule increases the estimated annual recordkeeping burden for those who choose to use component part testing.

Because we do not know how many companies participate in component part testing and supply test reports or certifications to other certifiers in the supply chain, we have no concrete data to estimate the recordkeeping and third party disclosure requirements in the component part rule. Likewise, no clear method exists for estimating the number of finished product certifiers who conduct their own component part testing. In the component part rulemaking, we suggested that the recordkeeping burden for the

component part testing rule could amount to 10 percent of the burden estimated for the testing and labeling rule. 76 FR 69546, 69579 (Nov. 8, 2011). Currently, we have no basis to change this estimate.

In addition to recordkeeping, the component part rule requires third party disclosure of test reports and certificates, if any, to a certifier who intends to rely on such documents to issue its own certificate. Without data, allocation of burden estimation between the recordkeeping and third party disclosure requirements is difficult. However, based on our previous analysis, we continue to estimate that creating and maintaining records accounts for approximately 90 percent of the burden, while the third party disclosure burden is much less, perhaps approximately 10 percent. Therefore, if we continue to use the estimate that component part testing will amount to about 10 percent of the burden estimated for the testing rule, then the hour burden of the component part rule is estimated to be about 540,000 hours total annually (10% of 5.4 million hours); allocating 486,000 hours for recordkeeping and 54,000 hours for third party disclosure.

Section 104 Rules: The burden for marking and labeling for each section 104 rule is provided in Table 1. The estimated total number of respondent hours is 3,378.

Request for Comments

The Commission solicits written comments from all interested persons about the proposed renewal of this collection of information. The Commission specifically solicits information relevant to the following topics:

—Whether the collection of information described above is necessary for the proper performance of the Commission's functions, including whether the information would have practical utility;

—Whether the estimated burden of the proposed collection of information is accurate;

—Whether the quality, utility, and clarity of the information to be collected could be enhanced; and

—Whether the burden imposed by the collection of information could be minimized by use of automated, electronic or other technological collection techniques, or other forms of information technology.

Dated: November 9, 2015.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2015–28845 Filed 11–13–15; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2015–OS–0127]

Privacy Act of 1974; System of Records

AGENCY: Office of the Secretary of Defense, DoD.

ACTION: Notice to alter a System of Records.

SUMMARY: The Office of the Secretary of Defense proposes to alter a new system of records, DHRA 10 DoD, entitled ''Defense Sexual Assault Advocate Certification Program'' to track the certification of SARC and SAPR VAs. Information will be used to review, process, and report on the status of SARC and SAPR VA certification to Congress.

DATES: Comments will be accepted on or before December 16, 2015. This proposed action will be effective the day following the end of the comment period unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

* *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

* *Mail:* Department of Defense, Office of the Deputy Chief Management Officer, Directorate of Oversight and Compliance, Regulatory and Audit Matters Office, 9010 Defense Pentagon, Washington, DC 20301–9010.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Cindy Allard, Chief, OSD/JS Privacy Office, Freedom of Information Directorate, Washington Headquarters Service, 1155 Defense Pentagon, Washington, DC 20301–1155, or by phone at (571) 372–0461.

SUPPLEMENTARY INFORMATION: The Office of the Secretary of Defense notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT** or at *http://dpcld.defense.gov/.* The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on November 4, 2015, to the House Committee on Oversight and Government Reform, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: November 10, 2015.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

DHRA 10 DoD

SYSTEM NAME:

Defense Sexual Assault Advocate Certification Program (July 11, 2012, 77 FR 40861).

CHANGES:

* * * * *

SYSTEM LOCATION:

Delete entry and replace with ''National Organization for Victim Assistance, 510 King Street, Suite 424, Alexandria, VA 22314–3132.

Back-up: Suntrust Bank, 515 King Street, Alexandria, VA 22314–3157.''

* * * * *

CATEGORIES OF RECORDS IN THE SYSTEM:

Delete entry and replace with ''Applicant's first name, middle initial, and last name; position type (Sexual Assault Response Coordinator (SARC) or Sexual Assault Prevention Representative Victim Advocate (SAPR VA)); Service/DoD affiliation and status; grade/rank; installation/command; work email address and telephone number; official military address of applicant and applicant's SARC (commanding officer, street, city, state, ZIP code, country); position level (Level I, II, III, or IV); certificates of training; date of application; verification of sexual assault victim advocacy experience (position, dates, hours, supervisor; name, title, and work telephone number of verifier); evaluation of sexual assault victim experience (description of

applicant skills, abilities, and experience; name, title, and office of evaluator), letters of recommendation by the first person in the chain of command, SARC, and the Senior Commander or the Commander; supervisor and commander statement of understanding, documentation of continuing education training courses; Defense Sexual Assault Advocate Certification Program (D–SAACP) identification (ID) number.''

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Delete entry and replace with ''10 U.S.C. 136, Under Secretary of Defense for Personnel and Readiness; DoD Directive 6495.01, Sexual Assault Prevention and Response (SAPR) Program; DoD Instruction 6495.02, Sexual Assault Prevention and Response (SAPR) Program Procedures; and Directive-type Memorandum (DTM) 14–001, Defense Sexual Assault Advocate Certification Program (D–SAACP).''

* * * * *

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

Delete entry and replace with ''In addition to those disclosures generally permitted in accordance with 5 U.S.C. 552a(b) of the Privacy Act of 1974, as amended, the records contained herein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

To the Department of Justice Office for Victims of Crime and Training Technical Assistance Center for the purpose of verifying certified SARCs and SAPR VAs for participation in Advance Military Sexual Assault Advocate Training.

LAW ENFORCEMENT ROUTINE USE:

If a system of records maintained by a DoD Component to carry out its functions indicates a violation or potential violation of law, whether civil, criminal, or regulatory in nature, and whether arising by general statute or by regulation, rule, or order issued pursuant thereto, the relevant records in the system of records may be referred, as a routine use, to the agency concerned, whether federal, state, local, or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute, rule, regulation, or order issued pursuant thereto.

DISCLOSURE WHEN REQUESTING INFORMATION ROUTINE USE:

A record from a system of records maintained by a DoD Component may be disclosed as a routine use to a federal, state, or local agency maintaining civil, criminal, or other relevant enforcement information or other pertinent information, such as current licenses, if necessary to obtain information relevant to a DoD Component decision concerning the hiring or retention of an employee, the issuance of a security clearance, the letting of a contract, or the issuance of a license, grant, or other benefit.

DISCLOSURE OF REQUESTED INFORMATION ROUTINE USE:

A record from a system of records maintained by a DoD Component may be disclosed to a federal agency, in response to its request, in connection with the hiring or retention of an employee, the issuance of a security clearance, the reporting of an investigation of an employee, the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

CONGRESSIONAL INQUIRIES DISCLOSURE ROUTINE USE:

Disclosure from a system of records maintained by a DoD Component may be made to a congressional office from the record of an individual in response to an inquiry from the congressional office made at the request of that individual.

DISCLOSURE TO THE OFFICE OF PERSONNEL MANAGEMENT ROUTINE USE:

A record from a system of records subject to the Privacy Act and maintained by a DoD Component may be disclosed to the Office of Personnel Management (OPM) concerning information on pay and leave, benefits, retirement deduction, and any other information necessary for the OPM to carry out its legally authorized government-wide personnel management functions and studies.

DISCLOSURE OF INFORMATION TO THE NATIONAL ARCHIVES AND RECORDS ADMINISTRATION ROUTINE USE:

A record from a system of records maintained by a DoD Component may be disclosed as a routine use to the National Archives and Records Administration for the purpose of records management inspections conducted under authority of 44 U.S.C. 2904 and 2906.

DISCLOSURE TO THE MERIT SYSTEMS PROTECTION BOARD ROUTINE USE:

A record from a system of records maintained by a DoD Component may be disclosed as a routine use to the Merit Systems Protection Board, including the Office of the Special Counsel for the purpose of litigation, including administrative proceedings, appeals, special studies of the civil service and other merit systems, review of OPM or component rules and regulations, investigation of alleged or possible prohibited personnel practices; including administrative proceedings involving any individual subject of a DoD investigation, and such other functions, promulgated in 5 U.S.C. 1205 and 1206, or as may be authorized by law.

DATA BREACH REMEDIATION PURPOSES ROUTINE USE:

A record from a system of records maintained by a Component may be disclosed to appropriate agencies, entities, and persons when (1) The Component suspects or has confirmed that the security or confidentiality of the information in the system of records has been compromised; (2) the Component has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identity theft or fraud, or harm to the security or integrity of this system or other systems or programs (whether maintained by the Component or another agency or entity) that rely upon the compromised information; and (3) the disclosure made to such agencies, entities, and persons is reasonably necessary to assist in connection with the Components efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

The DoD Blanket Routine Uses set forth at the beginning of the Office of the Secretary of Defense (OSD) compilation of systems of records notices may apply to this system. The complete list of DoD blanket routine uses can be found Online at: *http://dpclo.defense.gov/Privacy/SORNsIndex/BlanketRoutineUses.aspx.''*

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Delete entry and replace with ''Paper file folders and electronic storage media.''

RETRIEVABILITY:

Delete entry and replace with ''First and last name and/or D–SAACP ID number.''

SAFEGUARDS:

Delete entry and replace with ''Records are maintained in a controlled

facility that employs physical restrictions such as double locks and is accessible only to authorized persons who hold key fobs. Access to electronic data files in the system is role-based, restricted to essential personnel only, and requires the use of a password. The data server is locked in a windowless room with restricted access. Data is encrypted, and backup data is also encrypted and removed to an off-site secure location for storage. Paper files are stored in a locked filing cabinet in a locked room in the controlled facility. System access to case files will be limited to computers within a closed network, not connected to the internet or other servers.''

RETENTION AND DISPOSAL:

Delete entry and replace with ''Temporary, Destroy when 5 years old.''

SYSTEM MANAGER(S) AND ADDRESS:

Delete entry and replace with ''Sexual Assault Prevention and Response Office, ATTN: D–SAACP Manager, 4800 Mark Center Drive, Alexandria, VA 22350–1500.''

NOTIFICATION PROCEDURE:

Delete entry and replace with ''Individuals seeking to determine whether information about themselves is contained in this system of records should address written inquiries to the Sexual Assault Prevention and Response Office, ATTN: D–SAACP Manager, 4800 Mark Center Drive, Alexandria, VA 22350–1500.

Signed, written requests should contain first and last name and/or D–SAACP ID number.''

RECORD ACCESS PROCEDURES:

Delete entry and replace with ''Individuals seeking access to records about themselves contained in this system should address written inquiries to the OSD/Joint Staff Freedom of Information Act, Requester Service Center, Office of Freedom of Information, 1155 Defense Pentagon, Washington, DC 20301–1155.

Signed, written requests should contain first and last name, D–SAACP ID number, and the name and number of this system of records notice.''

* * * * *

[FR Doc. 2015–28927 Filed 11–13–15; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD–2015–OS–0125]

Privacy Act of 1974; System of Records

AGENCY: National Guard Bureau, DoD.

ACTION: Notice to add a new System of Records.

SUMMARY: The National Guard Bureau proposes to add a new system of records INGB 009, entitled ''National Guard Family Program Volunteers,'' to document and manage volunteer activities including recruitment, training, recognition and support for eligible individuals who donate their services to the National Guard Family Program.

DATES: Comments will be accepted on or before December 16, 2015. This proposed action will be effective the day following the end of the comment period unless comments are received which result in a contrary determination.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

* *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

* *Mail:* Department of Defense, Office of the Deputy Chief Management Officer, Directorate of Oversight and Compliance, Regulatory and Audit Matters Office, 9010 Defense Pentagon, Washington, DC 20301–9010.

Instructions: All submissions received must include the agency name and docket number for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Ms. Jennifer Nikolaisen, 111 South George Mason Drive, AH2, Arlington, VA 22204–1373 or telephone: (703) 601–6884.

SUPPLEMENTARY INFORMATION: The National Guard Bureau notices for systems of records subject to the Privacy Act of 1974 (5 U.S.C. 552a), as amended, have been published in the **Federal Register** and are available from the address in **FOR FURTHER INFORMATION CONTACT** or from the Defense Privacy and Civil Liberties Division Web site at *http://dpcld.defense.gov/.*

The proposed system report, as required by 5 U.S.C. 552a(r) of the Privacy Act of 1974, as amended, was submitted on October 23, 2015, to the House Committee on Oversight and Government Reform, the Senate Committee on Governmental Affairs, and the Office of Management and Budget (OMB) pursuant to paragraph 4c of Appendix I to OMB Circular No. A–130, ''Federal Agency Responsibilities for Maintaining Records About Individuals,'' dated February 8, 1996 (February 20, 1996, 61 FR 6427).

Dated: November 10, 2015.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

INGB 009

SYSTEM NAME:

National Guard Family Program Volunteers.

SYSTEM LOCATION:

National Guard Bureau (NGB) Family Program, 111 South George Mason Drive, Arlington Hall 2, Arlington, VA 22204–1373.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Any individual that volunteers to participate in the National Guard Family Program.

CATEGORIES OF RECORDS IN THE SYSTEM:

Individual's name, mailing address, email address, telephone numbers, DoD ID Number, date of birth, gender, qualifications/skills, interests, program surveys, recommendation letters, volunteer awards, volunteer hours, volunteer services provided, start and completion date of volunteer service, volunteer training and incidental reimbursement expenses, sponsor name, background suitability check determination and completion date, employment and education information.

For individuals under the age of 18 the following additional data may be in the record: Parental consent letter, report card, medication dispensation permission, health history including allergies, dietary restrictions, emergency contact information, signatures authorizing program/training participation and emergency treatment.

Note: This system of records contains individually identifiable health information. The DoD Health Information Privacy Regulation (DoD 6025.18–R) issued pursuant to the Health Insurance Portability and Accountability Act of 1996, applies to most such health information. DoD 6025.18–R may place additional procedural requirements on the uses

and disclosures of such information beyond those found in the Privacy Act of 1974 or mentioned in this system of records notice.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

10 U.S.C. 10502, Chief of the National Guard Bureau: Appointment; adviser on National Guard matters; grade; succession; 10 U.S.C. 10503, Functions of National Guard Bureau: Charter; 10 U.S.C. 1588, Authority to accept certain voluntary services; DoDD 5105.77, National Guard Bureau (NGB); DoD Instruction 1100.21, Voluntary Services in the Department of Defense; and National Guard Regulation 600–12/Air National Guard Instruction 36–3009, National Guard Family Program.

PURPOSE(S):

To document and manage volunteer activities including recruitment, training, recognition and support for eligible individuals who donate their services to the National Guard Family Program.

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

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act of 1974, as amended, the records contained therein may specifically be disclosed outside the DoD as a routine use pursuant to 5 U.S.C. 552a(b)(3) as follows:

The DoD Blanket Routine Uses set forth at the beginning of the National Guard Bureau's compilation of systems of records notices may apply to this system. The complete list of DoD blanket routine uses can be found online at: *http://dpcld.defense.gov/Privacy/SORNsIndex/BlanketRoutineUses.aspx.*

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Paper files and electronic storage media.

RETRIEVABILITY:

Records are retrieved by the full name of volunteer in Joint Service Support (JSS).

SAFEGUARDS:

Records are maintained in monitored or controlled areas accessible only to authorized personnel. Electronic records are protected by software programs that are password protected or restricted from access through use of the Common Access Card (CAC) by National Guard personnel that have a need-to-know in the performance of their official duties.

RETENTION AND DISPOSAL:

Disposition pending (treat as permanent until the National Archives and Records Administration has approved the retention and disposal schedule).

SYSTEM MANAGER(S) AND ADDRESS:

National Guard Bureau (NGB) Family Program, 111 South George Mason Drive, Arlington Hall 2, Arlington, VA 22204–1373.

NOTIFICATION PROCEDURE:

Individuals seeking to determine whether this system of records contains information about themselves should address written inquiries to National Guard Bureau (NGB), Manpower and Personnel Directorate (J1), Family Programs; 111 South George Mason Drive, Arlington Hall 2, Arlington, VA 22204–1373.

Written requests must include the individual's DoD ID number or their name and date of birth, and full mailing address to receive a response.

In addition, the requester must provide a notarized statement or an unsworn declaration made in accordance with 28 U.S.C. 1746, in the following format:

If executed outside the United States: 'I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date). (Signature)'.

If executed within the United States, its territories, possessions, or commonwealths: 'I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature)'.

RECORD ACCESS PROCEDURES:

Individuals seeking access to information about themselves contained in this system of records should address written inquiries to National Guard Bureau (NGB), Manpower and Personnel Directorate (J1), Family Programs; 111 South George Mason Drive, Arlington Hall 2, Arlington, VA 22204–1373.

Written requests must include the individual's DoD ID number or their name and date of birth, and full mailing address to receive a response.

In addition, the requester must provide a notarized statement or an unsworn declaration made in accordance with 28 U.S.C. 1746, in the following format:

If executed outside the United States: 'I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date). (Signature)'.

If executed within the United States, its territories, possessions, or commonwealths: 'I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date). (Signature)'.

CONTESTING RECORDS PROCEDURES:

The National Guard Bureau's rules for accessing records, and for contesting contents, and appealing initial agency determinations are published at 32 CFR part 329 or may be obtained from the system manager.

RECORD SOURCE CATEGORIES:

Information is collected directly from the individual when registering as a volunteer.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 2015–28920 Filed 11–13–15; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

Privacy Act of 1974; Computer Matching Program Between the Department of Education and the Department of Justice

AGENCY: Department of Education.

ACTION: Notice.

SUMMARY: This document provides notice of the continuation of a computer matching program between the Department of Education and the Department of Justice. The continuation is effective on the date in paragraph 5.

SUPPLEMENTARY INFORMATION: Section 421(a)(1) of the Controlled Substances Act (21 U.S.C. 862(a)(1)) includes provisions regarding the judicial denial of Federal benefits. Section 421 of the Controlled Substances Act, which was originally enacted as section 5301 of the Anti-Drug Abuse Act of 1988, and which was amended and redesignated as section 421 of the Controlled Substances Act by section 1002(d) of the Crime Control Act of 1990, Public Law 101–647 (hereinafter referred to as ''section 5301''), authorizes Federal and State judges to deny certain Federal benefits (including student financial assistance under title IV of the Higher Education Act of 1965, as amended (HEA)) to individuals convicted of drug trafficking or possession of a controlled substance.

In order to ensure that HEA student financial assistance is not awarded to individuals subject to denial of benefits under court orders issued pursuant to section 5301, the Department of Justice and the Department of Education

implemented a computer matching program. The 18-month computer matching agreement (CMA) was recertified for an additional 12 months on December 20, 2014. The 12-month recertification of the CMA will automatically expire on December 19, 2015.

For the purpose of ensuring that HEA student financial assistance is not awarded to individuals denied benefits by court orders issued under the Denial of Federal Benefits Program, the Department of Education must continue to obtain from the Department of Justice identifying information regarding individuals who are the subject of section 5301 denial of benefits court orders. The purpose of this notice is to announce the continued operation of the computer matching program and to provide certain required information concerning the computer matching program.

In accordance with the Privacy Act of 1974 (5 U.S.C. 552a), as amended by the Computer Matching and Privacy Protection Act of 1988 (Pub. L. 100–503), the Office of Management and Budget (OMB) Guidelines on the Conduct of Matching Programs (54 FR 25818, June 19, 1989), and OMB Circular A–130, the following information is provided:

1. *Names of Participating Agencies.*

The Department of Education (ED) and the Department of Justice (DOJ).

2. *Purpose of the Match.*

The purpose of this matching program is to ensure that the requirements of section 421 of the Controlled Substances Act (originally enacted as section 5301 of the Anti-Drug Abuse Act of 1988, Pub. L. 100–690, 21 U.S.C. 853a, which was amended and redesignated as section 421 of the Controlled Substances Act by section 1002(d) of the Crime Control Act of 1990, Pub. L. 101–647) (hereinafter referred to as ''section 5301'') are met.

DOJ is the lead contact agency for information related to section 5301 violations and, as such, provides this data to ED. ED seeks access to the information contained in the DOJ Denial of Federal Benefits Clearinghouse System (DEBARS) database that is authorized under section 5301 for the purpose of ensuring that HEA student financial assistance is not awarded to individuals subject to denial of benefits under court orders issued pursuant to the Denial of Federal Benefits Program.

3. *Authority for Conducting the Matching Program.*

Under section 5301, ED must deny Federal benefits to any individual upon whom a Federal or State court order has imposed a penalty denying eligibility for those benefits. Student financial assistance under the HEA is a Federal benefit and under section 5301, ED must, in order to meet its obligations under the HEA, have access to information about individuals who have been declared ineligible under section 5301.

While DOJ provides information under section 5301 about individuals who are ineligible for Federal benefits to the General Services Administration (GSA) for inclusion in GSA's List of Parties Excluded from Federal Procurement and Nonprocurement Programs, DOJ and ED have determined that matching against the DOJ database is more efficient and effective than matching against the GSA List. The DOJ database has specific information about the HEA programs for which individuals are ineligible, as well as the expiration of the debarment period, making the DOJ database more complete than the GSA List. Both of these elements are essential for a successful match.

4. *Categories of Records and Individuals Covered by the Match.*

ED receives data from the DOJ DEBARS system that is used to match title IV, HEA applicant data in ED's Central Processing System (Federal Student Aid Application File (18–11–01)). ED will use the Social Security number (SSN), date of birth, and the first two letters of an applicant's last name for the match.

The DOJ DEBARS system contains the names, SSNs, dates of birth, and other identifying information regarding individuals convicted of Federal or State offenses involving drug trafficking or possession of a controlled substance who have been denied Federal benefits by Federal or State courts. This system of records also contains information concerning the specific program or programs for which benefits have been denied, as well as the duration of the period of ineligibility. DOJ will make available for the matching program the records of only those individuals who have been denied Federal benefits under one or more of the title IV, HEA programs.

5. *Effective Dates of the Matching Program.*

The matching program will be effective on the latest of the following three dates: (A) December 20, 2015; (B) thirty (30) days after notice of the matching program has been published in the **Federal Register**; or (C) forty (40) days after a report concerning the matching program has been transmitted to OMB and transmitted to Congress along with a copy of this agreement, unless OMB waives 10 days of this 40-day period for compelling reasons, in which case, 30 days after transmission of the report to OMB and Congress.

The matching program will continue for 18 months after the effective date of the CMA and may be extended for an additional 12 months thereafter, if the conditions specified in 5 U.S.C. 552a(o)(2)(D) have been met.

6. *Address for Receipt of Public Comments or Inquiries.*

Individuals wishing to comment on this matching program or obtain additional information about the program, including requesting a copy of the computer matching agreement between ED and DOJ, may contact Marya Dennis, Management and Program Analyst, U.S. Department of Education, Federal Student Aid, Union Center Plaza, 830 First Street NE., Washington, DC 20202–5454. Telephone: (202) 377–3385.

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

Individuals with disabilities can obtain this document in an accessible format (*e.g.,* braille, large print, audiotape, or compact disc) by contacting the contact person listed in the preceding paragraph.

Electronic Access to This Document: The official version of this document is the document published in the **Federal Register**. Free Internet access to the official edition of the **Federal Register** and the Code of Federal Regulations is available via the Federal Digital System at: *www.gpo.gov/fdsys.* At this site you can view this document, as well as all other documents of this Department published in the **Federal Register,** in text or Adobe Portable Document Format (PDF). To use PDF you must have Adobe Acrobat Reader, which is available free at the site.

You may also access documents of the Department published in the **Federal Register** by using the article search feature at: *www.federalregister.gov.* Specifically, through the advanced search feature at this site, you can limit your search to documents published by the Department.

Authority: 5 U.S.C. 552a; 21 U.S.C. 862(a)(1).

James W. Runcie,

Chief Operating Officer Federal Student Aid.

[FR Doc. 2015–29170 Filed 11–13–15; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Bonneville Power Administration

Melvin R. Sampson Hatchery, Yakima Basin Coho Project

AGENCY: Bonneville Power Administration (BPA), Department of Energy (DOE).

ACTION: Notice of Intent to prepare an Environmental Impact Statement (EIS) and notice of floodplain and wetlands assessment.

SUMMARY: In accordance with the National Environmental Policy Act (NEPA), BPA intends to prepare an EIS to determine whether to fund the Confederated Tribes of the Yakama Nation's proposal to construct and operate a hatchery for coho salmon in the upper Yakima basin.

The Melvin R. Sampson Hatchery would involve construction of a hatchery on 50 acres of land owned by the Yakama Nation in Kittitas County, Washington. Hatchery operations would include collection of adult coho for broodstock at the existing Roza and Sunnyside dams, incubation and rearing of up to 200,000 juvenile coho salmon, and release of smolts into the Yakima and Naches rivers.

Coho were extirpated from the Yakima basin by the early 1980s. The proposal would augment anadromous fish populations available for harvest and aid natural spawning of coho in the Yakima basin.

With this Notice of Intent, BPA is initiating the public scoping process for the EIS. BPA is requesting comments about potential environmental impacts that should be considered as an EIS is prepared.

In accordance with DOE floodplain and wetland regulations, BPA will analyze impacts to floodplain and wetlands as well as measures to avoid or minimize potential effects. The assessment will be included in the EIS.

DATES: Written comments are due to the address below no later than January 4, 2016. Comments may also be made at the scoping meeting to be held on December 9, 2015 at the addresses below.

ADDRESSES: Comments on the proposed scope of the Draft EIS and requests to be placed on the project mailing list may be mailed by letter to Bonneville Power Administration, Public Affairs Office—DKE–7, P.O. Box 3621, Portland, OR 97208–3621, or sent by fax to 503–230–4019. You may also call BPA's toll-free comment hotline at 1–800–622–4519 and leave a message (please include the name of the project), or submit comments online at *www.bpa.gov/comment*. All comments received will be accessible from the project Web site at *www.bpa.gov/goto/MelvinSampsonHatchery*.

On Wednesday, December 9, 2015, a scoping meeting will be held from 6:00 p.m. to 8:00 p.m. at the Hal Holmes Community Center, 209 N. Ruby Street, Ellensburg, Washington 98926. At this informal open-house meeting, BPA will provide project information and maps and will make members of the project team available to answer questions and accept verbal and written comments.

FOR FURTHER INFORMATION CONTACT: Dave Goodman, Environmental Protection Specialist, Bonneville Power Administration, KEC–4, P.O. Box 3621, Portland, OR 97208–3621; toll-free telephone 1–800–282–3713; direct telephone 503–230–4764; or email *jdgoodman@bpa.gov*. Additional information can be found at the project Web site: *www.bpa.gov/goto/MelvinSampsonHatchery*.

SUPPLEMENTARY INFORMATION: BPA's funding of the Yakama Nation's project would support efforts to protect, mitigate, and enhance fish and wildlife affected by the development and operation of the Federal Columbia River Power System in the mainstem Columbia River and its tributaries under the Pacific Northwest Electric Power Planning and Conservation Act of 1980 (Act) (16 U.S.C. 839b(h)(10)). The Act requires BPA to fund fish and wildlife protection, mitigation, and enhancement actions consistent with the Northwest Power and Conservation Council's (Council) Fish and Wildlife Program and the purposes of the Act. Under this program, the Council makes recommendations to BPA concerning which fish and wildlife projects to fund. This project was recommended to BPA by the Council. In addition to its responsibilities under the Act, on May 2, 2008, BPA, the Bureau of Reclamation, and the U.S. Army Corps of Engineers signed the 2008 Columbia Basin Fish Accords Memorandum of Agreement with the Yakama Nation. The agreement includes funding for this hatchery project, subject to compliance with NEPA and other environmental review requirements. The project is a component of the Yakima-Klickitat Fisheries Project EIS, which was completed in 1996. The proposal is also consistent with the policy direction in BPA's Fish and Wildlife Implementation Plan, which calls for protecting weak stocks while sustaining overall populations of fish for their economic and cultural value, including long-term harvest opportunities.

The hatchery would be located approximately 5 miles northwest of Ellensburg, WA, between Interstate 90 and Highway 10. Construction of the hatchery would include a 28,000-square-foot hatchery and administration building, an adult holding and spawning facility, intake screens and a pump station to provide water from an existing irrigation canal, three new groundwater wells and acquisition of water rights, a new centralized degassing head box for groundwater treatment and supply, a waste treatment pond, and two 2,000-square-foot residences for hatchery staff.

The proposed hatchery would produce up to 200,000 yearling coho smolts. Project operations would include collection of broodstock from the Roza Dam in Kittitas County, Washington and the Sunnyside Dam in Yakima County, Washington. Fish would be acclimated at existing acclimation sites adjacent to release locations and released into the tributaries and mainstem reaches of the upper Yakima and Naches rivers. Fish would be 100 percent coded wire-tagged and different wire tag codes would be used to distinguish release locations.

BPA will be the lead agency for preparation of the EIS. Cooperating agencies for the EIS may be identified as the proposed project proceeds through the NEPA process.

Alternatives Proposed for Consideration: In the EIS, BPA is considering two alternatives: To fund the proposed hatchery and a no action alternative of not funding the proposal. Other viable alternatives brought forth through the scoping process may also be evaluated in the EIS.

Public Participation and Identification of Environmental Issues: The potential environmental issues identified so far for this project include effects of hatchery operations on water quality; the risk of competition between increasing numbers of coho and Endangered Species Act-listed fish such as bull trout; potential effects on soil, aesthetics, water quality, and climate change due to the construction of permanent facilities; and the social, cultural, and economic effects of project construction and operations, as well as harvest.

BPA has established a 30-day scoping period during which affected landowners, concerned citizens, special interest groups, local governments, and any other interested parties are invited to comment on the scope of the proposed EIS. Scoping will help BPA ensure that a full range of issues related to this proposal are addressed in the EIS, and will help to identify significant

or potentially significant impacts that may result from the proposed project.

When completed, the Draft EIS will be circulated for review and comment, and BPA will hold at least one public comment meeting for the Draft EIS. BPA will consider and respond in the Final EIS to comments received on the Draft EIS. BPA's subsequent decision will be documented in a Record of Decision.

Maps and further information are available from BPA at the address above.

Issued in Portland, Oregon on November 4, 2015.

Elliot E. Mainzer,

Administrator and Chief Executive Officer.

[FR Doc. 2015–28936 Filed 11–13–15; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP16–12–000]

Tennessee Gas Pipeline Company, L.L.C.; Notice of Application

Take notice that on October 26, 2015, Tennessee Gas Pipeline Company, L.L.C. (Tennessee), 1001 Louisiana Street, Houston, Texas 77002, filed an application pursuant to section 7(c) of the Natural Gas Act (NGA) requesting authorization to construct and operate its Southwest Louisiana Supply Project to provide 295,000 dekatherms per day of incremental capacity to serve Mitsubishi Corporation and MMGS, Inc. Specifically, Tennessee proposes to construct (i) approximately 2.4 miles of 30-inch-diameter pipeline lateral in Madison Parish, Louisiana; (ii) approximately 1.4 miles of 30-inch-diameter pipeline lateral in Richland and Franklin Parishes, Louisiana; (iii) five meter stations to allow Tennessee to receive gas on its existing 800 Line from five interconnecting pipelines; (iv) one new compressor station in Franklin Parish, Louisiana; and (v) to replace a turbine engine at an existing compressor station in Rapides Parish, Louisiana. Tennessee estimates the cost of the Project to be $170,453,208, all as more fully set forth in the application which is on file with the Commission and open to public inspection. The filing is available for 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, contact FERC at *FERCOnlineSupport@ferc.gov* or call toll-free, (886) 208–3676 or TYY, (202) 502–8659.

Any questions concerning this application may be directed to Patrick Stewart, Senior Counsel, Tennessee Gas Pipeline Company, L.L.C., 1001 Louisiana Street, Houston, Texas 77002, by telephone at (713) 369–8765, by facsimile at (713) 420–1601, or by email at *Patrick_Stewart@kindermorgan.com.*

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice, the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit five copies of filings made in the proceeding with the Commission and must mail a copy to the applicant and to every other party. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commenters will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commenters will not be required to serve copies of filed documents on all other parties. However, the non-party commenters will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

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

Comment Date: 5:00 p.m. Eastern Time on November 30, 2015.

Dated: November 9, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–29148 Filed 11–13–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP16–14–000]

Columbia Gas Transmission, LLC; Notice of Request Under Blanket Authorization

Take notice that on November 2, 2015, Columbia Gas Transmission, LLC (Columbia), pursuant to its blanket certificate authorization granted in

Docket No. CP83–76–000,[1] filed an application in accordance to sections 157.205, 157.208, and 157.216(b) of the Commission's Regulations under the Natural Gas Act (NGA) as amended, requesting authority to abandon and construct certain pipeline facilities located in Fairfield County, Ohio. The proposed abandonment and construction are parts of Columbia's comprehensive modernization program to address its aging infrastructure, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Columbia proposes to abandon in-place, as well as replaces a portion of Line G that was originally constructed in 1902, and to abandon in-place Line G–137. These sections of Line G and Line G–137 pipelines consist of 13.57 miles and 1.31 miles, respectively, of 4-, 6-, and 8-inch diameter bare steel pipe. The existing pipelines will be abandoned in-place without earth disturbance and Columbia will retain the easement rights. Also, a 5,000 foot section at the end of Line G from Pleasantville valve to the Gatherco point of receipt will be replaced with a 4-inch diameter plastic pipe to maintain service from Gatherco. The new 4-inch diameter plastic Line G pipeline will be installed within Columbia's existing right-of-way at a 15-foot offset to the east of the existing Line G pipeline. The reduction in pipeline diameter will have no adverse impact on Columbia's ability to meet operational needs and firm commitment on this pipeline. The proposed abandonment will have no impact on the services presently provided by Columbia. Continuity of service to the affected consumers will be maintained by converting them to an alternate energy source. Columbia does not propose abandonment of any tariff-based interstate gas transportation service when it abandons the proposed facilities.

Any questions concerning this application may be directed to Tyler R. Brown, Senior Counsel, Columbia Gas Transmission, LLC, 5151 San Felipe, Suite 2500, Houston, Texas 77056, or by phone at (713) 386–3797.

This filing is available for review at the Commission 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 filed to access the document. For assistance, please contact FERC Online Support at FERC *OnlineSupport@ferc.gov* or call toll-free at (866) 206–3676, or, for TTY, contact (202) 502–8659. Comments, protests and interventions may be filed electronically via the Internet in lieu of paper. See, 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site under the ''e-Filing'' link. The Commission strongly encourages interveners to file electronically.

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice, the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

Any person or the Commission's staff may, within 60 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to Section 157.205 of the regulations under the NGA (18 CFR 157.205), a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the allowed time for filing a protest, the instant request shall be treated as an application for authorization pursuant to Section 7 of the NGA.

Dated: November 9, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–29149 Filed 11–13–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of Petition for Enforcement

Allco Renewable Energy Limited	Docket Nos. EL16–11–000
Allco Finance Limited	QF14–109–001
	QF14–114–001
	QF14–115–001
	QF14–116–001
	QF15–117–001

Take notice that on November 9, 2015, Allco Renewable Energy Limited and Allco Finance Limited (collectively, ALLCO) filed a Petition for Enforcement, pursuant to section 210(h)(2)(B) of the Public Utility Regulatory Policies Act of 1978 (PURPA), requesting that the Federal Energy Regulatory Commission (Commission) exercise its authority and initiate enforcement action against the Connecticut Department of Energy and Environmental Protection and the Connecticut Public Utilities Regulatory Authority (collectively, the Connecticut Agencies) to remedy the Connecticut Agencies' implementation of PURPA. ALLCO asserts that the Connecticut Agencies' implementation is improper and outside the confines of PURPA, all as more fully explained in the petition.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

[1] 22 FERC ¶ 62,029 (1983).

The Commission encourages electronic submission of protests and interventions 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 protest or intervention 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 electronic 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 November 30, 2015.

Dated: November 9, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–29151 Filed 11–13–15; 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 corporate filings:

Docket Numbers: EC16–28–000.

Applicants: Sagebrush, a California partnership.

Description: Application for Authorization for Disposition of Jurisdictional Facilities, Request for Confidential Treatment, and Request for Expedited Action of Sagebrush, a California partnership, *et al.*

Filed Date: 11/5/15.

Accession Number: 20151105–5234.

Comments Due: 5 p.m. ET 11/27/15.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER14–2619–003.

Applicants: Illinois Power Marketing Company.

Description: Compliance filing: Compliance Unexecuted Revised Amended and Restated SSR Agreement to be effective 8/14/2014.

Filed Date: 11/6/15.

Accession Number: 20151106–5093.

Comments Due: 5 p.m. ET 11/27/15.

Docket Numbers: ER15–948–002.

Applicants: Illinois Power Marketing Company.

Description: Compliance filing: Compliance Unexecuted Revised Amended and Restated SSR Agreement to be effective 1/1/2015.

Filed Date: 11/6/15.

Accession Number: 20151106–5096.

Comments Due: 5 p.m. ET 11/27/15.

Docket Numbers: ER16–271–000.

Applicants: PJM Interconnection, L.L.C., American Transmission Systems, Incorporated, Trans-Allegheny Interstate Line Company, Pennsylvania Electric Company, Monongahela Power Company.

Description: § 205(d) Rate Filing: ATSI et al submits 6 service agreement nos. 3992, 3994, 3995, 4292, 4293, 4294 to be effective 1/5/2016.

Filed Date: 11/5/15.

Accession Number: 20151105–5198.

Comments Due: 5 p.m. ET 11/27/15.

Docket Numbers: ER16–272–000.

Applicants: Central Maine Power Company.

Description: § 205(d) Rate Filing: Supplement No. 3 to CMP FERC Electric Rate Schedule No. 60 to be effective 1/5/2016.

Filed Date: 11/5/15.

Accession Number: 20151105–5200.

Comments Due: 5 p.m. ET 11/27/15.

Docket Numbers: ER16–273–000.

Applicants: ISO New England Inc., Emera Maine.

Description: § 205(d) Rate Filing: Correction to ISO New England Tariff Schedule 21–EM to be effective 6/1/2015.

Filed Date: 11/6/15.

Accession Number: 20151106–5031.

Comments Due: 5 p.m. ET 11/27/15.

Docket Numbers: ER16–274–000.

Applicants: Louisville Gas and Electric Company.

Description: § 205(d) Rate Filing: OMU Amd and Rstd IA Rate Sched No 505 to be effective 1/6/2016.

Filed Date: 11/6/15.

Accession Number: 20151106–5048.

Comments Due: 5 p.m. ET 11/27/15.

Docket Numbers: ER16–275–000.

Applicants: Kentucky Utilities Company.

Description: § 205(d) Rate Filing: KU Concurrence to OMU Amd and Rstd Rate Sched 505 to be effective 1/6/2016.

Filed Date: 11/6/15.

Accession Number: 20151106–5065.

Comments Due: 5 p.m. ET 11/27/15.

Docket Numbers: ER16–276–000.

Applicants: Freepoint Commodities LLC.

Description: § 205(d) Rate Filing: Revised MBR Tariff re 784 & SPP to be effective 11/7/2015.

Filed Date: 11/6/15.

Accession Number: 20151106–5069.

Comments Due: 5 p.m. ET 11/27/15.

Docket Numbers: ER16–277–000.

Applicants: Talen Energy Marketing, LLC.

Description: § 205(d) Rate Filing: Reactive Supply and Voltage Control from Generation Sources Service to be effective 12/31/9998.

Filed Date: 11/6/15.

Accession Number: 20151106–5070.

Comments Due: 5 p.m. ET 11/27/15.

Docket Numbers: ER16–278–000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) Rate Filing: Service Agreement No. 4288; Queue No. AA1–112 to be effective 10/13/2015.

Filed Date: 11/6/15.

Accession Number: 20151106–5071.

Comments Due: 5 p.m. ET 11/27/15.

Docket Numbers: ER16–279–000.

Applicants: Southwest Power Pool, Inc.

Description: § 205(d) Rate Filing: Ministerial Filing to Correct Attachment AE Table of Contents to be effective 3/1/2014.

Filed Date: 11/6/15..

Accession Number: 20151106–5077

Comments Due: 5 p.m. ET 11/27/15.

Docket Numbers: ER16–280–000.

Applicants: Arizona Public Service Company.

Description: § 205(d) Rate Filing: Rate Schedule No. 244—Amendment 7 to be effective 1/6/2016.

Filed Date: 11/6/15.

Accession Number: 20151106–5079.

Comments Due: 5 p.m. ET 11/27/15.

Docket Numbers: ER16–281–000.

Applicants: Arizona Public Service Company.

Description: § 205(d) Rate Filing: Rate Schedule No. 217 Exhibit B.MEX to be effective 1/6/2016.

Filed Date: 11/6/15.

Accession Number: 20151106–5092.

Comments Due: 5 p.m. ET 11/27/15.

Docket Numbers: ER16–282–000.

Applicants: Arizona Public Service Company.

Description: § 205(d) Rate Filing: Rate Schedule No. 251—Amendment 3 to be effective 1/6/2016.

Filed Date: 11/6/15.

Accession Number: 20151106–5100.

Comments Due: 5 p.m. ET 11/27/15.

Docket Numbers: ER16–283–000.

Applicants: Arizona Public Service Company.

Description: § 205(d) Rate Filing: Rate Schedule No. 273—Amendment 1 to be effective 1/6/2016.

Filed Date: 11/6/15.

Accession Number: 20151106–5101.

Comments Due: 5 p.m. ET 11/27/15.

Docket Numbers: ER16–284–000.

Applicants: Arizona Public Service Company.

Description: § 205(d) Rate Filing: Rate Schedule No. 33—Exhibit A Revision 50 to be effective 1/6/2016.

Filed Date: 11/6/15.

Accession Number: 20151106–5108.

Comments Due: 5 p.m. ET 11/27/15.

Docket Numbers: ER16–285–000.

Applicants: NorthWestern Corporation.

Description: § 205(d) Rate Filing: Revised Point-to-Point TSAs with Talen (SA 557 2nd Rev, 749 & 750) to be effective 11/9/2015.

Filed Date: 11/6/15.

Accession Number: 20151106–5120.

Comments Due: 5 p.m. ET 11/27/15.

Docket Numbers: ER16–286–000.

Applicants: ISO New England Inc., New England Power Pool Participants Committee.

Description: § 205(d) Rate Filing: Revisions to ISO–NE Tariff Related to Hourly Requirements under the FAP to be effective 1/8/2016.

Filed Date: 11/6/15.

Accession Number: 20151106–5135.

Comments Due: 5 p.m. ET 11/27/15.

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES16–3–000.

Applicants: PacifiCorp.

Description: Revised Exhibits C, D and E to October 16, 2015 Application for Authorization to issue and sell up to $1.5 billion of promissory notes or other evidences of unsecured short-term indebtedness of PacifiCorp.

Filed Date: 11/6/15.

Accession Number: 20151106–5025.

Comments Due: 5 p.m. ET 11/27/15.

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: November 6, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–29143 Filed 11–13–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 14443–001]

Consolidated Irrigation Company; Notice of Surrender of Preliminary Permit

Take notice that Consolidated Irrigation Company (Consolidated), permittee for the proposed Consolidated Irrigation Glendale Conduit Hydro Project No. 14443 has requested that its preliminary permit be withdrawn from consideration. The permit was issued on October 3, 2013, and would have expired on September 30, 2016.[1] The project would have been located on Mink Creek canal and Cub River canal near the city of Preston in Franklin County, Idaho.

The preliminary permit for Project No. 14443 will remain in effect until the close of business, December 9, 2015. But, if the Commission is closed on this day, then the permit remains in effect until the close of business on the next day in which the Commission is open.[2] New applications for this site may not be submitted until after the permit surrender is effective.

Dated: November 9, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–29155 Filed 11–13–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL14–43–000; Docket No. EL14–69–000]

East Texas Electric Cooperative, Inc., Sam Rayburn Electric Cooperative, Inc., Tex-La Electric Cooperative of Texas, Inc. v. Entergy Texas, Inc., Entergy Texas, Inc. v. East Texas Electric Cooperative, Inc., Sam Rayburn Electric Cooperative, Inc., Tex-La Electric Cooperative of Texas, Inc.; Notice of Filing

Take notice that on November 6, 2015, Entergy Services, Inc., on behalf of Entergy Texas, Inc. submitted tariff filing: Refund Report to be effective N/A.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions 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 protest or intervention 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 November 27, 2015.

Dated: November 9, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–29150 Filed 11–13–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL16–10–000]

Industrial Energy Users—Ohio, Complainant, v. The Ohio Power Company and PJM Interconnection, LLC, Respondents: Notice of Complaint

Take notice that on November 6, 2015, pursuant to sections 206, 306, and

[1] 145 FERC ¶ 62,008 (2013).

[2] 18 CFR 385.2007(a)(2) (2015).

309 of the Federal Power Act (FPA), 16 U.S.C. 824e, 825e, and 825h, Rule 206 of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.206, Industrial Energy Users—Ohio filed a formal complaint against Ohio Power Company (AEP-Ohio) and PJM Interconnection, LLC (PJM) alleging that AEP-Ohio has taken, and PJM has allowed to be taken actions in contravention of the PJM Open Access Transmission Tariff and that such actions are unjust, unreasonable, and unduly discriminatory, in violation of the Federal Power Act, as more fully explained in the complaint.

The Complainant states that a copy of the complaint has been served on the Respondents.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. The Respondent's answer and all interventions, or protests must be filed on or before the comment date. The Respondent's answer, motions to intervene, and protests must be served on the Complainants.

The Commission encourages electronic submission of protests and interventions 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 protest or intervention 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 electronic 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 p.m. Eastern Time on November 25, 2015

Dated: November 6, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–29145 Filed 11–13–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP15–557–000]

Total Peaking Services, LLC; Notice of Intent To Prepare an Environmental Assessment for the Proposed Vaporization Capacity Increase and Bog Compressor Project, and Request for Comments on Environmental Issues

November 9, 2015.

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental assessment (EA) that will discuss the environmental impacts of the Vaporization Capacity Increase and BOG Compressor Project (Project) involving construction and operation of facilities by Total Peaking Services, LLC (Total Peaking) in Milford, Connecticut. The Commission will use this EA in its decision-making process to determine whether the Project is in the public convenience and necessity.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies on the Project. You can make a difference by providing us with your specific comments or concerns about the Project. Your comments should focus on the potential environmental effects, reasonable alternatives, and measures to avoid or lessen environmental impacts. Your input will help the Commission staff determine what issues they need to evaluate in the EA. To ensure that your comments are timely and properly recorded, please send your comments so that the Commission receives them in Washington, DC on or before December 9, 2015.

If you sent comments on this Project to the Commission before the opening of this docket on September 22, 2015, you will need to file those comments in Docket No. CP15–557–000 to ensure they are considered as part of this proceeding.

This notice is being sent to the Commission's current environmental mailing list for this Project. State and local government representatives should notify their constituents of this proposed Project and encourage them to comment on their areas of concern.

Total Peaking provided affected landowners with a fact sheet prepared by the FERC entitled ''An Interstate Natural Gas Facility On My Land? What Do I Need To Know?'' This fact sheet addresses a number of typically asked questions, including how to participate in the Commission's proceedings. It is also available for viewing on the FERC Web site (*www.ferc.gov*).

Public Participation

For your convenience, there are three methods you can use to submit your comments to the Commission. The Commission encourages electronic filing of comments and has expert staff available to assist you at (202) 502–8258 or *efiling@ferc.gov.* Please carefully follow these instructions so that your comments are properly recorded.

(1) You can file your comments electronically using the *eComment* feature on the Commission's Web site (*www.ferc.gov*) under the link to *Documents and Filings.* This is an easy method for submitting brief, text-only comments on a project;

(2) You can file your comments electronically by using the *eFiling* feature on the Commission's Web site (*www.ferc.gov*) under the link to *Documents and Filings.* With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on ''*eRegister.*'' If you are filing a comment on a particular project, please select ''Comment on a Filing'' as the filing type; or

(3) You can file a paper copy of your comments by mailing them to the following address. Be sure to reference the Project docket number (CP15–557–000) with your submission: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Room 1A, Washington, DC 20426.

Summary of the Proposed Project

Total Peaking proposes to modify its existing liquefied natural gas peak shaving facility [1] in Milford, Connecticut to increase the vaporization send out capabilities from 90 million standard cubic feet per day (MMscf/d) to 105 MMscf/d. According to Total Peaking, the Project would meet its future system needs and projected peak day requirements.

The Project would consist of the following modifications:

[1] Peak shaving facilities liquefy and store natural gas during warmer months for vaporization and injection into natural gas pipelines during peak conditions such as cold weather.

• Installation of two new vaporizers and removal of three existing vaporizers;
• installation of an additional boiloff gas (BOG) compressor;
• installation of a 1,500 kilovolt-ampere transformer and three new 400 kilowatt emergency generators to replace the existing transformer and emergency generator; and
• installation of a new 4,160 volt electric interconnection service line to provide the LNG facility with additional electricity to operate the new vaporization equipment.

The general location of the Project facilities is shown in appendix 1.[2]

Land Requirements for Construction

Construction of the proposed facilities would occur entirely within the fence line of the existing facility on paved and graveled areas. The construction would disturb about 0.44 acres of land within the approximately 24-acre facility site. Permanent operation of the Project's facilities would require about 0.18 acres.

The EA Process

The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of a Certificate of Public Convenience and Necessity. NEPA also requires us [3] to discover and address concerns the public may have about proposals. This process is referred to as ''scoping.'' The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this notice, the Commission requests public comments on the scope of the issues to address in the EA. We will consider all filed comments during the preparation of the EA.

In the EA we will discuss impacts that could occur as a result of the construction and operation of the proposed Project under these general headings:
• Geology and soils;
• land use;
• water resources, fisheries, and wetlands;
• cultural resources;
• vegetation and wildlife;
• air quality and noise;
• endangered and threatened species;
• public safety; and
• cumulative impacts

We will also evaluate reasonable alternatives to the proposed Project or portions of the Project, and make recommendations on how to lessen or avoid impacts on the various resource areas.

The EA will present our independent analysis of the issues. The EA will be available in the public record through eLibrary. Depending on the comments received during the scoping process, we may also publish and distribute the EA to the public for an allotted comment period. We will consider all comments on the EA before making our recommendations to the Commission. To ensure we have the opportunity to consider and address your comments, please carefully follow the instructions in the Public Participation section, beginning on page 2.

With this notice, we are asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues of this Project to formally cooperate with us in the preparation of the EA.[4] Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the Public Participation section of this notice.

Consultations Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation's implementing regulations for section 106 of the National Historic Preservation Act, we are using this notice to initiate consultation with the applicable State Historic Preservation Office (SHPO), and to solicit their views and those of other government agencies, interested Indian tribes, and the public on the Project's potential effects on historic properties.[5] We will define the Project-specific Area of Potential Effects (APE) in consultation with the SHPO as the Project develops. On natural gas facility projects, the APE at a minimum encompasses all areas subject to ground disturbance (examples include construction right-of-way, contractor/pipe storage yards, compressor stations, and access roads). Our EA for this Project will document our findings on the impacts on historic properties and summarize the status of consultations under section 106.

Environmental Mailing List

The environmental mailing list includes: Federal, state, and local government representatives and agencies; elected officials; Native American Tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for Project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the Project. We will update the environmental mailing list as the analysis proceeds to ensure that we send the information related to this environmental review to all individuals, organizations, and government entities interested in and/or potentially affected by the proposed Project.

If we publish and distribute the EA, copies will be sent to the environmental mailing list for public review and comment. If you would prefer to receive a paper copy of the document instead of the CD version or would like to remove your name from the mailing list, please return the attached Information Request (appendix 2).

Becoming an Intervenor

In addition to involvement in the EA scoping process, you may want to become an ''intervenor'' which is an official party to the Commission's proceeding. Intervenors play a more formal role in the process and are able to file briefs, appear at hearings, and be heard by the courts if they choose to appeal the Commission's final ruling. An intervenor formally participates in the proceeding by filing a request to intervene. Instructions for becoming an intervenor are in the ''Document-less Intervention Guide'' under the ''e-filing'' link on the Commission's Web site. Motions to intervene are more fully described at *http://www.ferc.gov/resources/guides/how-to/intervene.asp.*

Additional Information

Additional information about the Project is available from the Commission's Office of External Affairs, at (866) 208–FERC, or on the FERC Web site at *www.ferc.gov* using the ''eLibrary'' link. Click on the eLibrary link, click on ''General Search'' and enter the docket number, excluding the last three digits in the Docket Number

[2] The appendices referenced in this notice will not appear in the **Federal Register**. Copies of appendices were sent to all those receiving this notice in the mail and are available at *www.ferc.gov* using the link called ''eLibrary'' or from the Commission's Public Reference Room, 888 First Street NE., Washington, DC 20426, or call (202) 502–8371. For instructions on connecting to eLibrary, refer to the last page of this notice.

[3] ''We,'' ''us,'' and ''our'' refer to the environmental staff of the Commission's Office of Energy Projects.

[4] The Council on Environmental Quality regulations addressing cooperating agency responsibilities are at Title 40, Code of Federal Regulations, Part 1501.6.

[5] The Advisory Council on Historic Preservation's regulations are at Title 36, Code of Federal Regulations, Part 800. Those regulations define historic properties as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register of Historic Places.

field (*i.e.,* CP15–557). Be sure you have selected an appropriate date range. 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. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to *www.ferc.gov/docs-filing/esubscription.asp.*

Finally, public meetings or site visits will be posted on the Commission's calendar located at *www.ferc.gov/EventCalendar/EventsList.aspx* along with other related information.

Dated: November 9, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–29147 Filed 11–13–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. OR16–3–000]

Oryx Southern Delaware Oil Gathering and Transport LLC; Notice of Petition for Declaratory Order

Take notice that on November 3, 2015, pursuant to Rule 207(a)(2) of the Federal Energy Regulatory Commission's (Commission) Rules of Practice and Procedure, 18 CFR 385.207(a)(2) (2015), Oryx Southern Delaware Gathering and Transport LLC, filed a petition for a declaratory order seeking order approving general rate structure and terms of service for new crude oil pipeline from Permian Basin receipt points to delivery points in Crane and Midland, Texas, all as more fully explained in the petition.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. Anyone filing a motion to intervene or protest must serve a copy of that document on the Petitioner.

The Commission encourages electronic submission of protests and interventions 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 protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

This filing is accessible online 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 December 3, 2015.

Dated: November 9, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–29153 Filed 11–13–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric corporate filings:

Docket Numbers: EC15–210–000.

Applicants: Dominion Solar Projects A, Inc., Dominion Solar Projects I, Inc.

Description: Clarification to September 24, 2015 Application for Authorization Under Section 203 of the Federal Power Act of Dominion Solar Projects A, Inc., *et al.*

Filed Date: 10/30/15.

Accession Number: 20151030–5509.

Comments Due: 5 p.m. ET 11/13/15.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER14–1210–005.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Compliance filing: 2015–11–09_SA 6502 Edwards SSR 2014 Agreement Compliance to be effective 7/22/2014.

Filed Date: 11/9/15.

Accession Number: 20151109–5117.

Comments Due: 5 p.m. ET 11/30/15.

Docket Numbers: ER14–2605–002.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Compliance filing: 2015–11–09_SSR ER14–2605 Compliance Filing to be effective 7/22/2014.

Filed Date: 11/9/15.

Accession Number: 20151109–5103.

Comments Due: 5 p.m. ET 11/30/15.

Docket Numbers: ER15–943–003.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Compliance filing: 2015–11–09_SA 6502 Edwards SSR 2015 Agreement Compliance to be effective 1/1/2015.

Filed Date: 11/9/15.

Accession Number: 20151109–5122.

Comments Due: 5 p.m. ET 11/30/15.

Docket Numbers: ER16–293–000.

Applicants: Mesquite Solar 2, LLC.

Description: Baseline eTariff Filing: Mesquite Solar 2, LLC Certificate of Concurrence to be effective 11/20/2015.

Filed Date: 11/9/15.

Accession Number: 20151109–5073.

Comments Due: 5 p.m. ET 11/30/15.

Docket Numbers: ER16–294–000.

Applicants: Mesquite Solar 3, LLC.

Description: Baseline eTariff Filing: Mesquite Solar 3, LLC Certificate of Concurrence to be effective 11/20/2015.

Filed Date: 11/9/15.

Accession Number: 20151109–5074.

Comments Due: 5 p.m. ET 11/30/15.

Docket Numbers: ER16–295–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2015–11–09_SA 1503 NSP-Mankato 2nd Rev. GIA (G261) to be effective 11/10/2015.

Filed Date: 11/9/15.

Accession Number: 20151109–5085.

Comments Due: 5 p.m. ET 11/30/15.

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: November 9, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–29146 Filed 11–13–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

[Project No. 14723–000]

Jordan Whittaker; Notice of Preliminary Permit Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Competing Applications

On October 29, 2015, Jordan Whittaker filed an application for a preliminary permit, pursuant to section 4(f) of the Federal Power Act (FPA), proposing to study the feasibility of the Oxbow Hydroelectric Project (Oxbow Project or project) to be located on Clear and Tenmile Creeks, tributaries to Eighteenmile Creek and the Lemhi River, near Leadore in Lemhi County, Idaho. The sole purpose of a preliminary permit, if issued, is to grant the permit holder priority to file a license application during the permit term. A preliminary permit does not authorize the permit holder to perform any land-disturbing activities or otherwise enter upon lands or waters owned by others without the owners' express permission.

The proposed project would utilize two existing diversions on Clear and Tenmile Creeks and would use irrigation water that currently flows from approximately March to October within the existing Clear and Tenmile Creeks irrigation canals. The project would consist of the following: (1) Reconstruction of the two existing diversions to include flow control gates, pipeline intakes, and fish screens; (2) two new plastic or steel, buried penstocks to replace or supplement the existing irrigation canals, depending on available flows, including a 7.7-mile-long, 24-inch-diameter Clear Creek penstock, and a 6.7-mile-long, 21-inch diameter Tenmile Creek penstock; (3) a new 20-foot by 40-foot powerhouse containing a single Pelton turbine and generator with a generating capacity of 1,400 kilowatts; (4) a new 4-foot by 4-foot concrete splitter box where water would exit the powerhouse into the Tenmile canal, with gates, as needed, to segregate irrigation water; (5) a new 7.7-mile-long, 12.5-kilovolt (kV) transmission line from the powerhouse to an existing 69 kV transmission line at the point of interconnection near the town of Leadore; and (6) appurtenant facilities.

Applicant Contact: Mr. Jordan Whittaker, 270 Cold Springs Road, Leadore, Idaho 83464; phone: (208) 768–2058.

FERC Contact: Ken Wilcox; phone: (202) 502–6835.

Deadline for filing comments, motions to intervene, competing applications (without notices of intent), or notices of intent to file competing applications: 60 Days from the issuance of this notice. Competing applications and notices of intent must meet the requirements of 18 CFR 4.36.

The Commission strongly encourages electronic filing. Please file comments, motions to intervene, notices of intent, and competing applications using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at *http://www.ferc.gov/docs-filing/ecomment.asp.* You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–14723–000.

More information about this project, including a copy of the application, can be viewed or printed on the ''eLibrary'' link of Commission's Web site at *http://www.ferc.gov/docs-filing/elibrary.asp.* Enter the docket number (P–14723) in the docket number field to access the document. For assistance, contact FERC Online Support.

Dated: November 9, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–29156 Filed 11–13–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. TX16–1–000]

Public Service Company of Oklahoma: Notice of Filing

Take notice that on November 6, 2015, pursuant to sections 210, 211 and 212 of the Federal Power Act, 16 U.S.C. 824i, 824j and 824k (2012) and Part 36 of the Federal Energy Regulatory Commission's (Commission) Regulations, 18 CFR part 36 (2015), Public Service Company of Oklahoma requests the Commission to issue orders to implement a proposed arrangement to enable the provision of black start service between the Electric Reliability Council of Texas and the Southwest Power Pool regions.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions 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 protest or intervention 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 p.m. Eastern Time on November 27, 2015.

Dated: November 9, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–29157 Filed 11–13–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ID–7757–000]

Drury, Scott D.; Notice of Filing

Take notice that on November 6, 2015, Scott D. Drury filed an application for authorization to hold interlocking positions, pursuant to section 305(b) of the Federal Power Act, 16 U.S.C. 825d(b) and Part 45 of the Regulations of the Federal Energy Regulatory Commission (Commission), 18 CFR part 45.

Any person desiring to intervene or to protest this filing must file in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211, 385.214). Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a notice of intervention or motion to intervene, as appropriate. Such notices, motions, or protests must be filed on or before the comment date. On or before the comment date, it is not necessary to serve motions to intervene or protests on persons other than the Applicant.

The Commission encourages electronic submission of protests and interventions 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 protest or intervention 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 electronic 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 p.m. Eastern Time on November 27, 2015.

Dated: November 9, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–29152 Filed 11–13–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 3023–012]

Blackstone Hydro, Inc.; Notice of Intent To File License Application, Filing of Pre-Application Document, Approving Use of the Traditional Licensing Process

a. *Type of Filing:* Notice of Intent to File License Application and Request to Use the Traditional Licensing Process.

b. *Project No.:* 3023–012.

c. *Date Filed:* September 16, 2015.

d. *Submitted By:* Blackstone Hydro, Inc.

e. *Name of Project:* Tupperware Hydroelectric Project.

f. *Location:* On the Blackstone River in Providence County, Rhode Island and Worcester County, Massachusetts. No federal lands are occupied by the project works or located within the project boundary.

g. *Filed Pursuant to:* 18 CFR 5.3 of the Commission's regulations.

h. Potential *Applicant Contact:* Lewis C. Loon, Blackstone Hydro, Inc., 37 Alfred Plourde Parkway, Suite 2, Lewiston, ME 04240; (207) 786–8834; or by email at *Lewis.Loon@kruger.com.*

i. *FERC Contact:* Amy Chang at (202) 502–8250; or email at *amy.chang@ferc.gov.*

j. Blackstone Hydro, Inc. (Blackstone Hydro) filed its request to use the Traditional Licensing Process on September 16, 2015. Blackstone Hydro provided public notice of its request on September 15 and 16, 2015. In a letter dated November 9, 2015, the Director of the Division of Hydropower Licensing approved Blackstone Hydro request to use the Traditional Licensing Process.

k. With this notice, we are initiating informal consultation with the U.S. Fish and Wildlife Service and NOAA Fisheries under section 7 of the Endangered Species Act and the joint agency regulations thereunder at 50 CFR, Part 402. We are also initiating consultation with the Massachusetts and Rhode Island State Historic Preservation Officers, as required by section 106, National Historic Preservation Act, and the implementing regulations of the Advisory Council on Historic Preservation at 36 CFR 800.2.

l. With this notice, we are designating Blackstone Hydro as the Commission's non-federal representative for carrying out informal consultation pursuant to section 7 of the Endangered Species Act and consultation pursuant to section 106 of the National Historic Preservation Act.

m. Blackstone Hydro filed a Pre-Application Document (PAD; including a proposed process plan and schedule) with the Commission, pursuant to 18 CFR 5.6 of the Commission's regulations.

n. A copy of the PAD is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site (*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, contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). A copy is also available for inspection and reproduction at the address in paragraph h.

o. The licensee states its unequivocal intent to submit an application for a new license for Project No. 3023–012. Pursuant to 18 CFR 16.8, 16.9, and 16.10 each application for a new license and any competing license applications must be filed with the Commission at least 24 months prior to the expiration of the existing license. All applications for license for this project must be filed by September 30, 2018.

p. Register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filing and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

Dated: November 9, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–29154 Filed 11–13–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Project No. 13318–003]

Swan Lake North Hydro LLC; Notice of Application Tendered for Filing With the Commission and Soliciting Additional Study Requests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection.

a. *Type of Application:* Unconstructed major project.

b. *Project No.:* 13318–003.

c. *Date filed:* October 28, 2015.

d. *Applicant:* Swan Lake North Hydro LLC.

e. *Name of Project:* Swan Lake North Pumped Storage Hydroelectric Project.

f. *Location:* Approximately 11 miles northeast of the City of Klamath Falls, Klamath County, Oregon. The proposed project boundary would include about 730 acres of federal land managed by the U.S. Bureau of Land Management.

g. *Filed Pursuant to:* Federal Power Act 16 U.S.C. §§ 791(a)–825(r).

h. *Applicant Contact:* Joe Eberhardt, EDF-Renewable Energy, 1000 SW Broadway Ave., Ste. 1800, Portland, OR 97205; Phone: (503) 889–3838.

i. *FERC Contact:* Dianne Rodman, *dianne.rodman@ferc.gov;* phone: (202) 502–6077.

j. *Cooperating agencies:* Federal, state, local, and tribal agencies with jurisdiction and/or special expertise with respect to environmental issues that wish to cooperate in the preparation of the environmental document should follow the instructions for filing such requests described in item l below. Cooperating agencies should note the Commission's policy that agencies that cooperate in the preparation of the environmental document cannot also intervene. *See,* 94 FERC ¶ 61,076 (2001).

k. Pursuant to section 4.32(b)(7) of 18 CFR of the Commission's regulations, if any resource agency, Indian Tribe, or person believes that an additional scientific study should be conducted in order to form an adequate factual basis for a complete analysis of the application on its merit, the resource agency, Indian Tribe, or person must file a request for a study with the Commission not later than 60 days from the date of filing of the application, and serve a copy of the request on the applicant.

l. *Deadline for filing additional study requests and requests for cooperating agency status:* December 27, 2015.

The Commission strongly encourages electronic filing. Please file additional study requests and requests for cooperating agency status using the Commission's eFiling system at *http://www.ferc.gov/docs-filing/efiling.asp.* For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov,* (866) 208–3676 (toll free), or (202) 502–8659 (TTY). In lieu of electronic filing, please send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P–13318–003.

m. The application is not ready for environmental analysis at this time.

n. The proposed project would be a closed-loop system using groundwater for initial fill and consist of the following new facilities: (1) A 7,972–foot-long earthen embankment forming a geomembrane-lined upper reservoir with a surface area of 64.21 acres and a storage capacity of 2,568 acre-feet at a maximum surface elevation of 6,135 feet above mean sea level (msl); (2) a 8,003-foot-long earthen embankment forming a geomembrane-lined lower reservoir with a surface area of 60.14 acres and a storage capacity of 3,206 acre-feet at a maximum surface elevation of 4,457 feet msl; (3) a 500-foot-long, rip-rap lined trapezoidal spillway built into the crest of each embankment; (4) a 0.5-percent slope perforated polyvinyl chloride tube of varying diameter and accompanying optical fiber drainage system designed to detect, collect, and monitor water leakage from the reservoirs; (5) a 25-inch-diameter bottom outlet with manual valve for gravitational dewatering of the lower reservoir; (6) an upper intake consisting of a bell mouth, 38.6-foot-wide by 29.8-foot-long inclined screen, head gate, and 13.8-foot-diameter foundational steel pipe; (7) a 36.5-foot-diameter, 9,655-foot-long steel high-pressure penstock from the upper reservoir to the powerhouse that is predominantly above ground with a 14-foot-long buried segment; (8) three 9.8-foot-diameter, 1,430-foot-long steel low-pressure penstocks from the lower reservoir to the powerhouse that are predominantly above ground with a 78-foot-long buried segment; (9) a partially-buried powerhouse with three 131.1-megawatt (MW) reversible pump-turbine units with a total installed capacity of 393.3 MW; (10) a 32.8 mile, 230-kilovolt above-ground transmission line interconnecting to an existing non-project substation; (11) approximately 10.7 miles of improved project access road; (12) approximately 3.4 miles of new permanent project access road; (13) approximately 8.3 miles of temporary project access road; and (14) appurtenant facilities. The project would generate about 1,187 gigawatt-hours annually.

o. A copy of the application is available for 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, contact FERC Online Support. A copy is also available for inspection and reproduction at the address in item h above.

You may also register online at *http://www.ferc.gov/docs-filing/esubscription.asp* to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

p. *Procedural schedule:* The application will be processed according to the following preliminary Hydro Licensing Schedule. Revisions to the schedule will be made as appropriate.

Issue Notice of Acceptance—March 2016
Issue Scoping Document 1 for comments—April 2016
Comments on Scoping Document 1—June 2016
Issue Scoping Document 2—July 2016
Issue notice of ready for environmental analysis—July 2016
Commission issues draft EIS—December 2017
Comments on draft EIS—February 2017
Commission issues final EIS—June 2017

Dated: November 9, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–29158 Filed 11–13–15; 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 corporate filings:

Docket Numbers: EC16–29–000.

Applicants: Holtwood, LLC, BIF III Holtwood LLC.

Description: Joint Application of Holtwood, LLC *et al.* for Authorization under Section 203 of the FPA and Request for Limited Waivers.

Filed Date: 11/6/15.

Accession Number: 20151106–5197.

Comments Due: 5 p.m. ET 11/27/15.

Docket Numbers: EC16–30–000.

Applicants: Talen Ironwood, LLC, Talen Energy Marketing, LLC, TransCanada Facility USA, Inc., TransCanada Power Marketing, Ltd.

Description: Joint Application of Talen Ironwood, LLC *et al.* for Authorization of Disposition of Jurisdictional Facilities under Section 203 of the FPA and Requests for Waivers.

Filed Date: 11/6/15.

Accession Number: 20151106–5198.

Comments Due: 5 p.m. ET 11/27/15.

Take notice that the Commission received the following exempt wholesale generator filings:

Docket Numbers: EG16–19–000.

Applicants: BIF III Holtwood LLC.

Description: Notice of Self-Certification of Exempt Wholesale Generator Status of BIF III Holtwood LLC.

Filed Date: 11/6/15.
Accession Number: 20151106–5169.
Comments Due: 5 p.m. ET 11/27/15.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–1790–012; ER10–2596–005; ER10–276–003; ER11–3325–004.
Applicants: BP Energy Company, Fowler Ridge II Wind Farm LLC, Rolling Thunder I Power Partners, LLC, Whiting Clean Energy, Inc.
Description: Supplement to June 26, 2015 Updated Market Power Analysis for Central Region of BP Energy Company, *et al.*
Filed Date: 11/6/15.
Accession Number: 20151106–5186.
Comments Due: 5 p.m. ET 11/27/15.
Docket Numbers: ER16–287–000.
Applicants: BIF III Holtwood LLC.
Description: Baseline eTariff Filing: BIF III Holtwood LLC MBR Application to be effective 11/9/2015.
Filed Date: 11/6/15.
Accession Number: 20151106–5139.
Comments Due: 5 p.m. ET 11/27/15.
Docket Numbers: ER16–288–000.
Applicants: Entergy Services, Inc.
Description: § 205(d) Rate Filing: Entergy Services, Inc., Amended Service Agreements to be effective 11/8/2015.
Filed Date: 11/6/15.
Accession Number: 20151106–5141.
Comments Due: 5 p.m. ET 11/27/15.
Docket Numbers: ER16–289–000.
Applicants: Pacific Gas and Electric Company.
Description: § 205(d) Rate Filing: COTP CIRS Appendix F Update to be effective 1/6/2016.
Filed Date: 11/6/15.
Accession Number: 20151106–5142.
Comments Due: 5 p.m. ET 11/27/15.
Docket Numbers: ER16–290–000.
Applicants: Mesquite Solar 1, LLC.
Description: § 205(d) Rate Filing: Mesquite Solar 1, LLC Assignment, Co-Tenancy and Shared Facilities Agreement to be effective 11/20/2015.
Filed Date: 11/6/15.
Accession Number: 20151106–5143.
Comments Due: 5 p.m. ET 11/27/15.
Docket Numbers: ER16–291–000.
Applicants: Arizona Public Service Company.
Description: Notice of Cancellation of Rate Schedule No. 25 of Arizona Public Service Company.
Filed Date: 11/6/15.
Accession Number: 20151106–5185.
Comments Due: 5 p.m. ET 11/27/15.
Docket Numbers: ER16–292–000.
Applicants: Northern Virginia Electric Cooperative, Inc.
Description: Notice of Cancellation of Rate Schedule No. 1 of Northern Virginia Electric Cooperative, Inc.
Filed Date: 11/6/15.
Accession Number: 20151106–5195.
Comments Due: 5 p.m. ET 11/27/15.

Take notice that the Commission received the following land acquisition reports:

Docket Numbers: LA15–3–000.

Applicants: Cimarron Windpower II, LLC, CinCap V, LLC, Conetoe II Solar, LLC, Duke Energy Beckjord, LLC, Duke Energy Beckjord Storage, LLC, Duke Energy Carolinas, LLC, Duke Energy Commercial Enterprises, Inc., Duke Energy Florida, LLC, Duke Energy Indiana, Inc., Duke Energy Kentucky, Inc., Duke Energy Ohio, Inc., Duke Energy Piketon, LLC, Duke Energy Progress, LLC, Duke Energy Renewable Services, LLC, Happy Jack Windpower, LLC, Ironwood Windpower, LLC, Kit Carson Windpower, LLC, Laurel Hill Wind Energy, LLC, North Allegheny Wind, LLC, Silver Sage Windpower, LLC, Three Buttes Windpower, LLC, Top of the World Wind Energy, LLC, Seville Solar One LLC, Seville Solar Two, LLC, Tallbear Seville LLC.

Description: Quarterly Land Acquisition Report of the Duke Energy MBR Affiliates.

Filed Date: 11/6/15.

Accession Number: 20151106–5154.

Comments Due: 5 p.m. ET 11/27/15.

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: November 9, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–29144 Filed 11–13–15; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2015–0216; FRL–9937–13–OAR]

Release of Draft Control Techniques Guidelines for the Oil and Natural Gas Industry

AGENCY: Environmental Protection Agency (EPA).

ACTION: Extension of comment period.

SUMMARY: On September 18, 2015, the Environmental Protection Agency (EPA) announced the availability of a draft Control Techniques Guidelines (CTG) document titled, ''Release of Draft Control Techniques Guidelines for the Oil and Natural Gas Industry.'' The EPA is extending the comment period on the notice of availability of the draft CTG document that was scheduled to close on November 17, 2015. The EPA has received several letters from trade and business organizations, states and tribes requesting additional time to review and comment on the notice of availability of the draft CTG document.

DATES: The public comment period for notice of availability of the CTG document published in the **Federal Register** on September 18, 2015 (80 FR 56577), is being extended. Written comments must be received on or before December 4, 2015.

ADDRESSES: The EPA has established a docket for the draft CTG document (available at *http://www.regulations.gov*). For the notice of availability titled, ''Release of Draft Control Techniques Guidelines for the Oil and Natural Gas Industry,'' the Docket ID No. is EPA–HQ–OAR–2015–0216. Information on this document is posted at *http://www.epa.gov/airquality/oilandgas/actions.html*. Submit your comments, identified by the appropriate Docket ID, to the *Federal eRulemaking Portal: http://www.regulations.gov*. Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or withdrawn. The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. If you need to include CBI as part of your comment, please visit *http://www.epa.gov/dockets/comments.html* for instructions. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include

discussion of all points you wish to make.

For additional submission methods, the full EPA public comment policy, and general guidance on making effective comments, please visit *http://www.epa.gov/dockets/comments.html*.

FOR FURTHER INFORMATION CONTACT: For additional information on this action, contact Cheryl Vetter, Office of Air Quality Planning and Standards, Environmental Protection Agency (C504–03), Research Triangle Park, North Carolina 27711; telephone number (919) 541–4391; fax number (919) 541–5509; email address: *vetter.cheryl@epa.gov*.

SUPPLEMENTARY INFORMATION: After considering the requests to extend the public comment period received from various trade and business organizations, states and tribes, the EPA has decided to extend the public comment period until December 4, 2015. This extension will ensure that the public has additional time to comment on the draft CTG document.

Dated: November 10, 2015.

Mary E. Henigin,

Acting Director, Office of Air Quality Planning and Standards.

[FR Doc. 2015–29174 Filed 11–13–15; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060–0016]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (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 PRA comments should be submitted on or before January 15, 2016. 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.: 3060–0016.

Title: FCC Form 2100, Application for Media Bureau Audio and Video Service Authorization, Schedule C (Former FCC Form 346); Sections 74.793(d) and 74.787; LPTV Out-of-Core Digital Displacement Application; Section 73.3700(g)(1)–(3), Post-Incentive Auction Licensing and Operations

Form No.: FCC Form 2100, Schedule C.

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

Respondents: Business or other for-profit entities; Not for profit institutions; State, local or Tribal government.

Number of Respondents and Responses: 4,250 respondents and 4,250 responses.

Estimated Time per Response: 2.5–7 hours (total of 9.5 hours).

Frequency of Response: One-time reporting requirement; on occasion reporting requirement; third party disclosure requirement.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection is contained in Section 154(i), 303, 307, 308 and 309 of the Communications Act of 1934, as amended.

Total Annual Burden: 40,375 hours.

Annual Cost Burden: $23,579,000.

Privacy Act Impact Assessment: No impact(s).

Nature and Extent of Confidentiality: There is no need for confidentiality with this collection of information.

Needs and Uses: The collection is being made to the Office of Management (OMB) for the approval of information collection requirements contained in the Commission's Incentive Auction Order, FCC 14–50, which adopted rules for holding an Incentive Auction, as required by the Middle Class Tax Relief and Job Creation Act of 2012 (Spectrum Act). The information gathered in this collection will be used to allow Low Power television stations and TV Translator stations that are displaced as a result of the Federal Communications Commission's Incentive Auction to submit an application for displacement relief during a restricted filing window. Form 2100, Schedule C is also used to apply for authority to construct or make changes to a Low Power Television, TV Translator or TV Booster broadcast station.

Federal Communications Commission.

Gloria J. Miles,

Federal Register Liaison Officer, Office of the Secretary.

[FR Doc. 2015–28899 Filed 11–13–15; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

AGENCY: Federal Election Commission.

DATE & TIME: Tuesday, November 17, 2015 at 10:00 a.m. and Thursday, November 19, 2015 at 1:30 p.m.

PLACE: 999 E Street NW., Washington, DC.

STATUS: This meeting will be closed to the public.

FEDERAL REGISTER NOTICE OF PREVIOUS ANNOUNCEMENT —Scheduled to be published on November 13, 2015.

CHANGE IN THE MEETING: The meeting will commence at the conclusion of the Open Meeting on November 17, 2015.

* * * * *

PERSON TO CONTACT FOR INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Shelley E. Garr,

Deputy Secretary.

[FR Doc. 2015–29279 Filed 11–12–15; 11:15 am]

BILLING CODE 6715–01–P

FEDERAL ELECTION COMMISSION

Sunshine Act Meeting

AGENCY: Federal Election Commission.

DATE & TIME: Tuesday, November 10, 2015 at 10:00 a.m.

PLACE: 999 E Street NW., Washington, DC (Ninth Floor)

STATUS: This meeting will be open to the public.

Federal Register Notice of Previous Announcement—80 FR 68539

CHANGE IN THE MEETING: The meeting will continue on Tuesday, November 17, 2015 at 10:00 a.m.

Individuals who plan to attend and require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Shawn Woodhead Werth, Secretary and Clerk, at (202) 694–1040, at least 72 hours prior to the meeting date.

PERSON TO CONTACT FOR INFORMATION: Judith Ingram, Press Officer, Telephone: (202) 694–1220.

Shelley E. Garr,

Deputy Secretary of the Commission.

[FR Doc. 2015–29278 Filed 11–12–15; 11:15 am]

BILLING CODE 6715–01–P

FEDERAL RESERVE SYSTEM

[Docket No. OP–1522]

Federal Reserve Bank Services

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Notice.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) has approved the private sector adjustment factor (PSAF) for 2016 of $13.1 million and the 2016 fee schedules for Federal Reserve priced services and electronic access. These actions were taken in accordance with the Monetary Control Act of 1980, which requires that, over the long run, fees for Federal Reserve priced services be established on the basis of all direct and indirect costs, including the PSAF.

DATES: The new fee schedules become effective January 1, 2016.

FOR FURTHER INFORMATION CONTACT: For questions regarding the fee schedules: Susan V. Foley, Senior Associate Director, (202) 452–3596; Slavea A. Assenova, Financial Services Analyst, (202) 452–2087, Division of Reserve Bank Operations and Payment Systems. For questions regarding the PSAF: Gregory L. Evans, Deputy Associate Director, (202) 452–3945; Lawrence Mize, Deputy Associate Director, (202) 452–5232; Manuel Garcia, Senior Financial Analyst, (202) 452–3480, Division of Reserve Bank Operations and Payment Systems. For users of Telecommunications Device for the Deaf (TDD) *only,* please call (202) 263–4869. Copies of the 2016 fee schedules for the check service are available from the Board, the Federal Reserve Banks, or the Reserve Banks' financial services Web site at *www.frbservices.org.*

SUPPLEMENTARY INFORMATION:

I. Private Sector Adjustment Factor, Priced Services Cost Recovery, and Overview of 2016 Price Changes

A. Overview—Each year, as required by the Monetary Control Act of 1980, the Reserve Banks set fees for priced services provided to depository institutions. These fees are set to recover, over the long run, all direct and indirect costs and imputed costs, including financing costs, taxes, and certain other expenses, as well as the return on equity (profit) that would have been earned if a private business firm provided the services. The imputed costs and imputed profit are collectively referred to as the PSAF. From 2005 through 2014, the Reserve Banks recovered 102.9 percent of their total expenses (including imputed costs) and targeted after-tax profits or return on equity (ROE) for providing priced services.[1]

Table 1 summarizes 2014 actual, 2015 estimated, and 2016 budgeted cost-recovery rates for all priced services. Cost recovery is estimated to be 104.1 percent in 2015 and budgeted to be 101.9 percent in 2016.

TABLE 1—AGGREGATE PRICED SERVICES PRO FORMA COST AND REVENUE PERFORMANCE [a]

[Dollars in millions]

Year	Revenue	Total expense	Net income	Targeted ROE	Recovery rate after targeted ROE [1/(2+4)]
	1 [b]	2 [c]	3	4 [d]	5 [e]
2014 (actual)	433.1	418.7	14.5	5.5	102.1%
2015 (estimate)	427.1	404.6	22.6	5.6	104.1%
2016 (budget)	426.9	414.9	12.0	4.1	101.9%

[a] Calculations in this table and subsequent pro forma cost and revenue tables may be affected by rounding.

[b] Revenue includes imputed income on investments when equity is imputed at a level that meets minimum capital requirements and, when combined with liabilities, exceeds total assets (attachment 1).

[c] The calculation of total expense includes operating, imputed, and other expenses. Imputed and other expenses include taxes, Board of Governors' priced services expenses, the cost of float, and interest on imputed debt, if any. Credits or debits related to the accounting for pension plans under FAS 158 [ASC 715] are also included.

[d] Targeted ROE is the after-tax ROE included in the PSAF.

[e] The recovery rates in this and subsequent tables do not reflect the unamortized gains or losses that must be recognized in accordance with FAS 158 [ASC 715]. Future gains or losses, and their effect on cost recovery, cannot be projected.

Table 2 provides an overview of cost-recovery performance for the ten-year period from 2005 to 2014, 2014 actual, 2015 budget, 2015 estimate, and 2016 budget by priced service.

[1] The ten-year recovery rate is based on the pro forma income statement for Federal Reserve priced services published in the Board's *Annual Report.* Effective December 31, 2006, the Reserve Banks implemented Statement of Financial Accounting Standards (SFAS) No. 158: *Employers' Accounting for Defined Benefit Pension and Other Postretirement Plans* [Accounting Standards Codification (ASC) 715 *Compensation—Retirement Benefits*], which resulted in recognizing a cumulative reduction in equity related to the priced services' benefit plans. Including this cumulative reduction in equity from 2005 to 2014 results in cost recovery of 95.1 percent for the ten-year period. This measure of long-run cost recovery is also published in the Board's *Annual Report.*

TABLE 2—PRICED SERVICES COST RECOVERY

[Percent]

Priced service	2005–2014	2014 actual	2015 budget [a]	2015 estimate	2016 budget [b]
All services	102.9	102.1	102.0	104.1	101.9
Check	103.7	115.6	105.2	110.1	106.7
FedACH	100.0	86.7	100.4	100.0	99.0
Fedwire Funds and NSS	101.9	103.2	100.7	100.7	100.0
Fedwire Securities	102.3	104.1	97.5	105.7	98.7

[a] The 2015 budget figures reflect the final budgets as approved by the Board in December 2014.
[b] The 2016 budget figures reflect preliminary budget information from the Reserve Bank. The Reserve Banks will submit final budget data to the Board in November 2015, for Board consideration in December 2015.

1. *2015 Estimated Performance*—The Reserve Banks estimate that they will recover 104.1 percent of the costs of providing priced services in 2015, including total expense and targeted ROE, compared with a 2015 budgeted recovery rate of 102.0 percent, as shown in table 2. Overall, the Reserve Banks estimate that they will fully recover actual and imputed costs and earn net income of $22.6 million, compared with the targeted ROE of $5.6 million. The Reserve Banks estimate that all services will achieve full cost recovery, despite higher-than-budgeted pension expenses. Greater-than-expected check volume processed by the Reserve Banks has been the single most significant factor influencing priced services cost recovery.

2. *2016 Private-Sector Adjustment Factor*—The 2016 PSAF for Reserve Bank priced services is $13.1 million. This amount represents a decrease of $4.9 million from the 2015 PSAF of $18.0 million. This decrease is primarily the result of a reduction in the assets to be financed on the imputed priced-services balance sheet and an associated decline in the cost of debt and equity.

3. *2016 Projected Performance*—The Reserve Banks project a priced services cost-recovery rate of 101.9 percent in 2016, with net income of $12.0 million, compared with a targeted ROE of $4.1 million. The Reserve Banks project that the check service and the Fedwire® Funds and National Settlement Service will fully recover their costs; however, the Reserve Banks project that the FedACH® Service and the Fedwire Securities Service will not achieve full cost recovery because of investment costs associated with multiyear technology initiatives to modernize their processing platforms.[2] These investments are expected to enhance efficiency, the overall quality of operations, and the Reserve Banks' ability to offer additional services to depository institutions.

The primary risks to the Reserve Banks' ability to achieve their targeted cost-recovery rates are unanticipated volume and revenue reductions and the potential for cost overruns with the technology modernization initiatives. In light of these risks, the Reserve Banks will continue to refine their business and operational strategies to manage operating costs, to increase product revenue, and to capitalize on efficiencies gained from technology initiatives.

4. *2016 Pricing*—The following summarizes the Reserve Banks' changes in fee schedules for priced services in 2016:

Check

• The Reserve Banks will increase the per-item fee for FedReturn® items that are qualified to the Reserve Bank in instances in which the bank of first deposit cannot be identified from $8 to $15.

• The Reserve Banks will increase the fees for traditional paper check forward and return collection deposits. The Reserve Banks will increase the per-item fee for paper forward deposits from $2.00 to $2.50 and the per-item fee for each unencoded item from $1.00 to $1.50.[3] The Reserve Banks will increase the per-item fee for paper return-collection deposits from $5.00 to $5.50 and the per-item fee for unqualified paper returns from $7.00 to $7.50. The Reserve Banks will discontinue image retrievals by fax for both incoming and outgoing retrievals within FedImage® Services.[4]

• The Reserve Banks will introduce Select Mixed Level 3 to the Select Mixed image cash letter (ICL) product.[5] The new level will have a daily fee of $3,000 and per-item fees from $0.002 to $0.350.

• The Reserve Banks will eliminate the FedForward® Fine Sort (ICL) product in January 2017 as part of the Reserve Banks' effort to reflect today's electronic check processing environment in their check fee schedule.[6] To encourage depositors to shift volume from the fine-sort products to mixed deposit options in advance of this elimination, the Reserve Banks will increase the FedForward Fine Sort ICL product per-item fees at the 9 p.m., 1 a.m., and 5 a.m. deadlines by $0.002, $0.004, and $0.006, respectively.[7] The Reserve Banks will increase the FedForward Deferred Fine Sort ICL product per-item fees at the 1 a.m., 5

[2] The Reserve Banks have been engaged in a multiyear technology initiative to modernize the FedACH processing platform by migrating the service from a mainframe system to a distributed computing environment. In late 2013, the Reserve Banks conducted an assessment focused on the viability and cost-effectiveness of the program. As a result, the Reserve Banks in 2014 suspended the program and began to investigate the use of other technology solutions. In 2015, the Reserve Banks evaluated alternative processing solutions, including commercially available options.

[3] Unencoded items are those items deposited without encoding of certain elements, such as amount, added to the magnetic ink character recognition (MICR) line.

[4] FedImage Services offer depository institutions products for the capture, archive, and retrieval of check images. A current list of services can be found at *https://www.frbservices.org/serviceofferings/check/fed_image_services.html.*

[5] A current list of Select Mixed endpoints can be found at *https://www.frbservices.org/servicefees/check21_endpoint_listing.html.*

[6] In a paper check processing environment, the fine sort product allowed the Reserve Banks to gain efficiencies because the checks did not require processing on reader-sorters. In today's electronic check processing environment, all image cash letters are processed through the Reserve Banks' electronic system in the same manner, and the Reserve Banks do not gain any efficiencies by having the depositing bank fine sort electronic checks prior to deposit.

[7] All times are stated in the Eastern Time zone (ET).

Depository institutions may deposit image cash letters using nine deposit options within the FedForward product line; the options vary in price structure and funds availability. The Reserve Banks offer customers the option of sending FedForward ICLs for items drawn on specific endpoints in a separate cash letter, which combines a high fixed fee with a lower variable fee. All eligible items in the cash letter receive immediate availability, while ineligible items receive deferred availability of the next business day. A current list of FedForward deposit options can be found at *https://www.frbservices.org/servicefees/check_services_2015.html.*

a.m., and 10 a.m. deadlines by $0.004, $0.006, and $0.008, respectively.

• In addition to the above changes, the Reserve Banks plan to announce further modifications to the check fee schedule during 2016 that reflect the efficiencies of today's electronic check processing environment. The new schedule may include elimination of certain sorted deposit options and modifications to the current endpoint-based tiered pricing structure.

FedACH

• The Reserve Banks will increase the minimum monthly fee for forward origination from $35 to $45.[8]

• The Reserve Banks will increase the minimum monthly fee for receipt from $25 to $35.[9]

• The Reserve Banks will eliminate the large file and small file per-item fees and introduce a single base fee of $0.0032 for all origination files. The Reserve Banks will provide a discount of $0.0005 for origination volume between 750,000 to 1,500,000 items per month and $0.0007 for origination volume greater than 1,500,000 items per month.

• The Reserve Banks will lower the top-tier volume origination discount level based on monthly receipt volume from 17,500,000 to 15,000,000 items per month, while maintaining the current discount amounts.[10]

• The Reserve Banks will increase the forward item receipt fee from $0.0025 to $0.0032 per item, while keeping the return item receipt fee at $0.0075 per item.

• The Reserve Banks will change the volume-based receipt discount structure to encourage additional receipt volume. The changes will include a decrease in the first volume-based discount by 250,000 items per month to 750,001 items a month, the introduction of a new volume-based discount tier for volume between 1,500,001 and 2,500,000 items per month, and an increase for all existing volume-based receipt discounts by $0.0007.[11]

• The Reserve Banks will implement a $20 monthly billing discount for any customer that pays the origination minimum fee, subscribes to a FedLine Web® Plus or higher package, and subscribes to either FedACH RDFI Alert, FedACH Risk® Origination Monitoring, or FedPayments® Reporter. In addition to the above changes, the Reserve Banks plan to reassess the FedGlobal® ACH fee schedule during 2016.

Fedwire Funds and National Settlement

• The Reserve Banks will increase the Tier 1 per-item pre-incentive fee from $0.73 to $0.79 per transaction, increase the Tier 3 per-item pre-incentive fee from $0.150 to $0.155 per transaction, and leave Tier 2 per-item pre-incentive fees unchanged.[12]

• The Reserve Banks will increase the surcharge for offline transactions from $50 to $55. The Reserve Banks will increase the monthly participation fee from $90 to $95.

Fedwire Securities and National Settlement Services

• The Reserve Banks will keep prices at existing levels for the priced Fedwire Securities and National Settlement Services.

FedLine® Access Solutions

• The Reserve Banks will increase the fee for the FedLine Exchange℠ subscriber pack by $5 per month.[13] The Reserve Banks will keep all other existing FedLine fees unchanged.

• The Reserve Banks will introduce a 256K/T1 legacy router surcharge of $5,000 per month to encourage customers to migrate to more efficient access solutions.[14]

• The Reserve Banks will introduce a fee for customers that choose to implement FedLine using a customized (nonstandard) router setup. The fee will vary from $2,500 to $5,000 based on the complexity of the setup.

• The Reserve Banks will include two virtual private network (VPN) devices in the FedLine Direct® Premier package (rather than one) to align better with the FedLine Advantage® Premier package.

• Depository institutions with more than 250 Fedwire transactions per month, or more than one routing number, will only have access to the FedPayments Manager Import/Export (FPM) tool via FedLine Advantage Premier.[15] Affected customers will experience a fee increase ranging from $15 to $75 per month to upgrade to FedLine Advantage Premier.

5. *2016 Price Index*—Figure 1 compares indexes of fees for the Reserve Banks' priced services with the GDP price index.[16] The price index for Reserve Bank priced services is projected to increase approximately 1 percent in 2016 from the 2015 level. The price index for Check 21 services is projected to increase less than 1 percent. The price index for the FedACH Service is projected to decrease nearly 1 percent. The price index for the Fedwire Funds and National Settlement Services is projected to increase approximately 5 percent. The price index for the Fedwire Securities Services is projected to decrease nearly 1 percent. For the period 2006 to 2015, the price index for total priced services is expected to decrease 26 percent.

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[8] Any originating depository financial institution (ODFI) incurring less than $45 for the following fees will be charged the difference to reach the minimum: Forward value and nonvalue item origination fees, FedGlobal ACH origination surcharges, and FedACH SameDay forward origination surcharges.

[9] Any receiving depository financial institution (RDFI) originating forward value and nonvalue items below the minimum level and incurring less than $35 in receipt fees will be charged the difference to reach the minimum based on origination. RDFIs not originating forward value and nonvalue items will incur the $35 minimum monthly fee for receipt.

[10] Origination discounts apply only to those items received by FedACH receiving points and are available only to Premium Receivers.

[11] Premium Receivers (institutions receiving a certain portion of volume through FedACH) with volume greater than 1,500,000 items a month will receive the increased discount for all items received.

[12] The per-item pre-incentive fee is the fee that the Reserve Banks charge for transfers that do not qualify for incentive discounts. The Tier 1 per-item pre-incentive fee applies to the first 14,000 transfers, the Tier 2 per-item pre-incentive fee applies to the next 76,000 transfers, and the Tier 3 per-item pre-incentive fee applies to any additional transfers. The Reserve Banks apply an 80 percent incentive discount to transfers over 60 percent of a customer's historic benchmark volume.

[13] FedLine packages do not include user subscriptions for priced services. Depository institutions that wish to access priced services must purchase user subscriptions in packs of five (5-packs).

[14] The $5,000 per month surcharge will be effective July 1, 2016. The price will increase to $10,000 per month on September 1, 2016 and $20,000 per month on November 1, 2016.

[15] These customers are generally large institutions that may benefit from the expanded suite of services included in the FedLine Advantage Premier package. For example, large customers may benefit from the enhanced contingency preparedness solutions (such as a secondary VPN device) that are included in FedLine Premier packages.

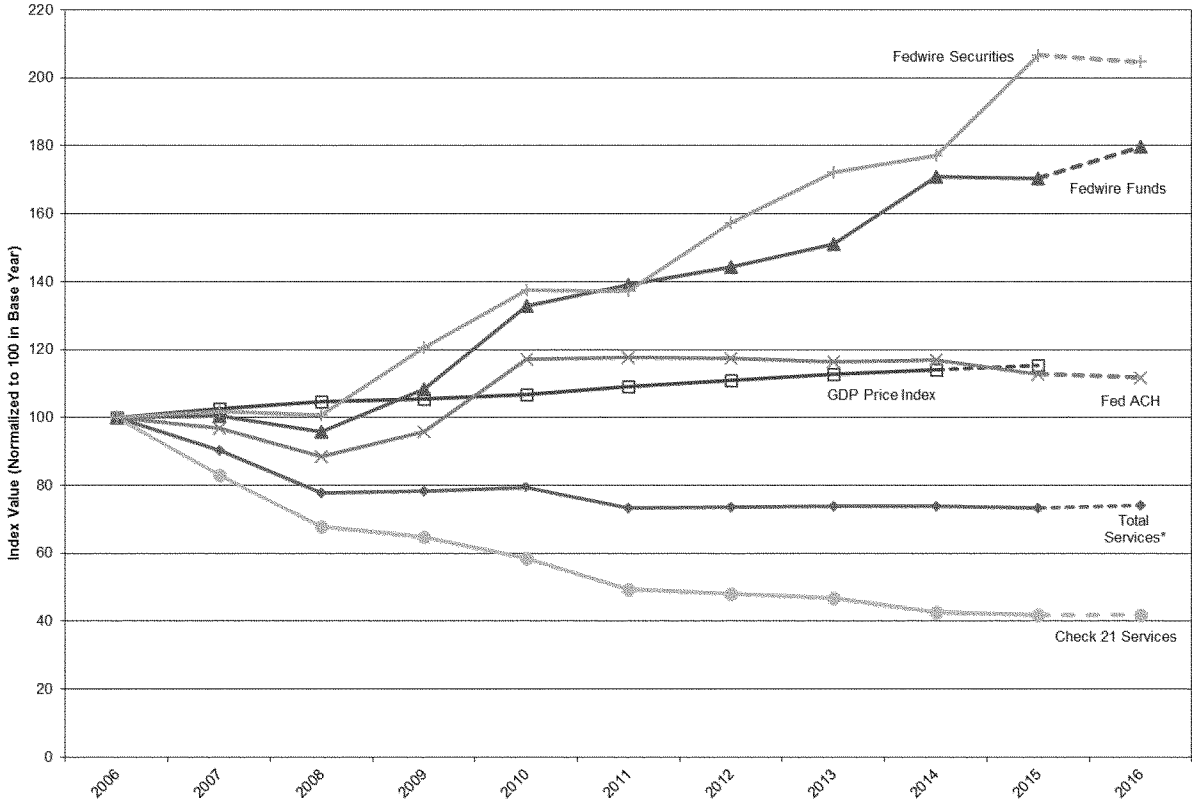
FedComplete Plus customers with more than 250 Fedwire transactions per month that use the FPM tool will also be transferred to FedComplete Premier packages with the associated fee increase because FedComplete Plus packages incorporate FedLine Advantage Plus. The transfer will affect about 10 current FedCompelete customers.

[16] For the period 2006 to 2014, the GDP price index increased 15 percent.

FIGURE 1

2016 Price Index

PRICE INDEXES FOR FEDERAL RESERVE PRICED SERVICES



* Total Services excludes legacy paper services which now have minimal volume and are expected to generate less than $9 million in revenue in 2016.

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B. Private Sector Adjustment Factor—The imputed debt financing costs, targeted ROE, and effective tax rate are based on a U.S. publicly traded firm market model.[17] The method for calculating the financing costs in the PSAF requires determining the appropriate imputed levels of debt and equity and then applying the applicable financing rates. In this process, a pro forma balance sheet using estimated assets and liabilities associated with the Reserve Banks' priced services is developed, and the remaining elements that would exist are imputed as if these priced services were provided by a private business firm. The same generally accepted accounting principles that apply to commercial-entity financial statements apply to the relevant elements in the priced services pro forma financial statements.

The portion of Federal Reserve assets that will be used to provide priced services during the coming year is determined using information about actual assets and projected disposals and acquisitions. The priced portion of these assets is determined based on the allocation of depreciation and amortization expenses of each asset class. The priced portion of actual Federal Reserve liabilities consists of postemployment and postretirement benefits, accounts payable, and other liabilities. The priced portion of the actual net pension asset or liability is also included on the balance sheet.[18]

The equity financing rate is the targeted ROE produced by the capital asset pricing model (CAPM). In the CAPM, the required rate of return on a firm's equity is equal to the return on a risk-free asset plus a market risk premium. The risk-free rate is based on the three-month Treasury bill; the beta is assumed to be equal to 1.0, which approximates the risk of the market as a whole; and the market risk premium is based on the monthly returns in excess of the risk-free rate over the most recent 40 years. The resulting ROE reflects the return a shareholder would expect when investing in a private business firm.

For simplicity, given that federal corporate income tax rates are graduated, state income tax rates vary, and various credits and deductions can apply, an actual income tax expense is not explicitly calculated for Reserve Bank priced services. Instead, the Board targets a pretax ROE that would provide sufficient income to fulfill the priced services' imputed income tax obligations. To the extent that performance results are greater or less than the targeted ROE, income taxes are adjusted using the effective tax rate.

[17] Data for U.S. publicly traded firms is from the Standard and Poor's Compustat® database. This database contains information on more than 6,000 U.S. publicly traded firms, which approximates the entirety of the U.S. market.

[18] The pension assets are netted with the pension liabilities and reported as a net asset or net liability as required by ASC 715 *Compensation—Retirement Benefits.*

Capital structure. The capital structure is imputed based on the imputed funding need (assets less liabilities), subject to minimum equity constraints. Short-term debt is imputed to fund the imputed short-term funding need. Long-term debt and equity are imputed to meet the priced services long-term funding need at a ratio based on the capital structure of the U.S. publicly traded firm market. The level of equity must meet the minimum equity constraints, which follow the FDIC requirements for a well-capitalized institution. The priced services must maintain equity of at least 5 percent of total assets and 10 percent of risk-weighted assets.[19] Any equity imputed that exceeds the amount needed to fund the priced services' assets and meet the minimum equity constraints is offset by a reduction in imputed long-term debt. When imputed equity is larger than what can be offset by imputed debt, the excess is imputed as investments in Treasury securities; income imputed on these investments reduces the PSAF.

Application of the Payment System Risk (PSR) Policy to the Fedwire Services. The Board's PSR policy reflects the new international standards for financial market infrastructures (FMIs) developed by the Committee on Payment and Settlement Systems and the Technical Committee of the International Organization of Securities Commissions in the *Principles for Financial Market Infrastructures.* The revised policy retains the expectation that the Fedwire Services meet or exceed the applicable risk-management standards. Principle 15 states that an FMI should identify, monitor, and manage general business risk and hold sufficient liquid net assets funded by equity to cover potential general business losses so that it can continue operations and services as a going concern if those losses materialize. Further, liquid net assets should at all times be sufficient to ensure a recovery or orderly wind-down of critical operations and services. The Fedwire Services do not face the risk that a business shock would cause the service to wind down in a disorderly manner and disrupt the stability of the financial system. In order to foster competition with private-sector FMIs, however, the Reserve Banks' priced services will hold six months of the Fedwire Funds Service's current operating expenses as liquid financial assets and equity on the pro forma balance sheet.[20] Current operating expenses are defined as normal business operating expenses on the income statement less depreciation, amortization, taxes, and interest on debt. The Fedwire Funds Service's six months of current operating expenses are computed based on its preliminary 2016 budget at $53.8 million. In 2016, $51.1 million of equity was imputed to meet the FDIC capital requirements; however, an additional $2.7 million of equity was imputed to meet the PSR policy requirement. The additional equity is solely allocated to Fedwire Funds Service.

Effective tax rate. Like the imputed capital structure, the effective tax rate is calculated based on data from U.S. publicly traded firms. The tax rate is the mean of the weighted average rates of the U.S. publicly traded firm market over the past 5 years.

Debt and equity financing. The imputed short- and long-term debt financing rates are derived from the nonfinancial commercial paper rates from the Federal Reserve Board's H.15 Selected Interest Rates release (AA and A2/P2) and the annual Merrill Lynch Corporate & High Yield Index rate, respectively. The rates for debt and equity financing are applied to the priced services estimated imputed short-term debt, long-term debt, and equity needed to finance short- and long-term assets and meet equity requirements.

The decrease in the 2016 PSAF is primarily due to lower financing costs as a result of fewer priced services assets to be financed than in 2015. Debt and equity financing rates declined and less debt and equity was imputed to fund priced services assets.

Projected 2016 Federal Reserve priced-services assets, reflected in table 3, have decreased $486.3 million from 2015. This reduction is primarily due to a $589.0 million decrease in the balance of imputed investments in federal funds, driven by recent changes in the PSR policy resulting in a decrease in daily float balances and a corresponding effect on imputed investments. The reduction is offset by an increase of $170.0 million from 2015 in items in process of collection. As shown in table 3, imputed equity for 2016 is $53.8 million, a decrease of $18.1 million from the equity imputed for 2015. In accordance with FAS 158 [ASC 715], this amount includes an accumulated other comprehensive loss of $666.1 million.

Table 4 reflects the portion of short- and long-term assets that must be financed with actual or imputed liabilities and equity. Debt and equity imputed to fund the 2016 priced services assets within the observed market leverage ratio produced an equity level that did not meet the FDIC minimum equity requirements. As a result, additional equity was imputed to meet the FDIC requirements, and imputed long-term debt was reduced. The ratio of capital to risk-weighted assets exceeds the required 10 percent of risk-weighted assets and equity exceeds 5 percent of total assets (table 6). In 2015, long-term debt and equity was imputed to meet the asset funding requirements and reflects the leverage ratio observed in the market; additional equity of $7.6 million was required (table 5) to meet the market leverage ratio.

Table 5 shows the derivation of the 2016 and 2015 PSAF. Financing costs for 2016 are $6.1 million lower than in 2015. In addition to the decline in the levels of debt and equity mentioned above, the cost of equity declined 3 basis points. The reduced equity balance and the lower cost of equity result in a pretax ROE that is $2.0 million lower than the 2015 pretax ROE. Imputed sales taxes declined to $2.8 million in 2016 from $3.3 million in 2015. The priced services portion of the Board's expenses increased $1.7 million to $5.0 million in 2016 from $3.3 million in 2015. The effective income tax rate used in 2016 decreased to 21.6 percent from 22.4 percent in 2015.

[19] The FDIC rule, which was adopted as final on April 8, 2014, requires that well-capitalized institutions meet or exceed the following standards: (1) Total capital to risk-weighted assets ratio of at least 10 percent, (2) tier 1 capital to risk-weighted assets ratio of at least 8 percent, (3) common equity tier 1 capital to risk-weighted assets ratio of at least 6.5 percent, and (4) a leverage ratio (tier 1 capital to total assets) of at least 5 percent. Because all of the Federal Reserve priced services' equity on the pro forma balance sheet qualifies as tier 1 capital, only requirements 1 and 4 are binding. The FDIC rule can be located at *https://www.fdic.gov/news/board/2014/2014-04-08_notice_dis_c_fr.pdf.*

[20] This requirement does not apply to the Fedwire Securities Service. There are no competitors to the Fedwire Securities Service that will face such a requirement, and imposing such a requirement when pricing securities services could artificially increase the cost of these services.

TABLE 3—COMPARISON OF PRO FORMA BALANCE SHEETS FOR BUDGETED FEDERAL RESERVE PRICED SERVICES

[Millions of dollars—projected average for year]

	2016	2015	Change
Short-term assets:			
Receivables	$35.6	$34.5	$1.0
Materials and supplies	0.5	0.6	(0.1)
Prepaid expenses	10.2	11.0	(0.9)
Items in process of collection[21]	321.0	151.0	170.0
Total short-term assets	367.2	197.2	170.1
Imputed investments:[22]			
Imputed investment in Treasury Securities	55.8	.....	55.8
Imputed investment in Fed Funds	11.0	600.00	(589.0)
Total imputed investments	66.8	600.00	(533.2)
Long-term assets:			
Premises[23]	111.0	116.2	(5.2)
Furniture and equipment	38.5	39.9	(1.5)
Leasehold improvements and long-term prepayments	89.5	91.5	(2.0)
Pension asset	.....	79.6	(79.6)
Deferred tax asset	187.9	222.8	(35.0)
Total long-term assets	426.8	550.0	(123.2)
Total assets	860.9	1,347.2	(486.3)
Short-term liabilities:			
Deferred credit items	332.0	751.0	(419.0)
Short-term debt	19.0	18.5	0.5
Short-term payables	27.2	27.6	(0.4)
Total short-term liabilities	378.2	797.2	(418.9)
Long-term liabilities:			
Pension liability	17.6	.....	17.6
Long-term debt	.....	81.9	(81.9)
Postemployment/postretirement benefits and net pension liabilities[24]	411.3	396.3	15.0
Total liabilities	807.1	1,275.3	(468.3)
Equity[25]	53.8	71.9	(18.1)
Total liabilities and equity	860.9	1,347.2	(486.3)

TABLE 4—IMPUTED FUNDING FOR PRICED-SERVICES ASSETS

[Millions of dollars]

	2016	2015
A. Short-term asset financing		
Short-term assets to be financed:		
Receivables	$35.6	$34.5
Materials and supplies	0.5	0.6
Prepaid expenses	10.2	11.0
Total short-term assets to be financed	46.2	46.2
Short-term payables	27.2	27.6
Net short-term assets to be financed	19.0	18.5

[21] Credit float, which represents the difference between items in process of collection and deferred credit items, occurs when the Reserve Banks debit the paying bank for transactions prior to providing credit to the depositing bank. Float is directly estimated at the service level.

[22] Consistent with the Board's PSR policy, the Reserve Banks' priced services will hold six months of the Fedwire Funds Service's current operating expenses as liquid net financial assets and equity on the pro forma balance sheet. Six months of the Fedwire Funds Service's projected current operating expenses is $53.8 million. In 2016, $51.1 million of equity was imputed to meet the regulatory capital requirements; however, an additional $2.7 million of equity was imputed to meet the PSR policy requirement.

[23] Includes the allocation of Board of Governors assets to priced services of $1.3 and $0.7 million for 2016 and 2015, respectively.

[24] Includes the allocation of Board of Governors liabilities to priced services of $0.6 million for 2016 and 2015.

[25] Includes an accumulated other comprehensive loss of $666.1 million for 2016 and $523.7 million for 2015, which reflects the ongoing amortization of the accumulated loss in accordance with FAS 158 [ASC 715]. Future gains or losses, and their effects on the pro forma balance sheet, cannot be projected. See table 5 for calculation of required imputed equity amount.

TABLE 4—IMPUTED FUNDING FOR PRICED-SERVICES ASSETS—Continued

[Millions of dollars]

	2016	2015
Imputed short-term debt financing [26]	19.0	18.5
B. Long-term asset financing		
Long-term assets to be financed:		
Premises	111.0	116.2
Furniture and equipment	38.5	39.9
Leasehold improvements and long-term prepayments	89.5	91.5
Pension asset	.....	79.6
Deferred tax asset	187.9	222.8
Total long-term assets to be financed	426.8	550.0
Pension liability	17.6	.....
Postemployment/postretirement benefits and net pension liabilities	411.3	396.3
Net long-term assets to be financed	(2.0)	153.8
Imputed long-term debt [26]	.....	81.9
Imputed equity [26]	53.8	71.9
Total long-term financing	53.8	153.8

TABLE 5—DERIVATION OF THE 2016 AND 2015 PSAF

[Dollars in millions]

	2016		2015	
	Debt	Equity	Debt	Equity
A. Imputed long-term debt and equity				
Net long-term assets to finance	$(2.0)	$(2.0)	$153.8	$153.8
Capital structure observed in market	58.5%	41.5%	58.2%	41.8%
Pre-adjusted long-term debt and equity	$(1.2)	$(0.8)	$89.5	$64.3
Equity adjustments [27]:				
Equity to meet capital requirements	.....	51.1	.....	71.9
Adjustment to debt and equity funding given capital requirements [28]	1.2	(1.2)	(7.6)	7.6
Adjusted equity balance	.....	(2.0)	.....	71.9
Equity to meet capital requirements [29]	.....	53.1	.....	.....
	.....	$51.1	$81.9	$71.9
B. Cost of capital:				
Elements of capital costs				
Short-term debt [30]	$19.0 × 0.3% = $0.1		$18.5 × 0.2% = $0.0	
Long-term debt [30]	× 4.2% =		81.9 × 5.0% = 4.1	
Equity [31]	51.1 × 9.8% = 5.0		71.9 × 10.1% =7.3	
	.....	5.1	.....	11.4
C. Incremental cost of PSR policy:				
Equity to meet policy	$2.7 × 9.8% = $0.3		× 10.1% = $	
D. Other required PSAF costs:				
Sales taxes	.....	$2.8	.....	$3.3
Board of Governors expenses	.....	5.0	.....	3.3
	.....	.....	7.8	6.6
	.....	.....	$13.1	$18.0
E. Total PSAF:				
As a percent of assets	.....	1.5%	.....	1.0%
As a percent of expenses	.....	3.6%	.....	4.5%

[26] See table 5 for calculation.

TABLE 5—DERIVATION OF THE 2016 AND 2015 PSAF—Continued

[Dollars in millions]

	2016		2015	
	Debt	Equity	Debt	Equity
F. Tax rates		21.6%		22.4%

[27] If minimum equity constraints are not met after imputing equity based on the capital structure observed in the market, additional equity is imputed to meet these constraints. The long-term funding need was met by imputing long-term debt and equity based on the capital structure observed in the market (see tables 4 and 6). In 2016, the amount of imputed equity exceeded the minimum equity requirements for risk-weighted assets.

[28] Equity adjustment offsets due to a shift of long-term debt funding to equity in order to meet FDIC capital requirements for well-capitalized institutions.

[29] Additional equity in excess of that needed to fund priced services assets is offset by an asset balance of imputed investments in treasury securities.

[30] Imputed short-term debt and long-term debt are computed at table 4.

[31] The 2016 ROE is equal to a risk-free rate plus a risk premium (beta * market risk premium). The 2016 after-tax CAPM ROE is calculated as 0.03% + (1.0 * 7.62%) = 7.65%. Using a tax rate of 21.6%, the after-tax ROE is converted into a pretax ROE, which results in a pretax ROE of (7.65%/(1–21.6%)) = 9.76%. Calculations may be affected by rounding.

TABLE 6—COMPUTATION OF 2016 CAPITAL ADEQUACY FOR FEDERAL RESERVE PRICED SERVICES

[Dollars in millions]

	Assets	Risk weight	Weighted assets
Imputed investments:			
1-Year Treasury securities [32]	$55.8		
Federal funds [33]	11.0	0.2	2.2
Total imputed investments	66.8		2.2
Receivables	$35.6	0.2	$7.1
Materials and supplies	0.5	1.0	0.5
Prepaid expenses	10.2	1.0	10.2
Items in process of collection	321.0	0.2	64.2
Premises	111.0	1.0	111.0
Furniture and equipment	38.5	1.0	38.5
Leasehold improvements and long-term prepayments	89.5	1.0	89.5
Pension asset		1.0	
Deferred tax asset	187.9	1.0	187.9
Total	860.9		511.0
Imputed equity	$53.8		
Capital to risk-weighted assets	10.5%		
Capital to total assets	6.2%		

[32] If minimum equity constraints are not met after imputing equity based on all other financial statement components, additional equity is imputed to meet these constraints. Additional equity imputed to meet minimum equity requirements is invested solely in Treasury securities. The imputed investments are similar to those for which rates are available on the Federal Reserve's H.15 statistical release, which can be located at *http://www.federalreserve.gov/releases/h15/data.htm.*

[33] The investments are imputed based on the amounts arising from the collection of items prior to providing credit according to established availability schedules.

C. *Check Service*—Table 7 shows the 2014 actual, 2015 estimated, and 2016 budgeted cost-recovery performance for the commercial check service.

TABLE 7—CHECK SERVICE PRO FORMA COST AND REVENUE PERFORMANCE

[Dollars in millions]

Year	Revenue	Total expense	Net income (ROE)	Targeted ROE	Recovery rate after targeted ROE [1/(2 + 4)]
	1	2	3	4	5
2014 (actual)	174.7	149.3	25.4	1.8	115.6%
2015 (estimate)	159.3	142.7	16.5	2.0	110.1
2016 (budget)	149.9	139.1	10.7	1.3	106.7

1. *2015 Estimate*—The Reserve Banks estimate that the check service will recover 110.1 percent of total expenses and targeted ROE, compared with a 2015 final budgeted recovery rate of 105.2 percent. Greater-than-expected check volumes processed by the Reserve Banks and lower-than-expected costs have influenced significantly the check services cost recovery.

The decline in Reserve Bank check volume, which is attributable to the decline in the number of checks written generally, was not as great as anticipated.[34] Through August, total forward check volume is 4.6 percent lower and total return check volume is 11.9 percent lower-than for the same period last year. For full-year 2015, the Reserve Banks estimate that their total forward check volume will decline 5.6 percent (compared with a budgeted decline of nearly 7 percent) and their total return check volume will decline 11.6 percent (compared with a budgeted decline of about 14 percent) from 2014 levels.[35]

2. *2016 Pricing*—The Reserve Banks expect the check service to recover 106.7 percent of total expenses and targeted ROE in 2016. The Reserve Banks project revenue to be $149.9 million, a decline of 5.9 percent from the 2015 estimate. This decline is driven largely by projected reductions in both forward check and return check volume. The Reserve Banks estimate that total Reserve Bank forward check volumes will decline 6.2 percent, to 5.1 billion, and return check volumes will decline 12.7 percent to 28.5 million in 2016. Total expenses for the check service are projected to be $139.1 million, a decline of 2.5 percent from 2015.[36]

The Reserve Banks will increase the per-item fee for FedReturn items that are qualified to the Reserve Bank in instances in which the bank of first deposit cannot be identified from $8 to $15.

The Reserve Banks will increase the fees for traditional paper check forward and return collection deposits. The Reserve Banks will increase the per-item fee for paper forward deposits from $2.00 to $2.50 and the per-item fee for each unencoded item from $1.00 to $1.50.[37] The Reserve Banks will increase the per-item fee for paper return collection deposits from $5.00 to $5.50 as well as the per-item fee for unqualified paper returns from $7.00 to $7.50. The Reserve Banks will discontinue image retrievals by fax for both incoming and outgoing retrievals within FedImage Services.[38]

The Reserve Banks will introduce Select Mixed Level 3 tier to the Select Mixed image cash letter (ICL) product.[39] The new level will have a daily fee of $3,000 and per-item fees from $0.002 to $0.350, as seen in table 8.

TABLE 8—FEDFORWARD SELECT MIXED IMAGE CASH LETTER [a] [b]

Deadline	5 a.m.			12 p.m.		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Daily fixed fee	$2,200.00	$900.00	$3,000.00	$2,200.00	$900.00	$3,000.00
Cash letter surcharge	.....	.....	.....	25.00	25.00	25.00
Tier 1	0.0020	0.0020	0.0020	0.0020	0.0020	0.0020
Tier 2	0.0040	0.0060	0.0040	0.0040	0.0060	0.0040
Tier 3	0.0060	0.0080	0.0060	0.0060	0.0080	0.0060
Tier 4	.....	.....	0.0130	.....	.....	0.0130
Tier 5	.....	.....	0.0220	.....	.....	0.0220
Tier 6	.....	.....	0.1000	.....	.....	0.3500
Non-eligible endpoints	0.1000	0.1000	N/A	0.3500	0.3500	N/A

[a] All deadlines are Monday through Friday.
[b] A current list of FedForward endpoint tier listings can be found at *http://www.frbservices.org/servicefees/check21_endpoint_listing.html.*

The Reserve Banks will eliminate the FedForward Fine Sort ICL product in January 2017 as part of the Reserve Banks effort to reflect today's electronic check processing environment in their check fee schedule.[40] To encourage depositors to shift volume from the fine-sort products to mixed deposit options in advance of this elimination, the Reserve Banks will increase the FedForward Fine Sort ICL product per-item fees at the 9 p.m., 1 a.m., and 5 a.m. deadlines by $0.002, $0.004, and $0.006, an average increase of 22.7 percent.[41] The Reserve Banks will increase the FedForward Deferred Fine Sort ICL product per-item fees at the 1 a.m., 5 a.m., and 10 a.m. deadlines by $0.004, $0.006, and $0.008, an average increase of 48.8 percent. The per item fees for each deadline are listed in table 9.

[34] The greater-than-expected check volume is attributed to the retention of current customers through continued enhancements of two FedForward product offerings: select mixed and premium mixed.

[35] Total Reserve Bank forward check volumes are expected to drop from 5.7 billion in 2014 to 5.4 billion in 2015. Total Reserve Bank return check volumes are expected to drop from roughly 36.5 million in 2014 to 32.3 million in 2015.

[36] The reduction in check costs is driven in part by lower pension costs in 2016.

[37] Unencoded items are those items deposited without encoding of certain elements, such as amount, added to the MICR line.

[38] FedImage Services offer depository institutions products for the capture, archive, and retrieval of check images. A current list of services can be found at *https://www.frbservices.org/serviceofferings/check/fed_image_services.html.*

[39] A current list of Select Mixed endpoints can be found at *https://www.frbservices.org/servicefees/check21_endpoint_listing.html.*

[40] In a paper check processing environment, the fine sort product allowed the Reserve Banks to gain efficiencies because the checks did not require processing on reader-sorters. In today's electronic check processing environment, all image cash letters are processed through the Reserve Banks' electronic system in the same manner, and the Reserve Banks do not gain any efficiencies by having the depositing bank fine sort electronic checks prior to deposit.

[41] All times are stated in the eastern time zone (ET).

Depository institutions may deposit image cash letters using nine deposit options within the FedForward product line; the options vary in price structure and funds availability. The Reserve Banks offer customers the option of sending FedForward ICLs for items drawn on specific endpoints in a separate cash letter, which combines a high fixed fee with a lower variable fee. All eligible items in the cash letter receive immediate availability, while ineligible items receive deferred availability of the next business day. A current list of FedForward deposit options can be found at *https://www.frbservices.org/servicefees/check_services_2015.html.*

TABLE 9

FedForward Fine Sort Image Cash Letter[a b]			
Deadline	9 p.m.	1 a.m.	5 a.m.
Cash letter fee	$3.50	$6.50	$12.50
Tier 1	0.0080	0.0120	0.0250
Tier 2	0.0120	0.0170	0.0290
Tier 3	0.0210	0.0260	0.0380
Tier 4	0.0310	0.0360	0.0480
FedForward Fine Deferred Sort Image Cash Letter[a b]			
Deadline	1 a.m.	5 a.m.	10 a.m.
Cash letter fee	$3.50	$3.50	$3.50
Tier 1	0.0100	0.0130	0.0160
Tier 2	0.0130	0.0160	0.0190
Tier 3	0.0220	0.0250	0.0280
Tier 4	0.0320	0.0350	0.0380

[a] All deadlines are Monday through Friday.
[b] A current list of FedForward endpoint tier listings can be found at *http://www.frbservices.org/servicefees/check21_endpoint_listing.html.*

The Reserve Banks estimate that the price changes will result in a 0.5 percent average price increase for check customers. In addition to the above changes, the Reserve Banks plan to announce further modifications to the check fee schedule during 2016 that reflect the efficiencies of today's electronic check processing environment. The new schedule may include elimination of certain sorted deposit options and modifications to the current endpoint-based tiered pricing structure.

Risks to the Reserve Banks' ability to achieve budgeted 2016 cost recovery for the check service include lower-than-expected check volume due to reductions in check writing overall and competition from correspondent banks, aggregators, and direct exchanges, which will result in lower-than-anticipated revenue.

D. *FedACH Service*—Table 10 shows the 2014 actual, 2015 estimate, and 2016 budgeted cost-recovery performance for the commercial FedACH service.

TABLE 10—FEDACH SERVICE PRO FORMA COST AND REVENUE PERFORMANCE

[Dollars in millions]

Year	Revenue	Total expense	Net income (ROE)	Targeted ROE	Recovery rate after targeted ROE [1/(2 + 4)]
	1	2	3	4	5
2014 (actual)	124.4	141.4	−17.0	2.0	86.7%
2015 (estimate)	125.5	123.7	1.8	1.7	100.0
2016 (budget)	129.8	129.9	−0.0	1.2	99.0

1. *2015 Estimate*—The Reserve Banks estimate that the FedACH service will recover 100.0 percent of total expenses and targeted ROE, compared with a 2015 final budgeted recovery rate of 100.4 percent.[42] Through August, FedACH commercial origination and receipt volume was 5.1 percent higher-than the same period last year. For full-year 2015 the Reserve Banks estimate that FedACH commercial origination and receipt volume will increase 5.5 percent, compared with a budgeted increase of 3.5 percent.

2. *2016 Pricing*—The Reserve Banks expect the FedACH service to recover 99.0 percent of total expenses and targeted ROE in 2016. FedACH commercial origination and receipt volume is projected to grow 4.5 percent contributing to an increase of $4.4 million in total revenue from the 2015 estimate. Total expenses are budgeted to increase $7.2 million from 2015 budgeted expenses of $122.6 million, primarily because of costs associated with the development of a new FedACH technology platform.

The Reserve Banks will increase the minimum monthly fee for forward origination from $35 to $45 and the minimum monthly fee for receipt from $25 to $35.[43]

The Reserve Banks will eliminate large- and small-file per-item origination fees and introduce a single base fee of $0.0032 for all origination files with a discount of $0.0005 for origination volume between 750,000 to 1,500,000

[42] The Reserve Banks have been engaged in a multiyear technology initiative to modernize the FedACH processing platform by migrating the service from a mainframe system to a distributed computing environment. In late 2013, the Reserve Banks conducted an assessment focused on the viability and cost-effectiveness of the program. As a result, the Reserve Banks in 2014 suspended the program and began to investigate the use of other technology solutions. In 2015, the Reserve Banks evaluated alternative processing solutions, including commercially available options.

[43] Any originating depository financial institution (ODFI) incurring less than $45 for the following fees will be charged the difference to reach the minimum: Forward value and nonvalue item origination fees, FedGlobal ACH origination surcharges, and FedACH SameDay forward origination surcharges.

Any receiving depository financial institution (RDFI) originating forward value and nonvalue items below the minimum level and incurring less than $35 in receipt fees will be charged the difference to reach the minimum based on origination. RDFIs not originating forward value and nonvalue items will incur the $35 minimum monthly fee for receipt.

items per month and $0.0007 for origination volume greater than 1,500,000 items per month. The Reserve Banks will lower the top-tier volume origination discount level based on monthly receipt volume from 17,500,000 to 15,000,000 items per month, while maintaining the current discount amounts.[44]

The Reserve Banks will increase the forward item receipt fee from $0.0025 to $0.0032 per item, while keeping the return item receipt fee at $0.0075 per item. The Reserve Banks will change the volume-based receipt discount structure to encourage additional receipt volume. The changes will include a decrease in the first volume-based discount by 250,000 items per month to 750,001 items a month, the introduction of a new volume-based discount tier for volume between 1,500,001 and 2,500,000 items per month, and an increase for all existing volume-based receipt discounts by $0.0007 as seen in table 11.

Table 11

FedACH Service Volume-Based Receipt Discounts [a]

Volume	Non-Premium Receivers	Premium Receivers Level 1 [b]	Premium Receivers Level 2 [c]
Less than 750,000	$0.0000	$0.0000	$0.0000
750,001 to 1,500,000	$0.0014	$0.0014	$0.0014
1,500,001 to 2,500,000	$0.0014	$0.0014	$0.0014
2,500,0001 to 12,500,000	$0.0014	$0.0015	$0.0016
More than 12,500,000	$0.0016	$0.0017	$0.0018

[a] Shaded cells reflect volume levels where discounting applies to all items, including items below the volume amount listed. Nonshaded cells receive discounts only on the volume amounts listed.
[b] Level 1 Premium Receivers are those that receive at least 90 percent of FedACH-originated items through FedACH.
[c] Level 2 Premium Receivers are those that receive at least 90 percent all items through FedACH.

The Reserve Banks will implement a $20 monthly billing discount for any customer that pays the origination minimum fee, subscribes to a FedLine Web Plus or higher package, and subscribes to either FedACH RDFI Alert, FedACH Risk Origination Monitoring, or FedPayments Reporter.

The Reserve Banks estimate that the price changes will result in a 6.5 percent average price increase for FedACH customers. In addition to the above changes, the Reserve Banks plan to reassess the FedGlobal ACH fee schedule during 2016.

The primary risks to the Reserve Banks' ability to achieve budgeted 2016 cost recovery for the FedACH service are cost overruns associated with unanticipated problems related to efforts to modernize the FedACH processing platform and higher-than-expected support and overhead costs. Other risks include lower-than-expected volume and associated revenue due to unanticipated mergers and acquisitions and loss of market share due to direct exchanges and a shift of volume to the private-sector operator.

E. *Fedwire Funds and National Settlement Services*—Table 12 shows the 2014 actual, 2015 estimate, and 2016 budgeted cost-recovery performance for the Fedwire Funds and National Settlement Services.

Table 12—Fedwire Funds and National Settlement Services Pro Forma Cost and Revenue Performance

[Dollars in millions]

Year	Revenue	Total expense	Net income (ROE) [1–2]	Targeted ROE	Recovery rate after targeted ROE [1/(2 + 4)]
	1	2	3	4	5
2014 (actual)	110.1	105.2	4.8	1.4	103.2%
2015 (estimate)	115.1	112.7	2.4	1.6	100.7
2016 (budget)	121.4	120.1	1.3	1.3	100.0

1. *2015 Estimate*—The Reserve Banks estimate that the Fedwire Funds and National Settlement Services will recover 100.7 percent of total expenses and targeted ROE, equal to the final budgeted recovery rate. Through August, Fedwire Funds Service online volume was 6.9 percent higher than for the same period last year. For full-year 2015, the Reserve Banks estimate Fedwire Funds Service online volume to increase 4.0 percent from 2014 levels, compared with the 3.2 percent volume decrease that had been budgeted. The Reserve Banks do not expect the strong volume growth in late 2014 and early 2015 to continue at that level through year-end. Through August, National Settlement Service settlement file volume was 7.1 percent lower than for the same period last year, and settlement entry volume was 19.3 percent lower. For the full year, the Reserve Banks estimate that settlement file volume will decrease 5.9 percent (compared with a 1 percent budgeted decrease) and settlement entry volume

[44] Origination discounts apply only to those items received by FedACH receiving points and are available only to Premium Receivers (institutions receiving a certain portion of volume through FedACH).

will decrease 15.6 percent from 2014 levels (compared with a budgeted 7.2 percent decrease).

2. *2016 Pricing*—The Reserve Banks expect the Fedwire Funds Service to recover 100.0 percent of total expenses and targeted ROE. Revenue is projected to be $121.4 million, an increase of 5.5 percent from the 2015 estimate. The Reserve Banks project total expenses to be $7.4 million higher than the 2015 estimate. The Reserve Banks expect volume to grow 1.5 percent in 2016.

The Reserve Banks will adjust the incentive pricing fees for the Fedwire Funds Service by increasing the Tier 1 per item pre-incentive fee (the fee before volume discounts are applied) from $0.73 to $0.79 and increasing the Tier 3 per item pre-incentive fee from $0.150 to $0.155. The Reserve Banks will keep the Tier 2 per-item pre-incentive fee unchanged.[45]

The Reserve Banks will increase the surcharge for offline transactions from $50 to $55. In addition, the Reserve Banks will increase the monthly participation fee from $90 to $95.

The Reserve Banks estimate that the price changes will result in a 5.8 percent average price increase for Fedwire Funds customers.

The Reserve Banks will not change National Settlement Service fees for 2016. The Reserve Banks' Fedwire Funds and National Settlement Services fees are consistent with their multiyear strategy to minimize pricing volatility while undertaking ongoing technology upgrades and projects to further strengthen operational resiliency. The Reserve Banks recently completed a significant milestone in the Fedwire Funds portion of its modernization initiative by migrating its back-end settlement system from a mainframe to a distributed platform, although key work to complete the initiative remains in progress.

The primary risk to the Reserve Banks' ability to achieve budgeted 2016 cost recovery for these services is cost overruns from unanticipated problems with completing the final stages of complex technology programs.

F. *Fedwire Securities Service*—Table 13 shows the 2014 actual, 2015 estimate, and 2016 budgeted cost recovery performance for the Fedwire Securities Service.[46]

TABLE 13—FEDWIRE SECURITIES SERVICE PRO FORMA COST AND REVENUE PERFORMANCE

[Dollars in millions]

Year	Revenue	Total expense	Net income (ROE) [1–2]	Targeted ROE	Recovery rate after targeted ROE [1/(2 + 4)]
	1	2	3	4	5
2014 (actual)	24.0	22.7	1.2	0.3	104.1%
2015 (estimate)	27.3	25.5	1.8	0.4	105.7
2016 (budget)	25.8	25.9	−0.1	0.2	98.7

1. *2015 Estimate*—The Reserve Banks estimate that the Fedwire Securities Service will recover 105.7 percent of total expenses and targeted ROE, compared with a 2015 final budgeted recovery rate of 97.5 percent. The higher-than-expected cost recovery is primarily due to not spending contingency funds that were budgeted for the Fedwire Modernization Program. Increased revenues generated from higher-than-expected volumes from online agency transfers and account maintenance also increased cost recovery.

Through August, Fedwire Securities Service online volume was 8.0 percent lower than during the same period last year. For full-year 2015, the Reserve Banks estimate Fedwire Securities Service online volume will decline 5.4 percent from 2014 levels, compared with a budgeted decline of 12.9 percent. The higher-than-expected online agency transfer volume resulted from the continued low interest-rate environment, which has supported mortgage underwriting activity and mortgage-backed securities issuance, and is generally associated with increased online agency transfer activity over the Fedwire Securities Service. Through August, account maintenance volume was 9.1 percent lower than during the same period last year. For the full year, the Reserve Banks estimate that account maintenance volume will decline 8.4 percent over 2014 levels, compared with a budgeted decline of 14.1 percent. The higher account maintenance volume is the result of conservative estimates for customer account closures that have not materialized.

2. *2016 Pricing*—The Reserve Banks expect the Fedwire Securities Service to recover 98.7 percent of total expenses and targeted ROE in 2016. The Reserve Banks project that 2016 revenue will decrease by $1.5 million and expenses will increase by $0.4 million, compared with 2015 estimates.

The Reserve Banks project that online transfer activity will decline 7.7 percent in 2016, the number of accounts maintained will decrease 8.5 percent, and the number of agency securities maintained will decrease 3.3 percent.[47] The projected decline in account maintenance activity reflects customer closures of empty accounts to avoid unnecessary expenses and increased competition in collateral management services.[48] The Reserve Banks project a decrease in online transfers as gradually increasing interest rates lead to less

[45] The per-item pre-incentive fee is the fee that the Reserve Banks charge for transfers that do not qualify for incentive discounts. The Tier 1 per-item pre-incentive fee applies to the first 14,000 transfers, the Tier 2 per-item pre-incentive fee applies to the next 76,000 transfers, and the Tier 3 per-item pre-incentive fee applies to any additional transfers. The Reserve Banks apply an 80 percent incentive discount to transfers over 60 percent of a customer's its historic benchmark volume.

[46] The Reserve Banks provide transfer services for securities issued by the U.S. Treasury, federal government agencies, government-sponsored enterprises, and certain international institutions. The priced component of this service, reflected in this memorandum, consists of revenues, expenses, and volumes associated with the transfer of all non-Treasury securities. For Treasury securities, the U.S. Treasury assesses fees for the securities transfer component of the service. The Reserve Banks assess a fee for the funds settlement component of a Treasury securities transfer; this component is not treated as a priced service.

[47] The online transfer fee, monthly account maintenance fee, and monthly issue maintenance fee accounted for approximately 92 percent of total Fedwire Securities Service revenue through June 2015.

[48] Specifically, collateral management services refers to the Fedwire Securities Joint Custody Service, which facilitates the collateralization of deposits made by a government entity, through the pledging of book-entry securities by its depository institution. Approximately 72 percent of Fedwire Securities priced accounts are collateral accounts related to the Joint Custody Service.

mortgage refinancing, and, in turn, reduce issuances of mortgage-backed securities. The reduction in agency debt issuance reflects a reduction in government-sponsored enterprise portfolios, as required by the U.S. Treasury and the Federal Housing Finance Agency, leading to a reduced funding need for new debt issuance.[49] New settlement logic introduced by the Fixed Income Clearing Corporation in late 2015 is also expected to reduce the number of agency debt transfers over the Fedwire Securities Service.[50]

Expenses are budgeted to remain approximately the same as 2015 estimates, reflecting higher expected operating costs offset by increased reimbursements from Treasury for fiscal agency services.[51] Higher operating costs in 2016 reflect the full-year impact of the completion of a multiyear technology modernization initiative and the advancement of new initiatives to improve resiliency and operational functionality.

The Reserve Banks will not change priced Fedwire Securities Service fees for 2016.

The primary risk to the Reserve Banks' ability to achieve budgeted 2016 cost recovery for these services is cost overruns and schedule delays from unanticipated problems with managing complex technology upgrades.

G. *FedLine Access*—The Reserve Banks charge fees for the electronic connections that depository institutions use to access priced services and allocate the costs and revenue associated with this electronic access to the various priced services. There are currently five FedLine channels through which customers can access the Reserve Banks' priced services: FedMail®, FedLine Web, FedLine Advantage, FedLine Command®, and FedLine Direct.[52] The Reserve Banks package these channels into nine FedLine packages, described below, that are supplemented by a number of premium (or à la carte) access and accounting information options. In addition, the Reserve Banks offer FedComplete® packages, which are bundled offerings of a FedLine Advantage connection and a fixed number of FedACH, Fedwire Funds, and Check 21-enabled services.

Six attended access packages offer access to critical payment and information services via a web-based interface. The FedLine Exchange package provides access to basic information services via email, while two FedLine Web packages offer an email option plus online attended access to a range of services, including cash services, FedACH information services, and check services. Three FedLine Advantage packages expand upon the FedLine Web packages and offer attended access to critical transactional services: FedACH, Fedwire Funds, and Fedwire Securities.

Three unattended access packages are computer-to-computer, IP-based interfaces designed for medium- to high-volume customers. The FedLine Command package offers an unattended connection to FedACH, as well as most accounting information services. The two remaining options are FedLine Direct packages, which allow for unattended connections at one of two connection speeds to FedACH, Fedwire Funds, and Fedwire Securities transactional and information services and to most accounting information services.[53]

For the 2016 FedLine fees, the Reserve Banks will make a minor adjustment to existing fees—a $5-per-month increase for the FedLine Exchange subscriber pack—keeping the remaining existing FedLine fees unchanged.[54] As in previous years, the Reserve Banks will introduce new fees on outdated legacy services in 2016. In particular, the Reserve Banks will implement a $5,000-per-month surcharge for 256K/T1 legacy routers to encourage customers to migrate to more efficient access solutions.[55] The Reserve Banks will also introduce a new custom implementation fee in 2016 for institutions that request tailored FedLine Direct or WAN router setups. The fee, which will vary from $2,500 to $5,000 based on the complexity of the setup, is intended to help the Reserve Banks recover costs that result from nonstandard installations.

In addition, the Reserve Banks will make two structural changes to existing FedLine packages. First, the Reserve Banks will include two Virtual Private Network (VPN) devices in the FedLine Direct Premier package (rather than one) to help ensure consistency across existing Premier level FedLine packages. Second, the Reserve Banks will modify the availability of the FedPayments Manager Import/Export (FPM) tool within the FedLine Advantage Plus and Premier packages based on Fedwire volume thresholds. In particular, depository institutions with more than 250 Fedwire transactions per month, or more than one routing number, will only have access to the FPM tool via FedLine Advantage Premier. Affected customers will experience a fee increase ranging from $15 to $75 per month to upgrade to FedLine Advantage Premier.[56] Customers that wish to maintain their FedLine Advantage Plus package will be able to do so by removing the FPM tool from their subscription.

The Reserve Banks estimate that the price changes will result in a 1.5 percent average price increase for FedLine customers.

II. Analysis of Competitive Effect

All operational and legal changes considered by the Board that have a substantial effect on payment system participants are subject to the competitive impact analysis described in the March 1990 policy ''The Federal Reserve in the Payments System.'' [57] Under this policy, the Board assesses whether proposed changes would have a direct and material adverse effect on the ability of other service providers to compete effectively with the Federal Reserve in providing similar services because of differing legal powers or

[49] Government sponsored enterprises are reducing their retained portfolio by 15 percent annually through 2018, as mandated by the Senior Preferred Stock Purchase Agreements, until each portfolio reaches a target level of $250 billion. Further information on these agreements can be found at: *http://www.fhfa.gov/Conservatorship/Pages/Senior-Preferred-Stock-Purchase-Agreements.aspx.*

[50] Information on the new settlement logic can be found at *http://www.dtcc.com/~/media/Files/pdf/2015/6/22/GOV045-15.pdf.*

[51] Treasury reimbursement is calculated by multiplying costs by the ratio of Treasury to agency transfers. In 2015, Treasury projects its transfer volume will increase 7.0 percent, while the Reserve Banks expect agency transfers to decrease. Therefore, the higher projected ratio of Treasury to agency transfers will result in Treasury reimbursing a higher portion of total costs.

[52] FedMail, FedLine Web, FedLine Advantage, FedLine Command, and FedLine Direct are registered trademarks of the Federal Reserve Banks.

[53] None of the FedLine packages offer an unattended connection to check services. The Reserve Banks offer an unattended check product, Check 21 Large File Delivery, outside of the FedLine suite that allows a depository institution to upload and download check image cash letters automatically via a direct network connection to the Reserve Banks.

[54] FedLine packages do not include user subscriptions for priced services. Depository institutions that wish to access priced services must purchase user subscriptions in packs of five (5-packs).

[55] The $5,000 per month surcharge will be effective July 1, 2016. The price will increase to $10,000 per month on September 1, 2016 and $20,000 per month on November 1, 2016.

[56] The $75 fee increase is the difference in pricing between the corresponding Plus and Premier packages. Affected customers that currently subscribe to the $60-per-month a la carte option for a secondary VPN device will experience only a $15 fee increase because a secondary VPN device is included in Premier packages. Affected customers include FedComplete Plus subscribers with more than 250 Fedwire transactions per month, or more than one routing number, that use the FPM tool because FedComplete Plus packages include a subscription to FedLine Advantage Plus.

[57] Federal Reserve Regulatory Service (FRRS) 9–1558.

constraints or because of a dominant market position deriving from such legal differences. If any proposed changes create such an effect, the Board must further evaluate the changes to assess whether the benefits associated with the changes—such as contributions to payment system efficiency, payment system integrity, or other Board objectives—can be achieved while minimizing the adverse effect on competition.

The 2016 fees, fee structures, and changes in service will not have a direct and material adverse effect on the ability of other service providers to compete effectively with the Reserve Banks in providing similar services.[58] The changes should permit the Reserve Banks to earn a ROE that is comparable to overall market returns and provide for full cost recovery over the long run.

III. 2016 Fee Schedules

FedACH Service 2016 Fee Schedule

[Effective January 1, 2016. **Bold indicates changes from 2015 prices.**]

	Fee
FedACH minimum monthly fee	
Originating Depository Financial Institution (ODFI)[59]	**$45.00.**
Receiving Depository Financial Institution (RDFI)[60]	**35.00.**
Origination (per item or record)	
Forward or return items	**0.0032.**
Addenda record	0.0015.
FedLine Web®-originated returns and notification of change (NOC)[61]	0.35.
Facsimile exception returns/NOC[62]	45.00.
Automated NOC	0.20.
Volume-based discounts (based on monthly billed origination volume) per item when origination volume is:	
750,000 to 1,500,000 items per month	**0.0005 discount.**
More than 1,500,000 items per month	**0.0007 discount.**
Volume-based discounts (based on monthly billed receipt volume)[63] per item when receipt volume is:.	
10,000,001 to **15,000,000** items per month	0.0002 discount.
More than **15,000,000** items per month	0.0003 discount.
Receipt (per item or record)	
Forward Item	**0.0032.**
Return Item	0.0075.
Addenda record	0.0015.
On-Us Receipt Credit[64]	0.0032 discount.
Volume-based discounts (forward items excluding FedACH SameDay service items)	
Non-Premium Receivers—RDFIs receiving less than 90 percent of total network volume through FedACH per item when volume is:	
750,001 to 12,500,000 items per month[65]	**0.0014 discount.**
more than 12,500,000 items per month[66]	**0.0016 discount.**
Premium Receivers, Level One—RDFIs receiving at least 90 percent of FedACH-originated volume through FedACH per item when volume is:	
750,001 to 1,500,000 items per month[65]	**0.0014 discount.**
1,500,001 to 2,500,000 items per month[66]	**0.0014 discount.**
72,500,001 to 12,500,000 items per month[66]	**0.0015 discount.**
more than 12,500,000 items per month[66]	**0.0017 discount.**
Premium Receivers, level two—RDFIs receiving at least 90 percent of ACH volume originated through FedACH or EPN per item when volume is:	
750,001 to 1,500,000 items per month[65]	**0.0014 discount.**
1,500,001 to 2,500,000 items per month[66]	**0.0014 discount.**
2,500,001 to 12,500,000 items per month[66]	**0.0016 discount.**
more than 12,500,000 items per month[66]	**0.0018 discount.**
FedACH Bundled Service Discount	
Monthly Bundled Service Package Discount[67]	**20.00 discount.**
FedACH SameDay Service	
Origination	
Forward item[68]	0.0035 surcharge.
Addenda record[68]	0.0015 surcharge.
Return item[69]	0.0025 discount.
Return addenda record[69]	0.0015 discount.
Receipt	
Forward item[65]	0.0025 discount.
Return item[65]	0.0075 discount.
Addenda record (forward/return)[65]	0.0015 discount.
Monthly FedACH Risk® Management fees[70]	
Risk Origination Monitoring Service/RDFI Alert Service package pricing	
For up to 5 criteria sets	35.00.
For 6 through 11 criteria sets	70.00.
For 12 through 23 criteria sets	125.00.

[58] Certain correspondent banks believe that the FedForward Fine Sort ICL product, which the Reserve Banks will eliminate in January 2017, enables them to compete more effectively with the Reserve Banks in the collection of checks destined to paying banks with which the correspondent banks do not have electronic presentment agreements. Paying banks, however, may not have an incentive to accept electronic presentment unless the correspondent bank makes a decision to present checks directly and provides the paying bank the choice of receiving presentments in paper or electronic form (as the Reserve Banks do). We do not believe that the elimination of the product will have a direct and material adverse effect on the ability of such service providers to compete effectively with the Reserve Banks in providing similar services due to legal differences.

[59] Any ODFI incurring less than $45 in forward value and nonvalue item origination fees will be charged a variable amount to reach the minimum.

[60] Any RDFI not originating forward value and nonvalue items and incurring less than $35 in receipt fees will be charged a variable amount to reach the minimum.

[61] The fee includes the item and addenda fees in addition to the conversion fee.

[62] The fee includes the item and addenda fees in addition to the conversion fee. Reserve Banks also assess a $30 fee for every government paper return/NOC they process.

[63] Origination discounts based on monthly volume apply only to those items received by FedACH receiving points and are available only to Premium Receivers (institutions receiving volume above a specified threshold through FedACH).

[64] RDFI originating and receiving items on the same RTN.

[65] This per-item discount is a reduction to the standard receipt fees listed in this fee schedule.

FEDACH SERVICE 2016 FEE SCHEDULE—Continued

[Effective January 1, 2016. **Bold indicates changes from 2015 prices.**]

	Fee
For 24 through 47 criteria sets	150.00.
For 48 through 95 criteria sets	250.00.
For 96 through 191 criteria sets	425.00.
For 192 through 383 criteria sets	675.00.
For 384 through 584 criteria sets	850.00.
For more than 585 criteria sets	1,100.00.
Risk origination monitoring batch (based on total monthly volume)	
For 1 through 100,000 batches (per batch)	0.007.
For more than 100,000 batches (per batch)	0.0035.
Monthly FedPayments Reporter Service	
FedPayments Reporter Service package pricing includes	
Standard reports [71].	
ACH volume summary by SEC code report—customer [72]	
Daily return ratio report	
Monthly return ratio report	
Receiver setup report	
Report delivery via FedLine file access solution (monthly fee)	
For up to 50 reports	35.00.
For 51 through 150 reports	55.00.
For 151 through 500 reports	100.00.
For 501 through 1,000 reports	180.00.
For 1,001 through 1,500 reports	260.00.
For 1,501 through 2,500 reports	420.00.
For 2,501 through 3,500 reports	580.00.
For 3,501 through 4,500 reports	740.00.
For 4,501 through 5,500 reports	900.00.
For 5,501 through 7,000 reports	1,100.00.
For 7,001 through 8,500 reports	1,300.00.
For more than 8,501 reports	1,500.00.
Premier reports (per report generated) [73]	
ACH volume summary by SEC code report—depository financial institution	
For 1 through 5 reports	10.00.
For 6 through 10 reports	6.00.
For more than 11 reports	1.00.
On Demand Surcharge	1.00
ACH volume summary by SEC code report—customer	
On Demand Surcharge	1.00.
Monthly ACH routing number activity report	
For 1 through 5 reports	10.00.
For 6 through 10 reports	6.00.
For more than 11 reports	1.00.
On Demand Surcharge	1.00.
On-us inclusion	
Participation (monthly fee per RTN)	10.00.
Per-item	0.0030.
Per-addenda	0.0015.
Report delivery via encrypted email (per email)	0.20.
Other fees	
Monthly fee (per routing number)	
Account servicing fee [74]	45.00.
FedACH settlement [75]	55.00.
FedACH Information extract file	100.00.
IAT Output File Sort	75.00.
Automated NOC participation fee [76]	5.00.
Non-electronic input/output fee [77]	
CD/DVD (CD or DVD)	50.00.
Paper (file or report)	50.00.
FedGlobal ACH Payments [78]	
Canada service fee	
Item originated to Canada [79]	0.62.
Return received from Canada [80]	0.99.
Item trace at receiving gateway	5.50.
Item trace not at receiving gateway	7.00.
Mexico service fee	
Item originated to Mexico [79]	0.67.
Return received from Mexico [80]	0.91.
Account-to-receiver (A2R) item originated to Mexico [79]	3.45.
Foreign currency to foreign currency (F3X) item originated to Mexico [79]	0.67.
Item trace	13.50.
Panama service fee	
Item originated to Panama [79]	0.72.
Return received from Panama [80]	1.00.
NOC	0.72.
Item trace	7.00.
Latin America service fee	
A2R item originated to Latin America [79]	4.40.
Return received from Latin America [80]	0.72.
Item trace	5.00.
Europe service fee	
Item originated to Europe [79]	1.25.

FEDACH SERVICE 2016 FEE SCHEDULE—Continued

[Effective January 1, 2016. **Bold indicates changes from 2015 prices.**]

	Fee
F3X item originated to Europe[79]	1.25.
Return received from Europe[80]	1.35.
Item trace	7.00.

FEDWIRE FUNDS AND NATIONAL SETTLEMENT SERVICES 2016 FEE SCHEDULE

[Effective January 1, 2016. **Bold indicates changes from 2015 prices**.]

Fedwire Funds Service	
Monthly Participation Fee	**$95.00**
Basic volume-based pre-incentive transfer fee (originations and receipts)—per transfer for:	
the first 14,000 transfers per month	**0.79**
additional transfers up to 90,000 per month	0.24
every transfer over 90,000 per month	**0.155**
Volume-based transfer fee with the incentive discount (originations and receipts)—per eligible transfer for:[81]	
the first 14,000 transfers per month	**0.158**
additional transfers up to 90,000 per month	0.048
every transfer over 90,000 per month	**0.031**
Surcharge for Off-line Transfers (Originations and Receipts)	**55.00**
Surcharge for End-of-Day Transfer Originations[82]	0.26
Monthly FedPayments Manager import/export fee[83]	50.00
Surcharge for high-value payments:	
>$10 million	0.14
>$100 million	0.36
Surcharge for Payment Notification:	
Origination Surcharge[84]	0.20
Receipt Volume[85]	N/A
National Settlement Service	
Basic	
Settlement Entry Fee	1.50
Settlement File Fee	30.00
Surcharge for Off-line File Origination[86]	45.00
Minimum Monthly Fee (account maintenance)[87]	60.00
Special Settlement Arrangements (fee per day)[88]	150.00

[66] Receipt volumes at these levels qualify for the waterfall discount which includes all FedACH receipt items.

[67] This monthly billing discount is available for any customer that (1) pays the FedACH minimum monthly fee; (2) purchases a FedLine Web Plus or higher package; and (3) subscribes to either FedACH RDFI Alert, FedACH Risk Origination Monitoring, or FedPayments Reporter.

[68] This per-item surcharge is in addition to the standard origination fees listed in the origination and receipt fee schedule.

[69] This per-item discount is a reduction to the standard origination fees listed in the origination and receipt fee schedule.

[70] Criteria may be set for both the origination monitoring service and the RDFI alert service. Subscribers with no criteria set up will be assessed the $45 monthly package fee.

[71] Standard reports include Customer Transaction Activity, Death Notification, International (IAT), Notification of Change, Payment Data Information File, Remittance Advice Detail, Remittance Advice Summary, Return Item, Return Ratio, Social Security Beneficiary, and Originator Setup Reports.

[72] ACH volume summary by SEC code reports generated on demand are subject to a $1.00 per report surcharge.

[73] Premier reports generated on demand are subject to the package/tiered fees plus a surcharge.

[74] The account servicing fee applies to routing numbers that have received or originated FedACH transactions. Institutions that receive only U.S. government transactions through the Reserve Banks or that elect to use a private sector operator exclusively are not assessed this fee.

[75] The FedACH settlement fee is applied to any routing number with activity during a month, including institutions that elect to use a private sector operator exclusively but also have items routed to or from customers that access the ACH network through FedACH. This fee does not apply to routing numbers that use the Reserve Banks for only U.S. government transactions.

[76] The notification of change fee will be assessed only when automated NOCs are generated.

[77] Limited services are offered in contingency situations.

[78] The international fees and surcharges vary from country to country as these are negotiated with each international gateway operator.

[79] This per-item surcharge is in addition to the standard domestic origination and input file processing fees.

[80] This per-item surcharge is in addition to the standard domestic receipt fees.

[81] The incentive discounts apply to the volume that exceeds 60 percent of a customer's historic benchmark volume. Historic benchmark volume is based on a customer's average daily activity over the previous five calendar years. If a customer has fewer than five full calendar years of previous activity, its historic benchmark volume is based on its daily activity for as many full calendar years of data as are available. If a customer has less than one year of past activity, then the customer qualifies automatically for incentive discounts for the year. The applicable incentive discounts are as follows: $0.632 for transfers up to 14,000; $0.192 for transfers 14,001 to 90,000; and $0.124 for transfers over 90,000.

[82] This surcharge applies to originators of transfers that are processed by the Reserve Banks after 5:00 p.m. ET.

[83] This fee is charged to any Fedwire Funds participant that originates a transfer message via the FedPayments Manager (FPM) Funds tool and has the import/export processing option setting active at any point during the month.

[84] Payment Notification and End-of-Day Origination surcharges apply to each Fedwire funds transfer message.

[85] Provided on billing statement for informational purposes only.

[86] Off-line files will be accepted only on an exception basis when a settlement agent's primary and backup means of transmitting settlement files are both unavailable. For information, contact the NSS Central Service Support Staff at (800) 758–9403.

[87] This minimum monthly charge is only assessed if total settlement charges during a calendar month are less than $60.

[88] Special settlement arrangements use Fedwire Funds transfers to effect settlement. Participants in

FEDWIRE SECURITIES SERVICE 2016 FEE SCHEDULE (NON-TREASURY SECURITIES)

[Effective January 1, 2016. **Bold indicates changes from 2015 prices**.]

	Fee
Basic Transfer Fee	
Transfer or reversal originated or received	0.65
Surcharge	
Offline origination & receipt surcharge	66.00
Monthly Maintenance Fees	
Account maintenance (per account)	48.00
Issues maintained (per issue/per account)	0.65
Claim Adjustment Fee	0.75
GNMA Serial Note CUSIP Fee	9.00
Joint Custody Origination Surcharge [89]	44.00
Delivery of Reports—Hard Copy Reports to On-Line Customers	50.00

FEDLINE 2016 FEE SCHEDULE

[Effective January 1, 2016. **Bold indicates changes from 2015 prices.**

	Fee
FedComplete Packages (Monthly) [90]	
FedComplete 100 Plus	775.00.
Includes:	
FedLine Advantage Plus package	
FedLine subscriber 5-pack	
FedLine Exchange subscriber 5-pack	
7,500 FedForward transactions	
70 FedReturn transactions	
14,000 FedReceipt® transactions	
35 Fedwire funds origination transfers	
35 Fedwire funds receipt transfers	
Fedwire participation fee	
1,000 FedACH origination items	
FedACH minimum fee	
7,500 FedACH receipt items	
FedACH receipt minimum fee	
10 FedACH web return/NOC	
500 FedACH addenda originated	
1,000 FedACH addenda received	
FedACH account servicing	
FedACH settlement	
FedComplete 100 Premier	850.00.
Includes:	
FedLine Advantage Premier package	
Volumes included in the FedComplete 100 Plus package	
FedComplete 200 Plus	1,300.00.
Includes:	
FedLine Advantage Plus package	
FedLine subscriber 5-pack	
FedLine Exchange subscriber 5-pack	
25,000 FedForward transactions	
225 FedReturn transactions	

arrangements and settlement agents are also charged the applicable Fedwire Funds transfer fee for each transfer into and out of the settlement account.

[89] Fedwire Securities Service charges customers the Joint Custody Origination Surcharge for both Agency and Treasury securities.

[90] FedComplete packages are all-electronic service options that bundle payment services with an access solution for one monthly fee.

[91] Per-item surcharges are in addition to the standard fees listed in the applicable priced services fee schedules.

[92] New FedComplete package customers with a new FedLine Advantage connection are eligible for a one-time $1,500 credit applied to their Federal Reserve service charges. Customers receiving credit must continue using the FedComplete package for a minimum of six months or forfeit the $1,500 credit.

[93] VPN hardware for FedLine Advantage and FedLine Command is billed directly by the vendor. A list of 2016 vendor fees can be found at *https://www.frbservices.org/files/servicefees/pdf/access/2016_vendor_fees.pdf.*

[94] These add-on services can be purchased only with a FedLine Customer Access Service option.

[95] There are no priced subscribers contained in the FedLine Exchange or FedLine packages.

[96] Additional FedLine Command Certificates available for FedLine Command and Direct packages only.

[97] Additional FedLine Direct Certificates available for FedLine Direct packages only.

[98] Additional VPNs are available for FedLine Advantage, FedLine Command, and FedLine Direct packages only.

[99] 56K option available to installed base only and is not available for new orders. Effective July 1, 2016, all remaining 56K connections will be disconnected. Network diversity supplemental charge of $2,000 a month may apply in addition to these fees.

[100] The FedLine Custom Implementation Fee will vary from $2,500 to $5,000 based on the complexity of the setup.

[101] FedLine Direct contingency solution is available only for FedLine Direct Plus & Premier packages.

[102] Cash Management Service options are limited to Plus and Premier packages.

[103] End of Day Reconcilement File option is available to FedLine Web Plus and FedLine Advantage Plus and Premier packages. Available for no extra fee in FedLine Command Plus and Direct packages.

[104] Statement of Account Spreadsheet File option is available to FedLine Web Plus and FedLine Advantage Plus and Premier packages. Available for no extra fee in FedLine Command Plus and Direct packages.

[105] Intra-day Download Search File option is available to the FedLine Web Plus package. Available for no extra fee in FedLine Advantage and higher packages.

[106] ACT Report options are limited to FedLine Command Plus and FedLine Direct Plus and Premier packages.

FEDLINE 2016 FEE SCHEDULE—Continued

[Effective January 1, 2016. **Bold indicates changes from 2015 prices.**

	Fee
25,000 FedReceipt transactions 100 Fedwire funds origination transfers 100 Fedwire funds receipt transfers Fedwire participation fee 2,000 FedACH origination items FedACH minimum fee 25,000 FedACH receipt items FedACH receipt minimum fee 20 FedACH web return/NOC 750 FedACH addenda originated 1,500 FedACH addenda received FedACH account servicing FedACH settlement	
FedComplete 200 Premier	1,375.00.
Includes: FedLine Advantage Premier package Volumes included in the FedComplete 200 Plus package	
FedComplete Excess Volume Surcharge [91]	
FedForward	0.01/item.
FedReturn	0.7500/item.
Fedwire Funds Origination	0.7000/item.
FedACH Origination	0.0025/item.
FedComplete package credit incentive [92]	(1,500.00).
FedComplete credit adjustment	various.
FedComplete debit adjustment	various.
FedLine Customer Access Solutions (Monthly) [93]	
FedLine Exchange	40.00.
Includes: FedMail access channel FedACH Advice and Settlement Information Fedwire Funds Offline Advices Check 21 Services Check 21 Duplicate Notification Service Check Adjustments Accounting Statements Daylight Overdraft Reports Billing Statements	
FedLine Web	110.00.
Includes: FedLine Web access channel Services included in the FedLine Exchange package FedACH Information Services & Derived Returns/NOCs FedACH Risk Services (includes RDFI Alert and Returns Reporting) FedACH information services (includes RDFI file Alert Service) FedCash Services Service Charge Information	
FedLine Web Plus	140.00.
Includes: FedLine Web traditional package FedACH Risk Origination Monitoring Service FedACH FedPayments Reporter Service Check Large Dollar Return Check FedImage Services Account Management Information Various accounting and inquiry services (ABMS inquiry, IAS/PSR inquiry, IAS detailed inquiries, notifications and advices, end-of-day accounting file (PDF))	
FedLine Advantage	380.00.
Includes: FedLine Advantage access channel Services included in the FedLine Web traditional package FedACH transactions Fedwire Funds transactions Fedwire Securities transactions National Settlement Service transactions Check Large Dollar Return Check FedImage Services Account Management Information with Intra-Day Download Search File Various accounting and inquiry services (ABMS inquiry, IAS/PSR inquiry, IAS detailed inquiries, notifications and advices, end-of-day accounting file (PDF))	
FedLine Advantage Plus	425.00.
Includes: FedLine Advantage traditional package FedACH Risk Origination Monitoring Service FedACH FedPayments Reporter Service Fedwire Funds FedPayments Manager Import/Export **(less than 250 Fedwire transactions and one routing number per month)** FedTransaction Analyzer® **(less than 250 Fedwire transactions and one routing number per month)**	
FedLine Advantage Premier	500.00.

FEDLINE 2016 FEE SCHEDULE—Continued

[Effective January 1, 2016. **Bold indicates changes from 2015 prices.**

	Fee
Includes:	
FedLine Advantage Plus package	
Secondary VPN device	
Fedwire Funds FedPayments Manager Import/Export (more than 250 Fedwire transactions or more than one routing number in a given month)	
FedTransaction Analyzer (more than 250 Fedwire transactions or more than one routing number per month)	
FedLine Command Plus	1,000.00.
Includes:	
FedLine Command access channel	
Services included in the FedLine Advantage Plus package	
Fedwire Statement Services	
Fedwire Funds FedPayments Manager Import/Export (more than 250 Fedwire transactions or more than one routing number in a given month)	
FedTransaction Analyzer (more than 250 Fedwire transactions or more than one routing number per month)	
Intra-Day File (I-Day CI File)	
Statement of Account Spreadsheet File (SASF)	
Financial Institution Reconcilement Data File (FIRD)	
Billing Data Format File (BDFF)	
FedLine Direct Plus	3,600.00.
Includes:	
FedLine Direct access channel	
256K Dedicated WAN Connection	
Services included in the FedLine Command Plus package	
Treasury Check Information System (TCIS)	
FedLine Direct Premier	6,500.00
Includes:	
FedLine Direct Plus package	
T1 dedicated WAN connection	
Secondary VPN device	
Cash Management Services Plus Own Report (No Respondent/Subaccount activity)	
A la carte Options (Monthly)[94]	
Electronic Access	
FedLine Exchange Subscriber 5-pack[95]	15.00.
FedLine Subscriber 5-pack[95]	80.00.
Additional FedLine Command Certificate[96]	100.00.
Additional FedLine Direct Certificate[97]	100.00.
Additional VPNs—Maintenance Fee[98]	60.00.
Additional dedicated connections[99]	56K
effective January 1, 2016	14,000.00.
effective April 1, 2016	28,000.00.
256K	2,500.00.
T1	3,200.00.
FedLine International Setup (one-time fee)	5,000.00.
FedLine Custom Implementation Fee[100]	**various**
FedLine Direct Contingency Solution[101]	1,000.00.
Check 21 Large File Delivery	various.
FedMail Fax	70.00.
VPN Device Modification	200.00.
VPN Device Missed Activation Appointment	175.00.
VPN Device Expedited Hardware Surcharge	100.00.
VPN Device Replacement or Move	300.00.
Electronic Access Training	
Learning Center	complimentary.
Certificate Retrieval Download Tutorial	complimentary.
Accounting Information Services	
Cash Management System (CMS) Plus—Own report—up to six files with:[102]	
no respondent/sub-account activity	60.00.
less than 10 respondent and/or sub-accounts	125.00.
10–50 respondent and/or sub-accounts	250.00.
51–100 respondents and/or sub-accounts	500.00.
101–500 respondents and/or sub-accounts	750.00.
>500 respondents and/or sub-accounts	1,000.00.
End-of-Day Financial Institution Reconcilement Data File[103]	150.00.
Statement of Account Spreadsheet File[104]	150.00.
Intra-day Download Search File (with AMI)[105]	150.00.
ACTS Report[106]	
<20 sub-accounts	500.00.
21–40 sub-accounts	1,000.00.
41–60 sub-accounts	1,500.00.
>60 sub-accounts	2,000.00.
Other	
Software Certification	0.00 to 8,000.00.
Vendor Pass-Through Fee	various.
Electronic Access Credit Adjustment	various.
Electronic Access Debit Adjustment	various.
Legacy Connection Service Fee	
(effective July 1, 2016)	**5,000.00**.
(effective September 1, 2016)	**10,000.00**.
(effective November 1, 2016)	**20,000.00**.

By order of the Board of Governors of the Federal Reserve System, November 2, 2015.

Robert deV. Frierson,

Secretary of the Board.

[FR Doc. 2015–28932 Filed 11–13–15; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

Sunshine Act Meeting

TIME AND DATE: *November 19, 2015, 8:30 a.m., In-Person Meeting.*

PLACE: Le Meridien, 333 Battery Street, Mercantile Room, San Francisco, CA 94111.

STATUS: Open to the public.

MATTERS TO BE CONSIDERED:

Open to the Public

Open Session

1. Approval of the Minutes for the October 27, 2015 Board Member Meeting.
2. Monthly Reports
a) Monthly Participant Activity Report.
b) Monthly Investment Report.
c) Legislative Report.
3. Office of Investments Report.
4. Investment Manager Annual Service Review.
5. 2016 Proposed Internal Audit Schedule.

Closed Session

Security
Adjourn

CONTACT PERSON FOR MORE INFORMATION: Kimberly Weaver, Director, Office of External Affairs, (202) 942–1640.

Dated: November 10, 2015.

James B. Petrick,

Secretary, Federal Retirement Thrift Investment Board.

[FR Doc. 2015–29242 Filed 11–12–15; 11:15 am]

BILLING CODE 6760–01–P

FEDERAL TRADE COMMISSION

Granting of Request for Early Termination of the Waiting Period Under the Premerger Notification Rules

Section 7A of the Clayton Act, 15 U.S.C. § 18a, as added by Title II of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, requires persons contemplating certain mergers or acquisitions to give the Federal Trade Commission and the Assistant Attorney General advance notice and to wait designated periods before consummation of such plans. Section 7A(b)(2) of the Act permits the agencies, in individual cases, to terminate this waiting period prior to its expiration and requires that notice of this action be published in the **Federal Register**.

The following transactions were granted early termination—on the dates indicated—of the waiting period provided by law and the premerger notification rules. The listing for each transaction includes the transaction number and the parties to the transaction. The grants were made by the Federal Trade Commission and the Assistant Attorney General for the Antitrust Division of the Department of Justice. Neither agency intends to take any action with respect to these proposed acquisitions during the applicable waiting period.

20151508	G	Envision Healthcare Holdings, Inc.; WP Rocket Holdings Inc.; Envision Healthcare Holdings, Inc.
		10/02/2015
20151506	G	Sensata Technologies Holding N.V.; Custom Sensors & Technologies Topco Ltd.; Sensata Technologies Holding N.V.
20151737	G	GSO Special Situations Fund L.P.; Upstate New York Power Producers, Inc.; GSO Special Situations Fund L.P.
20151739	G	B&G Foods, Inc.; General Mills, Inc.; B&G Foods, Inc.
20151740	Y	Agilent Technologies, Inc.; Seahorse Bioscience, Inc.; Agilent Technologies, Inc.
20151751	G	Parthenon Investors IV, L.P.; Millennium Trust Company, LLC; Parthenon Investors IV, L.P.
20151760	G	Omron Corporation; Adept Technology, Inc.; Omron Corporation.
20151764	G	Chih-Yaung Chu; MAG IAS Holdings, Inc.; Chih-Yaung Chu.
20151775	G	Roger S. Penske; R. Jerry Nelson; Roger S. Penske.
20151776	G	Roger S. Penske; Philip C. Schneider, Jr.; Roger S. Penske.
20151779	G	Dr. Ge Li; WuXi PharmaTech (Cayman) Inc.; Dr. Ge Li.
20151780	G	Investor AB; The Braun Corporation; Investor AB.
20151782	G	Phillips 66; DCP Southern Hills Pipeline, LLC; Phillips 66.
20151783	G	Phillips 66; DCP Sand Hills Pipeline, LLC; Phillips 66.
20151787	G	Audax Private Equity Fund IV, L.P.; CPC Holdco, Inc.; Audax Private Equity Fund IV, L.P.
		10/05/2015
20151671	Y	Medivation, Inc.; BioMarin Pharmaceutical, Inc.; Medivation, Inc.
20151761	G	Valeant Pharmaceuticals International, Inc.; Synergetics USA, Inc.; Valeant Pharmaceuticals International, Inc.
20151792	G	GlaxoSmithKline plc; Theravance Biopharma, Inc.; GlaxoSmithKline plc.
		10/06/2015
20151699	Y	Greatbatch, Inc.; KKR Millennium Fund L.P.; Greatbatch, Inc.
20151762	G	Telefonaktiebolaget LM Ericsson; Envivio, Inc.; Telefonaktiebolaget LM Ericsson.
		10/07/2015
20151716	G	Amazon.com, Inc.; Elemental Technologies, Inc.; Amazon.com, Inc.
20151726	G	GTT Communications, Inc.; One Source Networks Inc.; GTT Communications, Inc.
20151774	G	Pangea Private Holdings I, LLC; Premiere Global Services, Inc.; Pangea Private Holdings I, LLC.
		10/08/2015
20151753	Y	Allergan plc; AqueSys, Inc.; Allergan plc.
20151763	Y	Amgen Inc.; Forbion Capital Fund II C.V.; Amgen Inc.
20151735	G	Lannett Company, Inc.; UCB S.A.; Lannett Company, Inc.
20151745	G	Blackstone Capital Partners VI NQ/NF L.P.; Glenn B. Stearns; Blackstone Capital Partners VI NQ/NF L.P.

20151749	G	Deutsche Telekom AG; AT&T Inc.; Deutsche Telekom AG.
20151750	G	AT&T Inc.; Deutsche Telekom AG; AT&T Inc.
20151771	G	Vista Equity Partners Fund V, L.P.; Solera Holdings, Inc.; Vista Equity Partners Fund V, L.P.
20151788	G	John B. Poindexter; LLR Equity Partners II, L.P.; John B. Poindexter.
20151794	G	Korn/Ferry International; HG (Bermuda) Limited; Korn/Ferry International.
20151799	G	Autoliv, Inc.; Nissin Kogyo Co., Ltd.; Autoliv, Inc.
20151801	G	Cabot Microelectronics Corporation; NexPlanar Corporation; Cabot Microelectronics Corporation.
20151808	G	Cevian Capital II G.P. Limited; Platform Specialty Products Corporation; Cevian Capital II G.P. Limited.
20151809	G	Longleaf Partners Funds Trust; Actuant Corporation; Longleaf Partners Funds Trust.
20160002	G	Caterpillar Inc.; Amsted Industries Incorporated; Caterpillar Inc.
20160013	G	Tailwind Capital Partners II, L.P.; AEA Small Business Fund L.P.; Tailwind Capital Partners II, L.P.
10/13/2015		
20151711	G	BlackBerry Limited; Good Technology Corporation; BlackBerry Limited.
20151741	G	Accenture plc; Declarative Holdings Inc. (''DHI''); Accenture plc.
20151742	G	Archer-Daniels-Midland Company; Linsalata Capital Partners Fund V, L.P.; Archer-Daniels-Midland Company.
20151757	G	Abrams Capital Partners II, L.P.; Barnes & Noble Education, Inc.; Abrams Capital Partners II, L.P.
20151758	G	Abrams Capital Partners II, L.P.; Barnes & Noble, Inc.; Abrams Capital Partners II, L.P.
20151769	G	Molina Healthcare, Inc.; The Providence Service Corporation; Molina Healthcare, Inc.
20160014	G	1883247 Ontario Inc.; Kenneth L. Nelson; 1883247 Ontario Inc.
20160017	G	SandRidge Energy Inc.; EIG Pecos Midstream, LLC; SandRidge Energy Inc.
20160021	G	FS Equity Partners VII, L.P.; Regent Holding Company, LLC; FS Equity Partners VII, L.P.
10/14/2015		
20151717	G	Coca-Cola Bottling Company United, Inc.; The Coca-Cola Company; Coca-Cola Bottling Company United, Inc.
20151778	G	J. Frank Harrison, III; The Coca-Cola Company; J. Frank Harrison, III.
20160003	G	Windjammer Senior Equity Fund IV, L.P.; The Resolute Fund II, L.P.; Windjammer Senior Equity Fund IV, L.P.
20160006	G	Eugenie Patri Sebastien EPS, SA; Custom California Craft Beer, LLC; Eugenie Patri Sebastien EPS, SA.
20160007	G	Jorge Paulo Lemann; Custom California Craft Beer, LLC; Jorge Paulo Lemann.
20160008	G	Symrise AG; Pinova Holdings, Inc.; Symrise AG.
20160015	G	Charlesbank Equity Fund VIII, Limited Partnership; DGD Group, Inc.; Charlesbank Equity Fund VIII, Limited Partnership.
20160016	G	AltaGas Ltd.; GWF Energy Holdings LLC; AltaGas Ltd.
20151772	G	Marcato, L.P.; LPL Financial Holdings Inc.; Marcato, L.P.
20151773	G	Marcato International Ltd.; LPL Financial Holdings Inc.; Marcato International Ltd.
20151790	G	Roper Technologies, Inc.; Madison Dearborn Capital Partners VI–A, L.P.; Roper Technologies, Inc.
20151796	G	Deluxe Corporation; Halyard Capital Fund II, L.P.; Deluxe Corporation.
20160004	Y	Palmetto Health; Tuomey d/b/a Tuomey Healthcare System; Palmetto Health.
10/19/2015		
20151743	G	Navient Corporation; Xtend Holdco, LLC; Navient Corporation.
20151802	G	John B. Hess; Hess Corporation; John B. Hess.
20160011	G	TCO Holdings Inc.; Sulzer AG; TCO Holdings Inc.
20160026	G	HAL Trust; Philip Wolman; HAL Trust.
20160036	G	Terry Taylor; Swope Holdings, LLC; Terry Taylor.
20160040	G	CCMP Capital Investors III, L.P.; AEA Investors 2006 Fund L.P.; CCMP Capital Investors III, L.P.
20160043	G	TL Lighting Holdings, LLC; Truck-Lite Co., LLC; TL Lighting Holdings, LLC.
20160044	G	Newell Rubbermaid Inc.; The Berwind Company LLC; Newell Rubbermaid Inc.
20160045	G	New Litor Limited; Skalli Corporation; New Litor Limited.
20160057	G	ACON Funko Investors I, L.L.C.; Fundamental Capital, LLC; ACON Funko Investors I, L.L.C.
10/20/2015		
20160018	G	Vitol Investment Partnership Limited; Petroliam Nasional Berhad; Vitol Investment Partnership Limited.
20160025	G	Vitol Investment Partnership Limited; Vitol Holding B.V.; Vitol Investment Partnership Limited.
20160039	G	Sprint Co-Invest, L.P.; Walgreens Boots Alliance, Inc.; Sprint Co-Invest, L.P.
20160058	G	Paddy Power plc; Betfair Group plc; Paddy Power plc.
10/21/2015		
20160041	G	PSPLUX S.a.r.l; Grupo Isolux Corsan, S.A.; PSPLUX S.a.r.l.
20160048	G	Terraform Private II, LLC; Michael Polsky; Terraform Private II, LLC.
10/22/2015		
20160022	G	Meggitt PLC; Greenbriar Equity Fund II, L.P.; Meggitt PLC.
20151768	G	KPCB Green Growth Fund, LLC; Clean Power Finance, Inc.; KPCB Green Growth Fund, LLC.
20160010	G	Dr. h.c. Friede Springer; Business Insider, Inc.; Dr. h.c. Friede Springer.
20160023	G	Trian Partners Co-Investment Opportunities Fund, LLC; General Electric Company; Trian Partners Co- Investment Opportunities Fund, LLC.
20160031	G	Third Point Offshore Fund, Ltd.; Social Finance, Inc.; Third Point Offshore Fund, Ltd.
20160060	G	Joe's Jeans Inc.; TCP RG, LLC; Joe's Jeans Inc.
20160063	G	Ivy Holding Inc.; Eastern Connecticut Health Network, Inc.; Ivy Holding Inc.
20160068	G	Aegon N.V.; Marsh & McLennan Companies, Inc; Aegon N.V.
20160072	G	Kelso Investment Associates IX, L.P.; Kohlberg Management VII, L.P.; Kelso Investment Associates IX, L.P.

20160078	G	John D. Grier; Chevron Corporation; John D. Grier.
20160083	G	Agnaten SE; TSG5 L.P.; Agnaten SE.
20160084	G	John R. Charman; Endurance Speciality Holdings Ltd.; John R. Charman.
20160086	G	Buckeye Partners, L.P.; HOVENSA L.L.C.; Buckeye Partners, L.P.
10/26/2015		
20160046	G	Pandora Media, Inc.; Ticketfly, Inc.; Pandora Media, Inc.
20160049	G	BDT Capital Partners Annex Fund, L.P. Annex Fund, L.P.; BDT Capital Partners Fund II–X, L.P.; BDT Capital Partners.
20160050	G	BDT Capital Partners Fund II–X, L.P.; Fund II–X, L.P.; BDT Capital Partners Annex Fund, L.P.; BDT Capital Partners.
20160051	G	BDT Capital Partners Fund II–X, L.P.; Fund II–X, L.P.; BDT Capital Partners Annex Fund I–A, L.P.; BDT Capital Partners.
20160052	G	BDT Capital Partners Fund II–X, L.P.; Fund II–X, L.P.; BDT Capital Partners Fund II (INT), L.P.; BDT Capital Partners.
20160053	G	BDT Capital Partners Fund II–X, L.P.; Fund II–X, L.P.; BDT Capital Partners Fund II (TE), L.P.; BDT Capital Partners.
20160054	G	BDT Capital Partners Fund II–X, L.P.; II–X, L.P.; BDTCP Investments Fund II–X, L.P.; BDT Capital Partners Fund.
20160065	G	Meritage Co-Investors LLC SERIES 3; Ron Fowler; Meritage Co-Investors LLC SERIES 3.
20160077	G	Snow Phipps II, L.P.; CHS Private Equity V L.P.; Snow Phipps II, L.P.
20160082	G	Golden Gate Capital Opportunity Fund, L.P.; The Phoenix Companies, Inc.; Golden Gate Capital Opportunity Fund, L.P.
20160038	G	International Business Machines Corporation; Frank Selldorff; International Business Machines Corporation.
20160042	G	QUALCOMM Incorporated; Sony Corporation; QUALCOMM Incorporated.
20160059	G	Canfor Corporation; Anthony Family Property Holdings, Inc.; Canfor Corporation.
20160069	G	International Business Machines Corporation; Cleversafe, Inc.; International Business Machines Corporation.
20160071	G	Hainan Cihang Charitable Foundation; Avolon Holdings Limited; Hainan Cihang Charitable Foundation.
20160079	G	Desmarais Family Residuary Trust; Eagle Creek Renewable Energy LLC; Desmarais Family Residuary Trust.
20160085	G	EIF United States Power Fund IV, L.P.; WPX Energy, Inc.; EIF United States Power Fund IV, L.P.
10/28/2015		
20151703	G	ZF Friedrichshafen AG; Robert Bosch Industrietreuhand KG; ZF Friedrichshafen AG.
20160020	G	Amsurg Corp.; Valley Anesthesiology Consultants, Ltd.; Amsurg Corp.
20160047	G	Platinum Equity Capital Partners II, L.P.; American Electric Power Company, Inc.; Platinum Equity Capital Partners II, L.P.
20160089	G	Rockland Power Partners II, L.P.; ArcLight Energy Partners Fund V, L.P.; Rockland Power Partners II, L.P.
10/30/2015		
20160091	G	AmerisourceBergen Corporation; Clayton, Dubilier & Rice Fund IX, L.P.; AmerisourceBergen Corporation.
20160095	G	Treasury Wine Estates Limited; Diageo PLC; Treasury Wine Estates Limited.
20160103	G	US Development Group LLC; Casper Crude to Rail Holdings, LLC; US Development Group LLC.
20160106	G	Arbor Pharmaceuticals, Inc.; Sanofi; Arbor Pharmaceuticals, Inc.
20160107	G	Audax Private Equity Fund IV, L.P.; BCP V Limited Partnership; Audax Private Equity Fund IV, L.P.
20160108	G	JW Childs Equity Partners IV, L.P.; KeyImpact Holdings, Inc.; JW Childs Equity Partners IV, L.P.
20160110	G	Clearlake Capital Partner IV, L.P.; Spiral Holdings Inc.; Clearlake Capital Partner IV, L.P.
20160122	G	Henry Samueli; Pavonia Limited; Henry Samueli.
20160130	G	Wellspring Capital Partners V, L.P.; GI Partners Fund III L.P.; Wellspring Capital Partners V, L.P.

FOR FURTHER INFORMATION CONTACT: Theresa Kingsberry, Program Support Specialist, Federal Trade Commission Premerger Notification Office, Bureau of Competition, Room CC–5301, Washington, DC 20024, (202) 326–3100.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2015–28858 Filed 11–13–15; 8:45 am]

BILLING CODE 6750–01–P

GENERAL SERVICES ADMINISTRATION

[Notice–CECANF–2015–09; Docket No. 2015–0004; Sequence No. 9]

Commission To Eliminate Child Abuse and Neglect Fatalities; Announcement of Meetings

AGENCY: Commission to Eliminate Child Abuse and Neglect Fatalities, GSA.

ACTION: Meetings Notice.

SUMMARY: The Commission to Eliminate Child Abuse and Neglect Fatalities (CECANF), a Federal Advisory Committee established by the Protect Our Kids Act of 2012, will hold a meeting open to the public on Monday, December 7, 2015 and Tuesday, December 8, 2015 in Herndon, Virginia.

DATES: *Meeting Dates:* The meeting will be held on Monday, December 7, 2015, from 9:00 a.m. to 5:00 p.m., Eastern Standard Time (EST), and Tuesday, December 8, 2015, from 9:00 a.m. to 12:00 p.m., Eastern Standard Time (EST).

Comment due date: All comments must be received by midnight on Wednesday, December 2, 2015, to be addressed during the meeting.

ADDRESSES: CECANF will convene its meeting at the Hilton Washington Dulles, 13869 Park Center Drive, Herndon, Virginia 20171. This site is accessible to individuals with disabilities. The meeting also will be made available via teleconference.

Submit comments identified by ''Notice–CECANF–2015–09'' by either of the following methods:

- Regulations.gov: *http://www.regulations.gov.*

Submit comments via the Federal eRulemaking portal by searching for ''Notice–CECANF–2015–09.'' Select the link ''Comment Now'' that corresponds with ''Notice–CECANF–2015–09.'' Follow the instructions provided on the screen. Please include your name, organization name (if any), and ''Notice–CECANF–2015–09'' on your attached document.

- Mail: U.S. General Services Administration, 1800 F Street NW., Room 7003D, Washington, DC 20405, Attention: Tom Hodnett (CD) for CECANF.

Instructions: Please submit comments only and cite ''Notice–CECANF–2015–09'' in all correspondence related to this notice. All comments received will be posted without change to *http://www.regulations.gov,* including any personal and/or business confidential information provided. To confirm

receipt of your comment(s), please check *http://www.regulations.gov,* approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Visit the CECANF Web site at *https://eliminatechildabusefatalities.sites.usa.gov/* or contact Patricia Brincefield, Communications Director, at 202–818–9596, U.S. General Services Administration, 1800 F Street NW., Room 7003D, Washington, DC 20405, Attention: Tom Hodnett (CD) for CECANF.

SUPPLEMENTARY INFORMATION:

Background: CECANF was established to develop a national strategy and recommendations for reducing fatalities resulting from child abuse and neglect.

Agenda: Commission members will continue discussing the work plans of the Commission subcommittees, the information that they have obtained to date, and emerging recommendations.

Attendance at the Meeting: Individuals interested in attending the meeting in person or participating by webinar and teleconference must register in advance. To register to attend in person or by webinar/phone, please go to *http://meetingtomorrow.com/webcast/CECANF* and follow the prompts. Once you register, you will receive a confirmation email with the teleconference number. Detailed meeting minutes will be posted within 90 days of the meeting. Members of the public will not have the opportunity to ask questions or otherwise participate in the meeting.

However, members of the public wishing to comment should follow the steps detailed under the heading **ADDRESSES** in this publication or contact us via the CECANF Web site at *https://eliminatechildabusefatalities.sites.usa.gov/contact-us/*.

Dated: November 9, 2015.

Karen White,

Executive Assistant.

[FR Doc. 2015–29002 Filed 11–13–15; 8:45 am]

BILLING CODE 6820–34–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–8060–N]

RIN 0938–AS37

Medicare Program; CY 2016 Part A Premiums for the Uninsured Aged and for Certain Disabled Individuals Who Have Exhausted Other Entitlement

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This annual notice announces Medicare's Hospital Insurance (Part A) premium for uninsured enrollees in calendar year (CY) 2016. This premium is paid by enrollees age 65 and over who are not otherwise eligible for benefits under Medicare Part A (hereafter known as the ''uninsured aged'') and by certain disabled individuals who have exhausted other entitlement. The monthly Part A premium for the 12 months beginning January 1, 2016, for these individuals will be $411. The premium for certain other individuals as described in this notice will be $226.

DATES: *Effective Date:* This notice is effective on January 1, 2016.

FOR FURTHER INFORMATION CONTACT: Clare McFarland, (410) 786–6390.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1818 of the Social Security Act (the Act) provides for voluntary enrollment in the Medicare Hospital Insurance Program (Medicare Part A), subject to payment of a monthly premium, of certain persons aged 65 and older who are uninsured under the Old-Age, Survivors, and Disability Insurance (OASDI) program or the Railroad Retirement Act and do not otherwise meet the requirements for entitlement to Medicare Part A. These ''uninsured aged'' individuals are uninsured under the OASDI program or the Railroad Retirement Act, because they do not have 40 quarters of coverage under Title II of the Act (or are/were not married to someone who did). (Persons insured under the OASDI program or the Railroad Retirement Act and certain others do not have to pay premiums for Medicare Part A.)

Section 1818A of the Act provides for voluntary enrollment in Medicare Part A, subject to payment of a monthly premium for certain disabled individuals who have exhausted other entitlement. These are individuals who were entitled to coverage due to a disabling impairment under section 226(b) of the Act, but who are no longer entitled to disability benefits and free Medicare Part A coverage because they have gone back to work and their earnings exceed the statutorily defined ''substantial gainful activity'' amount (section 223(d)(4) of the Act).

Section 1818A(d)(2) of the Act specifies that the provisions relating to premiums under section 1818(d) through section 1818(f) of the Act for the aged will also apply to certain disabled individuals as described above.

Section 1818(d)(1) of the Act requires us to estimate, on an average per capita basis, the amount to be paid from the Federal Hospital Insurance Trust Fund for services incurred in the upcoming calendar year (CY) (including the associated administrative costs) on behalf of individuals aged 65 and over who will be entitled to benefits under Medicare Part A. We must then determine the monthly actuarial rate for the following year (the per capita amount estimated above divided by 12) and publish the dollar amount for the monthly premium in the succeeding CY. If the premium is not a multiple of $1, the premium is rounded to the nearest multiple of $1 (or, if it is a multiple of 50 cents but not of $1, it is rounded to the next highest $1).

Section 13508 of the Omnibus Budget Reconciliation Act of 1993 (Pub. L. 103–66) amended section 1818(d) of the Act to provide for a reduction in the premium amount for certain voluntary enrollees (section 1818 and section 1818A of the Act). The reduction applies to an individual who is eligible to buy into the Medicare Part A program and who, as of the last day of the previous month:

- Had at least 30 quarters of coverage under Title II of the Act;
- Was married, and had been married for the previous 1-year period, to a person who had at least 30 quarters of coverage;
- Had been married to a person for at least 1 year at the time of the person's death if, at the time of death, the person had at least 30 quarters of coverage; or
- Is divorced from a person and had been married to the person for at least 10 years at the time of the divorce if, at the time of the divorce, the person had at least 30 quarters of coverage.

Section 1818(d)(4)(A) of the Act specifies that the premium that these individuals will pay for CY 2016 will be equal to the premium for uninsured aged enrollees reduced by 45 percent.

II. Monthly Premium Amount for CY 2016

The monthly premium for the uninsured aged and certain disabled individuals who have exhausted other entitlement for the 12 months beginning January 1, 2016, is $411.

The monthly premium for the individuals eligible under section 1818(d)(4)(B) of the Act, and therefore, subject to the 45 percent reduction in the monthly premium, is $226.

III. Monthly Premium Rate Calculation

As discussed in section I of this notice, the monthly Medicare Part A premium is equal to the estimated monthly actuarial rate for CY 2016 rounded to the nearest multiple of $1 and equals one-twelfth of the average per capita amount, which is determined by projecting the number of Medicare Part A enrollees aged 65 years and over as well as the benefits and administrative costs that will be incurred on their behalf.

The steps involved in projecting these future costs to the Federal Hospital Insurance Trust Fund are:

- Establishing the present cost of services furnished to beneficiaries, by type of service, to serve as a projection base;
- Projecting increases in payment amounts for each of the service types; and
- Projecting increases in administrative costs.

We base our projections for CY 2016 on—(1) current historical data; and (2) projection assumptions derived from current law and the Mid-Session Review of the President's Fiscal Year 2016 Budget.

We estimate that in CY 2016, 47,251,107 people aged 65 years and over will be entitled to benefits (without premium payment) and that they will incur about $233.221 billion in benefits and related administrative costs. Thus, the estimated monthly average per capita amount is $411.31 and the monthly premium is $411. Subsequently, the full monthly premium reduced by 45 percent is $226.

IV. Costs to Beneficiaries

The CY 2016 premium of $411 is approximately 1 percent higher than the CY 2015 premium of $407. We estimate that approximately 652,000 enrollees will voluntarily enroll in Medicare Part A, by paying the full premium. Furthermore, the CY 2016 reduced premium of $226 is approximately 0.9 percent higher than the CY 2015 premium of $224. We estimate an additional 61,000 enrollees will pay the reduced premium. Therefore, we estimate that the total aggregate cost to enrollees paying these premiums in CY 2016, compared to the amount that they paid in CY 2015, will be about $32 million.

V. Waiver of Proposed Notice and Comment Period

We use general notices, rather than notice and comment rulemaking procedures, to make announcements such as this premium notice. In doing so, we acknowledge that, under the Administrative Procedure Act (APA), interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice are excepted from the requirements of notice and comment rulemaking. The agency may also waive notice and comment if there is ''good cause,'' as defined by the statute. We considered publishing a proposed notice to provide a period for public comment. However, under the APA, we may waive that procedure if we find good cause that prior notice and comment are impracticable, unnecessary, or contrary to the public interest.

We are not using notice and comment rulemaking in this notification of Medicare Part A premiums for CY 2016 as that procedure is unnecessary because of the lack of discretion in the statutory formula that is used to calculate the premium and the solely ministerial function that this notice serves. The APA permits agencies to waive notice and comment rulemaking when notice and public comment thereon are unnecessary. On this basis, we waive publication of a proposed notice and a solicitation of public comments.

VI. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

VII. Regulatory Impact Analysis

A. Statement of Need

Section 1818(d) of the Act requires the Secretary of the Department of Health and Human Services (the Secretary) during September of each year to determine and publish the amount to be paid, on an average per capita basis, from the Federal Hospital Insurance Trust Fund for services incurred in the impending calendar year (CY) (including the associated administrative costs) on behalf of individuals aged 65 and over who will be entitled to benefits under Medicare Part A.

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 (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. Part I, Ch. 8).

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 notices with economically significant effects ($100 million or more in any 1 year). As stated in section IV of this notice, we estimate that the overall effect of the changes in the Part A premium will be a cost to voluntary enrollees (section 1818 and section 1818A of the Act) of about $32 million. As a result, this notice is non-economically significant under section 3(f)(1) of Executive Order 12866 and is not a major action under the Congressional Review Act. In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million in any 1 year (for details, see the Small Business Administration's Web site at *http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf*).

Individuals and states are not included in the definition of a small

entity. As discussed above, this annual notice announces Medicare's Hospital Insurance (Part A) premium for uninsured enrollees in calendar year (CY) 2016. As a result, we are not preparing an analysis for the RFA because the Secretary has determined that this notice will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. As discussed above, we are not preparing an analysis for section 1102(b) of the Act, because the Secretary has determined that this notice will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2015, that threshold is approximately $144 million. This notice does not impose mandates that will have a consequential effect of $144 million or more 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 notice does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

Dated: November 6, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: November 9, 2015

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2015–29176 Filed 11–10–15; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–3427]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (the PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information (including each proposed extension or reinstatement of an existing collection of information) and to allow 60 days for public comment on the proposed action. Interested persons are invited to send comments regarding our burden estimates or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments must be received by January 15, 2016.

ADDRESSES: When commenting, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in any one of the following ways:

1. *Electronically.* You may send your comments electronically to *http://www.regulations.gov*. Follow the instructions for ''Comment or Submission'' or ''More Search Options'' to find the information collection document(s) that are accepting comments.

2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number _____, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995*.

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov*.

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION:

Contents

This notice sets out a summary of the use and burden associated with the following information collections. More detailed information can be found in each collection's supporting statement and associated materials (see **ADDRESSES**).

CMS–3427 End Stage Renal Disease Application and Survey and Certification Report

Under the PRA (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA requires federal agencies to publish a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice.

Information Collection

1. *Type of Information Collection Request:* Reinstatement with change of a previously approved collection; *Title of Information Collection:* End Stage Renal Disease Application and Survey and Certification Report; *Use:* Part I of this form is a facility identification and screening measurement used to initiate the certification and recertification of ESRD facilities. Part II is completed by the Medicare/Medicaid State survey agency to determine facility compliance with ESRD conditions for coverage.

Form Number: CMS–3427 (OMB control number: 0938–0360); *Frequency:* Every three years; *Affected Public:* Private sector (Business or other for-profit and Not-for profit institutions); *Number of Respondents:* 6,138; *Total Annual Responses:* 2,046; *Total Annual Hours:* 682. (For policy questions regarding this collection contact Judith Kari at 410–786–6829)

Dated: November 10, 2015.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2015–29160 Filed 11–13–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–8059–N]

RIN 0938–AS36

Medicare Program; CY 2016 Inpatient Hospital Deductible and Hospital and Extended Care Services Coinsurance Amounts

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in calendar year (CY) 2016 under Medicare's Hospital Insurance Program (Medicare Part A). The Medicare statute specifies the formulae used to determine these amounts. For CY 2016, the inpatient hospital deductible will be $1,288. The daily coinsurance amounts for CY 2016 will be: (1) $322 for the 61st through 90th day of hospitalization in a benefit period; (2) $644 for lifetime reserve days; and (3) $161.00 for the 21st through 100th day of extended care services in a skilled nursing facility in a benefit period.

DATES: *Effective Date:* This notice is effective on January 1, 2016.

FOR FURTHER INFORMATION CONTACT: Clare McFarland, (410) 786–6390 for general information. Gregory J. Savord, (410) 786–1521 for case-mix analysis.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1813 of the Social Security Act (the Act) provides for an inpatient hospital deductible to be subtracted from the amount payable by Medicare for inpatient hospital services furnished to a beneficiary. It also provides for certain coinsurance amounts to be subtracted from the amounts payable by Medicare for inpatient hospital and extended care services. Section 1813(b)(2) of the Act requires us to determine and publish each year the amount of the inpatient hospital deductible and the hospital and extended care services coinsurance amounts applicable for services furnished in the following calendar year (CY).

II. Computing the Inpatient Hospital Deductible for CY 2016

Section 1813(b) of the Act prescribes the method for computing the amount of the inpatient hospital deductible. The inpatient hospital deductible is an amount equal to the inpatient hospital deductible for the preceding CY, adjusted by our best estimate of the payment-weighted average of the applicable percentage increases (as defined in section 1886(b)(3)(B) of the Act) used for updating the payment rates to hospitals for discharges in the fiscal year (FY) that begins on October 1 of the same preceding CY, and adjusted to reflect changes in real case-mix. The adjustment to reflect real case-mix is determined on the basis of the most recent case-mix data available. The amount determined under this formula is rounded to the nearest multiple of $4 (or, if midway between two multiples of $4, to the next higher multiple of $4).

Under section 1886(b)(3)(B)(i)(XX) of the Act, the percentage increase used to update the payment rates for FY 2016 for hospitals paid under the inpatient prospective payment system is the market basket percentage increase, otherwise known as the market basket update, reduced by 0.2 percentage points (see section 1886(b)(3)(B)(xii)(IV) of the Act), and an adjustment based on changes in the economy-wide productivity (the multifactor productivity (MFP) adjustment) (see section 1886(b)(3)(B)(xi)(II) of the Act). Under section 1886(b)(3)(B)(viii) of the Act, for fiscal year 2016, the applicable percentage increase for hospitals that do not submit quality data as specified by the Secretary of the Department of Health and Human Services (the Secretary) is reduced by one quarter of the market basket update. We are estimating that after accounting for those hospitals receiving the lower market basket update in the payment-weighted average update, the calculated deductible will not be affected, since the majority of hospitals submit quality data and receive the full market basket update. Section 1886(b)(3)(B)(ix) of the Act requires that any hospital that is not a meaningful electronic health record (EHR) user (as defined in section 1886(n)(3) of the Act) will have three-quarters of the market basket update reduced by 33⅓ percent for FY 2015, 66⅔ percent for FY 2016, and 100 percent for FY 2017 and each subsequent fiscal year. We are estimating that after accounting for these hospitals receiving the lower market basket update, the calculated deductible will not be affected, since the majority of hospitals are meaningful EHR users and are expected to receive the full market basket update.

Under section 1886(b)(3)(B)(ii)(VIII) of the Act, the percentage increase used to update the payment rates for FY 2016 for hospitals excluded from the inpatient prospective payment system is as follows:

- The percentage increase for long term care hospitals is the market basket percentage increase reduced by 0.2 percentage points and the MFP adjustment (*see* sections 1886(m)(3)(A) and 1886(m)(4)(E) of the Act).
- The percentage increase for inpatient rehabilitation facilities is the market basket percentage increase reduced by 0.2 percentage points and the MFP adjustment (*see* sections 1886(j)(3)(C) and 1886(j)(3)(D)(iv) of the Act).
- The percentage increase used to update the payment rate for inpatient psychiatric facilities is the market basket percentage increase reduced by 0.2 percentage points and the MFP adjustment (see sections 1886(s)(2)(A)(i), 1886(s)(2)(A)(ii), and 1886(s)(3)(D) of the Act).

The Inpatient Prospective Payment System market basket percentage increase for 2016 is 2.4 percent and the MFP adjustment is 0.5 percent, as announced in the final rule that appeared in the **Federal Register** on August 17, 2015 entitled, ''Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System Policy Changes and Fiscal Year 2016 Rates'' (80 FR 49510). Therefore, the percentage increase for hospitals paid under the inpatient prospective payment system that submit quality data and are meaningful EHR users is 1.7 percent (that is, the FY 2016 market basket update of 2.4 percent less the MFP adjustment of 0.5 percentage point and less 0.2 percentage point). The average payment percentage increase for hospitals excluded from the inpatient prospective payment system is 1.82 percent. Weighting these percentages in accordance with payment volume, our best estimate of

the payment-weighted average of the increases in the payment rates for FY 2016 is 1.72 percent.

To develop the adjustment to reflect changes in real case-mix, we first calculated an average case-mix for each hospital that reflects the relative costliness of that hospital's mix of cases compared to those of other hospitals. We then computed the change in average case-mix for hospitals paid under the Medicare prospective payment system in FY 2015 compared to FY 2014. (We excluded from this calculation hospitals whose payments are not based on the inpatient prospective payment system because their payments are based on alternate prospective payment systems or reasonable costs.) We used Medicare bills from prospective payment hospitals that we received as of July 2015. These bills represent a total of about 7.6 million Medicare discharges for FY 2015 and provide the most recent case-mix data available at this time. Based on these bills, the change in average case-mix in FY 2015 is 0.21 percent. Based on these bills and past experience, we expect the overall case mix change to be 0.5 percent as the year progresses and more FY 2015 data become available.

Section 1813 of the Act requires that the inpatient hospital deductible be adjusted only by that portion of the case-mix change that is determined to be real. Real case-mix is that portion of case-mix that is due to changes in the mix of cases in the hospital and not due to coding optimization. We expect that all of the change in average case-mix will be real and estimate that this change will be 0.5 percent.

Thus as stated above, the estimate of the payment-weighted average of the applicable percentage increases used for updating the payment rates is 1.72 percent, and the real case-mix adjustment factor for the deductible is 0.5 percent. Therefore, using the statutory formula as stated in section 1813(b) of the Act, we calculate the inpatient hospital deductible for services furnished in CY 2016 to be $1,288. This deductible amount is determined by multiplying $1,260 (the inpatient hospital deductible for CY 2015 (79 FR 49854)) by the payment-weighted average increase in the payment rates of 1.0172 multiplied by the increase in real case-mix of 1.005, which equals $1,288.08 and is rounded to $1,288.

III. Computing the Inpatient Hospital and Extended Care Services Coinsurance Amounts for CY 2016

The coinsurance amounts provided for in section 1813 of the Act are defined as fixed percentages of the inpatient hospital deductible for services furnished in the same CY. The increase in the deductible generates increases in the coinsurance amounts. For inpatient hospital and extended care services furnished in CY 2016, in accordance with the fixed percentages defined in the law, the daily coinsurance for the 61st through 90th day of hospitalization in a benefit period will be $322 (one-fourth of the inpatient hospital deductible as stated in section 1813(a)(1)(A) of the Act); the daily coinsurance for lifetime reserve days will be $644 (one-half of the inpatient hospital deductible as stated in section 1813(a)(1)(B) of the Act); and the daily coinsurance for the 21st through 100th day of extended care services in a skilled nursing facility in a benefit period will be $161 (one-eighth of the inpatient hospital deductible as stated in section 1813(a)(3) of the Act).

IV. Cost to Medicare Beneficiaries

Table 1 below summarizes the deductible and coinsurance amounts for CYs 2015 and 2016, as well as the number of each that is estimated to be paid.

TABLE 1—PART A DEDUCTIBLE AND COINSURANCE AMOUNTS FOR CALENDAR YEARS 2015 AND 2016 TYPE OF COST SHARING

	Value		Number paid (in millions)	
	2015	2016	2015	2016
Inpatient hospital deductible	$1260	$1288	7.73	7.75
Daily coinsurance for 61st–90th Day	315	322	1.83	1.83
Daily coinsurance for lifetime reserve days	630	644	0.89	0.89
SNF coinsurance	157.50	161	41.47	42.67

The estimated total increase in costs to beneficiaries is about $610 million (rounded to the nearest $10 million) due to: (1) The increase in the deductible and coinsurance amounts, and (2) the increase in the number of deductibles and daily coinsurance amounts paid. We determine the increase in cost to beneficiaries by calculating the difference between the 2015 and 2016 deductible and coinsurance amounts multiplied by the increase in the number of deductible and coinsurance amounts paid.

V. Waiver of Proposed Notice and Comment Period

Section 1813(b)(2) of the Act requires publication of the inpatient hospital deductible and all coinsurance amounts—the hospital and extended care services coinsurance amounts—between September 1 and September 15 of the year preceding the year to which they will apply. These amounts are determined according to the statute as discussed above. As has been our custom, we use general notices, rather than notice and comment rulemaking procedures, to make the announcements. In doing so, we acknowledge that under the Administrative Procedure Act (APA), interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice are excepted from the requirements of notice and comment rulemaking.

We considered publishing a proposed notice to provide a period for public comment. However, we may waive that procedure if we find good cause that prior notice and comment are impracticable, unnecessary, or contrary to the public interest. We find that the procedure for notice and comment is unnecessary here, because the formulae used to calculate the inpatient hospital deductible and hospital and extended care services coinsurance amounts are statutorily directed, and we can exercise no discretion in following the formulae. Moreover, the statute establishes the time period for which the deductible and coinsurance amounts will apply and delaying publication would be contrary to the public interest.

Therefore, we find good cause to waive publication of a proposed notice and solicitation of public comments.

VI. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

VII. Regulatory Impact Analysis

A. Statement of Need

Section 1813(b)(2) of the Act requires the Secretary to publish, between September 1 and September 15 of each year, the amounts of the inpatient hospital deductible and hospital and extended care services coinsurance applicable for services furnished in the following calendar year (CY).

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 (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C., Part I, Ch. 8).

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 notices with economically significant effects ($100 million or more in any 1 year). As stated in section IV of this notice, we estimate that the total increase in costs to beneficiaries associated with this notice is about $610 million due to: (1) The increase in the deductible and coinsurance amounts, and (2) the increase in the number of deductibles and daily coinsurance amounts paid. As a result, this notice is economically significant under section 3(f)(1) of Executive Order 12866 and is a major action under the Congressional Review Act. In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of less than $7.5 million to $38.5 million in any 1 year (for details, see the Small Business Administration's Web site at *http://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf*). Individuals and states are not included in the definition of a small entity. As discussed above, this annual notice announces the inpatient hospital deductible and the hospital and extended care services coinsurance amounts for services furnished in CY 2016 under Medicare's Hospital Insurance Program (Medicare Part A). As a result, we are not preparing an analysis for the RFA because the Secretary has determined that this notice will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Social Security Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. As discussed above, we are not preparing an analysis for section 1102(b) of the Act because the Secretary has determined that this notice will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. For 2015, that threshold accounting for inflation is approximately $144 million. This notice does not impose mandates that will have a consequential effect of $144 million or more 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 notice does not impose any costs on state or local governments, preempt state law, or have Federalism implications, the requirements of Executive Order 13132 are not applicable.

Dated: November 6, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: November 9, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2015–29207 Filed 11–10–15; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifiers: CMS–2567 and CMS–10143]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information

technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by December 16, 2015.

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, Fax Number: (202) 395–5806 *OR* Email: *OIRA_submission@omb.eop.gov.*

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995.*

2. Email your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov.*

3. Call the Reports Clearance Office at (410) 786–1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786–1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term ''collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. *Type of Information Collection Request:* Extension without change of a currently approved collection; *Title of Information Collection:* Statement of Deficiencies and Plan of Correction Supporting Regulations; *Use:* Section 1864(a) of the Social Security Act requires that the Secretary use state survey agencies to conduct surveys to determine whether health care facilities meet Medicare and Clinical Laboratory Improvement Amendments participation requirements. The Form CMS–2567 is the means by which the survey findings are documented. This section of the law further requires that compliance findings resulting from these surveys be made available to the public within 90 days of such surveys. The Form CMS–2567 is the vehicle for this disclosure. The form is also used by health care facilities to document their plan of correction and by CMS, the states, facilities, purchasers, consumers, advocacy groups, and the public as a source of information about quality of care and facility compliance. The regulations at 42 CFR 488.18 require that state survey agencies document all deficiency findings on a statement of deficiencies and plan of correction, which is the CMS–2567. Sections 488.26 and 488.28 further delineate how compliance findings must be recorded and that CMS prescribed forms must be used. *Form Number:* CMS–2567 (OMB Control Number: 0938–0391); *Frequency:* Yearly and occasionally; *Affected Public:* Private Sector (Business or other for-profit and Not-for-profit institutions); *Number of Respondents:* 64,500; *Total Annual Responses:* 64,500; *Total Annual Hours:* 128,083. (For policy questions regarding this collection contact Karen Tritz at 410–786–8021.)

2. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Monthly File of Medicaid/Medicare Dual Eligible Enrollees; *Use:* The monthly data file is provided to CMS by states on dually eligible Medicaid and Medicare beneficiaries, listing the individuals on the Medicaid eligibility file, their Medicare status and other information needed to establish subsidy level, such as income and institutional status. The file is used to count the exact number of individuals who should be included in the phased-down state contribution calculation that month. We merge the data with other data files and establishes Part D enrollment for those individuals on the file. The file may be used by CMS partners to obtain accurate counts of duals on a current basis. *Form Number:* CMS–10143 (OMB Control Number: 0938–0958); *Frequency:* Monthly; *Affected Public:* State, Local, or Tribal Governments; *Number of Respondents:* 51; *Total Annual Responses:* 612; *Total Annual Hours:* 6,120. (For policy questions regarding this collection contact Vasanthi Kandasamy at 410–786–0433).

Dated: November 10, 2015.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2015–29159 Filed 11–13–15; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS–8061–N]

RIN 0938–AS38

Medicare Program; Medicare Part B Monthly Actuarial Rates, Premium Rate, and Annual Deductible Beginning January 1, 2016

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Notice.

SUMMARY: This notice announces the monthly actuarial rates for aged (age 65 and over) and disabled (under age 65) beneficiaries enrolled in Part B of the Medicare Supplementary Medical Insurance (SMI) program beginning January 1, 2016. In addition, this notice announces the monthly premium for aged and disabled beneficiaries, the deductible for 2016, the income-related monthly adjustment amounts to be paid by beneficiaries with modified adjusted gross income above certain threshold amounts, and the transfer amount equal to the reduction in premiums payable as a result of amendments made by the Bipartisan Budget Act of 2015. The monthly actuarial rates for 2016 are $237.60 for aged enrollees and $282.60 for disabled enrollees. The standard monthly Part B premium rate for all enrollees for 2016 is $121.80, which is equal to 50 percent of the monthly actuarial rate for aged enrollees (or approximately 25 percent of the expected average total cost of Part B coverage for aged enrollees) plus $3.00. (The 2015 standard premium rate was $104.90.) The Part B deductible for 2016 is $166.00 for all Part B beneficiaries. If a beneficiary has to pay an income-related monthly adjustment, they will have to pay a total monthly premium of about 35, 50, 65, or 80 percent of the total cost of Part B coverage plus $4.20, $6.00, $7.80, or $9.60. Section 1844(d) of the Social Security Act, as added by section 601(b) of the Bipartisan Budget Act of 2015, provides for a transfer from the general fund to the Part B account

of the SMI Trust Fund. This transfer of $7,440,648,000 consists of $5,237,880,000 in reduced premium revenue for enrollees age 65 and older, and $2,202,768,000 in reduced premium revenue for enrollees under age 65.

DATES: *Effective Date:* January 1, 2016.

FOR FURTHER INFORMATION CONTACT: M. Kent Clemens, (410) 786–6391.

SUPPLEMENTARY INFORMATION:

I. Background

Part B is the voluntary portion of the Medicare program that pays all or part of the costs for physicians' services, outpatient hospital services, certain home health services, services furnished by rural health clinics, ambulatory surgical centers, comprehensive outpatient rehabilitation facilities, and certain other medical and health services not covered by Medicare Part A, Hospital Insurance. Medicare Part B is available to individuals who are entitled to Medicare Part A, as well as to U.S. residents who have attained age 65 and are citizens, and aliens who were lawfully admitted for permanent residence and have resided in the United States for 5 consecutive years. Part B requires enrollment and payment of monthly premiums, as described in 42 CFR part 407, subpart B, and part 408, respectively. The premiums paid by (or on behalf of) all enrollees fund approximately one-fourth of the total incurred costs, and transfers from the general fund of the Treasury pay approximately three-fourths of these costs.

The Secretary of the Department of Health and Human Services (the Secretary) is required by section 1839 of the Social Security Act (the Act) to announce the Part B monthly actuarial rates for aged and disabled beneficiaries as well as the monthly Part B premium. The Part B annual deductible is included because its determination is directly linked to the aged actuarial rate.

The monthly actuarial rates for aged and disabled enrollees are used to determine the correct amount of general revenue financing per beneficiary each month. These amounts, according to actuarial estimates, will equal, respectively, one-half of the expected average monthly cost of Part B for each aged enrollee (age 65 or over) and one-half of the expected average monthly cost of Part B for each disabled enrollee (under age 65).

The Part B deductible to be paid by enrollees is also announced. Prior to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108–173), the Part B deductible was set in statute. After setting the 2005 deductible amount at $110, section 629 of the MMA (amending section 1833(b) of the Act) requires that the Part B deductible be indexed beginning in 2006. The inflation factor to be used each year is the annual percentage increase in the Part B actuarial rate for enrollees age 65 and over. Specifically, the 2016 Part B deductible is calculated by multiplying the 2015 deductible by the ratio of the 2016 aged actuarial rate to the 2015 aged actuarial rate. The amount determined under this formula is then rounded to the nearest $1.

The monthly Part B premium rate to be paid by aged and disabled enrollees is also announced. (Although the costs to the program per disabled enrollee are different than for the aged, the statute provides that they pay the same premium amount.) Beginning with the passage of section 203 of the Social Security Amendments of 1972 (Pub. L. 92–603), the premium rate, which was determined on a fiscal year basis, was limited to the lesser of the actuarial rate for aged enrollees, or the current monthly premium rate increased by the same percentage as the most recent general increase in monthly Title II social security benefits.

However, the passage of section 124 of the Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) (Pub. L. 97–248) suspended this premium determination process. Section 124 of TEFRA changed the premium basis to 50 percent of the monthly actuarial rate for aged enrollees (that is, 25 percent of program costs for aged enrollees). Section 606 of the Social Security Amendments of 1983 (Pub. L. 98–21), section 2302 of the Deficit Reduction Act of 1984 (DEFRA 84) (Pub. L. 98–369), section 9313 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA 85) (Pub. L. 99–272), section 4080 of the Omnibus Budget Reconciliation Act of 1987 (OBRA 87) (Pub. L. 100–203), and section 6301 of the Omnibus Budget Reconciliation Act of 1989 (OBRA 89) (Pub. L. 101–239) extended the provision that the premium be based on 50 percent of the monthly actuarial rate for aged enrollees (that is, 25 percent of program costs for aged enrollees). This extension expired at the end of 1990.

The premium rate for 1991 through 1995 was legislated by section 1839(e)(1)(B) of the Act, as added by section 4301 of the Omnibus Budget Reconciliation Act of 1990 (OBRA 90) (Pub. L. 101–508). In January 1996, the premium determination basis would have reverted to the method established by the 1972 Social Security Act Amendments. However, section 13571 of the Omnibus Budget Reconciliation Act of 1993 (OBRA 93) (Pub. L. 103–66) changed the premium basis to 50 percent of the monthly actuarial rate for aged enrollees (that is, 25 percent of program costs for aged enrollees) for 1996 through 1998.

Section 4571 of the Balanced Budget Act of 1997 (BBA) (Pub. L. 105–33) permanently extended the provision that the premium be based on 50 percent of the monthly actuarial rate for aged enrollees (that is, 25 percent of program costs for aged enrollees).

The BBA included a further provision affecting the calculation of the Part B actuarial rates and premiums for 1998 through 2003. Section 4611 of the BBA modified the home health benefit payable under Part A for individuals enrolled in Part B. Under this section, beginning in 1998, expenditures for home health services not considered ''post-institutional'' are payable under Part B rather than Part A. However, section 4611(e)(1) of the BBA required that there be a transition from 1998 through 2002 for the aggregate amount of the expenditures transferred from Part A to Part B. Section 4611(e)(2) of the BBA also provided a specific yearly proportion for the transferred funds. The proportions were 1/6 for 1998, 1/3 for 1999, 1/2 for 2000, 2/3 for 2001, and 5/6 for 2002. For the purpose of determining the correct amount of financing from general revenues of the Federal Government, it was necessary to include only these transitional amounts in the monthly actuarial rates for both aged and disabled enrollees, rather than the total cost of the home health services being transferred.

Section 4611(e)(3) of the BBA also specified, for the purpose of determining the premium, that the monthly actuarial rate for enrollees age 65 and over be computed as though the transition would occur for 1998 through 2003 and that 1/7 of the cost be transferred in 1998, 2/7 in 1999, 3/7 in 2000, 4/7 in 2001, 5/7 in 2002, and 6/7 in 2003. Therefore, the transition period for incorporating this home health transfer into the premium was 7 years while the transition period for including these services in the actuarial rate was 6 years.

Section 811 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Pub. L. 108–173, also known as the Medicare Modernization Act, or MMA), which amended section 1839 of the Act, requires that, starting on January 1, 2007, the Part B premium a beneficiary pays each month be based on their annual income. Specifically, if a beneficiary's ''modified adjusted gross

income'' is greater than the legislated threshold amounts (for 2016, $85,000 for a beneficiary filing an individual income tax return, and $170,000 for a beneficiary filing a joint tax return) the beneficiary is responsible for a larger portion of the estimated total cost of Part B benefit coverage. In addition to the standard 25 percent premium, these beneficiaries now have to pay an income-related monthly adjustment amount. The MMA made no change to the actuarial rate calculation, and the standard premium, which will continue to be paid by beneficiaries whose modified adjusted gross income is below the applicable thresholds, still represents 25 percent of the estimated total cost to the program of Part B coverage for an aged enrollee. However, depending on income and tax filing status, a beneficiary can now be responsible for 35, 50, 65, or 80 percent of the estimated total cost of Part B coverage, rather than 25 percent. (For 2018 and subsequent years, the income thresholds are lower for the two highest income ranges, as a result of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10).) The end result of the higher premium is that the Part B premium subsidy is reduced and less general revenue financing is required for beneficiaries with higher income because they are paying a larger share of the total cost with their premium. That is, the premium subsidy continues to be approximately 75 percent for beneficiaries with income below the applicable income thresholds, but will be reduced for beneficiaries with income above these thresholds. The MMA specified that there be a 5-year transition to full implementation of this provision. However, section 5111 of the Deficit Reduction Act of 2005 (DRA) (Pub. L. 109–171) modified the transition to a 3-year period.

Section 4732(c) of the BBA added section 1933(c) of the Act, which required the Secretary to allocate money from the Part B trust fund to the State Medicaid programs for the purpose of providing Medicare Part B premium assistance from 1998 through 2002 for the low-income Medicaid beneficiaries who qualify under section 1933 of the Act. This allocation, while not a benefit expenditure, was an expenditure of the trust fund and was included in calculating the Part B actuarial rates through 2002. For 2003 through 2015, the expenditure was made from the trust fund because the allocation was temporarily extended. However, because the extension occurred after the financing was determined, the allocation was not included in the calculation of the financing rates for these years. Section 211 of MACRA permanently extended this expenditure, which is included in the calculation of the Part B actuarial rates for 2016 and subsequent years.

Another provision affecting the calculation of the Part B premium is section 1839(f) of the Act, as amended by section 211 of the Medicare Catastrophic Coverage Act of 1988 (MCCA 88) (Pub. L. 100–360). (The Medicare Catastrophic Coverage Repeal Act of 1989 (Pub. L. 101–234) did not repeal the revisions to section 1839(f) of the Act made by MCCA 88.) Section 1839(f) of the Act, referred to as the ''hold-harmless'' provision, provides that if an individual is entitled to benefits under section 202 or 223 of the Act (the Old-Age and Survivors Insurance Benefit and the Disability Insurance Benefit, respectively) and has the Part B premium deducted from these benefit payments, the premium increase will be reduced, if necessary, to avoid causing a decrease in the individual's net monthly payment. This decrease in payment occurs if the increase in the individual's social security benefit due to the cost-of-living adjustment under section 215(i) of the Act is less than the increase in the premium. Specifically, the reduction in the premium amount applies if the individual is entitled to benefits under section 202 or 223 of the Act for November and December of a particular year and the individual's Part B premiums for December and the following January are deducted from the respective month's section 202 or 223 benefits. The ''hold-harmless'' provision does not apply to beneficiaries who are required to pay an income-related monthly adjustment amount.

A check for benefits under section 202 or 223 of the Act is received in the month following the month for which the benefits are due. The Part B premium that is deducted from a particular check is the Part B payment for the month in which the check is received. Therefore, a benefit check for November is not received until December, but has December's Part B premium deducted from it.

Generally, if a beneficiary qualifies for hold-harmless protection, the reduced premium for the individual for that January and for each of the succeeding 11 months is the greater of either—

- The monthly premium for January reduced as necessary to make the December monthly benefits, after the deduction of the Part B premium for January, at least equal to the preceding November's monthly benefits, after the deduction of the Part B premium for December; or
- The monthly premium for that individual for that December.

In determining the premium limitations under section 1839(f) of the Act, the monthly benefits to which an individual is entitled under section 202 or 223 of the Act do not include retroactive adjustments or payments and deductions on account of work. Also, once the monthly premium amount is established under section 1839(f) of the Act, it will not be changed during the year even if there are retroactive adjustments or payments and deductions on account of work that apply to the individual's monthly benefits.

Individuals who have enrolled in Part B late or who have re-enrolled after the termination of a coverage period are subject to an increased premium under section 1839(b) of the Act. The increase is a percentage of the premium and is based on the new premium rate before any reductions under section 1839(f) of the Act are made.

For 2016, social security benefits will receive no cost-of-living adjustment under section 215(i) of the Act. As a result, the majority of Part B enrollees can pay no increase in their monthly premium. The Bipartisan Budget Act of 2015 helps to ensure the financial adequacy of the Part B account of the SMI Trust Fund without transferring the financial burden of the entire increase in 2016 premium requirements to the minority of enrollees who are not held harmless.

Section 1839 of the Social Security Act, as amended by section 601(a) of the Bipartisan Budget Act of 2015 (Pub. L. 114–74), specifies that the 2016 actuarial rate for enrollees age 65 and older be determined as if the hold-harmless provision does not apply. The premium revenue that is lost by using the resulting lower premium (excluding the foregone income-related premium revenue) is to be replaced by a transfer of general revenue from the Treasury, which will be repaid over time to the general fund. The transfer amount will be $7,440,648,000, consisting of $5,237,880,000 for the lost aged premium revenue and $2,202,768,000 for the lost disabled premium revenue.

Starting in 2016, in order to repay the balance due (which is to include the transfer amount and the foregone income-related premium revenue), the Part B premium otherwise determined will be increased by $3.00. These repayment amounts will be added to the Part B premium otherwise determined each year and paid back to the general fund of the Treasury.

High-income enrollees will pay an additional $1.20, $3.00, $4.80, or $6.60 as part of the income-related monthly adjustment amount (IRMAA) premium dollars, which reduce (dollar for dollar) the amount of general revenue received by Part B from the general fund of the Treasury. Because of this general revenue offset, the repayment IRMAA premium dollars are not included in the direct repayments made to the general fund of the Treasury from Part B in order to avoid a double repayment. (Only the $3.00 monthly repayment amounts are included in the direct repayments).

These repayment amounts will continue until the total amount collected is equal to the beginning balance due. (In the final year of the repayment, the additional amounts may be modified in order to avoid an overpayment.) The repayment amounts (excluding the repayment amounts for high-income enrollees) are subject to the hold harmless provision. The beginning balance due is $9,066,409,000, consisting of the transfer amount plus $1,625,761,000 in foregone income-related premium revenue.

II. Provisions of the Notice

A. Notice of Medicare Part B Monthly Actuarial Rates, Monthly Premium Rates, Annual Deductible, and Transfer Amount

The Medicare Part B monthly actuarial rates applicable for 2016 are $237.60 for enrollees age 65 and over and $282.60 for disabled enrollees under age 65. In section II.B. of this notice, we present the actuarial assumptions and bases from which these rates are derived. The Part B standard monthly premium rate for all enrollees for 2016 is $121.80. The following are the 2016 Part B monthly premium rates to be paid by beneficiaries who file an individual tax return (including those who are single, head of household, qualifying widow(er) with dependent child, or married filing separately who lived apart from their spouse for the entire taxable year), or a joint tax return.

Beneficiaries who file an individual tax return with income:	Beneficiaries who file a joint tax return with income:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $85,000	Less than or equal to $170,000	$0.00	$121.80
Greater than $85,000 and less than or equal to $107,000.	Greater than $170,000 and less than or equal to $214,000.	48.70	170.50
Greater than $107,000 and less than or equal to $160,000.	Greater than $214,000 and less than or equal to $320,000.	121.80	243.60
Greater than $160,000 and less than or equal to $214,000.	Greater than $320,000 and less than or equal to $428,000.	194.90	316.70
Greater than $214,000	Greater than $428,000	268.00	389.80

In addition, the monthly premium rates to be paid by beneficiaries who are married and lived with their spouse at any time during the taxable year, but file a separate tax return from their spouse, are as follows:

Beneficiaries who are married and lived with their spouse at any time during the year, but file a separate tax return from their spouse:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $85,000	$0.00	$121.80
Greater than $85,000 and less than or equal to $129,000	194.90	316.70
Greater than $129,000	268.00	389.80

The Part B annual deductible for 2016 is $166.00 for all beneficiaries.

The transfer amount is the estimate by the Chief Actuary of the aggregate reduction in premiums payable, separately for enrollees age 65 and older and for enrollees under age 65, as a result of the amendments made by the Bipartisan Budget Act of 2015 (excluding the reduction in the income-related monthly adjustment amounts). The 2016 actuarial rate for enrollees age 65 and older is $237.60, and the actuarial rate portion of the 2016 premium is $118.80. If the only change to the 2016 actuarial rate for enrollees age 65 and older was the absence of the Bipartisan Budget Act amendments, then the 2016 actuarial rate for enrollees age 65 and older would be $318.00, and the actuarial rate portion of the 2016 premium would be $159.00.

The reduction in premiums payable as a result of the Bipartisan Budget Act amendments is estimated separately for—(1) enrollees held harmless; (2) enrollees not held harmless who are age 65 or older; and (3) enrollees not held harmless who are under age 65. All enrollees that are subject to the hold harmless provision will have no reduction in their premiums payable in 2016 as a result of these amendments. (The 2016 monthly premium for enrollees subject to the hold harmless provision in 2016 will be the same as their 2015 monthly premium.) An estimated 11.8 million enrollees age 65 and older (with 10.8 million enrollee years of premium payments) will not be held harmless and will have a reduction in monthly premiums payable from $159.00 to $118.80. Based on this difference in premiums payable and adjusting for the additional premiums payable by individuals subject to the late enrollment penalty (assuming a historical average penalty), the transfer amount for enrollees age 65 and older is $5,237,880,000. An estimated 4.9 million enrollees under age 65 (with 4.6 million enrollee years of premium payments) will not be held harmless and will have a reduction in monthly premiums payable from $159.00 to $118.80. Based on this difference in premiums payable and adjusting for the additional premiums payable by individuals subject to the late enrollment penalty (assuming a historical average penalty), the transfer amount for enrollees under age 65 is $2,202,768,000. The total transfer amount will be $7,440,648,000.

B. Statement of Actuarial Assumptions and Bases Employed in Determining the Monthly Actuarial Rates and the Monthly Premium Rate for Part B Beginning January 2016

Except where noted, the actuarial assumptions and bases used to determine the monthly actuarial rates and the monthly premium rates for Part B are established by the Centers for Medicare & Medicaid Services Office of the Actuary. The estimates underlying these determinations are prepared by actuaries meeting the qualification standards and following the actuarial standards of practice established by the Actuarial Standards Board.

1. Actuarial Status of the Part B Account in the Supplementary Medical Insurance Trust Fund

Under section 1839 of the Act, the starting point for determining the standard monthly premium is the amount that would be necessary to finance Part B on an incurred basis. This is the amount of income that would be sufficient to pay for services furnished during that year (including associated administrative costs) even though payment for some of these services will not be made until after the close of the year. The portion of income required to cover benefits not paid until after the close of the year is added to the trust fund and used when needed.

The premium rates are established prospectively and are, therefore, subject to projection error. Additionally, legislation enacted after the financing was established, but effective for the period in which the financing is set, may affect program costs. As a result, the income to the program may not equal incurred costs. Therefore, trust fund assets must be maintained at a level that is adequate to cover an appropriate degree of variation between actual and projected costs, and the amount of incurred, but unpaid, expenses. Numerous factors determine what level of assets is appropriate to cover variation between actual and projected costs. The three most important of these factors are the: (1) Difference from prior years between the actual performance of the program and estimates made at the time financing was established; (2) likelihood and potential magnitude of expenditure changes resulting from enactment of legislation affecting Part B costs in a year subsequent to the establishment of financing for that year; and (3) expected relationship between incurred and cash expenditures. These factors are analyzed on an ongoing basis, as the trends can vary over time.

Table 1 summarizes the estimated actuarial status of the trust fund as of the end of the financing period for 2014 and 2015.

TABLE 1—ESTIMATED ACTUARIAL STATUS OF THE PART B ACCOUNT IN THE SUPPLEMENTARY MEDICAL INSURANCE TRUST FUND AS OF THE END OF THE FINANCING PERIOD

Financing period ending	Assets ($ in millions)	Liabilities ($ in millions)	Assets less liabilities ($ in millions)
December 31, 2014	68,074	23,716	44,358
December 31, 2015	58,261	23,292	34,969

2. Monthly Actuarial Rate for Enrollees Age 65 and Older

The monthly actuarial rate for enrollees age 65 and older is one-half of the sum of monthly amounts for: (1) The projected cost of benefits; and (2) administrative expenses for each enrollee age 65 and older, after adjustments to this sum to allow for interest earnings on assets in the trust fund and an adequate contingency margin. The contingency margin is an amount appropriate to provide for possible variation between actual and projected costs and to amortize any surplus assets or unfunded liabilities.

The monthly actuarial rate for enrollees age 65 and older for 2016 is determined by first establishing per-enrollee cost by type of service from program data through 2015 and then projecting these costs for subsequent years. The projection factors used for financing periods from January 1, 2013 through December 31, 2016 are shown in Table 2.

As indicated in Table 3, the projected per-enrollee amount required to pay for one-half of the total of benefits and administrative costs for enrollees age 65 and over for 2016 is $227.86. Based on current estimates, the assets at the end of 2015 are not sufficient to cover the amount of incurred, but unpaid, expenses and to provide for a significant degree of variation between actual and projected costs. Thus, a positive contingency margin is needed to increase assets to a more appropriate level. The monthly actuarial rate of $237.60 provides an adjustment of $11.61 for a contingency margin (determined as if the hold harmless provision did not apply for 2016, as required by the Bipartisan Budget Act of 2015) and −$1.87 for interest earnings.

Two other factors affect the contingency margin for 2016. Starting in 2011, manufacturers and importers of brand-name prescription drugs have paid a fee that is allocated to the Part B account of the SMI trust. For 2016, the total of these brand-name drug fees is estimated to be $3.0 billion. The contingency margin has been reduced to account for this additional revenue.

Another factor impacting the contingency margin comes from the requirement that certain payment incentives, to encourage the development and use of health information technology (HIT) by Medicare physicians, are to be excluded from the premium determination. HIT positive incentive payments or penalties will be directly offset through transfers with the general fund of the Treasury. The monthly actuarial rate includes an adjustment of −$0.36 for HIT positive incentive payments in 2016.

The traditional goal for the Part B reserve has been that assets minus liabilities at the end of a year should represent between 15 and 20 percent of the following year's total incurred expenditures. To accomplish this goal, a 17 percent reserve ratio has been the normal target used to calculate the Part B premium.

The contingency margin included in establishing the 2016 actuarial rate of $237.60 per month for aged beneficiaries, as announced in this notice, is projected to fully restore the Part B assets under the projection assumptions listed in Table 2.

3. Monthly Actuarial Rate for Disabled Enrollees

Disabled enrollees are those persons under age 65 who are enrolled in Part B because of entitlement to Social Security disability benefits for more than 24 months or because of entitlement to Medicare under the end-stage renal disease (ESRD) program. Projected monthly costs for disabled enrollees (other than those with ESRD)

are prepared in a fashion parallel to the projection for the aged using appropriate actuarial assumptions (see Table 2). Costs for the ESRD program are projected differently because of the different nature of services offered by the program.

As shown in Table 4, the projected per-enrollee amount required to pay for one-half of the total of benefits and administrative costs for disabled enrollees for 2016 is $272.94. The monthly actuarial rate of $282.60 also provides an adjustment of −$2.86 for interest earnings and $12.52 for a contingency margin, reflecting the same factors described previously for the aged actuarial rate at magnitudes appropriate to the disabled rate determination. Based on current estimates, the assets associated with the disabled Medicare beneficiaries at the end of 2015 are not sufficient to cover the amount of incurred, but unpaid, expenses and to provide for a significant degree of variation between actual and projected costs. Thus, a positive contingency margin is needed to increase assets to an appropriate level.

The actuarial rate of $282.60 per month for disabled beneficiaries, as announced in this notice for 2016, reflects the combined net effect of the factors described previously for aged beneficiaries and the projection assumptions listed in Table 2.

4. Sensitivity Testing

Several factors contribute to uncertainty about future trends in medical care costs. It is appropriate to test the adequacy of the rates using alternative cost growth rate assumptions. The results of those assumptions are shown in Table 5. One set represents increases that are higher and, therefore, more pessimistic than the current estimate. The other set represents increases that are lower and, therefore, more optimistic than the current estimate. The values for the alternative assumptions were determined from a statistical analysis of the historical variation in the respective increase factors.

As indicated in Table 5, the monthly actuarial rates would result in an excess of assets over liabilities of $53,052 million by the end of December 2016 under the cost growth rate assumptions shown in Table 2 and assuming that the provisions of current law are fully implemented. This amounts to 17.0 percent of the estimated total incurred expenditures for the following year.

Assumptions that are somewhat more pessimistic (and that therefore test the adequacy of the assets to accommodate projection errors) produce a surplus of $8,962 million by the end of December 2016 under current law, which amounts to 2.5 percent of the estimated total incurred expenditures for the following year. Under fairly optimistic assumptions, the monthly actuarial rates would result in a surplus of $94,727 million by the end of December 2016, or 34.9 percent of the estimated total incurred expenditures for the following year.

The sensitivity analysis indicates that the premium and general revenue financing established for 2016, together with existing Part B account assets would be adequate to cover estimated Part B costs for 2016 under current law, even if actual costs prove to be somewhat greater than expected.

5. Premium Rates and Deductible

As determined in accordance with section 1839 of the Act, listed are the 2016 Part B monthly premium rates to be paid by beneficiaries who file an individual tax return (including those who are single, head of household, qualifying widow(er) with dependent child, or married filing separately who lived apart from their spouse for the entire taxable year), or a joint tax return.

Beneficiaries who file an individual tax return with income:	Beneficiaries who file a joint tax return with income:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $85,000	Less than or equal to $170,000	$0.00	$121.80
Greater than $85,000 and less than or equal to $107,000.	Greater than $170,000 and less than or equal to $214,000.	48.70	170.50
Greater than $107,000 and less than or equal to $160,000.	Greater than $214,000 and less than or equal to $320,000.	121.80	243.60
Greater than $160,000 and less than or equal to $214,000.	Greater than $320,000 and less than or equal to $428,000.	194.90	316.70
Greater than $214,000	Greater than $428,000	268.00	389.80

In addition, the monthly premium rates to be paid by beneficiaries who are married and lived with their spouse at any time during the taxable year, but file a separate tax return from their spouse, are listed as follows:

Beneficiaries who are married and lived with their spouse at any time during the year, but file a separate tax return from their spouse:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $85,000	$0.00	$121.80
Greater than $85,000 and less than or equal to $129,000	194.90	316.70
Greater than $129,000	268.00	389.80

TABLE 2—PROJECTION FACTORS [1] 12-MONTH PERIODS ENDING DECEMBER 31 OF 2013–2016

[In percent]

Calendar year	Physicians' services		Durable medical equipment	Carrier lab [4]	Other carrier services [5]	Outpatient hospital	Home health agency	Hospital lab [6]	Other inter-mediary services [7]	Managed care
	Fees [2]	Residual [3]								
Aged:										
2013	−0.1	0.2	−10.3	0.1	2.6	7.4	−0.7	−0.7	−0.6	1.4

TABLE 2—PROJECTION FACTORS [1] 12-MONTH PERIODS ENDING DECEMBER 31 OF 2013–2016—Continued

[In percent]

Calendar year	Physicians' services		Durable medical equipment	Carrier lab [4]	Other carrier services [5]	Outpatient hospital	Home health agency	Hospital lab [6]	Other intermediary services [7]	Managed care
	Fees [2]	Residual [3]								
2014	0.5	0.8	−14.4	6.6	2.8	12.7	−1.3	−28.8	4.7	7.0
2015	−0.4	−0.6	4.8	4.4	3.9	5.2	−0.3	4.1	5.7	2.2
2016	0.1	1.2	−5.8	4.6	1.6	4.1	1.6	3.9	4.8	2.8
Disabled:										
2013	−0.1	1.4	−9.2	10.8	1.1	7.0	3.9	−1.8	1.7	4.0
2014	0.5	2.5	−10.8	14.0	4.6	14.4	−1.1	−35.4	8.3	9.2
2015	−0.4	−0.8	4.4	6.5	4.8	5.6	−0.3	2.9	7.8	0.7
2016	0.1	1.3	−5.7	4.7	1.4	4.1	2.0	3.9	5.1	2.6

[1] All values for services other than managed care are per fee-for-service enrollee. Managed care values are per managed care enrollee.
[2] As recognized for payment under the program.
[3] Increase in the number of services received per enrollee and greater relative use of more expensive services.
[4] Includes services paid under the lab fee schedule furnished in the physician's office or an independent lab.
[5] Includes physician-administered drugs, ambulatory surgical center facility costs, ambulance services, parenteral and enteral drug costs, supplies, etc.
[6] Includes services paid under the lab fee schedule furnished in the outpatient department of a hospital.
[7] Includes services furnished in dialysis facilities, rural health clinics, Federally qualified health centers, rehabilitation, and psychiatric hospitals, etc.

TABLE 3—DERIVATION OF MONTHLY ACTUARIAL RATE FOR ENROLLEES AGE 65 AND OVER FOR FINANCING PERIODS ENDING DECEMBER 31, 2013 THROUGH DECEMBER 31, 2016

[In dollars]

	CY 2013	CY 2014	CY 2015	CY 2016
Covered services (at level recognized):				
Physician fee schedule	78.23	77.10	74.44	74.40
Durable medical equipment	7.29	6.07	6.21	5.77
Carrier lab [1]	4.21	4.37	4.45	4.60
Other carrier services [2]	22.07	22.06	22.36	22.43
Outpatient hospital	37.87	41.49	42.57	43.74
Home health	10.15	9.75	9.47	9.50
Hospital lab [3]	3.27	2.26	2.30	2.36
Other intermediary services [4]	16.53	16.83	17.35	17.95
Managed care	65.60	74.26	79.49	83.65
Total services	245.22	254.20	258.64	264.39
Cost sharing:				
Deductible	−5.63	−5.63	−5.64	−6.36
Coinsurance	−29.17	−28.38	−28.84	−28.26
Sequestration of benefits	−3.17	−4.40	−4.48	−4.59
HIT payment incentives	−2.04	−2.40	−0.43	−0.36
Total benefits	205.20	213.38	219.25	224.82
Administrative expenses	2.77	3.49	3.00	3.05
Incurred expenditures	207.97	216.87	222.25	227.86
Value of interest	−1.80	−1.93	−1.73	−1.87
Contingency margin for projection error and to amortize the surplus or deficit	3.63	−5.14	−10.72	11.61
Monthly actuarial rate	209.80	209.80	209.80	237.60

[1] Includes services paid under the lab fee schedule furnished in the physician's office or an independent lab.
[2] Includes physician-administered drugs, ambulatory surgical center facility costs, ambulance services, parenteral and enteral drug costs, supplies, etc.
[3] Includes services paid under the lab fee schedule furnished in the outpatient department of a hospital.
[4] Includes services furnished in dialysis facilities, rural health clinics, Federally qualified health centers, rehabilitation and psychiatric hospitals, etc.

TABLE 4—DERIVATION OF MONTHLY ACTUARIAL RATE FOR DISABLED ENROLLEES FOR FINANCING PERIODS ENDING DECEMBER 31, 2013 THROUGH DECEMBER 31, 2016

[In dollars]

	CY 2013	CY 2014	CY 2015	CY 2016
Covered services (at level recognized):				
Physician fee schedule	83.88	83.87	80.07	79.56
Durable medical equipment	13.88	11.99	12.08	11.15
Carrier lab [1]	6.54	7.21	7.42	7.61
Other carrier services [2]	25.26	25.43	25.55	25.42
Outpatient hospital	54.25	60.32	61.47	62.72
Home health	9.18	8.79	8.45	8.43

TABLE 4—DERIVATION OF MONTHLY ACTUARIAL RATE FOR DISABLED ENROLLEES FOR FINANCING PERIODS ENDING DECEMBER 31, 2013 THROUGH DECEMBER 31, 2016—Continued

[In dollars]

	CY 2013	CY 2014	CY 2015	CY 2016
Hospital lab [3]	4.64	2.87	2.86	2.91
Other intermediary services [4]	44.34	44.87	45.36	46.37
Managed care	55.05	65.50	72.71	78.31
Total services	297.03	310.86	315.95	322.46
Cost sharing:				
Deductible	−5.29	−5.29	−5.30	−5.97
Coinsurance	−44.36	−43.31	−42.74	−41.32
Sequestration of benefits	−3.73	−5.24	−5.36	−5.50
HIT payment incentives	−2.13	−2.58	−0.45	−0.39
Total benefits	241.52	254.43	262.10	269.28
Administrative expenses	3.26	4.16	3.59	3.65
Incurred expenditures	244.78	258.59	265.69	272.94
Value of interest	−3.47	−2.50	−1.88	−2.86
Contingency margin for projection error and to amortize the surplus or deficit	−5.81	−37.19	−9.01	12.52
Monthly actuarial rate	235.50	218.90	254.80	282.60

[1] Includes services paid under the lab fee schedule furnished in the physician's office or an independent lab.
[2] Includes physician-administered drugs, ambulatory surgical center facility costs, ambulance services, parenteral and enteral drug costs, supplies, etc.
[3] Includes services paid under the lab fee schedule furnished in the outpatient department of a hospital.
[4] Includes services furnished in dialysis facilities, rural health clinics, Federally qualified health centers, rehabilitation and psychiatric hospitals, etc.

TABLE 5—ACTUARIAL STATUS OF THE PART B ACCOUNT IN THE SMI TRUST FUND UNDER THREE SETS OF ASSUMPTIONS FOR FINANCING PERIODS THROUGH DECEMBER 31, 2016

As of December 31,	2014	2015	2016
Actuarial status (in $ millions):			
Assets	68,074	58,261	76,806
Liabilities	23,716	23,292	23,754
Assets less liabilities	44,358	34,969	53,052
Ratio (in percent) [1]	15.9	11.9	17.0
Low cost projection:			
Actuarial status (in $ millions):			
Assets	68,0741	73,027	117,319
Liabilities	23,716	21,651	22,592
Assets less liabilities	44,358	51,376	94,727
Ratio (in percent) [1]	16.9	19.3	34.9
High cost projection:			
Actuarial status (in $ millions):			
Assets	68,074	43,044	34,020
Liabilities	23,716	24,982	25,058
Assets less liabilities	44,358	18,062	8,962
Ratio (in percent) [1]	15.0	5.6	2.5

[1] Ratio of assets less liabilities at the end of the year to the total incurred expenditures during the following year, expressed as a percent.

III. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

IV. Regulatory Impact Analysis

A. Statement of Need

Section 1839 of the Act requires us to annually announce (that is by September 30th of each year) the Part B monthly actuarial rates for aged and disabled beneficiaries as well as the monthly Part B premium. We also announce the Part B annual deductible because its determination is directly linked to the aged actuarial rate.

B. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Public Law 96–354), section 1102(b) of the Social Security Act, section 202 of the

Unfunded Mandates Reform Act of 1995 (March 22, 1995, Public Law 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 notices with economically significant effects ($100 million or more in any 1 year). For 2016 approximately 70 percent of Part B enrollees will be held harmless and pay no increase in their Part B premium, but the standard Part B premium rate, the Part B income-related premium rates, and the Part B deductible are higher than the respective amounts for 2015 and have an annual effect on the economy of $100 million or more. As a result, this notice is economically significant under section 3(f)(1) of Executive Order 12866 and is a major action as defined under the Congressional Review Act (5 U.S.C. 804(2)).

As discussed earlier, this notice announces that the monthly actuarial rates applicable for 2016 are $237.60 for enrollees age 65 and over and $282.60 for disabled enrollees under age 65. It also announces the 2016 monthly Part B premium rates to be paid by beneficiaries who file an individual tax return (including those who are single, head of household, qualifying widow(er) with a dependent child, or married filing separately who lived apart from their spouse for the entire taxable year), or a joint tax return.

Beneficiaries who file an individual tax return with income:	Beneficiaries who file a joint tax return with income:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $85,000	Less than or equal to $170,000	$0.00	$121.80
Greater than $85,000 and less than or equal to $107,000.	Greater than $170,000 and less than or equal to $214,000.	48.70	170.50
Greater than $107,000 and less than or equal to $160,000.	Greater than $214,000 and less than or equal to $320,000.	121.80	243.60
Greater than $160,000 and less than or equal to $214,000.	Greater than $320,000 and less than or equal to $428,000.	194.90	316.70
Greater than $214,000	Greater than $428,000	268.00	389.80

In addition, the monthly premium rates to be paid by beneficiaries who are married and lived with their spouse at any time during the taxable year, but file a separate tax return from their spouse, are also announced and listed in the following chart:

Beneficiaries who are married and lived with their spouse at any time during the year, but file a separate tax return from their spouse:	Income-related monthly adjustment amount	Total monthly premium amount
Less than or equal to $85,000	$0.00	$121.80
Greater than $85,000 and less than or equal to $129,000	194.90	316.70
Greater than $129,000	268.00	389.80

The RFA requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Individuals and States are not included in the definition of a small entity. This notice announces the monthly actuarial rates for aged (age 65 and over) and disabled (under 65) beneficiaries enrolled in Part B of the Medicare SMI program beginning January 1, 2016. Also, this notice announces the monthly premium for aged and disabled beneficiaries as well as the income-related monthly adjustment amounts to be paid by beneficiaries with modified adjusted gross income above certain threshold amounts. As a result, we are not preparing an analysis for the RFA because the Secretary has determined that this notice will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. As we discussed previously, we are not preparing an analysis for section 1102(b) of the Act because the Secretary has determined that this notice will not have a significant effect on a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1-year of $100 million in 1995 dollars, updated annually for inflation. In 2015, that threshold is approximately $144 million. Part B enrollees who are also enrolled in Medicaid have their monthly Part B premiums paid by Medicaid. The 2016 premium increase is estimated to be a cost to the state Medicaid programs that is less than $144 million per state. This notice does not impose mandates that will have a consequential effect of $144 million or more on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it publishes a proposed rule (and subsequent final rule) that imposes substantial direct compliance costs on State and local governments, preempts State law, or otherwise has

Federalism implications. We have determined that this notice does not significantly affect the rights, roles, and responsibilities of States. Accordingly, the requirements of Executive Order 13132 do not apply to this notice.

In accordance with the provisions of Executive Order 12866, this notice was reviewed by the Office of Management and Budget.

V. Waiver of Proposed Notice

The Medicare statute requires the publication of the monthly actuarial rates and the Part B premium amounts in September. We ordinarily use general notices, rather than notice and comment rulemaking procedures, to make such announcements. In doing so, we note that, under the Administrative Procedure Act, interpretive rules, general statements of policy, and rules of agency organization, procedure, or practice are excepted from the requirements of notice and comment rulemaking.

We considered publishing a proposed notice to provide a period for public comment. However, we may waive that procedure if we find, for good cause, that prior notice and comment are impracticable, unnecessary, or contrary to the public interest. The statute establishes the time period for which the premium rates will apply, and delaying publication of the Part B premium rate such that it would not be published before that time would be contrary to the public interest. Moreover, we find that notice and comment are unnecessary because the formulas used to calculate the Part B premiums are statutorily directed. Therefore, we find good cause to waive publication of a proposed notice and solicitation of public comments.

Dated: November 6, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: November 9, 2015.

Sylvia M. Burwell,

Secretary. Department of Health and Human Services.

[FR Doc. 2015–29181 Filed 11–10–15; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3972]

Eighth Annual Sentinel Initiative; Public Workshop; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public workshop entitled ''Eighth Annual Sentinel Initiative Public Workshop.'' Convened by the Center for Health Policy at the Brookings Institution and supported by a cooperative agreement with FDA, this 1-day workshop will bring the stakeholder community together to discuss a variety of topics on active medical product surveillance. Topics will include an update on the state of FDA's Sentinel Initiative, including an overview of the transition from the Mini-Sentinel pilot to the full Sentinel System, and key activities and uses of the Sentinel System accomplished in 2015. In addition, panelists will discuss the future of the Sentinel System and opportunities to expand its medical product surveillance capabilities. This workshop will also engage stakeholders to discuss current and emerging Sentinel projects.

DATES: The public workshop will be held on February 3, 2016, from 9 a.m. to 4 p.m., Eastern Standard Time (EST).

Location: The public workshop will be held at the Renaissance Washington, DC Dupont Circle Hotel, 1143 New Hampshire Ave. NW., Washington, DC 20037. For additional travel and hotel information, please refer to *http://www.eventbrite.com/e/sentinel-public-event-2016-tickets-19294863456.* (FDA has verified the Web site addresses throughout this notice, but FDA is not responsible for subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

There will also be a live webcast for those unable to attend the meeting in person (see *Streaming Webcast of the Public Workshop*).

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–N–3972 for ''Eighth Annual Sentinel Initiative; Public Workshop.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the

claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR MORE INFORMATION CONTACT: Carlos Bell, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4343, Silver Spring, MD 20993–0002, 301–796–3714, FAX: 301–796–9832, email: *SentinelInitiative@fda.hhs.gov.*

Registration: To attend the public workshop, you must register before February 3, 2016, by visiting *http://www.eventbrite.com/e/sentinel-public-event-2016-tickets-19294863456.* You may also register for the live webcast by visiting this Web page. There will be no onsite registration. When registering, please provide the following information: Your name, title, company or organization (if applicable), postal address, telephone number, and email address. Those without Internet access should contact Carlos Bell to register (see **FOR MORE INFORMATION CONTACT**). There is no registration fee for the public workshop. However, registration will be on a first-come, first-served basis because seating is limited. Therefore, early registration is recommended. A 1-hour lunch break is scheduled, but food will not be provided. There are multiple restaurants within walking distance of the Renaissance Washington, DC Dupont Circle Hotel.

If you need special accommodations due to a disability, please contact Joanna Klatzman at the Brookings Institution (phone: 813–586–1201, email: *jklatzman@brookings.edu*) at least 7 days in advance.

Streaming Webcast of the Public Workshop: This public workshop will also be webcast (archived video footage will be available following the workshop). Persons interested in viewing the live webcast must register online by February 2, 2016, at 5 p.m. EST. Early registration is recommended because webcast connections are limited. Organizations are requested to register all participants but to view using one connection per location whenever possible. Webcast participants will be sent technical system requirements in advance of the event. Prior to joining the streaming webcast of the public workshop, it is recommended that you review these technical system requirements.

Meeting Materials: All event materials will be available to registered attendees via email before the workshop at the Eventbrite Web site at *http://www.eventbrite.com/e/sentinel-public-event-2016-tickets-19294863456.*

Transcripts: Please be advised that transcripts will not be available.

Dated: November 9, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–28851 Filed 11–13–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0986]

Center for Devices and Radiological Health: Experiential Learning Program; General Training Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH or Center) is announcing the 2015 Experiential Learning Program (ELP) General Training Program. This training component is intended to provide CDRH staff with an opportunity to understand the policies, laboratory practices, and challenges faced in broader disciplines that impact the device development life cycle. The purpose of this document is to invite medical device industry, academia, and health care facilities to request to participate in this formal training program for FDA's medical device review staff, or to contact CDRH for more information regarding the ELP General Training Program.

DATES: Submit either an electronic or written request for participation in the ELP General Training Program by December 16, 2015.

ADDRESSES: Submit either electronic requests to *http://www.regulations.gov* or written requests to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify proposals with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Latonya Powell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5232, Silver Spring, MD 20993–0002, 301–796–6965, FAX: 301–827–3079, *Latonya.powell@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

CDRH is responsible for helping to ensure the safety and effectiveness of medical devices marketed in the United States. Furthermore, CDRH assures that patients and providers have timely and continued access to high-quality, safe, and effective medical devices. In support of this mission, the Center launched various training and development initiatives to enhance performance of its staff involved in regulatory review and in the premarket review process. One of these initiatives, the ELP Pilot, was launched in 2012 and fully implemented on April 2, 2013 (78 FR 19711).

CDRH is committed to advancing regulatory science; providing industry with predictable, consistent, transparent, and efficient regulatory pathways; and helping to ensure consumer confidence in medical devices marketed in the United States and throughout the world. The ELP General Training Program component is intended to provide CDRH staff with an opportunity to understand the policies, laboratory practices, and challenges faced in broader disciplines that impact the device development life cycle. This component is a collaborative effort to enhance communication and facilitate the premarket review process. Furthermore, CDRH is committed to understanding current industry practices, innovative technologies, regulatory impacts, and regulatory needs.

These formal training visits are not intended for FDA to inspect, assess,

judge, or perform a regulatory function (*e.g.*, compliance inspection), but rather, they are an opportunity to provide CDRH review staff a better understanding of the products they review. Through this notice, CDRH is formally requesting participation from companies, academia, and clinical facilities, including those that have previously participated in the ELP or other FDA site visit programs.

II. CDRH ELP General Training Program

A. Areas of Interest

In this training program, groups of CDRH staff will observe operations at research, manufacturing, academia, and health care facilities. The focus areas and specific areas of interest for visits may include the following:

TABLE 1—AREAS OF INTEREST—OFFICE OF DEVICE EVALUATION

Focus area	Specific areas of interest
Biocompatibility testing	Decision making process for biocompatibility evaluation and test selection (if needed); considerations for use of animal testing vs. in vitro testing; sample preparation of nanoscale, bioabsorbable, and in situ polymerized materials; evaluation of color additives.
Combination products	Devices coated with drug(s) or biologic(s); drug/biologic delivery products.
Emerging manufacturing methods	3-D printing; additive manufacturing; additional or unique validation and verification activities.
Management of clinical trials for medical devices.	Conducting clinical trials, overcoming common obstacles to starting and completing clinical trials, and interacting with various other stakeholders; preparing applications to request approval to conduct Investigational Device Exemption (IDE) clinical studies and responding to feedback received from FDA.
Reprocessing and sterilization	Reprocessing challenges in clinical environment, including techniques for understanding and incorporating these challenges from the clinical environment to labeling and validation studies; techniques for validating cleaning, disinfection, or sterilization instructions; challenges in validating cleaning, disinfection, or sterilization instructions; simulated use testing, particularly for validating sterilization methods and instructions; unique sterilization methods (*e.g.*, use of flexible bags, mixed sterilants sound waves, ultraviolet light, microwave radiation).

TABLE 2—AREAS OF INTEREST—OFFICE OF IN VITRO DIAGNOSTIC DEVICES AND RADIOLOGICAL HEALTH

Focus area	Specific areas of interest
Manufacturing of in vitro diagnostic devices.	Pre-analytical devices (*i.e.*, blood tubes), pathogen collection devices, micro collection/transport devices; general reagents, manual reagents; general assays, common point-of-care devices.
Instrument training of medical devices (manufacturer or clinical laboratory).	Hands-on instrument and system training; clinical implication of common laboratory testing; hands on familiarization of medical imaging equipment in a hospital setting.
Quality system in manufacturing environments based on 21 CFR part 820.	Observation of implemented quality systems practices based on current Good Manufacturing Practices; the manufacturing of medical imaging or therapeutic radiology technologies.

B. Site Selection

CDRH will be responsible for CDRH staff travel expenses associated with the site visits. CDRH will not provide funds to support the training provided by the site to this ELP General Training Program. Selection of potential facilities will be based on CDRH's priorities for staff training and resources available to fund this program. In addition to logistical and other resource factors, all sites must have a successful compliance record with FDA or another Agency with which FDA has a memorandum of understanding. If a site visit involves a visit to a separate physical location of another firm under contract with the site, that firm must agree to participate in the ELP General Training program and must also have a satisfactory compliance history.

III. Request To Participate

Submit proposals for participation with the docket number found in the brackets in the heading of this document. Received requests may be seen in the Division of Dockets Management (see **ADDRESSES**) between 9 a.m. and 4 p.m., Monday through Friday.

The proposal should include a description of your facility relative to focus areas described in tables 1 or 2. Please include the Area of Interest (see tables 1 or 2) that the site visit will demonstrate to CDRH staff, a contact person, site visit location(s), length of site visit, proposed dates, and maximum number of CDRH staff that can be accommodated during a site visit. Proposals submitted without this minimum information will not be considered. In addition, please include an agenda outlining the proposed training for the site visit. A sample request and agenda are available on the ELP Web site at *http://www.fda.gov/downloads/ScienceResearch/ScienceCareerOpportunities/UCM392988.pdf* and *http://www.fda.gov/scienceresearch/sciencecareeropportunities/ucm380676.htm.*

Dated: November 5, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–28857 Filed 11–13–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1977–N–0356 (Formerly 77N–0240); DESI 1786]

Drugs for Human Use; Drug Efficacy Study Implementation; Nitroglycerin Transdermal Systems; Withdrawal of Hearing Request; Withdrawal of Applications; Final Resolution of Hearing Requests Regarding Transdermal Systems Under Docket

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing that all outstanding hearing requests regarding nitroglycerin drug

products in transdermal systems under Docket No. FDA–1977–N–0356 (formerly 77N–0240) (DESI 1786) have been withdrawn. Therefore, shipment in interstate commerce of any nitroglycerin drug product in a transdermal system identified in this docket, or any identical, related, or similar (IRS) product, that is not the subject of an approved new drug application (NDA) or abbreviated new drug application (ANDA) is unlawful as of the effective date of this notice.

DATES: *Effective Date:* This notice is effective November 16, 2015.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov*.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–1977–N–0356 for ''Drugs for Human Use; Drug Efficacy Study Implementation; Nitroglycerin Transdermal Systems; Withdrawal of Hearing Request; Withdrawal of Applications; Final Resolution of Hearing Requests Regarding Transdermal Systems Under Docket.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov*. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm*.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Barbara Wise, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 5160, Silver Spring, MD 20993–0002, 301–796–2089, email: *Barbara.Wise@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

When enacted in 1938, the Federal Food, Drug, and Cosmetic Act (the FD&C Act) required that ''new drugs'' (21 U.S.C. 321(p)) be approved for safety by FDA before they could legally be sold in interstate commerce. Between 1938 and 1962, if a drug obtained approval, FDA considered drugs that were IRS (see 21 CFR 310.6(b)(1)) to the approved drug to be covered by that approval, and allowed those IRS drugs to be marketed without independent approval.

In 1962, Congress amended the FD&C Act to require that new drugs be proven effective for their labeled indications, as well as safe, in order to obtain FDA approval. This amendment also required FDA to conduct a retrospective evaluation of the effectiveness of the drug products that FDA had approved as safe between 1938 and 1962. FDA contracted with the National Academy of Science/National Research Council (NAS/NRC) to make an initial evaluation of the effectiveness of over 3,400 products that had been approved only for safety between 1938 and 1962. The NAS/NRC reports for these drug products were submitted to FDA in the late 1960s and early 1970s. The Agency reviewed and reevaluated the reports and published its findings in **Federal Register** notices. FDA's administrative implementation of the NAS/NRC reports was called the Drug Efficacy Study Implementation (DESI). DESI covered the approximately 3,400 products specifically reviewed by the NAS/NRC, as well as the even larger number of IRS products that entered the market without FDA approval.

All drugs reviewed under DESI are ''new drugs'' under the FD&C Act. If FDA's final DESI determination classifies a drug product as lacking substantial evidence of effectiveness for one or more indications, that drug product and those IRS to it may no longer be marketed for such indications and are subject to enforcement action as unapproved new drugs. If FDA's final DESI determination classifies the drug product as effective for one or more of its labeled indications, the drug can be marketed for such indications, provided it is the subject of an application approved for safety and effectiveness. Sponsors of drug products that have been found to be effective for one or more indications through the DESI process may rely on FDA's effectiveness

determinations, but typically must update their labeling to conform to the indication(s) found to be effective by FDA and include any additional safety information required by FDA. Those drug products with NDAs approved before 1962 for safety therefore require approved supplements to their original applications if one or more indications are found to be effective under DESI; IRS drug products require an approved NDA or ANDA, as appropriate. Furthermore, labeling for drug products classified as effective may contain only those indications for which the review found the product effective unless the firm marketing the product has received an approval for the additional indication(s).

II. Final Resolution of Hearing Requests Regarding Nitroglycerin Transdermal Systems Under Docket No. FDA–1977–N–0356 (formerly 77N–0240); DESI 1786

In a **Federal Register** notice published in February 1972, FDA announced its evaluation of reports received from NAS/NRC regarding certain single-entity coronary vasodilators, including controlled-release nitroglycerin tablets, for indications relating to the management, prophylaxis, and treatment of angina attacks (37 FR 4001, February 25, 1972). In a **Federal Register** notice published in December 1972, FDA temporarily exempted specified single-entity coronary vasodilators covered by DESI from the time limits established for completing DESI (37 FR 26623 at 26624, December 14, 1972). The December 1972 notice did not initially include controlled-release forms of the drugs, but a notice published in July 1973 allowed the case-by-case addition of controlled-release dosage forms, pending the completion of scientific studies that showed a drug was released in a defined manner which would permit well-controlled clinical trials to determine effectiveness (38 FR 18477, 18478, July 11, 1973; corrected by 38 FR 19920, July 25, 1973).

The December 1972 notice was amended again in August 1977, to announce the addition of controlled-release forms of specified coronary vasodilators, and the availability of guidelines and methods for determining the bioavailability of coronary vasodilators (42 FR 43127, August 26, 1977). The August 1977 notice specifically added nitroglycerin (topical ointment forms, conventional oral forms, and controlled release forms) to the list of drugs allowed to remain on the market while efficacy studies were conducted (42 FR 43127 at 43128). The December 1972 notice was further amended in October 1977, to extend the deadlines for submission of data and applications required for the coronary vasodilator products, and to announce the availability of guidelines for alternative methods of determining bioavailability for these products (42 FR 56156, October 21, 1977). Controlled-release transdermal nitroglycerin patches were included among the types of drugs permitted to remain on the market pending completion of efficacy studies based on their similarity to nitroglycerin ointment products (58 FR 38129 at 38130, July 15, 1993).

In July 1993, FDA revoked the temporary exemption for single-entity coronary vasodilator products containing nitroglycerin in a transdermal delivery system, which had allowed the products to stay on the market beyond the time limit scheduled for the implementation of DESI (58 FR 38129). FDA found the products to be effective for prevention of angina pectoris caused by coronary artery disease, and required sponsors to submit bioavailability/bioequivalence studies within 1 year (see 58 FR 38129 at 38130 to 38131). In March 1999, FDA reclassified one NDA and five ANDAs for nitroglycerin transdermal systems to lacking substantial evidence of effectiveness, based on the sponsors' failure to submit the required bioavailability/bioequivalence data (64 FR 14451, March 25, 1999). In the March 1999 notice, FDA proposed to withdraw approval of the applications and offered an opportunity for a hearing on the proposal to withdraw the applications.

In response to the March 1999 notice, Schwarz Pharma, Inc. (Schwarz Pharma), now a subsidiary of UCB, S.A., which was the sponsor of two of the five ANDAs, and Hercon Laboratories Corp. (Hercon), which was the sponsor of the remaining three ANDAs, requested hearings.[1] G.D. Searle & Co., which was the sponsor of the identified NDA, did not submit a hearing request.

At the request of Hercon, in the **Federal Register** of March 4, 2005 (70 FR 10651 at 10656), FDA withdrew approval of Hercon's three ANDAs that were the subject of the 1999 notice of opportunity for a hearing. On January 10, 2011, FDA sent a letter to Hercon to determine whether it remained interested in pursuing its hearing request. On February 9, 2011, Hercon responded by withdrawing its hearing request. On July 17, 2002, Schwarz Pharma withdrew its hearing request and requested withdrawal of its ANDAs that were the subject of the 1999 notice of opportunity for a hearing.

There are no longer outstanding hearing requests for nitroglycerin drug products in transdermal systems under this docket. Therefore, as proposed in the March 1999 notice of opportunity for hearing, FDA finds that the following applications lack substantial evidence of effectiveness and hereby withdraws approval of the applications under section 505(e) of the FD&C Act (21 U.S.C. 355): ANDA 88–727, DEPONIT (release rate of 0.2 mg of nitroglycerin per hour), held by Schwarz Pharma; ANDA 89–022, DEPONIT (release rate of 0.4 mg of nitroglycerin per hour), held by Schwarz Pharma; and NDA 20–146, NITRODISC, held by G.D. Searle & Co. Shipment in interstate commerce of any nitroglycerin drug product in a transdermal system identified in this docket, or any IRS product, that is not the subject of an approved NDA or ANDA is unlawful as of the effective date of this notice (see **DATES**). Any person who wishes to determine whether a specific product is covered by this notice should write to Barbara Wise at the Center for Drug Evaluation and Research (see **FOR FURTHER INFORMATION CONTACT**). Firms should be aware that, after the effective date of this notice (see **DATES**), FDA intends to take enforcement action without further notice against any firm that manufactures or ships in interstate commerce any unapproved product covered by this notice.

III. Discontinued Products

Firms must notify the Agency of certain product discontinuations in writing under section 506C(a) of the FD&C Act (21 U.S.C. 356c). See *http://www.fda.gov/Drugs/DrugSafety/DrugShortages/ucm142398.htm.* Some firms may have previously discontinued manufacturing or distributing products covered by this notice without discontinuing the listing as required under section 510(j) of the FD&C Act (21 U.S.C. 360(j)). Other firms may discontinue manufacturing or distributing listed products in response to this notice. All firms are required to electronically update the listing of their products under section 510(j) of the FD&C Act to reflect discontinuation of unapproved products covered by this notice (21 CFR 207.21(b)). Questions on electronic drug listing updates should be sent to *eDRLS@fda.hhs.gov.* In addition to the required update, firms can also notify the Agency of product discontinuation by sending a letter, signed by the firm's chief executive officer and fully identifying the

[1] The March 1999 notice incorrectly referred to Hercon as ''Hercon Pharmaceutical Company, Inc.''

discontinued product(s), including the product NDC number(s), and stating that the manufacturing and/or distribution of the product(s) have been discontinued. The letter should be sent electronically to Barbara Wise (see **FOR FURTHER INFORMATION CONTACT**). FDA plans to rely on its existing records, including its drug listing records, the results of any future inspections, or other available information, when it targets violative products for enforcement action.

IV. Reformulated Products

FDA cautions firms against reformulating products into unapproved new drugs and marketing under the same name or substantially the same name (including a new name that contains the old name). Reformulated products marketed under a name previously identified with a different active ingredient or combinations of active ingredients have the potential to confuse health care practitioners and harm patients.

Dated: November 9, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–28853 Filed 11–13–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee; Amendment of Notice

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is canceling the November 18, 2015, session and postponing the November 19, 2015, session of the Gastroenterology and Urology Devices Panel meeting. The meeting was announced in the **Federal Register** of October 7, 2015 (80 FR 60686). The November 19, 2015, session has been postponed due to the cancellation of the November 18, 2015, meeting. Future meeting dates will be announced in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Patricio Garcia, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1535, Silver Spring MD 20993–0002, *patricio.garcia@fda.hhs.gov,* 301–796–6875, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington DC area), and follow the prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting.

Dated: November 9, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–28846 Filed 11–13–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–N–0394]

Request for Nominations for Voting Members on a Public Advisory Committee; Tobacco Products Scientific Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on the Tobacco Products Scientific Advisory Committee, Office of Science, Center for Tobacco Products.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore encourages nominations of appropriately qualified candidates from these groups.

DATES: Nominations received on or before January 15, 2016 will be given first consideration for membership on the Tobacco Products Scientific Advisory Committee. Nominations received after January 15, 2016 will be considered for nomination to the committee as later vacancies occur.

ADDRESSES: All nominations for membership should be sent electronically by logging into the FDA Advisory Committee Membership Nomination Portal: *http://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm* or by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002.

FOR FURTHER INFORMATION CONTACT: Regarding all nomination questions for membership, the primary contact is:

Caryn Cohen, Office of Science, Center for Tobacco Products, Food and Drug Administration, Center for Tobacco Products, Document Control Center, Building 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 1–877–287–1373 (choose Option 5), FAX: 240–276–3655, *TPSAC@fda.hhs.gov*.

Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's Web site by using the following link: *http://www.fda.gov/AdvisoryCommittees/default.htm.*

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting members on the Tobacco Products Scientific Advisory Committee.

I. General Description of the Committee Duties

The Tobacco Products Scientific Advisory Committee (the Committee) advises the Commissioner of Food and Drugs (the Commissioner) or designee in discharging responsibilities related to the regulation of tobacco products. The Committee reviews and evaluates safety, dependence, and health issues relating to tobacco products and provides appropriate advice, information, and recommendations to the Commissioner.

II. Criteria for Voting Members

The Committee consists of 12 members including the Chair. Members and the Chair are selected by the Commissioner or designee from among individuals knowledgeable in the fields of medicine, medical ethics, science, or technology involving the manufacture, evaluation, or use of tobacco products. Almost all non-Federal members of this committee serve as Special Government Employees. Members will be invited to serve for terms of up to 4 years. The Committee includes nine technically qualified voting members, selected by the Commissioner or designee. The nine voting members include seven members who are physicians, dentists, scientists, or health care professionals practicing in the area of oncology, pulmonology, cardiology, toxicology, pharmacology, addiction, or any other relevant specialty. The nine voting members also include one member who is an officer or employee of a state or local government or of the Federal Government, and one member who is a representative of the general public.

III. Nomination Procedures

Any interested person may nominate one or more qualified individuals for membership on the advisory committee. Self-nominations are also accepted. Nominations must include a current, complete résumé or curriculum vitae for each nominee, including current business address and/or home address, telephone number, and email address if available. Nominations must also

specify the advisory committee for which the nominee is recommended. Nominations must also acknowledge that the nominee is aware of the nomination unless self-nominated. FDA will ask potential candidates to provide detailed information concerning such matters related to financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of conflicts of interest.

This notice is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2) and 21 CFR part 14, relating to advisory committees.

Dated: November 9, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–28847 Filed 11–13–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request

AGENCY: Health Resources and Services Administration, HHS.

ACTION: Notice.

SUMMARY: In compliance with Section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) has submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period.

DATES: Comments on this ICR should be received no later than December 16, 2015.

ADDRESSES: Submit your comments, including the Information Collection Request Title, to the desk officer for HRSA, either by email to *OIRA_submission@omb.eop.gov* or by fax to 202–395–5806.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: National Health Service Corps Scholar/Students to Service Travel Worksheet.

OMB No. 0915–0278—Extension.

Abstract: Clinicians participating in the HRSA National Health Service Corps (NHSC) Scholarship Program and the Students to Service (S2S) Loan Repayment Program use the online Travel Request Worksheet to receive travel funds from the federal government to visit eligible NHSC sites to which they may be assigned in accordance with the Public Health Service Act (PHSA), section 331(c)(1).

The travel approval process is initiated when an NHSC scholar or S2S participant notifies the NHSC of an impending interview at one or more NHSC-approved practice sites. The Travel Request Worksheet is also used to initiate the relocation process after an NHSC scholar or S2S participant has successfully been matched to an approved practice site in accordance with the PHSA, section 331(c)(3). Upon receipt of the Travel Request Worksheet, the NHSC will review and approve or disapprove the request and promptly notify the scholar or S2S participant, and the NHSC logistics contractor regarding travel arrangements and authorization of the funding for the site visit or relocation.

Need and Proposed Use of the Information: This information will facilitate NHSC scholar and S2S clinicians' receipt of federal travel funds that are used to visit high-need NHSC sites. The Travel Request Worksheet is also used to initiate the relocation process after an NHSC scholar or S2S participant has successfully been matched to an approved practice site. This information will be used by the NHSC in order to make travel arrangements for NHSC scholar and S2S clinicians to potential practice sites and to assist them in relocation arrangements once clinicians have secured employment at one of these sites.

Likely Respondents: Clinicians participating in the National Health Service Corps Scholarship Program and the Students to Service Loan Repayment Program

Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN-HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Travel Request Worksheet	250	2	500	.0667	33
Total	250	2	500	.0667	33

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2015–29140 Filed 11–13–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

The National Advisory Council on the National Health Service Corps; Notice for Request for Nominations

SUMMARY: The Health Resources and Services Administration (HRSA) is requesting nominations to fill vacancies on The National Advisory Council on the National Health Service Corps (hereafter referred to as NACNHSC). The NACNHSC was established under 42 U.S.C. 254j (Section 337 of the Public Health Service Act), as amended by Section 10501 of the Affordable Care Act. The NAC is governed by provisions of 92 (5 U.S.C. App. 2), also known as the Federal Advisory Committee Act, which sets forth standards for the formation and use of advisory committees.

DATES: The agency will receive nominations on a continuous basis.

ADDRESSES: All nominations should be submitted to Regina Wilson, Advisory Council Operations, Bureau of Health Workforce, HRSA, 11w45c, 5600 Fishers Lane, Rockville, Maryland 20857. Mail delivery should be addressed to Regina Wilson, Advisory Council Operations, Bureau of Health Workforce, HRSA, at the above address, or via email to: *RWilson@hrsa.gov*.

FOR FURTHER INFORMATION CONTACT: CAPT Shari Campbell, Designated Federal Official, National Advisory Council on National Health Service Corps at (301) 594–4251 or email *scampbell@hrsa.gov.* A copy of the current committee membership, charter and reports can be obtained by accessing the *http://nhsc.hrsa.gov/corpsexperience/aboutus/nationaladvisorycouncil/index.html*.

SUPPLEMENTARY INFORMATION: The NACNHSC is a group of health care providers and health care site administrators who are experts in the issues that communities with a shortage of primary care professionals face in meeting their health care needs. The NACNHSC is committed to effectively implementing its mandate to advise the Secretary of the Department of Health and Human Services (HHS) and, by designation, the Administrator of the Health Resources and Services Administration (HRSA).

The NACNHSC consists of 15 members who are Special Government Employees. Responsibilities of the Council include: (1) Serving as a forum to identify the priorities for the NHSC and bring forward and anticipate future program issues and concerns through ongoing communication with program staff, professional organizations, communities and program participants; (2) functioning as a sounding board for proposed policy changes by utilizing the varying levels of expertise represented on the Council to advise on specific program areas; (3) developing and distributing white papers and briefs that clearly state issues and/or concerns relating to the NHSC with specific recommendations for necessary policy revisions.

Specifically, HRSA is requesting nominations for voting members of the NACNHSC representing primary care, dental health, and mental health that demonstrate the following areas of expertise: (1) Working with underserved populations; (2) health care policy, recruitment and retention; (3) site administration; (4) customer service; (5) marketing; (6) organizational partnerships; (7) research; (8) and clinical practice. We are looking for nominees that either currently hold or have previously filled a role as site administrators, physicians, dentists, mid-level professionals (*i.e.*, nurses, physician assistants), mental or behavioral health professionals, and National Health Service Corps scholars or loan repayors.

The Department of Health and Human Services (HHS) will consider nominations of all qualified individuals with the areas of subject matter expertise noted above. Individuals may nominate themselves or other individuals, and professional associations and organizations may nominate one or more qualified persons for membership. Nominations shall state that the nominee is willing to serve as a member of the NACNHSC and appears to have no conflict of interest that would preclude the NACNHSC membership. Potential candidates will be asked to provide detailed information concerning financial interests, consultancies, research grants, and/or contracts that might be affected by recommendations of the NACNHSC to permit evaluation of possible sources of conflicts of interest.

A nomination package should include the following information for each nominee:

(1) A letter of nomination stating the name, affiliation, and contact information for the nominee, the basis for the nomination (*i.e.*, what specific attributes, perspectives, and/or skills does the individual possess that would benefit the workings of the NACNHSC); (2) a biographical sketch of the nominee and a copy of his/her curriculum vitae; and (3) the name, address, daytime telephone number, and email address at which the nominator can be contacted. Nominations will be considered as vacancies occur on the NACNHSC. Nominations should be updated and resubmitted every 3 years to continue to be considered for committee vacancies.

HHS strives to ensure that the membership of HHS federal advisory committees is balanced in terms of points of view represented and the committee's function. Every effort is made to ensure that the views of women, all ethnic and racial groups, and people with disabilities are represented on HHS federal advisory committees. The Department also encourages geographic diversity in the composition of the committee. The Department encourages nominations of qualified candidates from all groups and locations. Appointment to the NACNHSC shall be made without discrimination on the basis of age, race, ethnicity, gender, sexual orientation, disability, and cultural, religious, or socioeconomic status.

Jackie Painter,

Director, Division of the Executive Secretariat.

[FR Doc. 2015–28917 Filed 11–13–15; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Secretary's Advisory Committee on Human Research Protections

AGENCY: Office of the Secretary, Office of the Assistant Secretary for Health, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: Pursuant to Section 10(a) of the Federal Advisory Committee Act, U.S.C. Appendix 2, notice is hereby given that the Secretary's Advisory Committee on Human Research Protections (SACHRP) will hold a meeting that will be open to the public. Information about SACHRP and the full meeting agenda will be posted on the SACHRP Web site at: *http://www.dhhs.gov/ohrp/sachrp/mtgings/index.html*.

DATES: The meeting will be held on Thursday, December 3, 2015, from 8:30 a.m. until 5:00 p.m. and Friday, December 4, 2015, from 8:30 a.m. until 4:30 p.m.

ADDRESSES: Fishers Lane Conference Center, Terrace Level, 5635 Fishers Lane, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Julia Gorey, J.D., Executive Secretary, SACHRP, or Jerry Menikoff, M.D., J.D., Director, Office for Human Research Protections (OHRP); U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; telephone: 240–453–8141; fax: 240–453–6909; email address: *SACHRP@hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services, through the Assistant Secretary for Health, on issues and topics pertaining to or associated with the protection of human research subjects.

The meeting will open to the public at 8:30 a.m., on Thursday, December 3, followed by opening remarks from Dr. Jerry Menikoff, OHRP Director, and Dr. Jeffrey Botkin, SACHRP Chair. The Committee will hear the Subpart A Subcommittee (SAS) and Subcommittee on Harmonization (SOH) reports on the recent Notice of Proposed Rulemaking (NPRM) entitled Federal Policy for the Protection of Human Subjects (80 FR 53933, Sep. 8, 2015). Both days will be devoted to the discussion of the NPRM.

SAS was established by SACHRP in October 2006 and is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment.

SOH was established by SACHRP at its July 2009 meeting and charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination.

The meeting will adjourn at 4:30 p.m. on December 4, 2015. Time for public comment sessions will be allotted both days.

Public attendance at the meeting is limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify one of the designated SACHRP points of contact at the address/phone number listed above at least one week prior to the meeting. Pre-registration is required for participation in the on-site public comment session; individuals may pre-register the day of the meeting. Individuals who would like to submit written statements as public comment should email or fax their comments to SACHRP at *SACHRP@hhs.gov* at least five business days prior to the meeting. Public comment should be relevant to agenda topics being discussed.

Dated: November 9, 2015.

Julia Gorey,

Executive Secretary, Secretary's Advisory Committee on Human Research Protections.

[FR Doc. 2015–29001 Filed 11–13–15; 8:45 am]

BILLING CODE 4150–36–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, PAR–13–266-Biomarkers for Kidney and Liver Diseases (R01).

Date: February 4, 2016.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Najma Begum, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 749, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–8894, *begumn@niddk.nih.gov*.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, Fatty Liver Ancillary Studies.

Date: December 7, 2015.

Time: 10:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Robert Wellner, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 706, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, 301–594–4721, *rw175w@nih.gov*.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, R01 Diabetes Ancillary Study.

Date: December 8, 2015.

Time: 5:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Robert Wellner, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 706, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, 301–594–4721, *rw175w@nih.gov*.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, T1D Ancillary Studies.

Date: December 11, 2015.

Time: 10:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6100 Executive Boulevard, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: Carol J. Goter-Robinson, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 748, 6707 Democracy Boulevard, Bethesda, MD 20892–5452, (301) 594–7791, *goterrobinsonc@extra.niddk.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: November 9, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–28834 Filed 11–13–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Minority Health and Health Disparities; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial

property such as patentable materials, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Minority Health and Health Disparities Special Emphasis Panel, TCC Precision Medicine Face-to-Face Review Meeting.

Date: December 8–December 9, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Conference Center, Marriott at Marinelli Road, 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: Maryline Laude-Sharp, Ph.D., Scientific Review Officer, National Institute on Minority Health and Health Disparities, National Institutes of Health, 6707 Democracy Blvd., Suite 800, Bethesda, MD 20892, (301) 451–9536, *mlaudesharp@nih.gov*.

Dated: November 9, 2015.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–28833 Filed 11–13–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Submission for OMB Review; 30-Day Comment Request Scientific Information Reporting System (SIRS) NIGMS

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 August 23, 2015, page 48549 and allowed 60-days for public comment. One public comment was received. The purpose of this notice is to allow an additional 30 days for public comment. The National Institute of General Medical Sciences (NIGMS), 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: Dr. W. Fred Taylor Ph.D., Branch Chief, Capacity-Building Branch (CBB), Division of Training, Workforce Development, and Diversity (TWD), NIGMS, NIH, 45 Center Drive, Room 2AS43S, Bethesda MD 20892, or call non-toll-free number (301) 435–0760 or Email your request, including your address to: *taylorwf@mail.nih.gov.* Formal requests for additional plans and instruments must be requested in writing.

Proposed Collection: Scientific Information Reporting System (SIRS), 0925-In Use Without OMB Control Number, National Institute of General Medical Sciences (NIGMS), National Institutes of Health (NIH).

Need and Use of Information Collection: The SIRS is an online data collection system whose purpose is to obtain supplemental information to the annual Research Performance Progress Report (RPPR) submitted by grantees of the Institutional Development Award (IDeA) Program and the Native American Research Center for Health (NARCH) Program. The SIRS will collect program-specific data not requested in the RPPR data collection system. The IDeA Program is a congressionally mandated, long-term interventional program administered by NIGMS aimed at developing and/or enhancing the biomedical research competitiveness of States and Jurisdictions that lag in NIH funding. The NARCH Program is an interagency initiative that provides support to American Indian and Alaska Native (AI/AN) tribes and organizations for conducting research in their communities in order to address health disparities, and to develop a cadre of competitive AI/AN scientists and health professionals. The data collected by SIRS will provide valuable information for the following purposes: (1) Evaluation of progress by individual grantees towards achieving grantee-designated and program-specified goals and objectives, (2) evaluation of the overall program for effectiveness, efficiency, and impact in building biomedical research capacity and capability, and (3) analysis of outcome measures to determine need for refinements and/or adjustments of different program features including but not limited to initiatives and eligibility criteria. Data collected from SIRS will be used for various regular or *ad hoc* reporting requests from interested stakeholders that include members of Congress, state and local officials, other federal agencies, professional societies, media, and other parties.

OMB approval is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 613.

ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Respondents	Number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
SIRS	Principal Investigators, COBRE Phase I	37	1	3.5	130
SIRS	Principal Investigators, COBRE Phase II	36	1	3.5	126
SIRS	Principal Investigators, COBRE Phase III	35	1	3.5	122
SIRS	Principal Investigators, INBRE	24	1	5.5	132
SIRS	Principal Investigators, IDeA–CTR	5	1	3.5	18
SIRS	Principal Investigators, NARCH	19	1	4.5	85

Dated: November 10, 2015.

Tammy Dean-Maxwell,

Project Clearance Branch Liaison, NIGMS, NIH.

[FR Doc. 2015–29085 Filed 11–13–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Opportunity for Public Comment on the Dietary Supplement Label Database

SUMMARY: This document, originally published on October 29, 2015 (80 FR 66549), has been amended to extend the comment receipt date to December 31, 2015. The Office of Dietary Supplements (ODS) at the National Institutes of Health, in partnership with the National Library of Medicine (NLM), has developed a Dietary Supplement Label Database (DSLD) that is compiling all information from the labels of dietary supplements marketed in the United States. ODS welcomes comments about features to add and functionality improvements to make so the DSLD may become a more useful tool to users.

A federal stakeholder panel for the DSLD will consider all comments received. The ODS requests input from academic researchers, government agencies, the dietary supplement industry, and other interested parties, including consumers. The DSLD can be accessed online at *http://dsld.nlm.nih.gov.*

DATES: To ensure full consideration, all comments must be received by 11:59 p.m. EST, December 31, 2015.

ADDRESSES: Interested individuals and organizations should submit their responses to *ODS@nih.gov.*

FOR FURTHER INFORMATION CONTACT: Richard Bailen MBA, MHA, Office of Dietary Supplements, National Institutes of Health, 6100 Executive Boulevard, Room 3B01, Bethesda, MD 20892–7517, Phone: 301–435–2920, Fax: 301–480–1845, Email: *ODS@nih.gov.*

SUPPLEMENTARY INFORMATION: The DSLD is a free resource that captures all information present on dietary supplement labels as provided by the seller, including contents, ingredient amounts, and any health-related product statements, claims, and cautions. It also provides a downloadable photo of each label. Users can search for and organize this information in various ways. Research scientists, for example, could use the DSLD to determine total nutrient intakes from food and supplements in populations they study. Health care providers can learn the content of products their patients are taking. Consumers might use the DSLD to search for and compare products of interest.

The DSLD currently contains 50,000 labels, and it is expected to grow rapidly over the next three years to include most of the estimated 75,000+ dietary supplement products sold to American consumers. The DSLD is updated regularly to include any formulation changes and label information in a product. It also includes the labels of products that have been discontinued and are no longer sold. More information about the DSLD and its current capabilities is available at *http://www.dsld.nlm.nih.gov* and at Dwyer *et al.,* 2014.[1]

ODS would like to receive ideas and suggestions for how the DSLD might evolve. What features might be added, improved, or enhanced—for example, in capabilities related to search, sorting, organization, and downloading of information—that would make it a more valuable tool for users?

Dated: November 5, 2015.

Lawrence A. Tabak,

Deputy Director, National Institutes of Health.

[FR Doc. 2015–29177 Filed 11–13–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

[1] Dwyer JT, Saldanha LG, Bailen RA, *et al.* A free new dietary supplement label database for registered dietitian nutritionists. J Acad Nutr Diet. 2014;114(10):1512–7.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, NIAID Clinical Trial Planning Grant (R34) and Implementation Cooperative Agreement (U01).

Date: December 9, 2015.

Time: 1:30 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 3C100, 5601 Fishers Lane, Rockville, MD 20892, (Telephone Conference Call).

Contact Person: Frank S. De Silva, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, Room #3E72A, National Institutes of Health/NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–9823, (240) 669–5023, *fdesilva@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: November 9, 2015.

Natasha Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–28835 Filed 11–13–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive License: Development of Cripto-1 Point of Care (POC) Tests and Kits for the Detection of Cancer

AGENCY: National Institutes of Health, Public Health Service, HHS.

ACTION: Notice.

SUMMARY: This notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Cancer Institute, National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to practice the inventions embodied in the following U.S. Patents and Patent Applications to Beacon Biomedical, Inc. (''Beacon'') located in Scottsdale, AZ, USA. A notice was previously published on December 6, 2013 in Volume 78, Number 235 for a period of thirty (30) days. Herein, the National Cancer Institute, National Institutes of Health, Department of Health and Human Services, is proposing a modification to the contents of the previous notice regarding the following intellectual property:

U.S. Provisional Patent Application No. 60/264,643 filed January 26, 2001 entitled ''Detection and Quantification of Cripto-1'' [HHS Ref. No. E–290–2000/0–US–01];

PCT Application No. PCT/US02/02225 filed January 23, 2002 entitled ''Detection and Quantification of Cripto-1'' [HHS Ref. No. E–290–2000/0–PCT–02];
U.S. Patent No. 7,078,176 issued July 18, 2006 entitled ''Detection and Quantification of Cripto-1'' [HHS Ref. No. E–290–2000/0–US–03];
Canada Patent No. 2,434,694 issued September 18, 2012 entitled ''Detection and Quantification of Cripto-1'' [HHS Ref. No. E–290–2000/0–CA–04];
Australian Patent No. 2002236871 issued April 12, 2007 entitled ''Detection and Quantification of Cripto-1'' [HHS Ref. No. E–290–2000/0–AU–05];
Europe Patent No. 1370869 issued December 27, 2006 entitled ''Detection and Quantification of Cripto-1'' [HHS Ref. No. E–290–2000/0–EP–06] and validated in Germany [HHS Ref. No. E–290–2000/0–DE–08], France [HHS Ref. No. E–290–2000/0–FR–09], Italy [HHS Ref. No. E–290–2000/0–IT–10], Spain [HHS Ref. No. E–290–2000/0–ES–12], Ireland [HHS Ref. No. E–290–2000/0–IE–12], Great Britain [HHS Ref. No. E–290–2000/0–GB–13] and Switzerland [HHS Ref. No. E–290–2000/0–CH–14];
Japan Patent No. 3821779 issued June 30, 2006 entitled ''Detection and Quantification of Cripto-1'' [HHS Ref. No. E–290–2000/0–JP–07].

The patent rights in these inventions have been assigned to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to the use of the Licensed Patent Rights to make, use and sell FDA approved and 510(k) cleared, or foreign equivalent, Point of Care (POC) tests, services and kits for the purpose of disease state recognition, detection, diagnosis, monitoring, association and risk-stratification of cancer.

DATES: Only written comments and/or applications for a license which are received by the NCI Technology Transfer Center on or before December 1, 2015 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated exclusive license should be directed to: Rose Freel, Ph.D. Licensing and Patenting Manager, Technology Transfer Center, National Cancer Institute, 8490 Progress Drive, Riverside 5, Suite 400, Frederick, MD 21702; Telephone: (301) 624–1257; Email: *rose.freel@nih.gov*.

SUPPLEMENTARY INFORMATION: Cripto-1 (Cr-1) is a member of the epidermal growth factor (EGF)-related families of peptides and is involved in the development and progression of various human carcinomas. In particular, Cr-1 overexpression has been detected in 50–90% of carcinomas of the colon, pancreas, stomach, gallbladder, breast, lung, endometrium and cervix. Current methodologies of cancer detection, *e.g.* immunohistochemistry, can be time consuming, inconvenient and oftentimes, inaccurate, and therefore, a need exists for more efficient, reliable and less time consuming methods of detection. The invention relates to such a method of detection. This test could be used to more effectively screen and perhaps stage cancers. Additionally, should particular tumor cells, *e.g.* breast tumor cells, express a sufficiently high level of Cr-1, it may be possible to use the disclosed assay to detect and measure Cr-1 in human serum and/or plasma and possibly other physiological fluids.

The previous notice published on December 6, 2013 contemplated the prospective grant of an exclusive license in a field of use that was limited to the use of the Licensed Patent Rights to develop FDA approved and/or 510K cleared Point of Care (POC) tests and kits for the purpose of disease state recognition, detection, diagnosis, monitoring, association and risk-stratification of colon and rectal cancer, breast cancer, and lung cancer. This notice serves to modify the prospective grant that may be limited to field of use as described in the Summary above.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the NCI receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Applications for a license in the field of use filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: November 9, 2015.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2015–28832 Filed 11–13–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

[167 A2100DD/AAKC001030/ A0A501010.999900]

Johnson-O'Malley Program

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Tribal consultation meetings.

SUMMARY: The Bureau of Indian Education (BIE) will be conducting three consultation sessions to obtain oral and written comments on issues concerning the Johnson O'Malley (JOM) program. The sessions continue the previous dialogues conducted by the Bureau of Indian Affairs (BIA) and BIE in 2012 and 2015.

DATES: See the **SUPPLEMENTARY INFORMATION** section of this document for the dates of Tribal consultation sessions. We will consider all comments received by January 15, 2016, 4:30 p.m. EST.

ADDRESSES: See the **SUPPLEMENTARY INFORMATION** section of this document for the location of these Tribal consultation sessions. Submit comments by mail or hand-deliver written comments to Ms. Jennifer L. Davis, Program Analyst-JOM, Bureau of Indian Education, 1951 Constitution Avenue NW., Mail Stop Room 312A–SIB Washington, DC 20245; facsimile to (202) 273–0030; or email to *JOMComments@bia.gov.*

FOR FURTHER INFORMATION CONTACT: Ms. Jennifer L. Davis, Program Analyst-JOM, telephone (202) 208–4397.

SUPPLEMENTARY INFORMATION: As required by 25 U.S.C. 2011(b), the purpose of this consultation is to provide Indian Tribes, school boards, parents, Indian organizations and other interested parties with an opportunity to comment on issues raised during previous consultation sessions and future plans for the JOM program. The topics for the JOM Tribal Consultation are use of the 2014 JOM student count and the JOM funding methodology for 2015, 2016, and thereafter. The issues will be described in more detail in a Tribal consultation booklet issued by the BIE before the consultation sessions.

Tribal consultation sessions will be held on the following dates at the following location:

Date	Time	Location
Tuesday, December 15, 2015	1 p.m.–4 p.m. (Eastern Standard Time).	Webinar/Teleconference. 1951 Constitution Ave. NW., South Interior Building, Room 304, Washington, DC 20240. Telephone Call-in #: 877–601–5705. Passcode: 2686962. Webinar Conference Access: URL: *https://www.mymeetings.com/nc/join/.* Conference number: PW5872129. Audience passcode: 2686962. Participants can join the event directly at: *https://www.mymeetings.com/nc/join.php?i=PW5872129&p=2686962&t=c.* Local Contact: Jennifer Davis. Phone: (202) 208–4397
Wednesday, December 16, 2015 ...	1 p.m.–4 p.m. (Eastern Standard Time).	Webinar/Teleconference. 1951 Constitution Ave. NW., South Interior Building, Room 304, Washington, DC 20240. Telephone Call-in #: 877–601–5705. Passcode: 2686962. Webinar Conference Access: URL: *https://www.mymeetings.com/nc/join/.* Conference number: PW5872131. Audience passcode: 2686962. Participants can join the event directly at:. *https://www.mymeetings.com/nc/join.php?i=PW5872131&p=2686962&t=c.* Local Contact: Jennifer Davis. Phone: (202) 208–4397
Thursday, December 17, 2015	1 p.m.–4 p.m. (Eastern Standard Time).	Webinar/Teleconference. 1951 Constitution Ave. NW., South Interior Building, Room 304, Washington, DC 20240. Telephone Call-in #: 877–601–5705. Passcode: 2686962. Webinar Conference Access: URL: *https://www.mymeetings.com/nc/join/.* Conference number: PW5975273. Audience passcode: 2686962. Participants can join the event directly at:. *https://www.mymeetings.com/nc/join.php?i=PW5975273&p=2686962&t=c.* Local Contact: Jennifer Davis. Phone: (202) 208–4397

A consultation booklet for the sessions will be distributed to all federally-recognized Indian Tribes, Bureau Regional and Agency Offices and Bureau-funded schools. The booklet will also be available at each session and on the BIE Web site at *www.bie.edu.*

Dated: November 10, 2015.

Kevin K. Washburn,

Assistant Secretary—Indian Affairs.

[FR Doc. 2015–29188 Filed 11–12–15; 11:15 am]

BILLING CODE 4337–15–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–IMR–GRTE–19244; PX. PD202594I.00.1]

Moose-Wilson Corridor Comprehensive Management Plan, Draft Environmental Impact Statement, Grand Teton National Park, Wyoming

AGENCY: National Park Service, Interior.

ACTION: Notice of availability.

SUMMARY: The National Park Service announces the availability of the Draft Environmental Impact Statement for the Moose-Wilson Corridor Comprehensive Management Plan, Grand Teton National Park, Wyoming. The Draft Environmental Impact Statement analyzes four alternatives for future management of the corridor. Alternative C has been identified as the NPS preferred alternative.

DATES: The National Park Service will accept comments from the public through January 15, 2016. In addition, a public meeting will be conducted in the Jackson, Wyoming, area in the fall of 2015. Please check local newspapers and the Web site below for additional information.

ADDRESSES: Information will be available for public review and comment online at *http://parkplanning.nps.gov/MooseWilson,* at the Grand Teton National Park Headquarters Building, 1 Teton Park Road, Moose, Wyoming, and at the Reference Desk of the Teton County Library, 125 Virginian Lane, Jackson, Wyoming.

FOR FURTHER INFORMATION CONTACT: David Vela, Superintendent, Grand Teton National Park, P.O. Drawer 170, Moose, Wyoming 83012–0170, (307) 739–3411, *GRTE_Superintendent@nps.gov,* or Daniel Noon, Chief of Planning and Environmental Compliance, P.O. Drawer 170, Moose, Wyoming 83012–0170, (307) 739–3465, *Daniel_Noon@nps.gov.*

SUPPLEMENTARY INFORMATION: In recent years, the Moose-Wilson corridor in Grand Teton National Park has experienced changes in ecological conditions, development patterns, and use by visitors and local residents. As a result, the National Park Service is conducting a comprehensive planning and environmental impact process to determine how best to protect park resources and values while providing appropriate opportunities for visitor

use, experience, and enjoyment of the corridor. The draft plan: (1) Identifies management strategies to address natural and cultural resource protection; (2) proposes management strategies to address visitor safety concerns and conflicts with wildlife; (3) addresses vehicle/bicycle management related to road use, trailhead parking areas and pullouts; (4) identifies management strategies related to the operation of facilities within the corridor; (5) considers if a multi-use pathway should be provided along Moose-Wilson Road; and (6) examines specific road realignment and paving options for the Moose-Wilson and Death Canyon Roads. Four management alternatives, Alternatives A through D, are analyzed in the Draft Environmental Impact Statement. Alternative A, the no-action alternative, would continue current management practices related to resources, visitor use, park operations, and maintenance of facilities within the Moose-Wilson corridor. Alternative B emphasizes managing the corridor as a visitor destination. Reduced crowding on Moose-Wilson Road and at destinations within the corridor would provide visitors an opportunity for self-discovery. Existing developed areas and facilities would be maintained where appropriate and removed or relocated in some areas to protect natural and cultural resources. Alternative C, the NPS preferred alternative, emphasizes the conservation legacy stories within the corridor. The intensity and timing of visitor use would be managed to effectively provide high quality visitor opportunities by reducing high traffic volumes and congestion. Development within the corridor would generally be maintained within the existing development footprint. Alternative D would enhance recreational opportunities with additional amenities. This alternative would integrate the Moose-Wilson corridor with the region's larger recreational network, and would enhance the recreational scenic driving experience by reducing high traffic volumes and congestion.

You are encouraged to comment on the draft plan via the Internet at *http://parkplanning.nps.gov/MooseWilson.* You may also mail comments to the Superintendent's Office, Attention: Moose-Wilson EIS, P.O. Drawer 170, Moose, Wyoming 83012–0170. You may also hand-deliver comments to the Grand Teton National Park Headquarters at Moose, Wyoming.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: October 22, 2015.

Sue E. Masica,

Regional Director, Intermountain Region, National Park Service.

[FR Doc. 2015–28016 Filed 11–13–15; 8:45 am]

BILLING CODE 4312–CB–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–513 and 731–TA–1249 (Final)]

Sugar From Mexico

Determinations

On the basis of the record [1] developed in the subject investigations, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that an industry in the United States is materially injured by reason of imports of sugar from Mexico, provided for in statistical subheadings 1701.12.1000, 1701.12.5000, 1701.13.1000, 1701.13.5000, 1701.14.1000, 1701.14.5000, 1701.91.1000, 1701.91.3000, 1701.99.1010, 1701.99.1025, 1701.99.1050, 1701.99.5010, 1701.99.5025, 1701.99.5050, 1702.90.4000 and 1703.10.3000 of the Harmonized Tariff Schedule of the United States, that have been found by the Department of Commerce (''Commerce'') to be sold in the United States at less than fair value (''LTFV''), and to be subsidized by the government of Mexico.[2]

Background

The Commission, pursuant to sections 705(b) and 735(b) of the Act (19 U.S.C. 1671d(b) and 19 U.S.C. 1673d(b)), instituted these investigations effective March 28, 2014, following receipt of a petition filed with the Commission and Commerce by the American Sugar Coalition and its members: American Sugar Cane League, Thibodaux, LA; American Sugarbeet Growers Association, Washington, DC; American Sugar Refining, Inc., West Palm Beach, FL; Florida Sugar Cane League, Washington, DC; Hawaiian Commercial and Sugar Company, Puunene, HI; Rio Grande Valley Sugar Growers, Inc., Santa Rosa, TX; Sugar Cane Growers Cooperative of Florida, Belle Glade, FL; and United States Beet Sugar Association, Washington, DC. The final phase of the investigations was scheduled by the Commission following notification of preliminary determinations by Commerce that imports of sugar from Mexico were subsidized within the meaning of section 703(b) of the Act (19 U.S.C. 1671b(b)) and dumped within the meaning of 733(b) of the Act (19 U.S.C. 1673b(b)). Notice of the scheduling of the final phase of the Commission's investigations and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** on December 18, 2014 (79 FR 75591). On December 19, 2014, the Department of Commerce suspended the antidumping and countervailing duty investigations on sugar from Mexico (79 FR 78039, 78044, December 29, 2014). Subsequently, Commerce received timely requests to continue the antidumping and countervailing duty investigations on sugar from Mexico and resumed its investigations on May 4, 2015 (80 FR 25278). The Commission, therefore, revised its schedule to conform with Commerce's new schedule (80 FR 28009, May 15, 2015). The hearing was held in Washington, DC, on September 16, 2015, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission made these determinations pursuant to sections 705(b) and 735(b) of the Tariff Act of 1930 (19 U.S.C. 1671d(b) and 19 U.S.C. 1673d(b)). It completed and filed its determinations in these investigations on November 6, 2015. The views of the Commission are contained in USITC Publication 4577 (November 2015), entitled *Sugar from Mexico: Investigation Nos. 701–TA–513 and 731–TA–1249 (Final).*

By order of the Commission.

Issued: November 9, 2015.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2015–28856 Filed 11–13–15; 8:45 am]

BILLING CODE 7020–02–P

[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] All six Commissioners voted in the affirmative.

INTERNATIONAL TRADE COMMISSION

[USITC SE–15–039]

Sunshine Act Meeting

AGENCY HOLDING THE MEETING: United States International Trade Commission.

TIME AND DATE: November 18, 2015 at 11:00 a.m.

PLACE: Room 101, 500 E Street SW., Washington, DC 20436, Telephone: (202) 205–2000.

STATUS: Open to the public

MATTERS TO BE CONSIDERED:

1. Agendas for future meetings: None.
2. Minutes.
3. Ratification List.
4. Vote in Inv. No. 701–TA–530 (Final) (Supercalendered Paper from Canada). The Commission is currently scheduled to complete and file its determination and views of the Commission on December 1, 2015.
5. Vote in Inv. Nos. 701–TA–473 and 731–TA–1173 (Review) (Potassium Phosphate Salts from China). The Commission is currently scheduled to complete and file its determinations and views of the Commission on December 4, 2015.
6. Outstanding action jackets: None.

In accordance with Commission policy, subject matter listed above, not disposed of at the scheduled meeting, may be carried over to the agenda of the following meeting.

Issued: November 12, 2015.

By order of the Commission.

William R. Bishop,

Supervisory Hearings and Information Officer.

[FR Doc. 2015–29334 Filed 11–12–15; 4:15 pm]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–929]

Certain Beverage Brewing Capsules, Components Thereof, and Products Containing the Same; Commission Determination To Review in Part a Final Initial Determination Finding No Violation; Schedule for Briefing on the Issues Under Review and on Remedy, the Public Interest, and Bonding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review in part a final initial determination (''ID'') issued by the presiding administrative law judge (''ALJ''), finding no violation of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337.

FOR FURTHER INFORMATION CONTACT: Robert Needham, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 708–5468. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server (*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.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on September 9, 2014, based on a complaint filed by Adrian Rivera of Whittier, California, and Adrian Rivera Maynez Enterprises, Inc., of Santa Fe Springs, California (together, ''ARM''). 79 FR 53445–46. The complaint alleges violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain beverage brewing capsules, components thereof, and products containing the same that infringe claims 5–8 and 18–20 of U.S. Patent No. 8,720,320 (''the '320 patent''). *Id.* at 53445. The Commission's notice of investigation named as respondents Solofill LLC of Houston, Texas (''Solofill''); DongGuan Hai Rui Precision Mould Co., Ltd. of Dong Guan City, China (''DongGuan''); Eko Brands, LLC (''Eko Brands''), of Woodinville, Washington; Evermuch Technology Co., Ltd., of Hong Kong, China and Ever Much Company Ltd. of Shenzhen, China (together, ''Evermuch''); Melitta USA, Inc. (''Melitta''), of North Clearwater, Florida; LBP Mfg., Inc. of Cicero, Illinois and LBP Packaging (Shenzhen) Co. Ltd. of Shenzhen, China (together, ''LBP''); Spark Innovators Corp. (''Spark''), of Fairfield, New Jersey; B. Marlboros International Ltd. (HK) (''B. Marlboros'') of Hong Kong, China; and Amazon.com, Inc. (''Amazon'') of Seattle, Washington. The Office of Unfair Import Investigations was also named as a party to the investigation. *Id.*

The Commission terminated the investigation with respect to Melitta, Spark, LBP, and B. Marlboros based on the entry of consent orders and terminated the investigation with respect to Amazon based on a settlement agreement. Notice (Dec. 18, 2014); Notice (Jan. 13, 2015); Notice (Mar. 27, 2015); Notice (Apr. 10, 2015). The Commission also found Eko Brands and Evermuch in default for failing to respond to the complaint and notice of investigation. Notice (May 18, 2015). Accordingly, Solofill and DongGuan (together, ''Respondents'') were the only respondents actively participating in the investigation at the time of the issuance of the final ID.

On September 4, 2015, the ALJ issued his final ID finding no violation of section 337. The ID found that ARM had established every element for finding a violation of section 337 except for infringement. The ID found that Respondents were not liable for direct infringement because direct infringement required the combination of Respondents' products with a third-party single serve beverage brewer, and that Respondents were not liable for induced or contributory infringement because they did not have pre-suit knowledge of the '320 patent. The ID did find that Respondents' products directly infringed when combined with a third-party single serve coffee brewer, that the asserted claims have not been shown invalid by clear and convincing evidence, and that ARM satisfied both the technical and economic prongs of the domestic industry requirement. The ALJ also issued his recommendation on remedy and bonding along with his ID.

On September 21, 2015, Complainants petitioned for review of the ID's findings that Respondents were not liable for induced and contributory infringement because of a lack of pre-suit knowledge, and Respondents petitioned for review of several of the ID's findings. On September 29, 2015, the parties opposed each other's petitions, and the Commission Investigative Attorney opposed both petitions.

Having examined the record of this investigation, including the ALJ's final ID, the petitions for review, and the responses thereto, the Commission has determined to review the final ID in part. Specifically the Commission has determined to review the following: (1) The ID's findings on the construction, infringement, and technical prong of the domestic industry requirement for the limitation ''a needle-like structure,

disposed below the base''; (2) the ID's findings on induced and contributory infringement; (3) the ID's findings that the asserted claims are not invalid for a lack of written description, as anticipated by Beaulieu and the APA, or as obvious; and (4) the ID's findings on the economic prong of the domestic industry requirement. The Commission has determined not to review the remaining findings in the ID.

In connection with its review, the Commission is interested in briefing only on the following issue:

The Commission recently determined that the ''knowledge of the patent'' element for contributory infringement can be satisfied through service of a section 337 complaint. *See* Commission Opinion in *Certain Television Sets, Television Receives, Television Tuners, and Components Thereof,* Inv. No. 337–TA–910, at 41–43 (public version dated Oct. 30, 2015). Please explain how that determination impacts the issues of contributory and induced infringement in this investigation.

The parties have been invited to brief only the discrete issue described above, with reference to the applicable law and evidentiary record. The parties are not to brief other issues on review, which are adequately presented in the parties' existing filings.

In connection with the final disposition of this investigation, the Commission may (1) issue an order that could result in the exclusion of the subject articles from entry into the United States, and/or (2) issue a cease and desist order that could result in the respondent being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, *see Certain Devices for Connecting Computers via Telephone Lines,* Inv. No. 337–TA–360, USITC Pub. No. 2843 (December 1994) (Commission Opinion).

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or a cease and desist order would have on (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve or disapprove the Commission's action. *See* Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

Written Submissions: The parties to the investigation are requested to file written submissions on the issue identified in this notice. Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the recommended determination by the ALJ on remedy and bonding. The complainants and the Commission Investigative Attorney are also requested to submit proposed remedial orders for the Commission's consideration. The complainants are additionally requested to state the date that the '320 patent expires, the HTSUS numbers under which the accused products are imported, and to supply a list of known importers of the products at issue. The entirety of the parties' written submissions must not exceed 50 pages, and must be filed no later than close of business on November 20, 2015. Reply submissions must not exceed 25 pages, and must be filed no later than the close of business on December 1, 2015. No further submissions on these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to § 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the investigation number (''Inv. No. 337–TA–929'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, *http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf*). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. A redacted non-confidential version of the document must also be filed simultaneously with any confidential filing. All non-confidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By order of the Commission.

Issued: November 9, 2015.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2015–28893 Filed 11–13–15; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—High Density Packaging User Group International, Inc.

Notice is hereby given that, on October 15, 2015, pursuant to Section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), High Density Packaging User Group International, Inc. (''HDPUG'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Hangzhou H3C Technologies Co., Ltd., Hangzhou City, PEOPLE'S REPUBLIC

OF CHINA; Semi, San Jose, CA; UL LLC, San Jose, CA; I3 Electronics, Endicott, NY; and DuPont, Durham, NC, have been added as parties to this venture.

Also, Philips Medical, Murray Hill, NJ; Arlon LLC, Bear, DE; and Integral Technology, Lake Forrest, CA, have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and HDPUG intends to file additional written notifications disclosing all changes in membership.

On September 14, 1994, HDPUG filed its original notification pursuant to Section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to Section 6(b) of the Act on March 23, 1995 (60 FR 15306).

The last notification was filed with the Department on February 23, 2015. A notice was published in the **Federal Register** pursuant to Section 6(b) of the Act on April 2, 2015 (80 FR 17785).

Patricia A. Brink,

Director of Civil Enforcement Antitrust Division.

[FR Doc. 2015–29030 Filed 11–13–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—OpenDaylight Project, Inc.

Notice is hereby given that, on October 22, 2015 pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), OpenDaylight Project, Inc. (''OpenDaylight'') has filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Transmode Systems AB, Stockholm, SWEDEN, has withdrawn as a party to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and OpenDaylight intends to file additional written notifications disclosing all changes in membership.

On May 23, 2013, OpenDaylight filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on July 1, 2013 (78 FR 39326).

The last notification was filed with the Department on August 3, 2015. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on September 28, 2015 (80 FR 58298).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2015–29056 Filed 11–13–15; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—TeleManagement Forum

Notice is hereby given that, on October 8, 2015, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), TeleManagement Forum (''The Forum'') filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, the following parties have been added as members to this venture: Applied BSS, Ronneby, SWEDEN; Continental Automated Buildings Association, Ottawa, CANADA; Chinese Society For Urban Studies National Smart City Joint Lab, Beijing, PEOPLE'S REPUBLIC OF CHINA; ZhongXing (Yinchuan) Intellectual Industry Co. Ltd., Jinfeng District, PEOPLE'S REPUBLIC OF CHINA; GLOBEOSS, Shah Alam, MALAYSIA; Kavitha Shreedhar Ltd., Mount Pleasant, AUSTRALIA; Sinefa, Bulleen, AUSTRALIA; Grameenphone Ltd., Baridhara, BANGLADESH; Telenor Pakistan, Islamabad, PAKISTAN; Italtel S.p.A, Settimo Milane, ITALY; OpenLimits Business Solutions Lda, Coimbra, PORTUGAL; Orange Caraibe, Baie-Mahault, GUADELOUPE; Ultrafast Fibre Limited, Hamilton, NEW ZEALAND; Singer TC GmbH, Schwedeneck, GERMANY; Resolvetel Ltd., Henley-on-Thames, UNITED KINGDOM; Sutherland Labs, London, UNITED KINGDOM; Retixa, Warsaw, POLAND; Polaris Consulting & Services Ltd., Piscataway, NJ; State Information Technology Agency (SITA), Erasmuskloof, SOUTH AFRICA; EXFO Inc., Chelmsford, MA; CommTel Network Solutions Pty Ltd., Keilor Park, AUSTRALIA; Jetsynthesys, Pune, INDIA; My Republic, Singapore, SINGAPORE; ISPIN AG, Bassersdorf, SWITZERLAND; Apttus Corporation, San Mateo, CA; Parkyeri, İstanbul, TURKEY; Blackbridge Associates, Dubai, UNITED ARAB EMIRATES; IPvideosys, Sunnyvale, CA; Windstream Communications, Little Rock, AR; T&BS SAS, Paris, FRANCE; Mind C.T.I. Ltd., Yoqneam Ilit, ISRAEL; Vision Consulting Turkey, İstanbul, TURKEY; Qualycloud, Paris, FRANCE; Etihad Atheeb Telecom Company, Riyadh, SAUDI ARABIA; Nethys SA—Betv/VOO, Liège, BELGIUM; Datalynx Holding AG, Basel, SWITZERLAND; Tacira Technologies, São Paulo, BRAZIL; and Master Merchant Systems, Dartmouth, CANADA.

Also, the following members have changed their names: TNBS.FR to T&BS SAS, Paris, FRANCE; Albanian Mobile Communications Sh. A. to Telekom Albania Sh.A., Laprake, ALBANIA; JDSU to Viavi Solutions, Muehleweg, GERMANY; Mobile Telecommunications Company K.S.C.P to Zain Group, Kuwait City, KUWAIT; Voo to Nethys SA—Betv/VOO, Liège, BELGIUM; and Quindell Telecoms to SMI Technologies, Portsmouth, UNITED KINGDOM.

In addition, the following parties have withdrawn as parties to this venture: 4STARS Ltd., Zagreb, CROATIA; Affinegy, Inc., Austin, TX; AIST Limited, Stanmore, UNITED KINGDOM; Alvenie Systems Ltd., Purley, UNITED KINGDOM; Aria Systems Ltd., Reading, UNITED KINGDOM; ARSAT, Buenos Aires, ARGENTINA; Beijing C-platform Digital Technology Co., Ltd., Beijing, PEOPLE'S REPUBLIC OF CHINA; BNM Incorporated, Indialantic, FL; Boss Portal, Auckland, NEW ZEALAND; CableVision, SA, Buenos Aires, ARGENTINA; CalIT Consulting, Hurth, GERMANY; Cellex Networks Systems (2007) Ltd., Bne Beraq, ISRAEL; CIMI Corporation, Voorhees, NJ; CircuitVision, Tampa, FL; Clarebourne Consultancy Ltd., Farnham, UNITED KINGDOM; Conexion S.A., Asuncion, PARAGUAY; CSN Technology Pty Ltd., Eveleigh, AUSTRALIA; Cycle30, Seattle, WA; DAM Solutions, Mexico, MEXICO; DIRECTV, Inc., El Segundo, CA; EA Principals, Inc., Alexandria, VA; Ebizu Sdn. Bhd., Kuala Lumpur, MALAYSIA;

Eirtech Communications, Cork, IRELAND; Enterprise Designer Institute, Daylesford, AUSTRALIA; e-Stratega S.R.L., Olivos, ARGENTINA; everis Chile S.A., Comuna De La Condes, CHILE; Frederick Serr Consulting, Concord, MA; Graphene, Palm Coast, FL; GVT, Curitiba, BRAZIL; Inidat Consulting, Capital Federal, ARGENTINA; Inline Telecom Solutions, Moscow, RUSSIA; Inswitch Solutions, Miami, FL; Integrated Architectures, LLC, Medway, MA; Integrated Research INC, Denver, CO; Intelligent Services Solutions Telecom, Giza, EGYPT; Interfacing Technologies Corp., Montreal, CANADA; iToolsOnline Ltd., Mt Albert, NEW ZEALAND; JSMN Inc., Cobh, IRELAND; Metabula Ltd., Cambridge, UNITED KINGDOM; MHM & Partner AG, Rotkreuz, SWITZERLAND; Millicom International Cellular S.A., Leudelange, LUXEMBOURG; NTG Clarity Networks Inc., Markham, CANADA; NVision group, Moscow, RUSSIA; OperTune Ltd., Oxford, UNITED KINGDOM; Optulink Inc., Naperville, IL; Piran Partners LLP, Windsor, UNITED KINGDOM; Polish Telephones Foundation, Warszawa, POLAND; Quantellia, Denver, CO; RampRate, Santa Monica, CA; Saugatuck Technology, Westport, CT; Semanticore Systems, Roodepoort, SOUTH AFRICA; Sequoia Telecom Associates, San Rafael, CA; SL Software Consult Hungary Ltd., Pécs, HUNGARY; Sprint, Overland Park, KS; Stanford McLeod & Associates Pty Ltd., Point Cook, AUSTRALIA; Stargue, Julianadorp, THE NETHERLANDS; tekten sp. z o.o., Warsaw, POLAND; TelecomAdvisors International S.A., Panama City, PANAMA; Telecom Argentina, S.A., Buenos Aires, ARGENTINA; Telecom Personal Argentina, Ciudad Autónoma de Buenos Aires, ARGENTINA; Tieto, Bühl, GERMANY; UBIqube Solutions, Grenoble, FRANCE; UNE EPM Telecomunicaciones S.A, S100 Loma Los Balsos, COLOMBIA; Unitel Group, Ulaanbaatar, MONGOLIA; Urbatech Group FZE, Casablanca, MOROCCO; VanceInfo Technologies Australia Pty. Ltd., Melbourne, AUSTRALIA; Velocent Systems, Inc., Naperville, IL; WANA CORPORATE, Casablanca, MOROCCO; Wataniya Palestine, Sateh Marhaba, Al Bireh, PALESTINE; Winkler Consulting, Rohr, GERMANY; Xenodon Consulting und Marketing GmbH, Darmstadt, GERMANY; Zimory, Berlin, GERMANY; Applied Network Solutions, Inc., Columbia, MD; Bobbil, Cobh, IRELAND; Broadband Infraco (SOC) Ltd., Woodmead, SOUTH AFRICA; Charter Communications, St. Louis, MO; Diplomatic Telecommunications Program Office (DTS–PO), Fairfax, VA; Forther Ltda, Sao Paulo, BRAZIL; IneoQuest Technologies, Inc., Mansfield, MA; Iprotel Limited, Reading, UNITED KINGDOM; Kaiser Permanente, Pleasanton, CA; Netformx, Inc., San Jose, CA; NISCERT Corporation, Toronto, CANADA; Northpower Fibre, Whangarei, NEW ZEALAND; one2tribe Sp. z o.o., Michalowice, POLAND; OPT Nouvelle Calédonie, Noumea, NEW CALEDONIA; POWERACT Consulting, Casablanca, MOROCCO; PT Indosat Tbk, Jakarta Pusat, INDONESIA; SpiderCloud Wireless, San Jose, CA; Tarantula, Slough, UNITED KINGDOM; Tata Communications Ltd., Mumbai, INDIA; Tom Sawyer Software, Berkley, CA; Vertek Corporation, Colchester, VT; and WebAction, Palo Alto, CA.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and The Forum intends to file additional written notifications disclosing all changes in membership.

On October 21, 1988, the Forum filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on December 8, 1988 (53 FR 49615).

The last notification was filed with the Department on July 8, 2015. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on July 30, 2015 (80 FR 45549).

Patricia A. Brink

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2015–29058 Filed 11–13–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

Antitrust Division

Notice Pursuant to the National Cooperative Research and Production Act of 1993—Silicon Integration Initiative, Inc.

Notice is hereby given that, on September 28, 2015, pursuant to section 6(a) of the National Cooperative Research and Production Act of 1993, 15 U.S.C. 4301 *et seq.* (''the Act''), Silicon Integration Initiative, Inc. (''Si2'') filed written notifications simultaneously with the Attorney General and the Federal Trade Commission disclosing changes in its membership. The notifications were filed for the purpose of extending the Act's provisions limiting the recovery of antitrust plaintiffs to actual damages under specified circumstances. Specifically, Advanced Micro Devices, Sunnyvale, CA; The National Institute of Advanced Industrial Science and Technology (AIST), Tokyo, JAPAN; Altera, San Jose, CA; ams AG, Unterpremstaetten, AUSTRIA; AnaGlobe Technology, Inc., Hsinchu, TAIWAN; Analog Devices, Inc., Norwood, MA; ANSYS, Inc., Canonsburg, PA; ARM, Cambridge, UNITED KINGDOM; Atoptech, Inc., Santa Clara, CA; Aurrion, Inc., Santa Barbara, CA; Avago Technologies, Inc., San Jose, CA; AWR/National Instruments Corporation, Austin, TX; Berkeley Wireless Research Center, Berkley, CA; Blackcomb Design Automation, Inc., Vancouver, CANADA; Broadcom Corporation, Irvine, CA; Concept Engineering GmbH, Freiburg, GERMANY; Coupling Wave Solutions, Grenoble, FRANCE; Computer Simulation Technology (CST), Darmstadt, GERMANY; Denso, Kariya, JAPAN; Dolphin Integration, Grenoble, FRANCE; eASIC Corporation, Santa Clara, CA; EDXACT, Voiron, FRANCE; Entasys Design, Seoul, REPUBLIC OF KOREA; Fractal Technologies, Los Gatos, CA; Fraunhofer Institute for Integrated Circuits IIS, Dresden, GERMANY; GLOBALFOUNDRIES, Santa Clara, CA; Huada Empyrean Software Co. Ltd./ICScape, Beijing, PEOPLE'S REPUBLIC OF CHINA; IMEC, Leuven, BELGIUM; Infineon Technologies, Nuebiberg, GERMANY; Jedat, Tokyo, JAPAN; Kenji Morohashi, Yokohama, JAPAN; Keysight Technologies, Santa Rosa, CA; Lattice Semiconductor Limited, Portland, OR; Luceda N.V., Dendermonde, BELGIUM; Lumerical Solutions, Inc., Vancouver, CANADA; Marvell Semiconductor, Inc., Santa Clara, CA; MediaTek, Hsinchu, TAIWAN,; Micron Technology, Inc., Folsom, CA; Monozukuri S.p.A., Rome, ITALY; NXP Semiconductors, Eindhoven, THE NETHERLANDS; Oracle, Redwood City, CA; PDF Solutions, Inc., San Jose, CA; Peregrine Semiconductor Corporation, San Diego, CA; Phoenix Software, Enschede, THE NETHERLANDS; ProPlus Design Solutions, San Jose, CA; Pulsic Limited, Bristol, UNITED KINGDOM; Qorvo, Inc., Richardson, TX; Qualcomm, Inc., San Diego, CA; Raytheon Company, Waltham, MA; Robust Chip Inc., Pleasanton, CA; Sage Design Automation, Santa Clara, CA; Samsung Electronics Co., Ltd., Hwasung-City, REPUBLIC OF KOREA; Sandia National Laboratories, Albuquerque, NM; Silicon

Frontline Technology, Campbell, CA; SiConTech, Inc., Austin, TX; Silvaco, Inc., Santa Clara, CA; SK Hynix, Inc., Icheon-si, REPUBLIC OF KOREA; Sony, Tokyo, JAPAN; Spectral Design & Test, Inc., Somerville, NJ; Semiconductor Technology Academic Research (STARC), Yokohama, JAPAN; Synopsys, Inc., Mountain View, CA; Taiwan Semiconductor Manufacturing Company Limited (TSMC), Hsinchu, TAIWAN; Teklatech A/S, Copenhagen, DENMARK; Texas Instruments, Dallas, TX; Thales Group, Paris, FRANCE; Tool Corporation, Tokyo, JAPAN; Toshiba Corporation, Kawasaki, JAPAN; Tyndall National Institute, Cork City, IRELAND; United Microelectronics Corporation (UMC), Hsinchu City, TAIWAN; and Zuken, Inc., Yokohama, JAPAN, have been added as parties to this venture.

Also, Chipdata, Inc., Richardson, TX; Electronic Tools Co., Sonoma, CA; Ericsson, Stockholm, SWEDEN; Fujitsu Ltd., Sunnyvale, CA; Monterey Design Systems, Inc., Sunnyvale, CA; Multi-Gig Limited, Wellingborough, UNITED KINGDOM; Semiconductor Research Corporation (SRC), Research Triangle Park, NC; Motorola, Inc., Tempe, AZ; and Sagantec, Fremont, CA, have withdrawn as parties to this venture.

No other changes have been made in either the membership or planned activity of the group research project. Membership in this group research project remains open, and Si2 intends to file additional written notifications disclosing all changes in membership.

On December 30, 1988, Si2 filed its original notification pursuant to section 6(a) of the Act. The Department of Justice published a notice in the **Federal Register** pursuant to section 6(b) of the Act on March 13, 1989 (54 FR 10456).

The last notification was filed with the Department on July 30, 2003. A notice was published in the **Federal Register** pursuant to section 6(b) of the Act on August 29, 2003 (68 FR 52057).

Patricia A. Brink,

Director of Civil Enforcement, Antitrust Division.

[FR Doc. 2015–29057 Filed 11–13–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF JUSTICE

[OMB Number 1103–NEW]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Acquisition 360 Survey

AGENCY: Justice Management Division, Department of Justice.

ACTION: 30-day notice.

SUMMARY: The Department of Justice (DOJ), Justice Management Division will submit the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. This proposed information was previously published in the **Federal Register** at 80 *FR* 53891, on September 8, 2015, allowing for a 60 day comment period.

DATES: Comments are encouraged and will be accepted for an additional 30 days until December 16, 2015.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Mr. Neil Ryder, Director, Internal Review and Evaluation, United States Department of Justice, Justice Management Division, Two Constitution Square, 145 N Street NE., Room 8W–222, Washington, DC 20530. Written comments and/or suggestions can also be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20503 or sent to *OIRA_submissions@omb.eop.gov*.

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Evaluate whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of this information collection:

1 *Type of Information Collection:* New Collection.

2 *The Title of the Form/Collection:* Acquisition 360 Survey.

3 *The agency form number, if any, and the applicable component of the Department sponsoring the collection:*

Form number: None.

Component: Department of Justice, Justice Management Division.

4 *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Business or other for-profit.

Other: Not-for-profit institutions and Federal Government stakeholders

Abstract: The Department of Justice (DOJ) Senior Procurement Executive will use the information to help identify DOJ acquisition process improvements and increase customer satisfaction.

5 *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* An estimated 450 respondents will take 20 minutes to complete the survey.

6 *An estimate of the total public burden (in hours) associated with the collection:* The estimated annual public burden associated with this collection is 150 hours.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., Room 3E–405B, Washington, DC 20530.

Dated: November 10, 2015.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2015–28919 Filed 11–13–15; 8:45 am]

BILLING CODE 4410–NL–P

DEPARTMENT OF JUSTICE

[OMB Number 1105–0025]

Agency Information Collection Activities; Proposed eCollection eComments Requested; Extension Without Change, of a Previously Approved Collection Federal Coal Lease Request

AGENCY: Antitrust Division, Department of Justice.

ACTION: 30-day notice.

SUMMARY: The Department of Justice (DOJ), Antitrust Division (ATR), will be submitting the following information collection request to the Office of

Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. This proposed information collection was previously published in the **Federal Register** at 80 FR 54594 on September 10, 2015, allowing for a 60 day comment period.

DATES: Comments are encouraged and will be accepted for 30 days until January 15, 2016.

FOR FURTHER INFORMATION CONTACT: If you have additional comments especially on the estimated public burden or associated response time, suggestions, or need a copy of the proposed information collection instrument with instructions or additional information, please contact Jill Ptacek, Attorney, Antitrust Division, United States Department of Justice, 450 Fifth Street NW., Suite 8000, Washington, DC 20530 (phone: 202–307–6607). Written comments and/or suggestions can also be directed to the Office of Management and Budget, Office of Information and Regulatory Affairs, Attention Department of Justice Desk Officer, Washington, DC 20530 or sent to *OIRA_submissions@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address one or more of the following four points:

—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;

—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;

—Whether and if so how the quality, utility, and clarity of the information to be collected can be enhanced; and

—Whether the agency's collection process minimizes the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of this information collection:

1 *Type of Information Collection:* Extension of a currently approved collection.

2 *The Title of the Form/Collection:* Federal Coal Lease Reserves.

3 *The agency form number, if any, and the applicable component of the Department sponsoring the collection:* The form numbers are ATR–139 and ATR–140. The applicable component within the Department of Justice is the Antitrust Division.

4 *Affected public who will be asked or required to respond, as well as a brief abstract:*

Primary: Business or other for profit.

Other: None.

Abstract: The Department of Justice evaluates the competitive impact of issuances, transfers and exchanges of federal coal leases. These forms seek information regarding a prospective coal lessee's existing coal reserves. The Department uses this information to determine whether the issuance, transfer or exchange of the federal coal lease is consistent with the antitrust laws.

5 *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* It is estimated that 20 respondents will complete each form, with each response taking approximately two hours.

6 *An estimate of the total public burden (in hours) associated with the collection:* There are an estimated 40 annual burden hours associated with this collection, in total.

If additional information is required contact: Jerri Murray, Department Clearance Officer, United States Department of Justice, Justice Management Division, Policy and Planning Staff, Two Constitution Square, 145 N Street NE., 3E.405B, Washington, DC 20530.

Dated: November 11, 2015.

Jerri Murray,

Department Clearance Officer for PRA, U.S. Department of Justice.

[FR Doc. 2015–28931 Filed 11–13–15; 8:45 am]

BILLING CODE 4410–11–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Amendment to Consent Decree Under the Comprehensive Environmental Repsonse, Compensation, and Liability Act

On November 5, 2015, the Department of Justice lodged a proposed Amendment to Consent Decree with the United States District Court for the Northern District of New York in the lawsuit entitled *United States of America* v. *Amphenol Corporation, et al.,* Civil Action No. 3:01–CV–0637. The caption is different from the caption in the original Consent Decree since companies have gone out of business, changed their names, etc.

The original Consent Decree, entered in 2001, resolved certain claims of the United States under Sections 106 and 107(a) of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980, as amended (''CERCLA''), 42 U.S.C. 9606 and 9607(a), in connection with the performance of the remedial design and remedial action (''RD/RA'') selected for the Tri-Cities Barrel Superfund Site, located in the Town of Fenton, Broome County, New York (the ''Site''), by the United States Environmental Protection Agency (''EPA'') in a Record of Decision executed March 31, 2000, and the reimbursement of response costs. The original Consent Decree required the active remediation of the soils, sediments and groundwater at the Site, with the soils and sediment remediation having now been completed. The Amendment to the Consent Decree is made necessary because EPA in 2011 issued a ROD Amendment which changes the active groundwater remediation to Monitoring Natural Attenuation (MNA).

The publication of this notice opens a period for public comment on the Amendment to Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, John C. Cruden and should refer to *United States of America* v. *Amphenol Corporation, et al.,* D.J. Ref. No. 90–11–3–1514/1. 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, D.C. 20044–7611.

During the public comment period, the Amendment to 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 Amendment to 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 $17.13 (25 cents per page reproduction cost) payable to the United States Treasury, if you are requesting the new Appendices to the Amendment, or $5.63 if you are only requesting the Amendment to the Consent Decree.

Robert E. Maher Jr.,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2015–28850 Filed 11–13–15; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF LABOR

Employment and Training Administration

Labor Certification Process for the Temporary Employment of Aliens in Agriculture in the United States: Adverse Effect Wage Rate for Range Occupations Through 2016

AGENCY: Employment and Training Administration, Department of Labor.

ACTION: Notice.

SUMMARY: The Employment and Training Administration (ETA) of the Department of Labor (Department) is issuing this notice to announce the new Adverse Effect Wage Rate (AEWR) for the employment of temporary or seasonal nonimmigrant foreign workers (H–2A workers) to perform herding or production of livestock on the range.

AEWRs are the minimum wage rates the Department has determined must be offered and paid by employers to H–2A workers and workers in corresponding employment so that the wages of similarly employed U.S. workers will not be adversely affected. 20 CFR 655.100(b). In this notice, the Department announces the new AEWR for workers engaged in the herding or production of livestock on the range, as required by the methodology established in the *Temporary Agricultural Employment of H–2A Foreign Workers in the Herding or Production of Livestock on the Range in the United States,* 80 FR 62958, 63067–63068 (Oct. 16, 2015); 20 CFR 655.211.

DATES: *Effective Date:* This notice is effective November 16, 2015.

FOR FURTHER INFORMATION CONTACT: William W. Thompson, II, Acting Administrator, Office of Foreign Labor Certification, U.S. Department of Labor, Room C–4312, 200 Constitution Avenue NW., Washington, DC 20210. Telephone: 202–693–3010 (this is not a toll-free number). Individuals with hearing or speech impairments may access the telephone number above via TTY by calling the toll-free Federal Information Relay Service at 1–800–877–8339.

SUPPLEMENTARY INFORMATION: On October 16, 2015, the Department published regulations in the **Federal Register** establishing standards and procedures for employers seeking to hire foreign temporary agricultural workers for occupations involving the herding and production of livestock on the range. *Temporary Agricultural Employment of H–2A Foreign Workers in the Herding or Production of Livestock on the Range in the United States,* 80 FR 62958 (Oct. 16, 2015) (H–2A Herder Rule). Effective for all work performed on or after November 16, 2015, including for work certified under earlier special procedures, the H–2A Herder Rule requires employers to offer, advertise in recruitment and pay each worker employed under 20 CFR 655.200–655.235 a wage that is at least the highest of: (i) The monthly AEWR, (ii) the agreed-upon collective bargaining wage, or (iii) the applicable minimum wage imposed by Federal or State law or judicial action. 20 CFR 655.211(a)(1). Further, when the monthly AEWR is adjusted during a work contract, and is higher than both the agreed-upon collective bargaining wage and the applicable minimum wage imposed by Federal or State law or judicial action in effect at the time the work is performed, the employer must pay that adjusted monthly AEWR upon publication by the Department in the **Federal Register**. 20 CFR 655.211(a)(2).

As provided in 20 CFR 655.211(c) of the H–2A Herder Rule, the methodology for establishing the monthly AEWR for range occupations in all states is based on the current Federal minimum wage ($7.25/hour) multiplied by 48 hours per week, and then multiplied by 4.333 weeks per month. In applying the transition wage rate methodology set forth under 20 CFR 655.211(d)(1), the Department is setting the initial national monthly AEWR at 80 percent of the full wage calculated using the H–2A Herder Rule methodology. Thus, the national monthly AEWR rate for all range occupations in the H–2A program is calculated at ($7.25 \times 48 \times 4.333 \times .80$ = 1,206.31) or $1,206.31.[1]

Accordingly, any employer certified or seeking certification for range workers must pay each worker a wage that is at least the highest of the monthly AEWR of $1,206.31, the agreed-upon collective bargaining wage, or the applicable minimum wage imposed by Federal or State legislation or judicial action, effective immediately. Given the mid-month effective date of the new AEWR, the prorated amount due for employers obligated to pay the new AEWR for work performed for the portion of November following the effective date is $603.15.

Portia Wu,

Assistant Secretary, Employment and Training Administration.

[FR Doc. 2015–28934 Filed 11–13–15; 8:45 am]

BILLING CODE 4510–FP–P

[1] Because less than two months remain in 2015, and the AEWR for workers engaged in the herding or production of livestock on the range announced in this notice applies through calendar year 2016 under 20 CFR 655.211(d), a separate notice will not be issued for 2016. Beginning with 2017, an updated AEWR will be published annually.

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Disclosures for Participant Directed Individual Account Plans

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Employee Benefits Security Administration (EBSA) sponsored information collection request (ICR) titled, ''Disclosures for Participant Directed Individual Account Plans,'' to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.* Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before December 16, 2015.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201510-1210-009* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs,

Attn: OMB Desk Officer for DOL–EBSA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor—OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR seeks to extend PRA authority for the Disclosures for Participant Directed Individual Account Plans information collection. Employee Retirement Income Security Act of 1974 (ERISA) section 404(c), 29 U.S.C. 1104(c), provides that, if an individual account pension plan permits a participant or beneficiary to exercise control over assets in his or her account and the participant or beneficiary in fact exercises such control (as determined under DOL regulations), the participant or beneficiary shall not be deemed to be a fiduciary by such exercise of control and no person otherwise a fiduciary to the plan shall be liable for any loss or breach that results solely from this exercise of control. Regulations 29 CFR 2550.404a–5 provides that, when a plan allocates investment responsibilities to participants or beneficiaries, the plan administrator must take action to ensure they are provided with sufficient information regarding the plan and its investment options, including fee and expense information, to make informed decisions with regard to the management of their individual accounts; therefore, the regulation requires a plan administrator to provide each participant or beneficiary with certain plan-related information and investment-related information. ERISA section 404 authorizes this information collection. *See* 29 U.S.C. 1104.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1210–0090.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the current approval for this collection is scheduled to expire on November 30, 2015. The DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related rulemaking notice published in the **Federal Register** on March 19, 2015 (80 FR 14301).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1210–0090. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: DOL–EBSA.

Title of Collection: Disclosures for Participant Directed Individual Account Plans.

OMB Control Number: 1210–0090.

Affected Public: Private Sector—businesses or other for-profits.

Total Estimated Number of Respondents: 518,282.

Total Estimated Number of Responses: 713,900,000.

Total Estimated Annual Time Burden: 7,300,000 hours.

Total Estimated Annual Other Costs Burden: $274,000,000.

Dated: November 9, 2015.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2015–28930 Filed 11–13–15; 8:45 am]

BILLING CODE 4510–29–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[Notice: 15–103]

Notice of Information Collection

AGENCY: National Aeronautics and Space Administration (NASA).

ACTION: Notice of information collection.

SUMMARY: The National Aeronautics and Space Administration, 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 (Pub. L. 104–13, 44 U.S.C. 3506(c)(2)(A)).

DATES: All comments should be submitted within 30 calendar days from the date of this publication.

ADDRESSES: Interested persons are invited to submit written comments regarding the proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 7th Street NW., Washington, DC 20543. Attention: Desk Officer for NASA.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument(s) and instructions should be directed to Ms. Frances Teel, NASA Clearance Officer, NASA Headquarters, 300 E Street SW., JF000, Washington, DC 20546, or *Frances.C.Teel@nasa.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract

The NASA Contractor Financial Management Reporting System is the basic financial medium for contractor reporting of estimated and incurred costs, providing essential data for projecting costs and hours to ensure that contractor performance is realistically planned and supported by dollar and labor resources. The data provided by

these reports is an integral part of the Agency's accrual accounting and cost based budgeting system. Respondents are reimbursed for associated cost to provide the information, per their negotiated contract price and associated terms of the contract. There are no ''total capital and start-up'' or ''total operation and maintenance and purchase of services'' costs associated since NASA policy requires that data reported is generated from the contractors' existing system. The contractors' internal management system shall be relied upon to the maximum extent possible.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval of this information collection. They will also become a matter of public record.

II. Method of Collection

NASA collects this information electronically and that is the preferred manner, however information may also be collected via mail or fax.

III. Data

Title: NASA Contractor Financial Management Reports.

OMB Number: 2700–0003.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit, not-for-profit institutions.

Estimated number of respondents: 800.

Estimated Time per Response: 9 hrs.

Estimated Total Annual Burden Hours: 7,200.

Estimated Total Annual Cost: $0.

IV: Request for Comments

Comments are invited on: (1) Whether the proposed collection of information is necessary for the proper performance of the functions of NASA, including whether the information collection has practical utility; (2) the accuracy of NASA's estimate of the burden (including hours and cost) of the proposed collection of information; (3) ways to minimize the burden of the collection of information on respondents.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval of this information collection. They will also become a matter of public record.

Frances Teel,

NASA PRA Clearance Officer.

[FR Doc. 2015–29141 Filed 11–13–15; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts

Arts Advisory Panel Meetings

AGENCY: National Endowment for the Arts, National Foundation on the Arts and Humanities.

ACTION: Notice of meetings.

SUMMARY: Pursuant to the Federal Advisory Committee Act, as amended, notice is hereby given that 20 meetings of the Arts Advisory Panel to the National Council on the Arts will be held by teleconference.

DATES: All meetings are Eastern time and ending times are approximate:

Arts Education (review of applications): This meeting will be closed.

Date and time: December 3, 2015; 1:30 p.m. to 3:30 p.m.

Local Arts Agencies (review of applications): This meeting will be closed.

Date and time: December 3, 2015; 1:00 p.m. to 3:00 p.m.

Local Arts Agencies (review of applications): This meeting will be closed.

Date and time: December 3, 2015; 3:30 p.m. to 5:30 p.m.

Arts Education (review of applications): This meeting will be closed.

Date and time: December 4, 2015; 1:30 p.m. to 3:30 p.m.

Presenting and Multidisciplinary Works (review of applications): This meeting will be closed.

Date and time: December 7, 2015; 2:00 p.m. to 4:00 p.m.

Museums (review of applications): This meeting will be closed.

Date and time: December 8, 2015; 11:30 a.m. to 1:30 p.m.

Museums (review of applications): This meeting will be closed.

Date and time: December 8, 2015; 2:30 p.m. to 4:30 p.m.

Opera (review of applications): This meeting will be closed.

Date and time: December 8, 2015; 12:00 p.m. to 2:00 p.m.

Opera (review of applications): This meeting will be closed.

Date and time: December 8, 2015; 3:00 p.m. to 5:00 p.m.

Presenting and Multidisciplinary Works (review of applications): This meeting will be closed.

Date and time: December 8, 2015; 2 p.m. to 4 p.m.

Arts Education (review of applications): This meeting will be closed.

Date and time: December 9, 2015; 1:30 p.m. to 3:30 p.m.

Literature (review of applications): This meeting will be closed.

Date and time: December 9, 2015; 3:00 p.m. to 5:00 p.m.

Presenting and Multidisciplinary Works (review of applications): This meeting will be closed.

Date and time: December 9, 2015; 2:00 p.m. to 4:00 p.m.

Literature (review of applications): This meeting will be closed.

Date and time: December 10, 2015; 3:00 p.m. to 5:00 p.m.

Museums (review of applications): This meeting will be closed.

Date and time: December 10, 2015; 11:30 a.m. to 1:30 p.m.

Museums (review of applications): This meeting will be closed.

Date and time: December 10, 2015; 2:30 a.m. to 4:30 p.m.

Presenting and Multidisciplinary Works (review of applications): This meeting will be closed.

Date and time: December 10, 2015; 2:00 p.m. to 4:00 p.m.

Folk and Traditional Arts (review of applications): This meeting will be closed.

Date and time: December 15, 2015; 2:00 p.m. to 4:00 p.m.

Arts Education (review of applications): This meeting will be closed.

Date and time: December 17, 2015; 1:30 p.m. to 3:30 p.m.

Folk and Traditional Arts (review of applications): This meeting will be closed.

Date and time: December 17, 2015; 2:00 p.m. to 4:00 p.m.

ADDRESSES: National Endowment for the Arts, Constitution Center, 400 7th St. SW., Washington, DC, 20506.

FOR FURTHER INFORMATION CONTACT: Further information with reference to these meetings can be obtained from Ms. Kathy Plowitz-Worden, Office of Guidelines & Panel Operations, National Endowment for the Arts, Washington, DC, 20506; *plowitzk@arts.gov,* or call 202/682–5691.

SUPPLEMENTARY INFORMATION: The closed portions of meetings are for the purpose of Panel review, discussion, evaluation, and recommendations on financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency. In accordance with the determination of the Chairman of February 15, 2012, these sessions will be closed to the public pursuant to subsection (c)(6) of section 552b of title 5, United States Code.

Dated: November 9, 2015.

Kathy Plowitz-Worden,

Panel Coordinator, National Endowment for the Arts.

[FR Doc. 2015–28852 Filed 11–13–15; 8:45 am]

BILLING CODE 7537–01–P

NATIONAL SCIENCE FOUNDATION

Proposal Review Panel for Computing and Communication Foundations; Notice of Meeting

In accordance with the Federal Advisory Committee Act (Pub., L. 92–463, as amended), the National Science Foundation announces the following meeting:

Name: Proposal Panel Review for Science and Technology Centers—Integrative Partnerships (#1192) Site Visit.

Date/Time: December 7, 2015, 6:30 p.m.–8:30 p.m.; December 8, 2015, 8:00 a.m.–8:00 p.m.; December 9, 2015, 8:30 a.m.–3:00 p.m.

Place: Purdue University, West Lafayette, IN 47907.

Type of Meeting: Part-Open.

Contact Person: John Cozzens, National Science Foundation, 4201 Wilson Boulevard, Room 1115, Arlington, VA 22230. Telephone: (703) 292–8910.

Purpose of Meeting: To assess the progress of the STC Award: 0939370 ''Emerging Frontiers of Science of Information: the Science and the Technology of Intelligence'', and to provide advise and recommendations concerning further NSF support for the Center.

Agenda: CSol Purdue Site Visit

Monday, December 7, 2015, 6:30 p.m. to 8:30 p.m.: Closed; Site Team and NSF Staff meets to discuss Site Visit materials, review process and charge.

Tuesday, December 8, 2015, 8:00 a.m. to 1:00 p.m.: Open; Presentations by Awardee Institution, faculty staff and students, to Site Team and NSF Staff; Discussions, question and answer sessions.

1:00 p.m.–8:00 p.m.: Closed; Draft report on education and research activities.

Wednesday, December 9, 2015, 8:30 a.m.–noon: Open; Response presentations by Site Team and NSF Staff Awardee Institution faculty staff; Discussions, question and answer sessions.

Noon to 3:00 p.m.: Closed; Complete written site visit report with preliminary recommendations.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information; financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: November 10, 2015.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2015–29165 Filed 11–13–15; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

Business and Operations Advisory Committee; Notice of Meeting

In accordance with Federal Advisory Committee Act (Pub. L. 92–463, as amended), the National Science Foundation announces the following meeting:

Name: Business and Operations Advisory Committee (9556).

Date/Time: December 8, 2015; 1:00 p.m. to 5:45 p.m. (EST).

December 9, 2015; 8:45 a.m. to 12:00 p.m. (EST).

Place: National Science Foundation, 4201 Wilson Boulevard, Arlington, Virginia 22230; Stafford I, Room 1235

Type of Meeting: PART–OPEN.

Contact Person: Joan Miller, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230 (703) 292–8200.

Purpose of Meeting: To provide advice concerning issues related to the oversight, integrity, development and enhancement of NSF's business operations.

Agenda:

December 8, 2015.

1:00 p.m.–4:30 p.m., OPEN—Welcome/Introductions; BFA/OIRM Updates; NSF Headquarters Relocation Update; Modernizing the Workforce—IT—Driven Change Management; Records Management/Digitization.

4:30 p.m.–5:45 p.m. CLOSED—Briefing on the National Academy of Public Administration Study of NSF's Use of Cooperative Agreements to Support Large Scale Investments in Science and Technology.

December 9, 2015

8:45 a.m.–12:00 p.m. OPEN—Preparation for discussion with NSF Director and Chief Operating Officer; Discussion with NSF Director and Chief Operating Officer; Presidential Transitions: What Agencies Can Do to Prepare; Meeting Wrap-Up.

Reason for Closing: This session of the meeting is closed to the public in accordance with the provisions of 5 U.S.C. 552b(c), (4) and (6) of the Government in the Sunshine Act.

Dated: November 10, 2015.

Crystal Robinson,

Committee Management Officer.

[FR Doc. 2015–29164 Filed 11–13–15; 8:45 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2015–0020]

Sodium Iodide–131 Patient Release Information Collection

AGENCY: Nuclear Regulatory Commission.

ACTION: Request for information.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting information from the general public on a number of issues associated with medical treatment of patients with sodium iodide I–131 (hereafter referred to as I–131). Specifically, the NRC would like input on patient concerns about medical treatment involving the use of I–131, information that physicians use to make decisions on when it is safe to release I–131 patients based on radiation exposure concerns, radiation safety information used by I–131 patients after their release, and the availability of a radiation safety informational guidance brochure for I–131 patients that can be distributed nationwide. The information collected will be used to develop a Web site to provide patients with clear and consistent information about radioactive iodine treatments and to revise NRC patient release guidance.

DATES: Submit information and comments by February 16, 2016. Information and comments received after this date will be considered if it is practical to do so, but the NRC is able to assure consideration only for information and comments received on or before this date.

ADDRESSES: You may submit information and comments by any of the following methods (unless this document describes a different method for submitting information and comments on a specific subject):

- Federal Rulemaking Web site: Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0020. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- Mail information and comments to: Cindy Bladey, Office of Administration,

Mail Stop: OWFN–12–H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining and submitting information and comments, see ''Obtaining and Submitting Information and Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Donna-Beth Howe, Ph.D., Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–7848; email: *Donna-Beth.Howe@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining and Submitting Information and Comments

A. Obtaining Information

Please refer to Docket ID NRC–2015–0020 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- Federal rulemaking Web site: Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0020.
- NRC's Agencywide Documents Access and Management System (ADAMS): You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''ADAMS Public Documents'' and then select ''Begin Web-based ADAMS Search.'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in the **SUPPLEMENTARY INFORMATION** section.
- NRC's PDR: You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Information and Comments

Please include Docket ID NRC–2015–0020 in your submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your submission. The NRC will post all submissions at *http://www.regulations.gov* as well as enter the submissions into ADAMS. The NRC does not routinely edit submissions to remove identifying or contact information.

If you are requesting or aggregating information from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their submission. Your request should state that the NRC does not routinely edit submissions to remove such information before making the submissions available to the public or entering the submission into ADAMS.

II. Background

In a March 10, 2014, memorandum to the Commission (COMAMM–14–0001/COMWDM–14–0001, ''Background and Proposed Direction to NRC Staff to Verify Assumptions Made Concerning Patient Release Guidance'' (see *http://www.nrc.gov/reading-rm/doc-collections/commission/comm-secy/2014/2014-0001comamm-0001-comwdm.pdf*), NRC Chairman MacFarlane and Commissioner Magwood brought into question whether patients receiving I–131 treatments are given consistent and useful information from medical facilities and whether patients can correctly follow those instructions. Anecdotal data from patients and patient advocacy groups indicated that while instructions are provided, the quality of the instructions varies significantly, and that some patients are provided with instructions that the patient and the medical facility know will be impractical to follow.

In the Staff Requirements Memorandum to COMAMM–14–0001/COMWDM–14–0001 (see *http://www.nrc.gov/reading-rm/doc-collections/commission/comm-secy/2014/2014-0001comamm-0001-comwdmsrm.pdf*), the Commission, among other things, directed the NRC staff to develop a Web site that provides patients with clear and concise information and links to relevant medical and patient advocacy Web sites about I–131 treatments, to revise NRC guidance to specify guidelines for patient instructions and information including a voluntary model patient/licensee acknowledgement form documenting the patient/licensee dialog leading to the licensee's decision of when to safely release the patient from its control based on radiation exposure concerns, and to develop a standard set of guidelines that licensees can use to provide instructions to released I–131 patients. The Commission also directed the NRC staff to consider whether the guidance information provided to the patients can be made into an NRC brochure, or whether a medical organization already has, or would produce, a brochure for nationwide distribution.

The NRC is interested in obtaining input from as many stakeholders as possible, including the NRC's Advisory Committee on the Medical Use of Isotopes, professional organizations, physicians, patients, patient advocacy groups, licensees, Agreement States, and other interested individuals. The focus of this information gathering effort is to obtain: Information that patients believe will help them understand the I–131 treatment (also referred to as Radioactive Iodine (RAI)) procedures, the physician's or licensee's best practices when making informed decisions on releasing RAI treatment patients, and information provided to patients on how to reduce radiation doses to others. The NRC is also interested in learning if patient advocacy, medical professional organizations, licensees, or other individuals have brochures that already contain the information requested.

III. Requested Information and Comments

A. Web Site Information

The NRC is considering establishing a Web site that provides potential patients with information on RAI treatment procedures so that patients will understand the reason for the procedures, the process, and how to reduce radiation exposure to others. Some of this is medical information that is outside the NRC's field of expertise. The NRC would like to be able to provide links to other sites providing this medical information. The NRC may develop the basic radiation safety information itself, but could provide links if established sites already have this information.

The NRC is also seeking input from patients, patient advocacy groups, and other interested individuals to articulate concerns that may not be included in the topics identified in this section.

If you have, or know of, a Web site that that can be used to explain the disease and treatment process, and addresses one or more of the following topics, please provide the link to the NRC.

- What is radioactivity?
- What is radioactive iodine (RAI)?
- RAI treatment:
- Any explanation of how radiation is used in the treatment should include clear information that the patient will receive radioactive material, emit radiation, retain radioactive material, and release radioactive material.

- Preparing for RAI treatment.
- What to expect before and after receiving the treatment.
- Side effects of RAI treatment.
- Basic radiation safety:
- Appropriate venues for recovery after release.
- Precautions to take after receiving treatment.
- Risks to others, to include risks to young children and pregnant women.
- Expected general behaviors after release.

When identifying a Web site, indicate the topic it addresses and provide a link to that specific information on the topic.

B. Patient/Licensee Acknowledgement Form and Best Practices in Making Informed Decisions on Releasing Patients Treated With I–131 Based on Radiation Exposure Considerations

The NRC is looking for best practices used by individual physicians and licensees that focus on enhancing the ability to make informed radiation safety decisions on the release of individual patients from their radiation safety control under the patient release criteria in the NRC's medical use regulations. The NRC expects the physician (licensee) to have a dialog with the patient that will ultimately lead to an informed decision on when the patient should be released from its radiation safety control based on radiation exposure considerations (this includes immediate or delayed release, in addition to hospitalization). The NRC is also interested in knowing whether a patient/licensee acknowledgment form documenting this dialog exists and is part of the physicians' best practices. The NRC believes this dialog would include some or all of the following:

- The patient's ability to understand the language of the physician (licensee) or need for an interpreter that understands the procedure.
- The need for a family member or another support person present to facilitate better retention of information.
- A discussion with the patient to determine suitability for release.
- Description of the patient's transportation from the medical facility to home.
- Discussion of the patient's normal daily behavior and patterns, including but not limited to:
- The patient's normal/routine social interactions.
- The patient's normal/routine working environment and tasks.
- The patient's normal/routine living arrangements.
- The planned changes to the patient's normal/routine behaviors during the treatment period (have friend or family member accompany the patient or spend time with patient, change in living arrangements, etc.).
- Financial considerations that will affect the patient's preference on early or delayed release.
- Discussion to evaluate patient's ability to understand and follow instructions.
- Discussion to evaluate of patient's willingness to follow instructions.
- Discussion to evaluate the level of disruption to patient routine lifestyle, if released, and the ability of the patient to make and follow the changes, if released.

If you have a policy or procedure that provides you with the confidence that you are releasing the patient at the appropriate time, please describe your policy or provide your procedure. If the policy or procedure includes a patient/licensee acknowledgement form, or if you have a stand-alone form, documenting the patient/licensee discussion, please provide it. The policy, procedure, or form could include some of the topics listed but may include others. Indicate when this type of discussion with the patients takes place (*e.g.,* when the patient is referred for the procedure, before administration, after administration, etc.). Does the timing of this discussion allow the patient enough time to make different living, working, or transportation arrangements or for the medical facility to make delayed release (may include hospitalization) arrangements? Please describe how your best practices are used in the decision making process.

The NRC would also like input from the patient's or other interested individual's perspective of the optimal time for the discussion to take place so that both the patient and the medical facility have confidence the release decision is appropriate. How much time is needed to allow patients to make different living, working, transportation arrangements? The NRC is also seeking input from patients, patient advocacy groups, and other interested individuals to articulate other topics that should be included in the discussion.

C. Guidance for Released Patients

The Commission directed the NRC staff to develop standardized guidance for licensees to provide to their patients that would help to reduce the variability of instructions provided to patients and eliminate some of the uncertainty regarding the type of information that is provided to the patient. While the NRC currently prefers to develop performance based guidance (articulating objectives but not telling licensees how to reach those objectives), prescriptive guidance (*i.e.,* very detailed and specific) may be necessary to reduce uncertainty and provide confidence that regulatory requirements are met. If the standardized guidance is performance-based, it would need to provide individual patients with the ''tools'' needed to follow the objectives in the guidance and protect others.

If you have guidance documents that you believe provide clear instructions to released patients, please provide a copy to the NRC. If your guidance includes topics not addressed below, indicate why you think each is an important topic to include. If it does not address one of the topics and you believe that topic is not needed, describe why it is not needed.

- What ''tools'' (or methods/means) can the patient use to protect others once released?
- Are both oral and written information presented in the patient's native language and presented in a manner understandable to both the patient and physician (licensee)?
- Does the medical facility/licensee have access to an interpreting service to make sure that oral and written information and instructions are understood?
- How are instructions personalized to the individual patient?
- Does the medical facility explain how to limit the exposures to others (especially to young children and pregnant women)?
- Arrangements for protecting others once arriving at home.
- Informed how long special care must be exercised.
- Are actions described that the patient can take to minimize the exposure of people both inside and outside the home?
- Do transportation instructions from the medical facility to home match the patient's plans?
- Are discussions held on managing biological wastes and trash in accordance with NRC, state, and local requirements?
- Are discussions held to identify whom to contact in the event that questions arise during the recovery period?
- Are discussions held on where to go for emergency care?

The NRC is also seeking input from patients, patient advocacy groups, and other interested individuals to articulate topics that should be included in the instructions provided to released patients. Further, when do you want to be provided with these instructions? Are the instructions provided in a manner that is easy to understand and

follow? What would have made the instructions better?

D. Brochure for Nationwide Use

The NRC is seeking identification of a brochure that you believe provides clear guidance on the release of patients treated with I–131. If you have or know of such a brochure please send the NRC a copy or a link to it. The intent is to identify a brochure that could be distributed nationwide.

IV. Paperwork Reduction Act Statement

This information request contains information collection requirements that are subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). These information collections were approved by the Office of Management and Budget (OMB), OMB control number 3150–0229, expiration date of October 31, 2018.

The burden to the public for these information collections is estimated to average 0.25 to 0.50 hours per response, including time for reviewing instructions, searching existing data sources, gathering data, performing necessary analyses, and completing and reviewing the information collection. This information collection request only information already possessed by the responder and does not request the responder develop any new data.

The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

Dated at Rockville, Maryland, this 5th day of November, 2015.

For the Nuclear Regulatory Commission.

Christian E. Einberg,

Acting Deputy Director, Division of Material Safety, State, Tribal and Rulemaking Programs, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2015–29027 Filed 11–13–15; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 40–38367, NRC–2015–0255]

Rare Element Resources, Inc.; Bear Lodge Project

AGENCY: Nuclear Regulatory Commission.

ACTION: License application; opportunity to request a hearing and petition for leave to intervene; order.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has received an application from Rare Element Resources, Inc., for a license to possess and use source material associated with its Bear Lodge Project. The Bear Lodge Project includes a mine in the Black Hills National Forest in Crook County, Wyoming for the purpose of extracting rare earth element ores, and a rare earth element processing plant in Weston County, Wyoming. In addition, the license application contains sensitive unclassified non-safeguards information (SUNSI).

DATES: A request for a hearing or petition for leave to intervene must be filed by January 15, 2016. Any potential party as defined in § 2.4 of title 10 of the *Code of Federal Regulations* (10 CFR), who believes access to SUNSI is necessary to respond to this notice must request document access by November 27, 2015.

ADDRESSES: Please refer to Docket ID NRC–2015–0255 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- Federal Rulemaking Web site: Go to *http://www.regulations.gov* and search for Docket ID NRC–2015–0255. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- NRC's Agencywide Documents Access and Management System (ADAMS): You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''*ADAMS Public Documents''* and then select ''*Begin Web-based ADAMS Search.*'' For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in the **SUPPLEMENTARY INFORMATION** section.
- NRC's PDR: You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Kenneth Kalman, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–6664, email: *Kenneth.Kalman@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC has received, by letter dated May 4, 2015 (ADAMS Accession No. ML15132A726), an application from Rare Element Resources Inc., to possess and use up to 10 curies of unsealed, non-volatile thorium hydroxide and to possess and use unlimited quantities of unsealed, non-volatile source material in any bound form. The source material will be uranium and thorium in their natural isotopic abundance in concentrations greater than 0.05 percent by weight. The NRC staff will document its review of this license application in a safety evaluation report and an environmental assessment.

The license application is available in ADAMS under Accession No. ML15134A378. The NRC has identified the following documents as containing SUNSI and is withholding these documents from public disclosure pursuant to Section 304 of the National Historic Preservation Act of 1966, 54 U.S.C. 307103.

- ''Stand Alone Report 10, A Class III Cultural Resource Inventory of the Bear Lodge Project—Upton Plant Site.''
- The two Tribal reports referenced in Section 7.3, ''Historic, Scenic, and Cultural Resources,'' of the application.

II. Opportunity to Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this notice, any person(s) whose interest may be affected by this action may file a request for a hearing and a petition to intervene with respect to issuance of the amendment to the subject facility operating license or combined license. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Agency Rules of Practice and Procedure'' in 10 CFR part 2. Interested person(s) should consult a current copy of 10 CFR 2.309, which is available at the NRC's PDR, located in One White Flint North, Room O1–F21 (first floor), 11555 Rockville Pike, Rockville, Maryland 20852. The NRC's regulations are accessible electronically from the NRC Library on the NRC's Web site at *http://www.nrc.gov/reading-rm/doc-collections/cfr/.* If a request for a hearing or petition for leave to intervene is filed within 60 days, the Commission or a presiding officer designated by the Commission or by the Chief Administrative Judge of the Atomic

Safety and Licensing Board Panel will rule on the request and/or petition. The Secretary or the Chief Administrative Judge of the Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.309, a petition for leave to intervene shall set forth, with particularity, the interest of the petitioner in the proceeding and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted, with particular reference to the following general requirements: (1) The name, address, and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The petition must also set forth the specific contentions which the requestor/petitioner seeks to have litigated at the proceeding.

Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the requestor/petitioner shall provide a brief explanation of the bases for the contention and a concise statement of the alleged facts or expert opinion that support the contention and on which the requestor/petitioner intends to rely in proving the contention at the hearing. The requestor/petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the requestor/petitioner intends to rely to establish those facts or expert opinion. The petition must include sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the requestor/petitioner to relief. A requestor/petitioner who fails to satisfy these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that person's admitted contentions, including the opportunity to present evidence and to submit a cross-examination plan for cross-examination of witnesses, consistent with NRC regulations, policies, and procedures. The Atomic Safety and Licensing Board will set the time and place for any prehearing conferences and evidentiary hearings, and the appropriate notices will be provided.

Petitions for leave to intervene must be filed no later than 60 days from the date of publication of this notice. Requests for hearing, petitions for leave to intervene, and motions for leave to file new or amended contentions that are filed after the 60-day deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i)–(iii).

A State, local governmental body, Federally-recognized Indian tribe, or agency thereof, may submit a petition to the Commission to participate as a party under 10 CFR 2.309(h)(1). The petition should state the nature and extent of the petitioner's interest in the proceeding. The petition should be submitted to the Commission by January 15, 2016. The petition must be filed in accordance with the filing instructions in the ''Electronic Submissions (E-Filing)'' section of this document, and should meet the requirements for petitions for leave to intervene set forth in this section, except that under § 2.309(h)(2) a State, local governmental body, or Federally-recognized Indian tribe, or agency thereof does not need to address the standing requirements in 10 CFR 2.309(d) if the facility is located within its boundaries. A State, local governmental body, Federally-recognized Indian tribe, or agency thereof may also have the opportunity to participate under 10 CFR 2.315(c).

If a hearing is granted, any person who does not wish, or is not qualified, to become a party to the proceeding may, in the discretion of the presiding officer, be permitted to make a limited appearance pursuant to the provisions of 10 CFR 2.315(a). A person making a limited appearance may make an oral or written statement of position on the issues, but may not otherwise participate in the proceeding. A limited appearance may be made at any session of the hearing or at any prehearing conference, subject to the limits and conditions as may be imposed by the presiding officer. Persons desiring to make a limited appearance are requested to inform the Secretary of the Commission by January 15, 2016.

III. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least ten 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at *hearing.docket@nrc.gov,* or by telephone at 301–415–1677, to request (1) a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals/getting-started.html.* System requirements for accessing the E-Submittal server are detailed in the NRC's ''Guidance for Electronic Submission,'' which is available on the agency's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the

participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange System, users will be required to install a Web browser plug-in from the NRC's Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.*

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the ''Contact Us'' link located on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html,* by email to *MSHD.Resource@nrc.gov,* or by a toll-free call at 1–866–672–7640. The NRC Meta System Help Desk is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at *http://ehd1.nrc.gov/ehd/*, unless excluded pursuant to an order of the Commission, or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. However, in some instances, a request to intervene will require including information on local residence in order to demonstrate a proximity assertion of interest in the proceeding. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

Order Imposing Procedures for Access to Sensitive Unclassified Non-Safeguards Information for Contention Preparation

Rare Element Resources, Docket No. 040–38367, Bear Lodge Project, Crook and Weston Counties, Wyoming

A. This Order contains instructions regarding how potential parties to this proceeding may request access to documents containing SUNSI.

B. Within 10 days after publication of this notice of hearing and opportunity to petition for leave to intervene, any potential party who believes access to SUNSI is necessary to respond to this notice may request such access. A ''potential party'' is any person who intends to participate as a party by demonstrating standing and filing an admissible contention under 10 CFR 2.309. Requests for access to SUNSI submitted later than 10 days after publication of this notice will not be considered absent a showing of good cause for the late filing, addressing why the request could not have been filed earlier.

C. The requester shall submit a letter requesting permission to access SUNSI to the Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, and provide a copy to the Associate General Counsel for Hearings, Enforcement and Administration, Office of the General Counsel, Washington, DC 20555–0001. The expedited delivery or courier mail address for both offices is: U.S. Nuclear Regulatory Commission, 11555 Rockville Pike, Rockville, Maryland 20852. The email address for the Office of the Secretary and the Office of the General Counsel are *Hearing.Docket@nrc.gov* and *OGCmailcenter@nrc.gov,* respectively.[1] The request must include the following information:

(1) A description of the licensing action with a citation to this **Federal Register** notice;

(2) The name and address of the potential party and a description of the potential party's particularized interest that could be harmed by the action identified in C.(1); and

(3) The identity of the individual or entity requesting access to SUNSI and the requester's basis for the need for the information in order to meaningfully participate in this adjudicatory proceeding. In particular, the request must explain why publicly-available versions of the information requested would not be sufficient to provide the basis and specificity for a proffered contention.

D. Based on an evaluation of the information submitted under paragraph C.(3) the NRC staff will determine within 10 days of receipt of the request whether:

(1) There is a reasonable basis to believe the petitioner is likely to

[1] While a request for hearing or petition to intervene in this proceeding must comply with the filing requirements of the NRC's ''E-Filing Rule,'' the initial request to access SUNSI under these procedures should be submitted as described in this paragraph.

establish standing to participate in this NRC proceeding; and

(2) The requestor has established a legitimate need for access to SUNSI.

E. If the NRC staff determines that the requestor satisfies both D.(1) and D.(2) above, the NRC staff will notify the requestor in writing that access to SUNSI has been granted. The written notification will contain instructions on how the requestor may obtain copies of the requested documents, and any other conditions that may apply to access to those documents. These conditions may include, but are not limited to, the signing of a Non-Disclosure Agreement or Affidavit, or Protective Order [2] setting forth terms and conditions to prevent the unauthorized or inadvertent disclosure of SUNSI by each individual who will be granted access to SUNSI.

F. Filing of Contentions. Any contentions in these proceedings that are based upon the information received as a result of the request made for SUNSI must be filed by the requestor no later than 25 days after the requestor is granted access to that information. However, if more than 25 days remain between the date the petitioner is granted access to the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline. This provision does not extend the time for filing a request for a hearing and petition to intervene, which must comply with the requirements of 10 CFR 2.309.

G. Review of Denials of Access.

(1) If the request for access to SUNSI is denied by the NRC staff after a determination on standing and need for access, the NRC staff shall immediately notify the requestor in writing, briefly stating the reason or reasons for the denial.

(2) The requester may challenge the NRC staff's adverse determination by filing a challenge within 5 days of receipt of that determination with: (a) The presiding officer designated in this proceeding; (b) if no presiding officer has been appointed, the Chief Administrative Judge, or if he or she is unavailable, another administrative judge, or an administrative law judge with jurisdiction pursuant to 10 CFR 2.318(a); or (c) officer if that officer has been designated to rule on information access issues.

H. Review of Grants of Access. A party other than the requester may challenge an NRC staff determination granting access to SUNSI whose release would harm that party's interest independent of the proceeding. Such a challenge must be filed with the Chief Administrative Judge within 5 days of the notification by the NRC staff of its grant of access.

If challenges to the NRC staff determinations are filed, these procedures give way to the normal process for litigating disputes concerning access to information. The availability of interlocutory review by the Commission of orders ruling on such NRC staff determinations (whether granting or denying access) is governed by 10 CFR 2.311.[3]

I. The Commission expects that the NRC staff and presiding officers (and any other reviewing officers) will consider and resolve requests for access to SUNSI, and motions for protective orders, in a timely fashion in order to minimize any unnecessary delays in identifying those petitioners who have standing and who have propounded contentions meeting the specificity and basis requirements in 10 CFR part 2. Attachment 1 to the Order summarizes the general target schedule for processing and resolving requests under these procedures.

It is so ordered.

Dated at Rockville, Maryland, this 6th day of November, 2015.

For the Nuclear Regulatory Commission.

Annette L. Vietti-Cook,

Secretary of the Commission.

ATTACHMENT 1—General Target Schedule for Processing and Resolving Requests for Access to Sensitive Unclassified Non-Safeguards Information in this Proceeding

Day	Event/Activity
0	Publication of Federal Register notice of hearing and opportunity to petition for leave to intervene, including order with instructions for access requests.
10	Deadline for submitting requests for access to Sensitive Unclassified Non-Safeguards Information (SUNSI) with information: Supporting the standing of a potential party identified by name and address; describing the need for the information in order for the potential party to participate meaningfully in an adjudicatory proceeding.
60	Deadline for submitting petition for intervention containing: (i) Demonstration of standing; and (ii) all contentions whose formulation does not require access to SUNSI (+25 Answers to petition for intervention; +7 petitioner/requestor reply).
20	U.S. Nuclear Regulatory Commission (NRC) staff informs the requester of the staff's determination whether the request for access provides a reasonable basis to believe standing can be established and shows need for SUNSI. (NRC staff also informs any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information.) If NRC staff makes the finding of need for SUNSI and likelihood of standing, NRC staff begins document processing (preparation of redactions or review of redacted documents).
25	If NRC staff finds no ''need'' or no likelihood of standing, the deadline for petitioner/requester to file a motion seeking a ruling to reverse the NRC staff's denial of access; NRC staff files copy of access determination with the presiding officer (or Chief Administrative Judge or other designated officer, as appropriate). If NRC staff finds ''need'' for SUNSI, the deadline for any party to the proceeding whose interest independent of the proceeding would be harmed by the release of the information to file a motion seeking a ruling to reverse the NRC staff's grant of access.
30	Deadline for NRC staff reply to motions to reverse NRC staff determination(s).
40	(Receipt +30) If NRC staff finds standing and need for SUNSI, deadline for NRC staff to complete information processing and file motion for Protective Order and draft Non-Disclosure Affidavit. Deadline for applicant/licensee to file Non-Disclosure Agreement for SUNSI.
A	If access granted: Issuance of presiding officer or other designated officer decision on motion for protective order for access to sensitive information (including schedule for providing access and submission of contentions) or decision reversing a final adverse determination by the NRC staff.
A + 3	Deadline for filing executed Non-Disclosure Affidavits. Access provided to SUNSI consistent with decision issuing the protective order.

[2] Any motion for Protective Order or draft Non-Disclosure Affidavit or Agreement for SUNSI must be filed with the presiding officer or the Chief Administrative Judge if the presiding officer has not yet been designated, within 30 days of the deadline for the receipt of the written access request.

[3] Requesters should note that the filing requirements of the NRC's E-Filing Rule (72 FR 49139; August 28, 2007) apply to appeals of NRC staff determinations (because they must be served on a presiding officer or the Commission, as applicable), but not to the initial SUNSI request submitted to the NRC staff under these procedures.

Day	Event/Activity
A + 28	Deadline for submission of contentions whose development depends upon access to SUNSI. However, if more than 25 days remain between the petitioner's receipt of (or access to) the information and the deadline for filing all other contentions (as established in the notice of hearing or opportunity for hearing), the petitioner may file its SUNSI contentions by that later deadline.
A + 53	(Contention receipt +25) Answers to contentions whose development depends upon access to SUNSI.
A + 60	(Answer receipt +7) Petitioner/Intervenor reply to answers.
>A + 60 ..	Decision on contention admission.

[FR Doc. 2015–29031 Filed 11–13–15; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2012–0167]

Preparing and Reviewing Licensing Applications for Instrumentation and Control Systems for Non-Power Reactors

AGENCY: Nuclear Regulatory Commission.

ACTION: Draft NUREG; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is requesting public comment on draft Chapter 7, ''Instrumentation and Control Systems,'' which augments the following: (1) NUREG–1537, Part 1, ''Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content;'' and (2) NUREG–1537, Part 2, ''Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria.'' This draft chapter of NUREG–1537 provides revised guidance for preparing and reviewing applications for instrumentation and control systems.

DATES: Submit comments by February 1, 2016. Comments received after this date will be considered, if it is practical to do so, but the Commission is able to ensure consideration only for comments received before this date.

ADDRESSES: You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2012–0167. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *Mail comments to:* Cindy Bladey, Office of Administration, Mail Stop: O12–H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on accessing information and submitting comments, see ''Obtaining Information and Submitting Comments'' in the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Duane A. Hardesty, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20005–0001; telephone: 301–415–3724; email: *Duane.Hardesty@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Accessing Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID NRC–2012–0167 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document by any of the following methods:

- Federal Rulemaking Web site: Go to *http://www.regulations.gov* and search for Docket ID NRC–2012–0167.
- NRC's Agencywide Documents Access and Management System (ADAMS): You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select ''ADAMS Public Documents'' and then select ''*Begin Web-based ADAMS Search.''* For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The draft NUREG is located in ADAMS as follows: Part 1, Chapter 7 (ADAMS Accession No. ML15134A484) and Part 2, Chapter 7 (ADAMS Accession No. ML15134A486).
- NRC's PDR: You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

B. Submitting Comments

Please include Docket ID NRC–2012–0167 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC posts all comment submissions at *http://www.regulations.gov* as well as entering the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

The NRC is issuing this notice to solicit public comment on draft Chapter 7, ''Instrumentation and Control System,'' which augments the following: (1) NUREG–1537, Part 1, ''Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Format and Content;'' and (2) NUREG–1537, Part 2, ''Guidelines for Preparing and Reviewing Applications for the Licensing of Non-Power Reactors: Standard Review Plan and Acceptance Criteria.'' After the NRC staff considers public comments, it will make a determination regarding issuance of the final NUREG.

Dated at Rockville, Maryland, this 9th day of November, 2015.

For the Nuclear Regulatory Commission.

Alexander Adams, Jr.,

Chief, Research and Test Reactors Licensing Branch, Division of Policy and Rulemaking, Office of Nuclear Reactor Regulation.

[FR Doc. 2015–29029 Filed 11–13–15; 8:45 am]

BILLING CODE 7590–01–P

POSTAL REGULATORY COMMISSION

[Docket No. CP2015–3; Order No. 2807]

New Postal Product

AGENCY: Postal Regulatory Commission.

ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning an amendment to Parcel Select Contract 8 negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

DATES: *Comments are due:* November 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 Filings
III. Ordering Paragraphs

I. Introduction

On November 6, 2015, the Postal Service filed notice that it has agreed to an Amendment to the existing Parcel Select Contract 8 negotiated service agreement approved in this docket.[1] In support of its Notice, the Postal Service includes a redacted copy of the Amendment and a certification of compliance with 39 U.S.C. 3633(a), as required by 39 CFR 3015.5.

The Postal Service also filed the unredacted Amendment and supporting financial information under seal. The Postal Service seeks to incorporate by reference the Application for Non-Public Treatment originally filed in this docket for the protection of information that it has filed under seal. *Id.*

The Amendment changes the prices offered to the customer under the existing contract. Notice at 1.

The Postal Service intends for the Amendment to become effective one business day after the date that the Commission completes its review of the Notice. *Id.* The Postal Service asserts that the Amendment will not impair the ability of the contract to comply with 39 U.S.C. 3633. Notice, Attachment B at 1.

II. Notice of Filings

The Commission invites comments on whether the changes presented in the Postal Service's Notice are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR 3015.5, and 39 CFR part 3020, subpart B. Comments are due no later than November 16, 2015. The public portions of these filings can be accessed via the Commission's Web site (*http://www.prc.gov*).

The Commission appoints Jennaca Upperman to represent the interests of the general public (Public Representative) in this docket.

III. Ordering Paragraphs

It is ordered:

1. The Commission reopens Docket No. CP2015–3 for consideration of matters raised by the Postal Service's Notice.

2. Pursuant to 39 U.S.C. 505, the Commission appoints Jennaca Upperman to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in this proceeding.

3. Comments are due no later than November 16, 2015.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Ruth Ann Abrams,

Acting Secretary.

[FR Doc. 2015–28880 Filed 11–13–15; 8:45 am]

BILLING CODE 7710–FW–P

[1] Notice of United States Postal Service of Amendment to Parcel Select Contract 8, with Portions Filed Under Seal, November 6, 2015 (Notice).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–76393; File No. SR–BATS–2015–57]

Self-Regulatory Organizations; BATS Exchange, Inc.; Notice of Withdrawal of a Proposed Rule Change, as Modified by Amendment No. 1 Thereto, To Adopt New Rule 8.17 To Provide a Process for an Expedited Suspension Proceeding and Rule 12.15 To Prohibit Layering and Spoofing on BATS Exchange, Inc.

November 9, 2015.

On July 30, 2015, BATS Exchange, Inc. (the ''Exchange'' or ''BATS'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 [1] and Rule 19b–4 thereunder,[2] a proposed rule change to adopt an expedited proceeding for issuing suspension orders, and if necessary, imposing other sanctions, to prohibit Exchange Members, or their clients, from engaging in trading activities that constitute continued layering or spoofing on the Exchange. On August 11, 2015, the Exchange filed Amendment No. 1 to the proposal.[3] The proposed rule change, as modified by Amendment No. 1, was published for comment in the **Federal Register** on August 19, 2015.[4] On September 23, 2015, the Commission extended the time period within which to approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to disapprove the proposed rule change to November 17, 2015.[5] The Commission received six comment letters on the proposed rule change.[6] On November 6, 2015, BATS withdrew the proposed rule change (SR–BATS–2015–57).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–28862 Filed 11–13–15; 8:45 am]

BILLING CODE 8011–01–P

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Amendment No. 1 amended and replaced the original proposal in its entirety.

[4] *See* Securities Exchange Act Release No. 75693 (August 13, 2015), 80 FR 50370.

[5] *See* Securities Exchange Act Release No. 75970, 80 FR 58527 (September 29, 2015).

[6] *See* letters from: Teresa Machado B., dated August 19, 2015; Samuel F. Lek, Chief Executive Officer, Lek Securities Corporation, dated September 3, 2015; R.T. Leuchtkafer to Brent J. Fields, Secretary, Commission, dated September, 4, 2015; Mary Ann Burns, Chief Operating Officer, FIA Principal Traders Group, to Brent J. Fields, Secretary, Commission, dated September, 9, 2015; Samuel F. Lek, Chief Executive Officer, Lek Securities Corporation, dated September 18, 2015; and Anders Franzon, VP, Associate General Counsel, BATS, to Brent J. Fields, Secretary, Commission, dated November 6, 2015.

[7] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–76395; File No. SR–NYSEARCA–2015–106]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Adopt a Principles-Based Approach To Prohibit the Misuse of Material Nonpublic Information by Lead Market Makers (''LMMs'') by Deleting Rule 6.83

November 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 October 28, 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 Substance of the Proposed Rule Change

The Exchange proposes to adopt a principles-based approach to prohibit the misuse of material nonpublic information by Lead Market Makers (''LMMs'') by deleting Rule 6.83. 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.

[1] 15 U.S.C.78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to adopt a principles-based approach to prohibit the misuse of material nonpublic information by LMMs by deleting Rule 6.83.

The Exchange believes that Rule 6.83 is no longer necessary because all OTP Holders and OTP Firms (collectively, ''OTPs''),[4] including LMMs, are subject to the Exchange's general principles-based requirements governing the protection against the misuse of material, non-public information, pursuant to Exchange Rule 11.3 (Prevention of the Misuse of Material, Nonpublic Information). This rule obviates the need for separately-prescribed requirements for a subset of market participants on the Exchange.

Background

The Exchange has two classes of registered market makers. Pursuant to Rule 6.32(a), a Market Maker is an individual who is registered with the Exchange for the purpose of making transactions as a dealer-specialist on the Floor of the Exchange or for the purpose of submitting quotes electronically and making transactions as a dealer-specialist through the NYSE Arca OX electronic trading system. As the rule further provides, a Market Maker registered on the Exchange will be either a Market Maker or a Lead Market Maker.[5]

Rule 6.82(c) specifies the obligations of LMMs, which, in addition to the Market Maker obligations of Rules 6.37 and 6.37A, must also honor guaranteed markets. The quoting obligations of all Market Makers, including LMMs, are set forth in Rule 6.37B. That rule sets forth the main difference between Market Makers and LMMs, namely that LMMs have a heightened quoting obligation as compared to Market Makers.[6] In addition to a heightened quoting obligation, pursuant to Rule 6.76A (Order Execution—OX), LMMs quoting at the NBBO are eligible to receive a guaranteed participation allocation in the execution of incoming bids and offers.[7]

Importantly, all Market Makers, including LMMs, have access to the same information in the Consolidated Book that is available to all other market participants. Moreover, none of the Exchange's Market Makers, including LMMs, have agency obligations to orders in the Exchange's Consolidated Book. As such, the key distinctions between Market Makers and LMMs are the quoting requirements set forth in Rule 6.37B and allocation guarantee for LMMs set forth in Rule 6.76A.

Notwithstanding that all Market Makers have access to the same Exchange trading information as all other market participants on the Exchange, the Exchange has specific rules governing how LMMs may operate. Rule 6.83 prohibits OTPs affiliated with an LMM from purchasing or selling any option to which the LMM is appointed, except to reduce or liquidate positions after appropriate identification and Trading Official approval of the transaction. The rule further provides an exemption from the prohibition for affiliated firms that implement specified Exchange-approved procedures to restrict the flow of material, non-public information. Rules 6.83(e)—(j) outline the ''Exemption Guidelines'' with which an affiliated firm must comply to obtain an exemption from the restriction in Rule 6.83. These specified ''Exemption Guidelines'' are meant to ensure that an LMM will not have access to material, non-public information possessed by its affiliated OTP(s), and that a firm will not misuse its affiliated LMM's material, non-public information.

Proposed Rule Change

The Exchange believes that the guidelines in Rule 6.83 for LMMs are no longer necessary and proposes to delete the Rule in its entirety. The Exchange believes that Rule 11.3, governing the misuse of material, non-public information, provides for an appropriate, principles-based approach to prevent the market abuses Rule 6.83 was designed to address. Specifically, Rule 11.3 requires every OTP to establish, maintain, and enforce written policies and procedures reasonably designed to prevent the misuse of material, non-public information by such OTP or associated persons. For

[4] An ''OTP'' is an Options Trading Permit issued by the Exchange for effecting approved securities transactions on the Exchange's Trading Facilities; OTP Holders and OTP Firms are natural persons or business entities, respectively, that have one or more OTP. *See* Rule 1.1(p)–(r).

[5] Unless specified, or unless the context requires otherwise, the term Market Maker refers to both Market Makers and Lead Market Maker. *See* Rule 6.32(a).

[6] *Compare* Rule 6.37B(b) (An LMM ''must provide continuous two-sided quotations throughout the trading day in its appointed issues for 90% of the time the Exchange is open for trading in each issue''[sic] *with* 6.37B(c) (''A Market Maker must provide continuous two-sided quotations throughout the trading day in its appointed issues for 60% of the time the Exchange is open for trading in each issue'').

[7] *See* Rule 6.76A(a)(1)(A).

purposes of this requirement, the misuse of material, non-public information includes, but is not limited to, the following:

(a) Trading in any securities issued by a corporation, or in any related securities or related options or other derivative securities, while in possession of material, non-public information concerning that issuer;

(b) trading in a security or related options or other derivative securities, while in possession of material, non-public information concerning imminent transactions in the security or related securities; or

(c) disclosing to another person or entity any material, non-public information involving a corporation whose shares are publicly traded or an imminent transaction in an underlying security or related securities for the purpose of facilitating the possible misuse of such material, non-public information.[8]

Because LMMs are already subject to the requirements of Rule 11.3, the Exchange does not believe that it is necessary to separately require specific limitations on dealings between LMMs and their affiliates. Deleting Rule 6.83 would provide LMMs with the flexibility to adapt their policies and procedures as appropriate to reflect changes to their business model, business activities, or the securities market in a manner similar to how Market Makers on the Exchange currently operate and consistent with Rule 11.3.

As noted above, LMMs are distinguished under Exchange rules from other types of Market Makers in that LMMs have heightened obligations and allocation guarantees. However, none of these heightened obligations provides different or greater access to nonpublic information than any other market participant on the Exchange.[9] Specifically, LMMs on the Exchange do not have access to trading information provided by the Exchange, either at, or prior to, the point of execution, that is not made available to all other market participants on the Exchange in a similar manner. Further, as noted above, LMMs on the Exchange do not have any agency responsibilities for orders in the Consolidated Book. Accordingly, because LMMs do not have any trading advantages at the Exchange due to their market role, the Exchange believes that they should be subject to the same rules regarding the protection against the misuse of material non-public information, which in this case, is existing Rule 11.3.[10]

The Exchange notes that even with this proposed rule change, pursuant to Rule 11.3, an LMM would still be obligated to ensure that its policies and procedures reflect the current state of its business and continue to be reasonably designed to achieve compliance with applicable federal securities law and regulations, and with applicable Exchange rules, including being reasonably designed to protect against the misuse of material, non-public information. While information barriers would not specifically be required under the proposal, Rule 11.3 already requires that an OTP consider its business model or business activities in structuring its policies and procedures, which may dictate that an information barrier or a functional separation be part of the appropriate set of policies and procedures that would be reasonably designed to achieve compliance with applicable securities law and regulations, and with applicable Exchange rules.

The Exchange is not proposing to change what is considered to be material, non-public information and, thus does not expect there to be any changes to the types of information that an affiliated brokerage business of an LMM could share with such LMM. In that regard, the proposed rule change will not permit the affiliates of LMMs to have access to any non-public order or quote information of the LMM, including hidden or undisplayed size or price information of such orders or quotes. Affiliates of LMMs would only have access to orders and quotes that are publicly available to all market participants. OTPs do not expect to receive any additional order or quote information as a result of this proposed rule change.

Further, the Exchange does not believe that there will be any material change to Market Maker information barriers as a result of removal of the Exchange's pre-approval requirements. In fact, the Exchange anticipates that eliminating the pre-approval requirement should facilitate implementation of changes to Market Maker information barriers as necessary to protect against the misuse of material, non-public information. The Exchange also suggests that the pre-approval requirement is unnecessary because LMMs do not have agency responsibilities to orders in the Consolidated Book, or time and place information advantages because of their market role. However, as is the case today with Market Makers, information barriers of new entrants would be subject to review as part of a new firm application. Moreover, the policies and procedures of market makers, including those relating to information barriers, would be subject to review by FINRA, on behalf of the Exchange, pursuant to a Regulatory Services Agreement.

The Exchange further notes that under Rule 11.3, an OTP would be able to structure its firm to provide for its options LMMs, or Market Makers, as applicable, to be structured with its equities and customer-facing businesses, provided that any such structuring would be done in a manner reasonably designed to protect against the misuse of material, non-public information. For example, pursuant to Rule 11.3, a Market Maker on the Exchange could be in the same independent trading unit, as defined in Rule 200(f) of Regulation SHO,[11] as an equities market maker and other trading desks within the firm, including options trading desks, so that the firm could share post-trade information to better manage its risk across related securities. The Exchange believes it is appropriate, and consistent with Rule 11.3 and Section 15(g) of the Act[12] for a firm to share options position and related hedging position information (*e.g.,* equities, futures, and foreign currency) within a firm to better manage risk on a firm-wide basis. The Exchange notes, however, that if so structured, a firm would need to have appropriate policies and procedures, including information barriers as applicable, to protect against the misuse of material non-public information, and specifically customer information, consistent with Rule 11.3.

The Exchange believes that the proposed reliance on the principles-based Rule 11.3 would help ensure that an OTP that operates an LMM would be required to protect against the misuse of any material non-public information. As noted above, Rule 11.3 already requires that firms refrain from trading while in possession of material non-public information concerning imminent transactions in the security or related

[8] *See* Commentary .01 to Rule 11.3.

[9] *See* Rules 6.37B and 6.76A.

[10] The Exchange notes that by deleting Rule 6.83, the Exchange would no longer require specific information barriers for LMMs or require pre-approval of any information barriers that an LMM would erect for purposes of protecting against the misuse of material non-public information. However, as is the case today with Market Makers, information barriers of new entrants, including new LMMs, would be subject to review as part of a new firm application. Moreover, the policies and procedures of LMMs, including those relating to information barriers, would be subject to review by FINRA, on behalf of the Exchange, pursuant to a Regulatory Services Agreement.

[11] 17 CFR part 242.200(f).

[12] 15 U.S.C. 78o(g).

product. The Exchange believes that moving to a principles-based approach rather than prescribing how and when to wall off an LMM from the rest of the firm would provide OTPs operating LMMs with appropriate tools to better manage risk across a firm, including integrating options positions with other positions of the firm or, as applicable, by the respective independent trading unit. Specifically, the Exchange believes that it is appropriate for risk management purposes for an OTP operating an LMM to be able to consider both options LMMs' traded positions for purposes of calculating net positions consistent with Rule 200 of Regulation SHO, calculating intra-day net capital positions, and managing risk both generally as well as in compliance with Rule 15c3–5 under the Act (the ''Market Access Rule'').[13] The Exchange notes that any risk management operations would need to operate consistent with the requirement to protect against the misuse of material non-public information.

The Exchange further notes that if LMMs are integrated with other market making operations, they would be subject to existing rules that prohibit OTPs from disadvantaging their customers or other market participants by improperly capitalizing on a member organization's access to the receipt of material, non-public information. As such, an OTP that integrates its LMM operations together with equity market making would need to protect customer information consistent with existing obligations to protect such information. The Exchange has rules prohibiting OTPs from disadvantaging their customers or other market participants by improperly capitalizing on the OTP's access to or receipt of material, non-public information. For example, Rule 11.18 requires OTPs to establish, maintain, enforce, and keep current a system of compliance and supervisory controls, reasonably designed to achieve compliance with applicable securities laws and Exchange rules. Additionally, Rule 6.49 prevents an OTP or person associated with an OTP, who has knowledge of an originating order, a solicited order, or a facilitation order, to enter, based on such knowledge, an order to buy or sell an option on the underlying securities of any option that is the subject of the order, an order to buy or sell the security underlying any option that is the subject of the order, or any order to buy or sell any related instrument unless certain circumstances are met.[14]

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act[15] in general, and furthers the objectives of Section 6(b)(5) of the Act[16] 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 the proposed rule change would remove impediments to and perfect the mechanism of a free and open market by adopting a principles-based approach to permit an OTP operating an LMM to maintain and enforce policies and procedures to, among other things, prohibit the misuse of material non-public information and eliminating restrictions on how an OTP structures it LMM operations. The Exchange notes that the proposed rule change is based on an approved rule of the Exchange to which LMMs are already subject—Rule 11.3—and harmonizes the rules governing LMMs and Market Makers. Moreover, OTPs operating LMMs would continue to be subject to federal and Exchange requirements for protecting material non-public order information.[17] The Exchange believes that the proposed rule change would remove impediments to and perfect the mechanism of a free and open market because it would harmonize the Exchange's approach to protecting against the misuse of material nonpublic information and no longer subject LMMs to additional requirements. The Exchange does not believes that the existing requirements applicable to LMMs are narrowly tailored to their respective roles because neither market participant has access to Exchange trading information in a manner different from any other market participant on the Exchange and they do not have agency responsibilities to the Consolidated Book.

The Exchange further believes the proposal is designed to prevent fraudulent and manipulative acts and practices and to promote just and equitable principles of trade because existing rules make clear to LMMs and OTPs the type of conduct that is prohibited by the Exchange. While the proposal eliminates requirements relating to the misuse of material non-public information, LMMs and OTPs would remain subject to existing Exchange rules requiring them to establish and maintain systems to supervise their activities, and to create, implement, and maintain written procedures that are reasonably designed to comply with applicable securities laws and Exchange rules, including the prohibition on the misuse of material, nonpublic information.

The Exchange notes that the proposed rule change would still require that OTPs operating LMMs maintain and enforce policies and procedures reasonably designed to ensure compliance with applicable federal securities laws and regulations and with Exchange rules. Even though there would no longer be pre-approval of LMM information barriers, any LMM written policies and procedures would continue to be subject to oversight by the Exchange and therefore the elimination of prescribed restrictions should not reduce the effectiveness of the Exchange rules to protect against the misuse of material non-public information. Rather, OTPs will be able to utilize a flexible, principles-based approach to modify their policies and procedures as appropriate to reflect changes to their business model, business activities, or to the securities market itself. Moreover, while specified information barriers may no longer be required, an OTP's business model or business activities may dictate that an information barrier or functional separation be part of the appropriate set of policies and procedures that would be reasonably designed to achieve compliance with applicable securities laws and regulations, and with applicable Exchange rules. The Exchange therefore believes that the proposed rule change will maintain the existing protection of investors and the public interest that is currently applicable to LMMs, while at the same time removing impediments to and perfecting a free and open market by moving to a principles-based approach to protect against the misuse of material non-public information.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[18] the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, the Exchange believes that the proposal will enhance competition by allowing Market Makers to comply with applicable Exchange

[13] 17 CFR part 240.15c3–5.

[14] *See* Rule 6.49(b).

[15] 15 U.S.C. 78f(b).

[16] 15 U.S.C. 78f(b)(5).

[17] *See* 15 U.S.C. 78o(g) and Rule 11.3.

[18] 15 U.S.C. 78f(b)(8).

rules in a manner best suited to their business models, business activities, and the securities markets, thus reducing regulatory burdens while still ensuring compliance with applicable securities laws and regulations and Exchange rules. The Exchange believes that the proposal will foster a fair and orderly marketplace without being overly burdensome upon Market Makers.

Moreover, the Exchange believes that the proposed rule change would eliminate a burden on competition for OTPs which currently exists as a result of disparate rule treatment between the options and equities markets regarding how to protect against the misuse of material non-public information. For those OTPs that are also members of equity exchanges, their respective equity market maker operations are now subject to a principles-based approach to protecting against the misuse of material non-public information.[19] The Exchange believes it would remove a burden on competition to enable OTPs to similarly apply a principles-based approach to protecting against the misuse of material nonpublic information in the options space. To this end, the Exchange notes that Rule 11.3 still requires an OTP that operates as a Market Maker on the Exchange, including an LMM, to evaluate its business to assure that its policies and procedures are reasonably designed to protect against the misuse of material nonpublic information. However, with this proposed rule change, an OTP that trades equities and options could look at its firm more holistically to structure its operations in a manner that provides it with better tools to manage its risks across multiple security classes, while at the same time protecting against the misuse of material non-public information.

[19] *See* Securities Exchange Act Release Nos. 60604 (Sept. 2, 2009), 76 FR 46272 (Sept. 8, 2009) (SR–NYSEArca–2009–78) (Order approving elimination of NYSE Arca rule that required market makers to establish and maintain specifically prescribed information barriers, including discussion of NYSE Arca and Nasdaq rules) (''Arca Approval Order''); 61574 (Feb. 23, 2010), 75 FR 9455 (Mar. 2, 2010) (SR–BATS–2010–003) (Order approving amendments to BATS Rule 5.5 to move to a principles-based approach to protecting against the misuse of material, non-public information, and noting that the proposed change is consistent with the approaches of NYSE Arca and Nasdaq) (''BATS Approval Order''); and 72534 (July 3, 2014), 79 FR 39440 (July 10, 2014), SR–NYSE–2014–12) (Order approving amendments to NYSE Rule 98 governing designated market makers to move to a principles-based approach to prohibit the misuse of material non-public information) (''NYSE Approval Order'').

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[20] and Rule 19b–4(f)(6) thereunder.[21] Because the proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative prior to 30 days from the date on which it was filed, or such shorter time as the Commission may designate, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act and Rule 19b–4(f)(6)(iii) thereunder.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[22] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEARCA–2015–106 on the subject line.

[20] 15 U.S.C. 78s(b)(3)(A)(iii).

[21] 17 CFR 240.19b–4(f)(6).

[22] 15 U.S.C. 78s(b)(2)(B).

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–2015–106. 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 20549–1090, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing will also be available for inspection and copying at the NYSE's principal office and on its Internet Web site at *www.nyse.com.* 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–2015–106 and should be submitted on or before December 7,2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[23]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–28864 Filed 11–13–15; 8:45 am]

BILLING CODE 8011–01–P

[23] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–76392; File No. SR–MIAX–2015–62]

Self-Regulatory Organizations; Miami International Securities Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend MIAX Rule 521

November 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 November 4, 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 Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend Rule 521, Nullification and Adjustment of Options Transactions Including Obvious Errors, to modify the amount to be charged to Members that appeal an Official ruling when the ruling is sustained and not overturned or modified, and to pass through other market center charges associated with obvious error determinations.

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.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

On May 7, 2015 the Exchange filed a proposed rule change to replace Exchange Rule 521 entitled ''Obvious and Catastrophic Errors'' with new Exchange Rule 521 entitled ''Nullification and Adjustment of Options Transactions Including Obvious Errors.'' Rule 521 became operative on May 8, 2015.[3] Rule 521 was amended in conjunction with amendments made by all U.S. options exchanges in order to harmonize their respective rules related to the adjustment and nullification of erroneous options transactions. The Exchange believes that Rule 521, together with comparable harmonized rules of the other U.S. options exchanges,[4] provides transparency and finality with respect to the adjustment and nullification of erroneous options transactions, achieving consistent results for participants across the options exchanges while maintaining a fair and orderly market, protecting investors and protecting the public interest.

The purpose of the proposed rule change is to further harmonize Rule 521 with the rules of other exchanges by modifying the amount to be charged to Members that appeal an Official ruling under Rule 521 if such ruling is sustained and not overturned or modified, and to permit the Exchange to pass along charges assessed by another market center in connection with Obvious Error and Catastrophic Error determination requests presented to that market center by the Exchange on a Member's behalf.

The Exchange proposes to amend Section (l)(2) of the Rule to charge $500.00 to MIAX Members that appeal an Official ruling when such ruling is sustained and not overturned or modified, and to add new language to permit the Exchange to pass along charges assessed by another market center in connection with Obvious Error and Catastrophic Error determination requests presented to that market center by the Exchange on a Member's behalf. Currently, the Exchange charges Members $250.00 in this circumstance. The Exchange proposes to increase this charge from $250.00 to $500.00.

2. Statutory Basis

The Exchange believes that its proposal to amend Rule 521 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 provides for an equitable allocation of reasonable fees and other charges among Exchange members.

The $500.00 charge and the provision to pass through charges from other market centers proposed herein is just and equitable and not unfairly discriminatory because it would apply equally to all MIAX Members seeking review on appeal of Official rulings pursuant to Rule 521(l), and will not be assessed if the ruling giving rise to the appeal is modified or reversed. The $500.00 charge is consistent with the amount charged by other U.S. options exchanges for unsuccessful appeals under their obvious error rules.[7]

The provision to pass through charges from other market centers proposed herein is just and equitable and not unfairly discriminatory because it would apply equally to all MIAX Members requesting Obvious Error or Catastrophic Error determinations from other market centers through the Exchange. The pass through charge is also consistent with pass through charges charged by other U.S. options exchanges under their obvious error rules.[8] The Exchange believes that it will prevent fraudulent and manipulative practices, promote just and equitable principles of trade, and remove impediments to and perfect the mechanisms of a free and open market and a national market system by discouraging frivolous appeals of Official rulings made under Rule 521. Further, it will allow the Exchange to recoup its administrative costs associated with Rule 521 appeals, and provide additional resources to the Exchange to administer its regulatory functions, including appeals of Official rulings under Rule 521(l).

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposal will have any impact on

[3] *See* Securities Exchange Act Release No. 74918 (May 8, 2015), 80 FR 27781 (May 14, 2015) (SR–MIAX–2015–35).

[4] *See, e.g.,* NASDAQ OMX PHLX LLC (''PHLX'') Rule 1092(l) and BATS Exchange, Inc. (''BATS'') Rule 20.6. *See also, e.g.,* Securities Exchange Act Release Nos. 74556 (March 20, 2015), 80 FR 16031 (March 26, 2015) (SR–BATS–2014–067), and 75488 (July 20, 2015), 80 FR 44164 (July 24, 2015) (SR–Phlx–2015–65).

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(4).

[7] *See supra* note 4.

[8] *See supra* note 4.

competition in that the $500.00 charge and the provision of pass through charges from other market centers proposed herein will apply equally to all MIAX Members submitting appeals pursuant to Rule 521(l).

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] and Rule 19b–4(f)(2) [10] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–MIAX–2015–62 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–2015–62. 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–2015–62, and should be submitted on or before December 7, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[11]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–28861 Filed 11–13–15; 8:45 am]

BILLING CODE 8011–01–P

[9] 15 U.S.C. 78s(b)(3)(A)(ii).

[10] 17 CFR 240.19b–4(f)(2).

[11] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–76394; File No. SR–BATS–2015–56]

Self-Regulatory Organizations; BATS Exchange, Inc.; Notice of Filing of Amendments Nos. 1 and 2 and Order Granting Accelerated Approval of a Proposed Rule Change to List and Trade Shares of the ProShares Managed Futures Strategy ETF of the ProShares Trust Under BATS Rule 14.11 on BATS Exchange, Inc.

November 9, 2015.

I. Introduction

On July 30, 2015, BATS Exchange, Inc. (''Exchange'' or ''BATS'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'' or ''Exchange Act'') [2] and Rule 19b–4 thereunder,[3] a proposed rule change to list and trade shares (''Shares'') of the ProShares Managed Futures Strategy ETF (''Fund'') of the ProShares Trust (''Trust'') under BATS Rule 14.11(i). The proposed rule change was published for comment in the **Federal Register** on August 17, 2015.[4] On August 19, 2015, the Exchange filed Amendment No. 1 to the proposed rule change, which replaced the proposed rule change in its entirety.[5] On September 4, 2015, the Exchange filed Amendment No. 2 to the proposed rule change, which replaced the proposed rule change in its entirety.[6] The Commission received no comments on the proposed rule change. The Commission is publishing this notice to solicit comments on Amendments Nos. 1 and 2 from interested persons, and is approving the proposed rule change, as modified by Amendments Nos. 1 and 2, on an accelerated basis.

II. Description of the Proposal

The Exchange proposes to list and trade the Shares under BATS Rule 14.11(i), which governs the listing and trading of Managed Fund Shares on the Exchange. The Exchange deems the Shares to be equity securities, thus rendering trading in the Shares subject to the Exchange's existing rules governing the trading of equity securities.

The Shares will be offered by the Trust, which is established as a Delaware statutory trust. The Trust is registered with the Commission as an open-end investment company and has filed a registration statement on behalf of the Fund on Form N–1A (''Registration Statement'') with the Commission.[7] ProShare Advisors LLC is the investment adviser (''Adviser'') to the Fund. JPMorgan Chase Bank, National Association is the

[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. 75664 (August 11, 2015), 80 FR 49288.

[5] In Amendment No. 1, the Exchange supplemented the information that will be included in the Fund's Disclosed Portfolio, clarified the investments that the Fund may hold, clarified how certain of the Fund's assets will be valued in calculating the Fund's net asset value (''NAV''), and provided additional information regarding the availability of price information for the assets that the Fund may hold. All amendments to the proposed rule change are available at: *http://www.sec.gov/comments/sr-bats-2015–56/bats201556–1.pdf.*

[6] In Amendment No. 2, the Exchange modified the description of the swaps that the Fund may hold and the availability of intraday price information for assets that the Fund may hold.

[7] *See* Registration Statement on Form N–1A for the Trust, dated May 31, 2013 (File Nos. 333–98922 and 811–21114). *See also* Investment Company Act Release No. 30562 (June 18, 2013) (File No. 812–14041).

administrator, custodian, fund account agent, index receipt agent and transfer agent for the Trust. SEI Investments Distribution Co. serves as the distributor for the Trust. The Exchange represents that the Adviser is not a registered broker-dealer but is affiliated with a broker-dealer, and in the future may affiliate with other broker-dealers, and has implemented a fire wall with respect to such broker-dealer regarding access to information concerning the composition and/or changes to the Fund's portfolio.[8] The Exchange further represents that Adviser personnel who make decisions regarding the Fund's portfolio are subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the Fund's portfolio.[9]

The Exchange's Description of the Fund [10]

The Fund will generally seek exposure to the commodity and financial markets included in the S&P® Strategic Futures Index (''Index''),[11] but the Fund is not an index tracking ETF and will generally seek to enhance its performance by actively selecting investments for the Fund with varying maturities from the underlying components of the Index.

Under normal market conditions,[12] the Fund will invest at least 80% of its assets directly, or indirectly through ProShares Cayman Trust I (''Subsidiary''),[13] a wholly-owned subsidiary of the Fund, in the exchange-listed futures contracts included in the Index, which include commodity futures, currency futures, and U.S. Treasury futures (collectively, ''Futures Contracts''). The Fund may also invest in swaps [14] if the market for a specific Futures Contract experiences emergencies (*e.g.,* natural disaster, terrorist attack, or an act of God) or disruptions (*e.g.,* a trading halt or a flash crash) that would prevent the Fund from obtaining the appropriate amount of investment exposure to the affected Futures Contracts or other futures contracts directly.

The Fund may also invest up to 100% of its assets in cash or cash equivalents such as U.S. Treasury securities or other high credit quality short-term fixed-income or similar securities (including shares of money market funds, bank deposits, bank money market accounts, certain variable rate-demand notes, and repurchase agreements collateralized by government securities) for direct investment or as collateral for the Futures Contracts or swap agreements. The Fund will use the fixed-income securities as investments and to meet asset coverage tests resulting from the Subsidiary's derivative exposure on a day-to-day basis.

III. Discussion and Commission Findings

After careful review, the Commission finds that the Exchange's proposal to list and trade the Shares is consistent with the Exchange Act and the rules and regulations thereunder applicable to a national securities exchange.[15] In particular, the Commission finds that the proposed rule change is consistent with Section 6(b)(5) of the Exchange Act,[16] which requires, among other things, that the Exchange's rules be designed 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 Commission also finds that the proposal to list and trade the Shares on the Exchange is consistent with Section 11A(a)(1)(C)(iii) of the Exchange Act,[17] which sets forth Congress' finding that it is in the public interest and appropriate for the protection of investors and the maintenance of fair and orderly markets to assure the availability to brokers, dealers and investors of information with respect to quotations for and transactions in securities. Quotation and last-sale information for the Shares will be available on the facilities of the Consolidated Tape Association (''CTA''). Information regarding market price and volume of the Shares will be continually available on a real-time basis throughout the day on brokers' computer screens and other electronic services. The previous day's closing price and trading volume information for the Shares will be generally published daily in the print and online financial press. The Web site for the Fund will include a form of the prospectus for the Fund and additional data relating to NAV and other applicable quantitative information.

Intraday price quotations on repurchase agreements and U.S. Government securities of the type held by the Fund are available from major broker-dealer firms and from third-parties, which may provide prices free with a time delay, or ''live'' with a paid fee. Major broker-dealer firms will also provide intraday quotes on swaps of the type held by the Fund.[18] Pricing information related to money market fund shares will be available through issuer Web sites and publicly available quotation services.[19] For Futures Contracts, such intraday information is available directly from the applicable listing exchange. Intraday price information is also available through subscription services, such as Bloomberg and Thomson Reuters, which can be accessed by authorized participants and other investors.[20]

On each business day, before commencement of trading in Shares during Regular Trading Hours on the Exchange, the Fund will disclose on its

[8] *See* Amendment No. 2, *supra* note 6, at 29.

[9] *See id.* at 6; *see also* BATS Rule 14.11(i)(7). The Exchange also represents that in the event that (a) the Adviser becomes registered as a broker-dealer or newly affiliated with another broker-dealer, or (b) any new adviser or sub-adviser is a registered broker-dealer or becomes affiliated with a broker-dealer, it will implement a fire wall with respect to its relevant personnel or such broker-dealer affiliate, as applicable, regarding access to information concerning the composition and/or changes to the portfolio, and will be subject to procedures designed to prevent the use and dissemination of material non-public information regarding such portfolio.

[10] The Commission notes that additional information regarding the Trust, the Fund, and the Shares, investment strategies, risks, NAV calculation, creation and redemption procedures, fees and expenses, portfolio holdings disclosure policies, distributions, and taxes, among other information, is included in the Amendment No. 2 and Registration Statement. *See supra* notes 6 and 8, respectively.

[11] The Index seeks to reflect trends (in either direction) in the commodity, foreign currency and fixed income markets by taking long or short positions in the related futures contracts.

[12] The term ''under normal market conditions'' includes, but is not limited to, the absence of extreme volatility or trading halts in the fixed income markets, futures markets or the financial markets generally; operational issues causing dissemination of inaccurate market information; or force majeure type events such as systems failure, natural or manmade disaster, act of God, armed conflict, act of terrorism, riot or labor disruption or any similar intervening circumstance.

[13] The Subsidiary will be advised by the Adviser and will have the same investment objective as the Fund. The Fund's investment in the Subsidiary is intended to provide the Fund with exposure to markets (in general, the commodity markets) within the limits of current federal income tax laws applicable to investment companies such as the Fund, which limit the ability of investment companies to invest directly in certain Futures Contracts. Generally, references to the Fund's investments may also be deemed to include the Fund's indirect investments through the Subsidiary. The Fund will invest up to 25% of its total assets in the Subsidiary.

[14] The Fund may invest in swap agreements whose value is derived from the level of the Benchmark, one or more Futures Contracts or from the reference assets underlying one or more of such Futures Contracts.

[15] In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[16] 15 U.S.C. 78f(b)(5).

[17] 15 U.S.C. 78k–1(a)(1)(C)(iii).

[18] *See* Amendment No. 2, *supra* note 6, at 25.

[19] *See id.*

[20] *See id.* at 31.

Web site the identities and quantities of the portfolio Futures Contracts and other assets (''Disclosed Portfolio'') held by the Fund that will form the basis for the Fund's calculation of NAV at the end of the business day.[21] In addition, for the Fund, an estimated value, defined in BATS Rule 14.11(i)(3)(C) as the ''Intraday Indicative Value,'' that reflects an estimated intraday value of the Fund's portfolio, will be disseminated. The Intraday Indicative Value will be based upon the current value for the components of the Disclosed Portfolio and will be updated and widely disseminated by one or more major market data vendors at least every 15 seconds during the Exchange's Regular Trading Hours.[22]

The Commission also believes that the proposal to list and trade the Shares is reasonably designed to promote fair disclosure of information that may be necessary to price the Shares appropriately and to prevent trading when a reasonable degree of transparency cannot be assured. The Commission notes that the Exchange will obtain a representation from the issuer of the Shares that the NAV per Share will be calculated daily and that the NAV and the Disclosed Portfolio will be made available to all market participants at the same time.[23] The Exchange will halt trading in the Shares under the conditions specified in BATS Rule 11.18. Trading may be halted because of market conditions or for reasons that, in the view of the Exchange, make trading in the Shares inadvisable. These may include: (1) The extent to which trading is not occurring in the Futures Contracts and other assets composing the Disclosed Portfolio of the Fund; or (2) whether other unusual conditions or circumstances detrimental to the maintenance of a fair and orderly market are present. Trading in the Shares also will be subject to Rule 14.11(i)(4)(B)(iv), which sets forth circumstances under which Shares of the Fund may be halted. The Exchange prohibits the distribution of material non-public information by its employees. The Exchange represents that the Adviser is not a registered broker-dealer, but is affiliated with a broker-dealer, and in the future may affiliate with other broker-dealers, and has implemented a fire wall with respect to such broker-dealer regarding access to information concerning the composition and/or changes to the Fund's portfolio.[24] The Exchange further represents that Adviser personnel who make decisions regarding the Fund's portfolio are subject to procedures designed to prevent the use and dissemination of material nonpublic information regarding the Fund's portfolio.[25] In addition, the Commission notes that, consistent with BATS Rule 14.11(i)(4)(B)(ii)(b), the Reporting Authority, as defined in BATS Rule 14.11(i)(3)(D), must implement and maintain, or be subject to, procedures designed to prevent the use and dissemination of material, non-public information regarding the actual components of the portfolio. The Exchange may obtain information regarding trading in the Shares and the underlying shares in exchange traded equity securities via the Intermarket Surveillance Group (''ISG''), from other exchanges that are members or affiliates of the ISG, or with which the Exchange has entered into a comprehensive surveillance sharing agreement.[26] In addition, the Exchange is able to access, as needed, trade information for certain fixed income instruments reported to FINRA's Trade Reporting and Compliance Engine.

In support of this proposal, the Exchange has made the following representations:

(1) The Shares will be subject to BATS Rule 14.11(i), which sets forth the initial and continued listing criteria applicable to Managed Fund Shares.

(2) The Exchange has appropriate rules to facilitate transactions in the Shares during all trading sessions.

(3) Trading of the Shares through the Exchange will be subject to the Exchange's surveillance procedures for derivative products, including Managed Fund Shares, and that these procedures are adequate to properly monitor the trading of the Shares on the Exchange during all trading sessions and to deter and detect violations of Exchange rules and the applicable federal securities laws.

(4) Prior to the commencement of trading, the Exchange will inform its members in an Information Circular of the special characteristics and risks associated with trading the Shares. Specifically, the Information Circular will discuss the following: (a) The procedures for purchases and redemptions of Shares in Creation Units (and that Shares are not individually redeemable); (b) BATS Rule 3.7, which imposes suitability obligations on Exchange members with respect to recommending transactions in the Shares to customers; (c) how information regarding the Intraday Indicative Value is disseminated; (d) the risks involved in trading the Shares during the Pre-Opening [27] and After Hours Trading Sessions [28] when an updated Intraday Indicative Value will not be calculated or publicly disseminated; (e) the requirement that members deliver a prospectus to investors purchasing newly issued Shares prior to or concurrently with the confirmation of a transaction; and (f) trading information.

(5) For initial and/or continued listing, the Fund must be in compliance with Rule 10A–3 under the Act.[29]

(6) As it relates to futures contracts, all Futures Contracts in the Disclosed Portfolio for the Fund will trade on markets that are a member of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement.

(7) A minimum of 100,000 Shares will be outstanding at the commencement of trading on the Exchange.

This approval order is based on all of the Exchange's representations, including those set forth above and in the Notice. For the foregoing reasons, the Commission finds that the proposed rule change, as modified by Amendments Nos. 1 and 2, is consistent with Section 6(b)(5) of the Act [30] and the rules and regulations thereunder applicable to a national securities exchange.

IV. Solicitation of Comments on Amendments Nos. 1 and 2

Interested persons are invited to submit written data, views, and

[21] The Disclosed Portfolio will include, as applicable: ticker symbol or other identifier, a description of the holding, identity of the asset upon which the derivative is based, the strike price for any options, the quantity of each security or other asset held as measured by select metrics, maturity date, coupon rate, effective date, market value and percentage weight of the holding in the portfolio. The Web site and information will be publicly available at no charge. Under accounting procedures to be followed by the Fund, trades made on the prior business day (''T'') will be booked and reflected in NAV on the current business day (''T+1''). Accordingly, the Fund will be able to disclose at the beginning of the business day the portfolio that will form the basis for the NAV calculation at the end of the business day.

[22] It is the Exchange's current understanding that several major market data vendors display and/or make widely available Intraday Indicative Values published via the CTA or other data feeds. *See id.* at 24, n.20.

[23] *See id.* at 25.

[24] *See id.* at 29.

[25] *See id.* at 6.

[26] For a list of the current members of ISG, see *www.isgportal.org.* All of the Futures Contracts held by the Fund will trade on markets that are a member of ISG or with which the Exchange has in place a comprehensive surveillance sharing agreement. *See id.* at 27, n.22.

[27] The Pre-Opening Session is from 8:00 a.m. to 9:30 a.m. Eastern Time.

[28] The After Hours Trading Session is from 4:00 p.m. to 5:00 p.m. Eastern Time.

[29] *See* 17 CFR 240.10A–3.

[30] 15 U.S.C. 78f(b)(5).

arguments concerning whether Amendments Nos. 1 and 2 are 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–2015–56 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–BATS–2015–56. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BATS–2015–56 and should be submitted on or before December 7, 2015.

V. Accelerated Approval of Proposed Rule Change as Modified by Amendments Nos. 1 and 2

The Commission finds good cause to approve the proposed rule change, as modified by Amendments Nos. 1 and 2, prior to the thirtieth day after the date of publication of notice in the **Federal Register**. No comments were received after publication of the Notice. Amendments Nos. 1 and 2 only supplement the proposed rule change by clarifying certain points and providing additional detail. Therefore, the Commission finds good cause, pursuant to Section 19(b)(2) of the Act,[31] to approve the proposed rule change, as modified by Amendments Nos. 1 and 2 on an accelerated basis.

VI. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Exchange Act,[32] that the proposed rule change (SR–BATS–2015–56), as modified by Amendment Nos. 1 and 2, is hereby approved on an accelerated basis.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[33]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–28863 Filed 11–13–15; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–76400; File No. SR–NYSE–2015–56]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Its Price List to Modify Certain Fees for Transactions that Remove Liquidity from the Exchange

November 9, 2015.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on November 2, 2015, New York Stock Exchange LLC (''NYSE'' or ''Exchange'') 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 self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Price List to modify certain fees for transactions that remove liquidity from the Exchange, effective November 2, 2015. 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 the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its Price List to increase certain fees that remove liquidity from the Exchange, effective November 2, 2015. The proposed change would only apply to transactions in securities priced $1.00 or more.

In particular, the Exchange currently charges $0.0027 per share for non-Floor broker transactions that remove liquidity from the Exchange, including those of Designated Market Makers (''DMM''). The Exchange proposes to increase this fee to $0.00275 per share.

Similarly, the Exchange currently charges $0.0027 per share for all Midpoint Passive Liquidity (''MPL'') Orders[4] that remove liquidity from the Exchange and are not designated with a Retail Modifier as defined in Rule 13. The Exchange proposes to increase the fee for executions of MPL Orders that remove liquidity from the NYSE to $0.00275 per share.

The Exchange currently charges $0.0024 per share or $0.0027 if an MPL Order for all other Floor broker transactions that remove liquidity from the Exchange. MPL orders designated with a Retail Modifier as defined in Rule 13 are not charged a fee. The Exchange proposes to increase the $0.0027 per share fee for Floor broker MPL Orders that take liquidity from the

[31] 15 U.S.C. 78s(b)(2).

[32] 15 U.S.C. 78s(b)(2).

[33] 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] MPL Order is defined in Rule 13 as an undisplayed limit order that automatically executes at the mid-point of the protected best bid or offer (''PBBO'').

NYSE to $0.00275 per share. The current $0.0024 per share fee for Floor broker transactions that take liquidity from the Exchange would remain unchanged.

The proposed change is not otherwise intended to address any other issues, and the Exchange is not aware of any problems that member organizations would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[5] in general, and furthers the objectives of Sections 6(b)(4) and 6(b)(5) of the Act,[6] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange believes that the proposed fee increase for non-Floor broker transactions that remove liquidity is reasonable because non-Floor brokers would continue to receive credits for their transactions that provide liquidity on the Exchange, including (i) for member organizations that add liquidity that satisfies certain thresholds under the Tier Adding Credits, (ii) for DMMs under the DMM credits, and (iii) for MPL Orders under various pricing categories in the Price List. The resulting fee also is equitable and not unfairly discriminatory because it would continue to be consistent with, and in some cases lower than, the applicable rate on other marketplaces. For example, the standard fee for removing liquidity from NASDAQ in both NASDAQ-listed and NYSE-listed securities is $0.0030 per share, which is higher than the proposed $0.00275 per share fee.[7]

The Exchange believes that the proposed increase to the fee for executions of MPL Orders, including Floor broker MPL orders, that remove liquidity from the Exchange is reasonable because the charge would be the same as the $0.00275 per share fee proposed for all other non-Floor broker transactions that take liquidity from the NYSE. The proposed fee is also reasonable because it would be lower than the applicable rate on other marketplaces. For example, NASDAQ charges $0.0030 per share to execute against resting midpoint liquidity, which is greater than both the existing $0.0027 per share rate and the proposed $0.00275 per share rate that would apply to MPL Orders.[8]

The Exchange believes that the proposed fee increase for MPL Orders, including Floor broker MPL orders, that remove liquidity from the Exchange is equitable and not unfairly discriminatory because MPL Orders may provide opportunities for market participants to interact with orders priced at the midpoint of the PBBO, thus providing price improving liquidity to market participants and thereby increase the quality of order execution on the Exchange's market, which benefits all market participants. The Exchange also believes the proposed fee is equitable and not unfairly discriminatory because all market participants that use the MPL Order type will pay the same proposed fee.

The Exchange also believes it is equitable and not unfairly discriminatory to continue to charge Floor brokers that take liquidity a lower fee ($0.0024) than non-Floor brokers that take liquidity because Floor brokers have slower access to the Exchange (via handheld technology) than non-Floor brokers and are prohibited from routing directly to other market centers from handheld devices, which prevents them from accessing any associated pricing opportunities that might exist at those away markets.

Finally, the Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,[9] the Exchange believes that the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Instead, the Exchange believes that the proposed change would encourage the submission of additional liquidity to a public exchange, thereby promoting price discovery and transparency and enhancing order execution opportunities for member organizations. The Exchange believes that this could promote competition between the Exchange and other execution venues, including those that currently offer similar order types and comparable transaction pricing, by encouraging additional orders to be sent to the Exchange for execution.

Finally, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees and rebates to remain competitive with other exchanges and with alternative trading systems that have been exempted from compliance with the statutory standards applicable to exchanges. Because competitors are free to modify their own fees and credits in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited. As a result of all of these considerations, the Exchange does not believe that the proposed changes will impair the ability of member organizations 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 solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to Section 19(b)(3)(A) [10] of the Act and subparagraph (f)(2) of Rule 19b–4 [11] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the

[5] 15 U.S.C. 78f(b).

[6] 15 U.S.C. 78f(b)(4) and (5).

[7] *See, e.g.,* NASDAQ Rule 7018(d). The fee for removing liquidity on NYSE Arca is also $0.0030. *See* NYSE Arca Equities, Inc., Schedule of Fees and Charges, available at *https://www.nyse.com/publicdocs/nyse/markets/nyse-arca/NYSE_Arca_Marketplace_Fees.pdf*.

[8] *See, e.g.,* NASDAQ Rule 7018(a).

[9] 15 U.S.C. 78f(b)(8).

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f)(2).

Commission shall institute proceedings under Section 19(b)(2)(B) [12] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSE–2015–56 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSE–2015–56. 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–NYSE–2015–56 and should be submitted on or before December 7, 2015.[13]

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–28865 Filed 11–13–15; 8:45 am]

BILLING CODE 8011–01–P

[12] 15 U.S.C. 78s(b)(2)(B).

[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

In the Matter of Tirex Corporation, Order of Suspension of Trading

November 12, 2015.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of The Tirex Corporation (''Tirex'') because it has not filed any periodic reports since it filed a Form 10–K for the period ended June 30, 2009 on March 1, 2011. Tirex is a Delaware corporation based in Wilton, Connecticut. Its securities are quoted on OTC Link (previously ''Pink Sheets''), operated by OTC Markets Group, Inc. under the ticker symbol ''TXMC.''

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. EST on November 12, 2015, through 11:59 p.m. EST on November 25, 2015.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2015–29287 Filed 11–12–15; 4:15 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–76391; File No. SR–FINRA–2015–044]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Establish an Examination Fee for the Securities Trader Qualification Examination (Series 57)

November 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 October 29, 2015, Financial Industry Regulatory Authority, Inc. (''FINRA'') 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 FINRA. FINRA has designated the proposed rule change as ''establishing or changing a due, fee or other charge'' under Section 19(b)(3)(A)(ii) of the Act [3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposal effective upon receipt of this filing by the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

FINRA is proposing to amend Section 4(c) of Schedule A to the FINRA By-Laws to establish an examination fee for the Securities Trader qualification examination (Series 57).

The text of the proposed rule change is available on FINRA's Web site at *http://www.finra.org,* at the principal office of FINRA and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FINRA has prepared summaries, set forth in sections A, B,

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

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

Background

The SEC recently approved amendments to FINRA rules to establish two new registration categories for associated persons who engage in the securities trading activities specified in NASD Rule 1032(f) and for principals who supervise such activities: (1) Securities Traders; and (2) Securities Trader Principals.[5] The Securities Trader registration category and associated examination (Series 57)[6] will replace the current Equity Trader registration category and associated examination (Series 55).[7] Further, unlike Equity Trader registration, there is no prerequisite registration requirement for Securities Trader registration.[8] To qualify for registration as a Securities Trader, an eligible candidate must only pass the Series 57 examination. In addition, to qualify for registration as a Securities Trader Principal, an associated person must be registered as a Securities Trader and pass the General Securities Principal qualification examination (Series 24).[9]

FINRA is expecting the national securities exchanges to also file amendments to their respective registration rules relating to securities trading activities to replace the Proprietary Trader qualification examination (Series 56) with the Series 57 examination.[10] In addition, the Series 57 examination will replace the Series 56 examination for those exchange registration categories, such as the Proprietary Trader Principal registration category, where the Series 56 examination is currently an acceptable prerequisite.

Proposal

FINRA currently administers examinations electronically through the PROCTOR® system [11] at testing centers operated by vendors under contract with FINRA. FINRA charges an examination fee to candidates for FINRA-sponsored and co-sponsored examinations to cover the development, maintenance and delivery of these examinations.[12] Consistent with this practice, FINRA is proposing to amend Section 4(c) of Schedule A to the FINRA By-Laws to establish a fee of $120 for the Series 57 examination.[13]

FINRA has filed the proposed rule change for immediate effectiveness. FINRA is expecting to implement the proposed rule change on January 4, 2016, which coincides with the anticipated implementation date for the Securities Trader registration category and examination program.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(5) of the Act,[14] which requires, among other things, that FINRA rules provide for the equitable allocation of reasonable dues, fees and other charges among members and issuers and other persons using any facility or system that FINRA operates or controls.

FINRA believes that the proposed rule change constitutes an equitable allocation of fees as the examination fee will be used to cover FINRA's costs in developing, maintaining and delivering the examination and will be assessed only on those individuals who will take the Series 57 examination. FINRA further believes that the proposed fee for the Series 57 examination is reasonable because it is aligned with the overall cost associated with the Series 57 examination program. Accordingly, FINRA believes that the proposed fee for the Series 57 examination is equitably allocated and reasonable.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. FINRA believes that the establishment of the fee for the Series 57 examination will have a limited economic impact on the industry.

In proposing a fee of $120 for the Series 57 examination, FINRA applied the same criteria as it does for establishing the fees for other FINRA qualification examinations. The primary factors that FINRA considered include the number of test questions, test session time, staff effort associated with test development and delivery, corporate overhead and operational and technology costs associated with maintaining the PROCTOR system (*i.e.,* item banking, test authoring and test delivery). The proposed fee was also compared with the fees for qualification examinations with comparable test session times (*e.g.,* the Series 24 and Series 27 examinations [15]), because a primary cost of administering examinations is vendor fees.

Moreover, the proposed rule change will reduce the examination fees for the registration of associated persons who are required to be registered to engage in or supervise securities trading.

Economic Impact Assessment

The need for the rule and the regulatory objective are discussed previously.

• Economic Baseline

Currently, associated persons who engage in the securities trading activities specified under NASD Rule 1032(f) or who directly supervise such activities, including principals, are required to take and pass the Series 55 examination in combination with other examinations. As described above, the new registration categories of Securities Trader and Securities Trader Principal will allow such individuals to engage in

[5] *See* Securities Exchange Act Release No. 75783 (August 28, 2015), 80 FR 53369 (September 3, 2015) (Order Approving File No. SR–FINRA–2015–017).

[6] FINRA has filed the Series 57 examination program with the SEC for immediate effectiveness. *See* SR–FINRA–2015–042 (October 13, 2015) (Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to the New Securities Trader Qualification Examination (Series 57)).

[7] The fee for the Series 55 examination is $110.

[8] Before registration as an Equity Trader may become effective, an associated person must be registered as either a General Securities Representative (Series 7) or Corporate Securities Representative (Series 62). The fee for the Series 7 examination is $305, and the fee for the Series 62 examination is $95.

[9] The fee for the Series 24 examination is $120.

[10] For instance, under the rules of the Chicago Board Options Exchange (CBOE), an individual trading permit holder or individual associated person who is engaged in proprietary trading, market-making or effecting transactions on behalf of a broker-dealer is required to register and qualify as a Proprietary Trader. *See* Interpretation and Policy .08(a)(1) to CBOE Rule 3.6A (Qualification and Registration of Trading Permit Holders and Associated Persons). To qualify as a Proprietary Trader under the CBOE rules, an individual must pass the Series 56 examination or be registered as a General Securities Representative. *See* Interpretation and Policy .08(b) to CBOE Rule 3.6A. FINRA administers the Series 56 examination on behalf of the national securities exchanges. The fee for the Series 56 examination is $195.

[11] PROCTOR is a computer system that is specifically designed for the administration and delivery of computer-based testing and training.

[12] Delivery costs vary based on the length of the examination because FINRA pays its delivery vendors an hourly rate for seat time at test delivery centers. The length of the Series 57 examination will be longer than the Series 55 examination as well as the Series 56 examination.

[13] Consequently, the total examination fee for associated persons registering as Securities Trader Principals will be $240, which includes the proposed fee for the Series 57 examination ($120) and the current fee for the Series 24 examination ($120).

[14] 15 U.S.C. 78*o*–3(b)(5).

[15] The Series 27 examination qualifies an associated person to function as a Financial and Operations Principal. The fee for the Series 27 examination is $120.

the same trading and supervisory activities by taking and passing fewer examinations. Specifically, individuals will no longer be required to take and pass a prerequisite examination, such as the Series 7 or Series 62 examination, to engage in or supervise securities trading. Thus, the proposed rule change will reduce the overall costs, including the cost of having to sit for additional examinations, on individuals who will engage in or supervise securities trading under the new categories, as well as the costs on their associated firms.

Based on a survey of Equity Traders, FINRA understands that some Equity Traders, albeit a limited number, currently engage in sales activities in addition to securities trading. Today, such individuals may engage in sales activities because, concurrent to registration as an Equity Trader, they are registered as either a General Securities Representative or Corporate Securities Representative. However, a newly-registered Securities Trader who will be engaging in sales activities in addition to securities trading must separately register in an appropriate sales-related registration category (*e.g.,* General Securities Representative or Corporate Securities Representative). As a result, such individuals may experience an increase in their total examination fees.

• Economic Impacts

The proposed rule change will reduce the examination fees for the registration of associated persons who are required to be registered to engage in or supervise securities trading. By way of example, the current examination fee for registering as an Equity Trader is $415 (for associated persons who take the Series 7 and 55 examinations) or $205 (for associated persons who take the Series 62 and 55 examinations). Under the proposed rule change, the examination fee for registering as a Securities Trader will be $120. Assuming a constant examination volume at the 2014 level, FINRA estimates that the aggregate cost savings will be approximately $188,000 per year for individuals who currently take the Series 7 and 55 examinations or Series 62 and 55 examinations to engage only in securities trading. In addition, the current examination fee for registering as a Proprietary Trader is $305 (for individuals who take the Series 7 examination) or $195 (for individuals who take the Series 56 examination). Assuming a constant volume at the 2014 level, FINRA estimates that the aggregate cost savings for individuals who currently take the Series 56 examination to engage in securities trading will be approximately $58,200 per year.[16]

As noted above, newly-registered persons who will engage in both sales and trading activities may experience an increase in their total examination fees. For instance, the examination fee for associated persons who will take the Series 7 and 57 examinations to engage in both sales and trading activities will be $425 compared to the current fee of $415 for associated persons who take the Series 7 and 55 examinations to engage in such activities.

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) of the Act [17] and paragraph (f)(2) of Rule 19b–4 thereunder.[18] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is 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–FINRA–2015–044 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–FINRA–2015–044. 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 FINRA. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FINRA–2015–044, and should be submitted on or before December 7, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–28860 Filed 11–13–15; 8:45 am]

BILLING CODE 8011–01–P

[16] FINRA does not have data on the number of individuals who take the Series 7 examination and register as General Securities Representatives in order to function as Proprietary Traders and engage in securities trading.

[17] 15 U.S.C. 78s(b)(3)(A).

[18] 17 CFR 240.19b–4(f)(2).

[19] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

In the Matter of Riverdale Mining Inc., and Tresoro Mining Corp., Order of Suspension of Trading

November 12, 2015.

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Riverdale Mining Inc. (CIK No. 1402357), a revoked Nevada corporation with its principal place of business listed as

Toronto, Ontario, Canada, with stock quoted on OTC Link (previously, ''Pink Sheets'') operated by OTC Markets Group, Inc. (''OTC Link'') under the ticker symbol RVDM, because it has not filed any periodic reports since the period ended December 31, 2012. On November 7, 2014, the Division of Corporation Finance sent Riverdale Mining a delinquency letter requesting compliance with their periodic filing obligations, but the letter was returned because of Riverdale Mining's failure to maintain a valid address on file with the Commission, as required by Commission rules (Rule 301 of Regulation S–T, 17 CFR 232.301 and Section 5.4 of EDGAR Filer Manual).

It appears to the Securities and Exchange Commission that there is a lack of current and accurate information concerning the securities of Tresoro Mining Corp. (CIK No. 1348788), a defaulted Nevada corporation with its principal place of business listed as Vancouver, British Columbia, Canada, with stock quoted on OTC Link under the ticker symbol TSOR, because it has not filed any periodic reports since the period ended November 30, 2012. On May 5, 2014, Tresoro Mining received a delinquency letter sent by the Division of Corporation Finance requesting compliance with their periodic filing obligations.

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 companies.

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 companies is suspended for the period from 9:30 a.m. EST on November 12, 2015, through 11:59 p.m. EST on November 25, 2015.

By the Commission.

Jill M. Peterson,

Assistant Secretary.

[FR Doc. 2015–29288 Filed 11–12–15; 4:15 pm]

BILLING CODE 8011–01–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2015–0115]

Petition for Waiver of Compliance

In accordance with part 211 of Title 49 Code of Federal Regulations (CFR), this document provides the public notice that by a document dated October 16, 2015, Kansas City Southern Railway (KCS) has petitioned the Federal Railroad Administration (FRA) for a waiver of compliance from certain provisions of the Federal railroad safety regulations contained at CFR part 213. FRA assigned the petition Docket Number FRA–2015–0115.

Pursuant to 49 CFR 213.113(a), KCS requests a waiver from the accepted practice of stop/start rail testing to start a 3-year pilot test process of nonstop continuous testing. The projected starting date for implementing the test process would be November 1, 2015. The test process would occur on the main tracks between Kansas City, MO, and Heavener, OK, on the Pittsburgh Subdivision and the Heavener Subdivision. Once the two initial subdivisions are completed, KCS would like to expand the test process to include the Shreveport Subdivision in Shreveport, LA. KCS intends to test the subdivisions within a 30- to 45-day frequency.

For this pilot test, the process would be similar to the waiver granted to Union Pacific Railroad in Docket Number FRA–2015–0003. KCS would not have parallel or redundant stop/start testing on the segments being tested in a nonstop process. KCS will produce a bimonthly report for FRA's Rail and Infrastructure Integrity Division managers. This report would include the in-service rail failure ratios per 49 CFR part 213, a report on the miles tested, and the frequency of testing.

The nonstop continuous rail testing vehicle will be a self-propelled ultrasonic induction unit capable of testing at speeds up to 30 mph. The data will be analyzed from a remote location facility by experts with experience reviewing Rail Flaw Detection test data. The field verification of suspected defects will be conducted by qualified and certified test professionals with recordable field validation equipment, based on GPS location and known track features. KCS believes nonstop continuous rail testing will provide the capability to test track more quickly and frequently, and to minimize the risk of rail service failures.

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 (DOT) Docket Operations Facility, 1200 New Jersey Avenue 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 December 16, 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 comment, 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 Monday, November 9, 2015.

Ron Hynes,

Director, Office of Technical Oversight.

[FR Doc. 2015–29162 Filed 11–13–15; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. NHTSA–2015–0055]

Coordinated Remedy Order With Annex A; Coordinated Remedy Program Proceeding

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Coordinated Remedy Order.

DATES: *Effective date:* This Coordinated Remedy Order went into effect on November 3, 2015.

Order: This Coordinated Remedy Order (''Order'') is issued by the Administrator of the National Highway Traffic Safety Administration (''NHTSA''), an operating administration of the U.S. Department of Transportation. Pursuant to NHTSA's authority under the National Traffic and Motor Vehicle Safety Act of 1966, as amended and recodified (the ''Safety Act''), 49 U.S.C. 30101, *et seq.*, and specifically, 49 U.S.C. 30118–30120, 30120(a)(1), 30120(c)(2)–(3), 30166(b), 30166(c), 30166(e), 30166(g)(1), and 49 CFR 573.6, 573.14, this Coordinated Remedy Order establishes a Coordinated Remedy Program and sets forth the requirements and obligations of certain motor vehicle manufacturers [1] and TK Holdings, Inc., (''Takata'') in connection with the recall and remedy of certain types of Takata air bag inflators.

I. Nature of the Matter and Findings

1. On June 5, 2015, NHTSA opened the Coordinated Remedy Program Proceeding and public Docket Number NHTSA–2015–0055 to address the recalls of certain Takata air bag inflators, which together constitute the largest Safety Act recall in NHTSA's history and one of the largest consumer product recalls in United States history. *See Notice of Coordinated Remedy Program Proceeding for the Replacement of Certain Takata Air Bag Inflators*, 80 FR 32,197 (June 5, 2015). As of the date of this Order, the number of recalled air bag inflators (currently, approximately 23 million), impacted vehicles (currently, approximately 19 million), and affected vehicle manufacturers (currently, twelve), in combination with the potential for expansion of existing recalls and issuance of new recalls, and the remedy part supply challenges related to the existing recalls, presents an unprecedented level of complexity to the routine recall and remedy process. Given the potential severity of the harm to vehicle occupants when an inflator rupture occurs and the wide-spread exposure to the risk across a large vehicle population, the risk of harm presented by the defective Takata air bag inflators transcends the scope of the processes ordinarily followed in a recall under the Safety Act. Accordingly, for the reasons that follow, and upon consideration of the entire record in this proceeding, NHTSA now issues this Order.

Factual Background

2. An air bag inflator (''inflator'') is a component inside an air bag module that contains explosive materials [2] which, when ignited, rapidly release gases to inflate air bags that protect vehicle occupants in vehicle crashes. Because inflators must fit into small and unique spaces including vehicle steering wheels and front instrument panels (*i.e.*, dashboards), and because they must also satisfy specific performance requirements, inflators must meet exacting size and configuration requirements for each air bag module they are paired with and each vehicle in which they are installed. When functioning properly, air bag inflators are life-saving devices.

3. The first recall involving a rupturing Takata driver side frontal air bag inflator was initiated by Honda on November 11, 2008. At that time, the defect was thought to be the result of a specific manufacturing issue involving a propellant press at Takata's Moses Lake, Washington plant. Due to various purported discrepancies in Takata's record keeping for the affected parts, and changing theories as to the root cause of the defect, Honda expanded the scope of the recall several times between 2009 and 2011.

4. The first recall involving a rupturing Takata passenger side frontal air bag inflator was initiated by Takata on April 11, 2013, and involved BMW, Honda, Mazda, Nissan, and Toyota. At that time, the defect was thought by Takata to be the result of two specific manufacturing issues: (1) The possibility that the auto-reject function on a propellant press had been manually disabled, and (2) the possibility that certain propellant lots were exposed to uncontrolled moisture conditions at Takata's Monclova, Mexico plant. In 2013 and 2014, GM recalled vehicles to address separate manufacturing problems specific to a limited number of inflators Takata supplied only to GM.

5. Between August 2013 and April 2014, NHTSA received three Vehicle Owner Questionnaires (VOQs) that alleged air bag inflator ruptures in vehicles outside the scope of the prior driver side and passenger side frontal air bag inflator recalls. In late May 2014, Takata confirmed the three ruptures with NHTSA's Office of Defects Investigation (ODI), and notified ODI of an additional three ruptures (for a total of six rupture incidents between August 2013 and May 2014). All of these ruptures occurred in vehicles experiencing long-term exposure to hot and humid climate conditions in Florida and Puerto Rico.

6. On June 10, 2014, at NHTSA's urging, Takata and the affected vehicle manufacturers agreed to initiate various field actions in Florida, Hawaii, Puerto Rico, and the U.S. Virgin Islands. The data supporting these field actions indicated that certain Takata frontal air bag inflators in regions prone to consistent long-term [3] exposure to high absolute humidity (''HAH'') and high temperatures posed a safety risk. The field actions were designed to mitigate the demonstrated risks in the HAH region, to make inflators available for future testing, and to produce data to guide future actions.

7. On June 11, 2014, NHTSA opened a preliminary evaluation (PE14–016) to investigate the six identified rupture incidents involving driver side and passenger side frontal air bag inflators manufactured by Takata.

8. During the period of October through December 2014, at NHTSA's direction, field actions were converted to recalls and the recalls were expanded, though some recalls remained limited to certain regions with higher absolute humidity. Also during this period, NHTSA urged Takata and the affected vehicle manufacturers to, among other things, speed up the

[1] Currently, BMW of North America, LLC (''BMW''), FCA US, LLC (''FCA'') (formerly Chrysler), Daimler Trucks North America, LLC (''Daimler Trucks''), Daimler Vans USA, LLC (''Daimler Vans''), Ford Motor Company (''Ford''), General Motors, LLC (''GM''), American Honda Motor Company (''Honda''), Mazda North American Operations (''Mazda''), Mitsubishi Motors North America, Inc. (''Mitsubishi''), Nissan North America, Inc. (''Nissan''), Subaru of America, Inc. (''Subaru''), and Toyota Motor Engineering and Manufacturing (''Toyota''). In accordance with Paragraphs 45, 46, and 48 below, this list may expand at some future date to include other motor vehicle manufacturers who have sold or otherwise made available in the United States motor vehicles equipped with Takata air bag inflators containing phase-stabilized ammonium nitrate.

[2] More precisely, air bag inflators contain pyrotechnic propellants, stored high pressure gases, or a combination of the two. To aid the reader's understanding, by using more familiar terminology, this is described herein as an ''explosive.''

[3] Consistent long-term exposure means multiple years of mostly continuous exposure throughout the year. It is not seasonal exposure.

remedy programs by increasing the supply of remedy air bag inflators. NHTSA emphasized the need to promptly and effectively remedy the serious safety risk posed to consumers by the defective Takata air bag inflators. Further, as part of its ongoing investigation and oversight, NHTSA issued two Special Orders to Takata on October 30, and November 18, 2014, a Special Order to Honda on November 5, 2014, and General Orders to BMW, FCA, Ford, GM, Honda, Mazda, Mitsubishi, Nissan, Subaru, Toyota, and Takata on November 18, 2014. All these Special and General Orders were designed and issued by NHTSA to obtain additional data required to assess and mitigate the risk of harm to the motoring public.

9. On November 18, 2014, NHTSA demanded that the five vehicle manufacturers with affected driver side frontal air bag inflators expand their regional field actions and conduct nationwide actions. This decision was based on, among other things, NHTSA's evaluation of a driver side frontal air bag failure in a vehicle outside the existing regional recall area. In response, beginning in December 2014, BMW, FCA, Ford, Honda and Mazda initiated national service campaigns or safety improvement campaigns on vehicles with driver side frontal air bag inflators.

10. On November 26, 2014, NHTSA demanded that Takata submit Defect Information Reports (''DIRs'') of driver side frontal air bag inflators. While Takata declined to do so in a December 2, 2014 response, NHTSA continued to insist that Takata accept responsibility for the rupturing air bag inflators and file DIRs.

11. On February 24, 2015, NHTSA upgraded PE14–016 to an engineering analysis (EA15–001).

12. On May 18, 2015, after NHTSA's consistent demands, and pursuant to its legal obligations under the Safety Act, 49 U.S.C. 30118(c)(1) and 49 CFR 573.6(c), Takata filed four DIRs with NHTSA (15E–040, 15E–041, 15E–042, 15E–043) (''Takata DIRs''). In the Takata DIRs, Takata admitted that certain types of air bag inflators manufactured by Takata with a phase-stabilized ammonium nitrate-based propellant (specifically, the PSDI, PSDI–4, PSDI–4K, SPI, PSPI and PSPI–L) contain defects constituting an unreasonable risk to safety.

13. Between May 13, 2015 and June 24, 2015, BMW, FCA, Daimler Trucks,[4] Daimler Vans, Ford, GM, Honda, Mazda, Mitsubishi, Nissan, Subaru, and Toyota (the ''Initial Vehicle Manufacturers'') each filed DIRs with NHTSA for vehicles containing the air bag inflators covered by the Takata DIRs (the ''Inflator Recalls'').

14. As part of the Coordinated Remedy Program Proceeding, launched on June 5, 2015, NHTSA sought information from each of the Initial Vehicle Manufacturers, Takata, and other major inflator suppliers[5] (the ''Suppliers''). As an initial matter, this included gathering data from the Initial Vehicle Manufacturers, Takata, and the other Suppliers through correspondence, and a Special Order to Takata, sent on June 18 and 19, 2015.[6] Thereafter, each of these companies provided answers responsive to NHTSA's correspondence, which were available in the public docket.

15. Among other things, NHTSA engaged in numerous teleconferences and in-person meetings with the Suppliers to enhance NHTSA's understanding of, among other things, each Supplier's current production capacities, capabilities or plans for increasing production, existing contractual obligations, and product reliability. NHTSA also engaged in teleconferences and in-person meetings with the Initial Vehicle Manufacturers to enhance NHTSA's understanding of, among other things, each Vehicle Manufacturer's anticipated timelines for receipt of replacement air bag units, anticipated timelines for remedy program launch and completion, number of impacted vehicles, number of replacement air bag units needed, and plans and efforts for promptly conducting recall remedies and effectively reaching consumers.

16. On September 22, 2015, NHTSA gathered supplemental data from additional vehicle manufacturers that NHTSA had learned were supplied with Takata air bag inflators containing phase-stabilized ammonium nitrate (''PSAN'')[7] not covered by the Takata DIRs (collectively, the ''Potential Expansion Vehicle Manufacturers''). Thereafter, each of these companies provided public comments to the docket responsive to the questions and issues raised in NHTSA's correspondence.

17. On September 23 and 24, 2015, NHTSA convened problem-solving meetings with the Initial Vehicle Manufacturers to examine aggregate data and engage in a collaborative risk analysis to aid NHTSA in developing a principled, rational, risk-mitigation based approach for the prioritization and phasing of recall plans. Factors considered included those currently associated with a higher risk of inflator rupture, specifically: age of the inflator (with older inflators presenting a greater risk); geographic location of vehicles with the recalled inflators (with HAH areas presenting a greater risk); position of the inflator in the vehicle (with the driver side frontal air bag inflator presenting a greater risk of serious injury or death when a rupture occurs); and the presence of recalled inflators in both the driver and passenger side airbag modules. During the meetings, the Initial Vehicle Manufacturers provided input on factors supporting a technically supported risk-assessment methodology for the Inflator Recalls. Following the meeting, each Initial Vehicle Manufacturer submitted a vehicle prioritization list that applied these factors, and other factors specific to their products, that prioritized vehicles into three risk categories. NHTSA analyzed these submissions and determined that the Initial Vehicle Manufacturers generally identified reasonable and appropriate priority groups based on the evidence known at this time.

18. Throughout this process, the public has been able to engage in this dialogue through submissions to the public Docket, NHTSA–2015–0055. In addition to the actions set forth above, NHTSA reviewed and considered all public comments to the docket.

19. While Takata is a manufacturer of air bag inflators, other Suppliers also manufacture inflators, some of which closely match the performance requirements of the original Takata inflator and thus can be modified and safely installed in Takata air bag modules for use as remedy parts for the

[4] Daimler Trucks' remedy program of approximately 2,500 vehicles is being conducted in cooperation with FCA.

[5] ARC Automotive, Inc. (''ARC''), Autoliv Americas (''Autoliv''), Key Safety Systems (''Key Safety''), Toyoda Gosei North America Corporation (''Toyoda''), Daicel Safety Systems America, LLC (''Daicel''), and TRW Automotive (''TRW'') which has subsequently become ZF TRW (''ZF TRW'').

[6] The correspondence sent to Takata and each of the Suppliers and Initial Vehicle Manufacturers, and their responses, are available for inspection in public Docket Number NHTSA–2015–0055. Given NHTSA's ongoing investigation into the defective Takata air bag inflators under EA15–001, the correspondence sent to Takata was in the form of a Special Order, with a cover letter. As with the other industry responses to the correspondence of June 18–19, Takata's response to the Special Order was made publicly available as a comment to the Docket.

[7] Correspondence was sent to Jaguar Land Rover North America, LLC (''Jaguar''); Mercedes-Benz US, LLC (''Mercedes-Benz''); Spartan Motors, Inc. (''Spartan''); Suzuki Motor of America, Inc. (''Suzuki''); Tesla Motors, Inc. (''Tesla''); Volkswagen Group of America, Inc. (''Volkswagen''); and Volvo Trucks NA (''Volvo''). The correspondence to each of these vehicle manufacturers, and their responses, are available for public inspection in public Docket Number NHTSA–2015–0055.

Inflator Recalls. This is significant because Takata alone does not have sufficient manufacturing capacity to produce remedy inflators for the Initial Vehicle Manufacturers within an adequate timeframe. According to Takata, it was capable of manufacturing approximately 85,000 replacement kits per week as of October 30, 2014. Takata's production capacity increased to 91,000 replacement kits per week by December 1, 2014, and to 122,000 replacement kits per week by January 26, 2015. By July 2015, Takata reported to NHTSA that, in May 2015, it had produced approximately 730,000 remedy inflators and 1,167,000 remedy kits, which included inflators obtained from other Suppliers. Takata further reported that these numbers were expected to reach 850,000 remedy inflators and 1,900,000 remedy kits produced per month, including inflators obtained from other Suppliers, by October 2015. Takata also reported that, as of June 2015, it had produced a total of approximately 8,900,000 replacement inflators. However, this production is not all directed to the U.S. market; it also serves the global market requiring replacement air bag inflators. Even at the increased rate of nearly 850,000 remedy inflators per month by October 2015, if working alone it would take Takata at least twenty-seven (27) months to produce enough remedy inflators for the Inflator Recalls, assuming all of that production went solely to the United States market.

20. Further, some of the Takata driver inflators, sometimes referred to as containing propellant in the shape of a ''batwing,'' have been used as interim replacement parts that will degrade if continuously exposed to long-term to HAH conditions, and are themselves subject to recall. These inflators will not be used as a final remedy of driver side frontal air bags. Further, Takata's passenger side frontal air bag inflators subject to the Inflator Recalls have not previously been recalled for vehicles later than model year 2008.

21. The Initial Vehicle Manufacturers recognized the need to increase the remedy parts supply in order to have sufficient remedy parts available. To do so, they were required find alternative suppliers to meet their demands for remedy air bag inflator parts. The Initial Vehicle Manufacturers found that necessary alternative supply source in other inflator suppliers, specifically, Autoliv, Daicel, and ZF TRW (collectively, the ''Alternative Inflator Suppliers'').

22. According to Takata, in October 2015, the Alternative Inflator Suppliers were scheduled to provide over 1.9 million remedy inflator parts per month for installation in remedy air bag kits. This totaled approximately seventy percent (70%) of the 2.8 million remedy inflator kits produced by Takata that month for global demand. Nonetheless, the sheer volume of remedy parts required across the vehicle manufacturing industry, for both U.S. and foreign markets, has created challenges for the Initial Vehicle Manufacturers in obtaining sufficient remedy parts to remedy all of the recalled inflators within a reasonable time.

23. Despite the efforts of each of the Initial Vehicle Manufacturers to procure remedy parts in a timely fashion, some vehicle manufacturers will not be able to obtain sufficient remedy parts to launch their remedy programs, in part or in full, until late 2015 or early 2016, more than six (6) months after filing their initial DIRs in regard to the Inflator Recalls.

24. Further, pursuant to a November 3, 2015 Consent Order to Takata (''November 2015 Takata Consent Order''), additional Takata air bag inflators not previously subject to a recall may need to be replaced. This would cause the Potential Expansion Vehicle Manufacturers to join the existing field of Initial Vehicle Manufacturers (collectively, the ''Vehicle Manufacturers'') in need of remedy air bag inflator parts.

25. Each time Takata air bag inflator recalls are issued under the November 2015 Takata Consent Order, or current recalls are expanded, similar challenges will arise for the Vehicle Manufacturers regarding supply chain and the need for risk-assessments based on principled rationales that utilize the most-current available science and data.

26. Throughout this sequence of events, Takata has conducted inflator testing in an effort to determine the ''root cause'' of the inflator ruptures and, by testing modules recovered from vehicles that have been remedied, to determine which inflators posed the greatest risk of rupture. While production issues at Takata manufacturing plants in Monclova, Mexico and Moses Lake, Washington, were identified early on as the purported root cause in some rupture incidents, those theories (even if correct) do not account for the ongoing issues with inflator rupture. For example, inflators installed in vehicles spending many consecutive years of their service lives in hot and humid climates have also ruptured even though they appear to have been manufactured within Takata's specifications. While Takata now believes that the ruptures are related to long-term exposure to HAH conditions, their root cause testing has not produced any conclusive answers regarding why the inflators rupture.

27. Moreover, Takata has been unable to provide a definitive explanation for other inflators rupturing, including the rupture of an SSI–20 side air bag inflator on June 7, 2015, in a Volkswagen vehicle involved in a crash, or the rupture of a PSDI–X inflator during Takata's testing of an air bag module on September 29, 2015 with a resulting recall by Honda. Takata has also been unable to definitively explain the October 2015, rupture of an SSI–20 inflator during Takata quality control testing. It therefore appears to the agency that Takata continues to have ongoing quality control issues with the volatile, explosive compound it has chosen as the propellant for most of its air bag inflators: PSAN.

28. While the ultimate responsibility for determining root cause rests squarely with Takata, testing has also been conducted by NHTSA and third parties in an effort to establish the root cause of the defect and to verify the results of Takata's testing of inflators returned from the field. NHTSA has conducted testing through Battelle Memorial Institute, 3D Engineering Solutions, and the Transportation Research Center of Ohio, testing organizations located in Ohio, to verify Takata's test results and examine the root cause of the defect. Testing has also been undertaken by the Independent Testing Coalition (''ITC''), which is comprised of BMW, FCA, Ford, GM, Honda, Mazda, Mitsubishi, Nissan, Subaru, and Toyota. Orbital ATK, a testing company located in Utah, has commenced testing on behalf of the ITC, and hopes to conclude root cause analysis in 2016. Multiple individual vehicle manufacturers have also conducted testing in efforts to confirm Takata's results or establish root cause for the defect. While this multitude of independent testing efforts have largely confirmed the observations made and patterns identified from Takata's test results, none of these efforts has identified any specific root cause(s) for the propellant failures and inflator ruptures. While progress is being made, it is unknown when, or if, root cause will ever be definitively determined.

29. Without a conclusive determination of root cause, the source of the problems with certain Takata inflators remains unknown. What is known, however, is that the propellant in inflators covered by the Inflator Recalls and the recalls within the scope of this Order have, at various rates of frequency, a propensity to ignite and/or

burn in an unexpected way that may cause the pressure inside the inflator to increase too quickly, causing the inflator to rupture. That rupture causes the metal canister of the inflator to break away in hot, shrapnel-like fragments, which shoot out of the air bag into the passenger cabin and towards the driver or any occupants who are nearby.

30. As of October 30, 2015, there have been 99 confirmed incidents in the United States where a ruptured Takata air bag inflator allegedly caused death or injury. Many of these incidents resulted in serious injury to vehicle occupants. In seven of the incidents, the vehicle's driver died as a result of injuries sustained from the rupture of the air bag inflator. In other incidents, vehicle occupants suffered injuries including cuts or lacerations to the face or neck, broken or fractured facial bones, loss of eyesight, and broken teeth. The risk of these tragic consequences is greatest for individuals sitting in the driver seat, where one in ten individuals' whose air bag inflator ruptured has died.

Findings

Based upon the agency's analysis and judgment, and upon consideration of the entire record, NHTSA finds that:

31. (1) There is a risk of serious injury or death if the remedy program of each of the Initial Vehicle Manufacturers is not accelerated; (2) acceleration of each Initial Vehicle Manufacturer's remedy program can be reasonably achieved by expanding the sources of replacement parts; and (3) each Initial Vehicle Manufacturer's remedy program is not likely to be capable of completion within a reasonable time without acceleration.

32. Each air bag inflator with the capacity to rupture, as the recalled Takata inflators do, presents an unreasonable risk of serious injury or death. Seven individuals have already been killed in the United States alone, with at least 92 more injured. Since the propensity for rupture increases with the age of the inflator, and increases even more when the vehicle has been exposed to consistent long-term HAH conditions, the risk for injurious or lethal rupture increases with each passing day. While each of the Initial Vehicle Manufacturers has made efforts towards the remedy of these defective air bag inflators, acceleration and coordination of the inflator remedy programs is necessary to reduce this risk to public safety. Acceleration and coordination will enable vehicle manufacturers to establish priorities based on principled rationales for risk-assessment, coordinate on safety-focused efforts to successfully complete their respective remedy programs, and allow for the organization and prioritization of remedy parts, if and as needed, with NHTSA's oversight.

33. Acceleration of the inflator remedy programs can be reasonably achieved by, among other things, expanding the sources of replacement parts. This acceleration can be accomplished in part by a vehicle manufacturer contracting with any of the Alternative Inflator Suppliers for remedy parts as Takata cannot manufacture sufficient remedy parts in a reasonable time for the estimated 23 million inflators in the U.S. market alone that require remedy under the Inflator Recalls.

34. In light of all the circumstances, including the safety risk discussed above, the Initial Vehicle Manufacturers' recall remedy programs are not likely capable of completion within a reasonable amount of time without acceleration of each remedy program. It is critical to the timely completion of each remedy program that the Initial Vehicle Manufacturers obtain remedy inflators from sources other than Takata. Takata's inflator production for October 2015 will make up only around thirty percent (30%) of the remedy inflators produced that month. Further, Takata's ability to supply remedy parts going forward may decrease, such that other Suppliers will need to fill the resulting void.

35. Pursuant to the conditions for expansion of the recalls in the Takata DIRs for Recall Nos. 15E–042 and 15E–043, Paragraphs 27–30 of the November 2015 Takata Consent Order, and as otherwise agreed by Takata, and after consultation throughout this Coordinated Remedy Program Proceeding with Takata and all of the vehicle manufacturers affected by said Recalls, NHTSA further finds that continued testing and analysis of Takata air bag inflators is necessary. If circumstances warrant the issuance of an Order expanding the production or geographic scope of the Inflator Recalls, the agency will do so in accordance with the November 2015 Takata Consent Order.

36. The issuance of this Coordinated Remedy Order is an appropriate exercise of NHTSA's authority under the Safety Act, 49 U.S.C. § 30101, *et seq.,* as delegated by the Secretary of Transportation, 49 CFR §§ 1.95, 501.2(a)(1), to inspect and investigate, 49 U.S.C. § 30166(b)(1), to ensure that defective vehicles and equipment are recalled and remedied and that owners are notified of a defect and how to have the defect remedied, 49 U.S.C. §§ 30118–30120, to ensure the adequacy of the remedy, including through acceleration of the remedy program, 49 U.S.C. § 30120(c), to require vehicle manufacturers and equipment manufacturers to keep records and make reports, 49 U.S.C. § 30166(e), and to require any person to file reports or answers to specific questions, 49 U.S.C. § 30166(g).

37. This Coordinated Remedy Order, developed after taking into account the input and concerns of each of the Vehicle Manufacturers, Suppliers, Takata, other interested parties and the public, will reduce the risk of serious injury or death to the motoring public and enable the Initial Vehicle Manufacturers and Takata to implement, and complete, the necessary remedy programs on an accelerated basis.

Accordingly, it is hereby *ordered* by NHTSA as follows:

II. Terms of the Coordinated Remedy Order

Priority Groups and Target Recall Program Completion Deadlines for the Coordinated Remedy Program

38. Each Initial Vehicle Manufacturer has previously submitted to NHTSA a vehicle prioritization plan based on a risk-assessment that takes into account the primary factors related to Takata inflator rupture, as currently known and understood, and other factors specific to that vehicle manufacturer's products. The primary factors utilized by all of the Initial Vehicle Manufacturers are: (1) Age of the inflator (with older presenting a greater risk of rupture); (2) geographic location of the inflator (with continuous long-term exposure to high absolute humidity [''HAH''] areas,[8] as defined by each vehicle manufacturer, presenting a greater risk of rupture); and (3) location of the Takata inflator in the vehicle (with both driver side and passenger side frontal air bag inflators in the same vehicle presenting the greatest risk of rupture,[9] and driver side only

[8] Each vehicle manufacturer has defined an HAH region for its vehicle prioritization and recall remedy program, resulting in slight variations as to which states and territories are included in the HAH area. However, all of the prioritizations include in the HAH area vehicles that were originally sold, or ever registered, in Alabama, Florida, Georgia, Hawaii, Louisiana, Mississippi, Texas, Puerto Rico, American Samoa, Guam, Saipan, and the U.S. Virgin Islands. None of the slight variations impact the risk mitigation established through this Order.

[9] All recalled Takata inflators have previously been determined to pose an unreasonable risk of death or serious injury in a crash, as established in the filing of each of the many DIRs for the recalled inflators. Comparative statements of risk in the priority groups are provided to explain relative risk among the inflators, all of which pose an

Continued

presenting an elevated risk of rupture, resulting in serious injury or death). In order to timely and adequately complete its remedy program, each Initial Vehicle Manufacturer shall, pursuant to 49 U.S.C. 30120(a)(1) and (c), carry out its remedy program in accordance with its prioritization plan as submitted to NHTSA. A complete listing of the vehicles in each priority group (''Priority Group'') developed using the above risk factors is attached hereto as Annex A,[10] and is hereby incorporated by reference as if fully set forth herein. The Priority Groups are as follows:

a. Priority Group 1

Vehicles in Priority Group 1 are equipped with Takata inflators that pose the highest risk of rupture and thus the highest risk of injury or death to the vehicle occupants. Generally, Priority Group 1 vehicles are currently model year 2008 and earlier, and have spent time [11] in the HAH region, and have either a recalled driver side inflator or *both* recalled driver side and passenger side inflators in the same vehicle.

b. Priority Group 2

Vehicles in Priority Group 2 are equipped with Takata inflators that pose an intermediate risk of rupture; that is, a lower risk of rupture and resulting injury or death to vehicle occupants than the inflators and vehicles in Priority Group 1, but a higher likelihood of rupture and injury or death than vehicles in Priority Groups 3 and 4. Generally, Priority Group 2 includes: (1) All remaining vehicles with recalled *driver* side inflators (this includes, vehicles 2009 and newer, and/or vehicles with recalled driver inflators only that have not spent time in the HAH region), and; (2) vehicles with certain recalled passenger inflator types that have a higher rupture frequency and that have also spent time in the HAH region.

c. Priority Group 3

Vehicles in Priority Group 3 are equipped with Takata inflators that pose an unreasonable risk of serious injury or death to vehicle occupants and should be remedied as soon as possible following the remedy of the highest risk vehicles in Priority Groups 1 and 2. The likelihood of these inflators rupturing is lower than Priority Groups 1 and 2. Generally, Priority Group 3 includes the remaining vehicles, specifically, vehicles that are model year 2009 and later and either: (1) Are outside the HAH region and contain only a passenger side inflator, or; (2) are in the HAH region and contain a specific passenger side inflator type with a lower rupture rate (the PSPI type) than other passenger side inflator types.

d. Priority Group 4

Some Initial Vehicle Manufacturers are replacing recalled inflators with newly manufactured ''like-for-like'' inflators while they work towards an alternative, final remedy. Vehicles in Priority Group 4 include those vehicles with driver side frontal air bag inflators that have received, or will receive, an ''interim remedy,'' meaning they have been, or will be, remedied with a Takata inflator that has been recalled, and will require a second remedy once the final remedy is available.[12] Once repaired with the interim remedy, these vehicles are at the lowest risk of an inflator rupture because the inflator is new and has not yet been subject to long-term continuous exposure to HAH conditions. Unless specifically added at a later date to a higher Priority Group for re-remedy by their vehicle manufacturer, all remaining vehicles requiring a second, final, remedy of the inflator(s) are included in Priority Group 4.

39. Pursuant to their obligations to remedy a defect within a reasonable time, as set forth in 49 U.S.C. § 30120(a)(1) and § 30120(c)(2), each Initial Vehicle Manufacturer shall acquire a sufficient supply of remedy parts to enable it to provide remedy parts, in a manner consistent with customary business practices, upon demand to dealers within their dealer network by the timelines set forth in this Paragraph. Each Initial Vehicle Manufacturer shall ensure that it has a sufficient supply of remedy parts on the following schedule:

Priority group	Sufficient supply timelines
Priority Group 1	March 31, 2016.
Priority Group 2	September 30, 2016.
Priority Group 3	December 31, 2016.

40. Further pursuant to their obligations to remedy a defect within a reasonable time, as set forth in 49 U.S.C. § 30120(a)(1) and § 30120(c)(2), each Initial Vehicle Manufacturer shall implement and execute its recall remedy program pursuant to the Safety Act with the target deadline to complete the recall remedy program for all vehicles in Priority Groups 1 through 3 of December 31, 2017, and a target deadline to remedy all vehicles in Priority Group 4 of December 31, 2019, as shown below:

Priority group	Remedy completion target deadline
Priority Group 1	December 31, 2017.
Priority Group 2	December 31, 2017.
Priority Group 3	December 31, 2017.
Priority Group 4	December 31, 2019.

Remedy Completion Maximization Efforts

41. Pursuant to 49 U.S.C. 30166(e), within 90 days of this Order, a vehicle manufacturer recalling inflators subject to this Order shall provide to NHTSA and the Monitor (as set forth at Paragraph 44 below), a written recall engagement process or plan for maximizing remedy completion rates for all vehicles covered by the Inflator Recalls. Such a process or plan shall, at a minimum, include but not be limited to the methodology and techniques presented at the Retooling Recalls Workshop [13] held by NHTSA on April 28, 2015, at the U.S. Department of Transportation Headquarters.

42. Pursuant to 49 U.S.C. 30166(e), a vehicle manufacturer recalling inflators subject to this Order shall, upon request, provide to NHTSA and the Monitor any and all information demonstrating the reasonableness of the efforts made by that vehicle manufacturer to maximize remedy completion rates.

43. The facts relating to supply, demand, and root cause may change during this Coordinated Remedy Program. Pursuant to Paragraph 32 of the November 2015 Takata Consent Order, Takata shall continue to cooperate with NHTSA in all ways to coordinate and accelerate remedy programs, and to adequately remedy the air bag inflators covered by the Inflator Recalls.

Monitor

44. Pursuant to Paragraphs 35 through 46 of the November 2015 Takata

unreasonable risk of death or serious injury in a crash.

[10] Because information about the risk factors may change throughout this Coordinated Remedy Program, these prioritizations are subject to change by a vehicle manufacturer, with NHTSA's oversight of the recall program including vehicle prioritization.

[11] While continuous long-term exposure to HAH is an identified risk factor, the Priority Groups take this into account by including in the risk-assessment vehicles originally sold or ever registered in the HAH region. Vehicle manufacturers are able to obtain registration information and have used that data in formulating their risk-assessment based Priority Groups.

[12] NHTSA has entered into Remedy Agreements with BMW and Mazda, which can be found in the investigation file for EA15–001 on *www.safercar.gov.*

[13] Each of the Initial Vehicle Manufacturers, other than Daimler Vans, registered to attend this Workshop. Presentations from the Workshop are available at: *http://www.nhtsa.gov/nhtsa/symposiums/april2015/index.html#.*

Consent Order, Takata has agreed to retain, at its sole cost and expense, an independent monitor (the ''Monitor''). The Monitor's authority includes, among other things, certain monitoring, review and assessment of progress of the Coordinated Remedy Program and of compliance with this Order. The powers, rights and responsibilities of the Monitor are set forth more fully in the November 2015 Takata Consent Order, which are hereby incorporated by reference as if fully set forth herein.

a. The Monitor shall have the authority to take such reasonable steps, in the Monitor's view, as are necessary to be fully informed about the operations of the Coordinated Remedy Program and this Order.

b. It is expected that the Monitor will develop and implement written procedures and may make additional recommendations aimed at enhancing the Coordinated Remedy Program and ensuring that all Coordinated Remedy Program deadlines, including those in this Order, are met.

c. The Monitor is not intended to supplant NHTSA's authority over decisions related to the Coordinated Remedy Program, this Order, motor vehicle safety, or otherwise. If the Monitor identifies a problem or issue, the Monitor shall make appropriate recommendations to NHTSA and provide all supporting information, including information contrary to the Monitor's recommendation, to enable NHTSA to make an informed decision on that recommendation.

d. Takata and Vehicle Manufacturers, along with all of their respective officers, directors, employees, agents, and consultants, shall have an affirmative duty to cooperate with and assist the Monitor in connection with the Coordinated Remedy Program and this Order.

Potential Future Recalls

45. The provisions of the November 2015 Takata Consent Order regarding future recalls and possible future recalls, contained at Paragraphs 29–30 of that document, are hereby incorporated by reference into this Order. Accordingly, any future recall(s) of Takata inflators pursuant to, or contemplated by, Paragraphs 29–30 of that Order shall become part of the Coordinated Remedy Program established herein.

46. Upon Takata's filing of a DIR pursuant to 49 CFR § 573, the affected vehicle manufacturer(s) shall timely file a DIR. Upon the filing of such DIRs NHTSA may, pursuant to 49 U.S.C. §§ 30118–30119, 49 U.S.C. § 30120(c), 49 CFR § 573.14, and 49 U.S.C. § 30166(b), (c), and (e), convene a meeting with the affected vehicle manufacturers to take place within forty-five (45) days of Takata's DIR filing, at an appropriate location within the United States, as determined by NHTSA, to address issues related to the Coordinated Remedy Program including, but not limited to, establishing a risk-assessment framework for the prioritization of vehicles and/or phasing of remedy programs, as appropriate. Any such prioritizations shall be made publicly available, and shall be annexed to this Order, in a format similar to the Priority Group lists in Annex A of this Order.

Record Keeping & Reports

47. Pursuant to 49 U.S.C. § 30166(b), (c), (e), and (g), in carrying out any recall remedy program covered by this Order, each affected vehicle manufacturer and Takata shall make any report, submit any information, and accommodate any inspection and/or investigation, as requested by NHTSA or the Monitor.

Miscellaneous

48. NHTSA may, after consultation with affected vehicle manufacturers, and/or Takata, or upon a recommendation of the Monitor, modify or amend provisions of this Order to, among other things: account for and timely respond to newly obtained facts, scientific data, changed circumstances, and/or other relevant information that may become available throughout the term of the Coordinated Remedy Program. This includes but is not limited to, changes to the Priority Groups contained in Annex A; allowing for reasonable extensions of time for the timelines contained in Paragraphs 39 and 40; facilitating further recalls as contemplated by Paragraphs 45 and 46; or for any other purpose arising under, or in connection with, the Coordinated Remedy Program and/or this Coordinated Remedy Order.

49. This Coordinated Remedy Order shall become effective upon issuance by the NHTSA Administrator. In the event of a breach of, or failure to perform, any term of this Order by Takata or any vehicle manufacturer, NHTSA may pursue any and all appropriate remedies, including, but not limited to, actions compelling specific performance of the terms of this Order, and/or commencing litigation to enforce this Order in any United States District Court.

50. This Coordinated Remedy Order shall not be construed to create rights in, or grant any cause of action to, any third party not subject to this Order.

51. In carrying out the directives of this Coordinated Remedy Order, vehicle manufacturers and vehicle equipment manufacturers (*i.e.* suppliers) shall not engage in any conduct prohibited under the antitrust laws, or other applicable law.

It is so ordered:

NATIONAL HIGHWAY TRAFFIC SAFETY ADMINISTRATION, U.S. DEPARTMENT OF TRANSPORTATION

Dated: November 3, 2015.

Mark R. Rosekind,

Administrator.

ANNEX A

Coordinated Remedy Program Priority Groups

In the Priority Groups listed below, the area of high absolute humidity (''HAH'') is defined by each vehicle manufacturer individually, but in all instances includes vehicles originally sold or ever registered in Alabama, Florida, Georgia, Hawaii, Louisiana, Mississippi, Texas, Puerto Rico, American Samoa, Guam, Saipan, and the U.S. Virgin Islands. In limited instances, parts for some HAH recalls are currently only available to a limited area within the HAH with the highest risk of rupture. ''Non-HAH'' means any vehicle that has not been identified by the vehicle manufacturer as having been originally sold or ever registered in the HAH region, as defined by the vehicle manufacturer.

PRIORITY GROUP 1

BMW:		
2002–2006	BMW	3 Series, M3 (HAH)
Daimler Vans USA:		
2007–2008	Freightliner	Sprinter (HAH)
2007–2008	Dodge	Sprinter (HAH)
Daimler Truck North America-DTNA:		

2008–2009	Sterling	Bullet (HAH and non-HAH)
FCA:		
2006–2008	Chrysler	300, 300C, SRT8 (HAH)
2005	Chrysler	300, 300C, SRT8 (HAH and non-HAH)
2008	Dodge	Challenger (HAH)
2006–2008	Dodge	Charger (HAH)
2005	Dodge	Dakota (HAH)
2004–2005	Dodge	Durango (HAH)
2006–2008	Dodge	Magnum (HAH)
2005	Dodge	Magnum (HAH and non-HAH)
2004–2005	Dodge	Ram 1500, 2500, 3500 Pickup (HAH)
Ford:		
2005–2006	Ford	GT (HAH)
2005–2008	Ford	Mustang (HAH)
2004–2005	Ford	Ranger (HAH)
GM:		
2003–2007	Pontiac	Vibe (HAH)
2005	GM-Saab	9–2X (HAH)

Priority Group 1 continued . . .
Priority Group 1 continued from prior page . . .

Honda:		
2003	Acura	3.2CL (HAH and non-HAH)
2002–2003	Acura	3.2TL (HAH and non-HAH)
2001–2003	Honda	Accord (HAH and non-HAH)
2001–2003	Honda	Civic (HAH and non-HAH)
2004–2005	Honda	Civic (HAH)
2003–2005	Honda	Civic IMA-Hybrid (HAH)
2003	Honda	Civic IMA-Hybrid (non-HAH)
2002	Honda	CR–V (HAH and non-HAH)
2003–2004	Honda	CR–V (HAH)
2003–2006	Honda	Element (HAH)
2002	Honda	Odyssey (HAH)
2003	Honda	Pilot (HAH and non-HAH)
2004–2005	Honda	Pilot (HAH)
2006	Honda	Ridgeline (HAH)
Mazda:		
2003–2008	Mazda	Mazda6 (HAH)
2004–2008	Mazda	RX8 (HAH)
2006–2007	Mazda	Speed6 (HAH)
Mitsubishi:		
2004–2006	Mitsubishi	Lancer and Lancer Evolution (HAH)
2004	Mitsubishi	Lancer Sportback (HAH)
2006–2009	Mitsubishi	Raider (HAH)
Nissan:		
2002–2003	Infiniti	QX4 (HAH)
2002–2004	Nissan	Pathfinder (HAH)
2002–2004	Nissan	Sentra (HAH)
Subaru:		
2004–2005	Subaru	Impreza/WRX/STI (HAH)
2005	Subaru	Legacy, Outback (HAH)
Toyota:		
2007	Lexus	SC430 (HAH)
2003–2007	Toyota	Corolla (HAH)
2003–2007	Toyota	Matrix (HAH)
2005–2007	Toyota	Sequoia (HAH)
2003–2004	Toyota	Tundra (HAH)
2005–2006	Toyota	Tundra (non-HAH)

PRIORITY GROUP 2

BMW:		
2000–2001	BMW	3 Series (HAH)
2002–2006	BMW	3 Series (non-HAH)
2002–2003	BMW	5 Series (HAH and non-HAH)
2003–2004	BMW	X5 SUV (HAH and non-HAH)
Daimler Vans USA:		
2007–2008	Freightliner	Sprinter (non-HAH)
FCA:		
2006–2008	Chrysler	300, 300C, SRT8 (non-HAH)
2009–2010	Chrysler	300, 300C, SRT8 (HAH and non-HAH)
2005	Chrysler	300, 300C, SRT8 (HAH)
2007–2008	Dodge	Aspen (HAH and non-HAH)
2008	Dodge	Challenger (non-HAH)
2009–2010	Dodge	Challenger (HAH)

2006–2008	Dodge	Charger (non-HAH)
2009–2010	Dodge	Charger (HAH and non-HAH)
2005–2011	Dodge	Dakota (HAH and non-HAH)
2004–2008	Dodge	Durango (HAH and non-HAH)
2005	Dodge	Magnum (HAH)
2006–2008	Dodge	Magnum (non-HAH)
2004–2005	Dodge	Ram 1500 Pickup (HAH)
2003	Dodge	Ram 1500, 2500, 3500 Pickup (HAH and non-HAH)
2006–2009	Dodge	Ram 1500, 2500, 3500 Pickup (HAH and non-HAH)
2006	Dodge	Ram 2500 (HAH)
2007–2008	Dodge	Ram 3500 Cab Chassis (HAH and non-HAH)
2008–2010	Dodge	Ram 4500, 5500 Cab Chassis (HAH and non-HAH)
2007–2008	Dodge	Sprinter (non-HAH)
Ford:		
2005–2006	Ford	GT (HAH)
2005–2008	Ford	Mustang (non-HAH)
2009–2014	Ford	Mustang (HAH)
2006	Ford	Ranger (HAH)
GM:		
2003–2007	Pontiac	Vibe (non-HAH)
2007–2008	Chev/GMC	Silverado/Sierra (HAH)

Priority Group 2 continued . . .
Priority Group 2 continued from prior page . . .

Honda:		
2003–2006	Acura	MDX (HAH and non-HAH)
2004–2007	Honda	Accord (HAH and non-HAH)
2004–2005	Honda	Civic (non-HAH)
2004–2005	Honda	Civic Hybrid (non-HAH)
2005–2006	Honda	CR–V (HAH)
2003–2006	Honda	CR–V (non-HAH)
2007–2011	Honda	Element (HAH)
2003–2007	Honda	Element (non-HAH)
2003–2004	Honda	Odyssey (HAH)
2002–2004	Honda	Odyssey (non-HAH)
2006–2008	Honda	Pilot (HAH)
2004–2007	Honda	Pilot (non-HAH)
2006	Honda	Ridgeline (non-HAH)
Mazda:		
2003–2008	Mazda	Mazda6 (non-HAH)
2004–2006	Mazda	B-Series (HAH)
2004–2005	Mazda	MPV (HAH)
2004–2008	Mazda	RX8 (non-HAH)
2006–2007	Mazda	Speed6 (HAH)
Mitsubishi:		
2004–2006	Mitsubishi	Lancer, Lancer Evolution (non-HAH)
2004	Mitsubishi	Lancer Sportback (non-HAH)
2006–2009	Mitsubishi	Raider (non-HAH)
Nissan:		
2003	Infiniti	FX (HAH)
2001	Infiniti	I30 (HAH)
2002–2003	Infiniti	I35 (HAH)
2002–2003	Infiniti	QX4 (non-HAH)
2001–2003	Nissan	Maxima (HAH)
2002–2004	Nissan	Pathfinder (HAH and non-HAH)
2004–2006	Nissan	Sentra (HAH and non-HAH)
Subaru:		
2003–2005	Subaru	Legacy, Outback, Baja (HAH)

Priority Group 2 continued . . .
Priority Group 2 continued from prior page . . .

Toyota:		
2007	Lexus	SC430 (non-HAH)
2003–2007	Toyota	Corolla (non-HAH)
2003–2007	Toyota	Matrix (non-HAH)
2004–2005	Toyota	RAV4 (HAH and non-HAH)
2002–2004	Toyota	Sequoia (HAH)
2005–2007	Toyota	Sequoia (non-HAH)
2003–2004	Toyota	Tundra (HAH)
2005–2006	Toyota	Tundra (non-HAH)

PRIORITY GROUP 3

BMW:		
2000–2001	BMW	3 Series (non-HAH)

Daimler Vans USA:		
2007–2008	Freightliner	Sprinter (non-HAH)
2007–2008	Dodge	Sprinter (non-HAH)
Ford:		
2005–2006	Ford	GT (non-HAH)
2009–2014	Ford	Mustang (non-HAH)
2004–2006	Ford	Ranger (non-HAH)
GM:		
2007–2008	Chev/GMC	Silverado/Sierra (non-HAH)
2005	GM-Saab	9–2X (non-HAH)
Honda:		
2005	Honda	RL (HAH and non-HAH)
2008–2011	Honda	Element (non-HAH)
2008	Honda	Pilot (non-HAH)
Mazda:		
2004–2006	Mazda	B-Series (non-HAH)
Nissan:		
2003	Infiniti	FX (non-HAH)
2004–2005	Infiniti	FX (HAH and non-HAH)
2001	Infiniti	I30 (non-HAH)
2002–2004	Infiniti	I35 (HAH and non-HAH)
2006	Infiniti	M (HAH and non-HAH)
2001–2003	Nissan	Maxima (non-HAH)
Subaru:		
2004–2005	Subaru	Impreza/WRX/STI (non-HAH)
2003–2004	Subaru	Legacy, Outback, Baja (non-HAH)
Toyota:		
2002–2006	Lexus	SC430 (HAH and non-HAH)
2002–2004	Toyota	Sequoia (non-HAH)
2003–2004	Toyota	Tundra (non-HAH)

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DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

[Docket No. PHMSA–RSPA 2000–7486; PDs 8(R)–11(R)]

Hazardous Materials: California and Los Angeles County Requirements Applicable to the On-Site Handling and Transportation of Hazardous Materials

AGENCY: Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: Decision on petitions for reconsideration of administrative determinations of preemption.

Petitioners: Hasa, Inc., National Propane Gas Association, National Tank Truck Carriers, Inc., Pioneer Chlor Alkali Company, Inc., The Society of the Plastics Industry, Inc.

State and Local Laws Affected: California Health & Safety Code (CHSC), Chapter 6.95, Los Angeles County Code (LACoC), Titles 2 and 32.

Mode Affected: Rail.

SUMMARY: Federal hazardous material transportation law does not preempt California and Los Angeles County requirements on (1) the unloading of hazardous materials from rail tank cars by a consignee and (2) the consignee's on-site storage of hazardous materials following delivery of the hazardous materials to their destination and departure of the carrier from the consignee's premises or private track adjacent to the consignee's premises.

FOR FURTHER INFORMATION CONTACT: Vincent Lopez or Joseph Solomey, Office of Chief Counsel (PHC–10), Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590–0001 (Tel. No. 202–366–4400).

SUPPLEMENTARY INFORMATION:

I. Background

This is a decision on petitions for reconsideration of PHMSA's determinations of preemption regarding certain of the State of California and Los Angeles County requirements applicable to unloading of hazardous materials from rail tank cars and the on-site storage of hazardous materials in rail tank cars or after unloading. The filing of these petitions for reconsideration rendered PHMSA's determinations of preemption non-final. With this decision on the petitions for reconsideration, the determinations of preemption that PHMSA was asked to reconsider become final.

A. Preemption Determinations (PDs) Nos. 8(R)–11(R)

In PDs Nos. 8(R)–11(R), published in the **Federal Register** on February 15, 1995 (60 FR 8774), PHMSA [1] considered certain requirements of the State of California and Los Angeles County applicable to unloading of hazardous materials from rail tank cars and the on-site storage of hazardous materials in rail tank cars or after unloading. In these determinations, PHMSA responded to applications by the Swimming Pool Chemical Manufacturers Association (SPCMA) and one of its members, Hasa, Inc. (Hasa), questioning whether Federal hazardous material transportation law, 49 U.S.C. 5101 *et seq.,* preempts the definition or classification of compressed gases and cryogenic fluids in the Uniform Fire Code (adopted in Title 32 of the Los Angeles County Code [LACoC]) and requirements on:

- Permits to store, transport, or handle these materials;
- unloading and storage of these materials, including the design and construction of tanks and containers;
- markings on containers of cryogenic liquids;

[1] Effective February 20, 2005, PHMSA was created to further the ''highest degree of safety in pipeline transportation and hazardous materials transportation,'' and the Secretary of Transportation redelegated hazardous materials safety functions from the Research and Special Programs Administration (RSPA) to PHMSA's Administrator. 49 U.S.C 108, as amended by the Norman Y. Mineta Research and Special Programs Improvement Act (Pub. L. 108–426, § 2, 118 Stat. 2423 (Nov. 30, 2004)), and 49 CFR 1.97(b), as redesignated at 77 FR 49964, 4987 (Aug. 17, 2012). For convenience, this decision refers to ''PHMSA'' in discussing actions taken by RSPA before February 20, 2005.

• placards and equipment on vehicles used to transport cryogenic liquids; and

• the fees in Title 2 of LACoC on ''handlers'' of hazardous materials.

SPCMA also challenged the definitions of ''handle'' and ''storage'' in Chapter 6.95 of the California Health and Safety Code (CHSC), which make substantive requirements in Chapter 6.95 applicable to on-site handling and storage of hazardous materials in rail tank cars at SPCMA members' facilities.[2]

In PDs 8(R)–11(R), PHMSA discussed its responsibility under 49 U.S.C. 5103(b) to ''prescribe regulations for the safe transportation of hazardous material in intrastate, interstate and foreign commerce,''[3] and the definition of ''transportation'' in former 49 U.S.C. 5102(12) as ''the movement of property and any loading, unloading, or storage incidental to the movement.''[4] 60 FR at 8777. PHMSA stated that ''Federal hazmat law and the HMR do not apply to the movement of hazardous material exclusively at a consignee's facility.'' *Id.* However,

• ''Unloading that is incidental to transportation includes consignee unloading of tank cars containing hazardous materials,'' and must be performed in accordance with 49 CFR 174.67. *Id.*

• ''Storage that is incidental to transportation includes storage by a carrier that may occur between the time a hazardous material is offered for transportation to a carrier and the time it reaches its intended destination and is accepted by the consignee,'' and is governed by requirements in 49 CFR 174.204(a)(2), but ''consignor and consignee storage of hazardous materials is not incidental to transportation in commerce.'' 60 FR at 8778.

• Other Federal agencies, including the Environmental Protection Agency (EPA) and the Department of Labor's Occupational Safety and Health Administration (OSHA) also regulate hazardous materials ''to ensure that they are not unintentionally or unlawfully released into the environment'' and ''to ensure worker safety'' in the workplace. *Id.*

PHMSA found there was insufficient information to make a determination whether four specific requirements were preempted and that Federal hazardous material transportation law preempts only the following specific provisions challenged in the applications of SPCMA and Hasa:

• The prohibition in Title 32 LACoC 79.809(c) against allowing a tank car to remain on a siding at point of delivery for more than 24 hours while connected for transfer operations, because tank car unloading requirements in 49 CFR 174.67 did not limit the amount of time a tank car may remain on a siding at a point of delivery while connected for transfer operations. 60 FR at 8788.

• The requirement in Title 32 LACoC 79.809(f) for in-person attendance of a tank car during unloading, because Los Angeles County did not recognize the authority granted to Hasa in former DOT exemption E 10552 for the use of electronic surveillance to monitor tank car unloading, under certain conditions and restrictions. 60 FR at 8789.

• The fees imposed on ''handlers'' of hazardous materials under Title 2 LACoC 2.20.140, 2.20.150, 2.20.160 and 2.20.170 to the extent that these fees applied to tank car unloading activities, because the fees collected were not being used for purposes related to hazardous materials transportation. 60 FR at 8784.

B. Petitions for Reconsideration; Initiation of Rulemaking

Within the 20-day time period provided in 49 CFR 107.211(a), petitions for reconsideration of PHMSA's determinations in PDs 8(R)–11(R) were submitted by Hasa, The Chlorine Institute and the American Chemistry Council (ACC),[5] National Propane Gas Association (NPGA), National Tank Truck Carriers, Inc. (NTTC), Pioneer Chlor Alkali Company, Inc., and The Society of the Plastics Industry, Inc. In general, all of these petitioners disagreed with PHMSA's finding that ''Federal hazmat law and the HMR do not apply to a consignee's transportation of hazardous materials solely within the gates of a private manufacturing facility.'' 60 FR at 8785. Hasa asked ''who regulates what and when?'' It stated that regulation of railroad tank cars ''while loading, unloading, and incidental storage occurs, by the State of California, the County of Los Angeles, and other local governmental agencies as well as by Federal requirements . . . is likely to be uneven, contradictory, confusing, and provide a lack of uniformity.''

In their jointly-filed petition, The Chlorine Institute and ACC asserted that, because ''49 CFR parts 174 and 177 set forth detailed regulations for the loading and unloading of hazardous materials on private property, loading and unloading on private property are held to be in commerce even though they clearly cannot be accomplished in commerce as that term is being construed by [PHMSA].'' These petitioners referred to other Federal statutes which apply to transportation-related activities on private property; they stated that the environmental statutes administered by EPA, which authorize State and local requirements, ''do not regulate the on-site transportation, handling or storage of hazardous materials.'' They also stated that PHMSA should resolve any ambiguity in a State or local law ''against the enforcing entity,'' and that a State or local requirement ''must be held to be preempted'' whenever its enforcement could create a conflict with a requirement in the HMR.

The Society of the Plastics Industry stated that it concurred with and supported the petition for reconsideration filed by The Chlorine Institute and ACC. It asserted that the decisions in PDs 8(R)–11(R) ignore ''the fact that the HMTA applies to loading and unloading, activities which occur within plant gates'' and also ''the 'stream of commerce' decisions adopted under the Interstate Commerce Act.''

NTTC expressed agreement with the position that the HMR do not apply to a hazardous material which ''has been removed from specification packaging . . . and not reloaded into another specification container or package.'' NTTC stated that the definition of ''commerce'' in Federal hazardous material transportation law ''embraces both 'transportation' and [that] which affects . . . transportation.'' NTTC also stated that the decisions in PDs 8(R)–11(R) were in conflict with prior interpretations that the HMR apply to representations that a packaging complies with a specification marking, ''regulations regarding the removal of placards from cargo tanks (prior to such being cleaned, purged and/or laden with another product),'' and enforcement actions against carriers who failed to report an unintentional release of hazardous materials during loading or

[2] CHSC Chapter 6.95 requires plans for emergency response and/or risk prevention, and these requirements are implemented at the local level—in this case, by Los Angeles County in LACoC Titles 2 and 32.

[3] In 2002, Congress amended this mandate to direct DOT to ''prescribe regulations for the safe transportation, including security, of hazardous material in intrastate, interstate, and foreign commerce.'' Homeland Security Act of 2002, Public Law 107–296 § 1711(a), 116 Stat. 2319 (Nov. 25, 2002).

[4] In 2005, this paragraph was redesignated § 5102(13). Hazardous Materials Transportation Safety and Security Reauthorization Act of 2005 (Title VII of the Safe, Accountable, Flexible, Efficient Transportation Equity Act: A Legacy for Users), Public Law 109–59 § 7102(8), 119 Stat. 1893 (Aug. 10, 2005).

[5] ACC was formerly known as the Chemical Manufacturers Association. For consistency, this decision refers to ''ACC'' throughout.

unloading, ''which invariably occur on private property.''

Pioneer Chlor Alkali Company addressed ''a loaded tank car on the receiver's property'' which it stated, prior to PHMSA's decisions, meant that ''the car is under Federal Jurisdiction from the time it is loaded, while it is being transported, held/stored, and up to the time it is unloaded.'' It stated that the ''change'' in PDs 8(R)–11(R) ''is not in the best interest of the general public,'' because, instead of ''one set of uniformly applied rules/regulations,'' there would be ''one set of rules/regulations covering the car at the loading point, another set (Federal) while it is in the so called 'Commerce' area and another third set at the unloading point.''

SPCMA and NPGA submitted further comments in support of the petitions for reconsideration. SPCMA stated that State and local regulations are likely to vary from place to place, so that hazardous materials ''will be subject to different—and without doubt conflicting—requirements throughout the journey'' from one place to another in commerce. NPGA stated that the decisions in PDs 8(R)–11(R) open up the possibility of ''a plethora of local regulations governing the loading and unloading operations that are already subject to DOT regulation.''

Additional comments on the petitions for reconsideration were submitted by the California Office of Emergency Services (OES), the Contra Costa County Health Services Department (Contra Costa County), and the Association of Waste Hazardous Materials Transporters (AWHMT). OES stated that the California regulatory scheme was aimed at facilities, not transporters, and does not apply to transportation or incidental activities regulated under Federal hazardous material transportation law or the HMR. It stated that the California statutes and implementing local regulations relate to emergency response planning and do not prohibit storage of hazardous materials; rather these provisions merely define ''storage'' and when compliance with the State law is triggered. OES argued that there is no evidence of any ''obstacle'' to accomplishing and carrying out the Federal hazardous material transportation law and the HMR, and that it is irrelevant how other Federal laws and the Commerce Clause have been interpreted. Contra Costa County indicated its concurrence with the OES comments and referred to a July 1993 incident involving the release of sulfur trioxide at Richmond, California, when the company allegedly failed to train its personnel, report the quantity of materials present, or implement a risk management and prevention program under CHSC Chapter 6.95.

AWHMT recommended that PHMSA delay taking action on the petitions for reconsideration and open a rulemaking docket with notice and opportunity for public comment and participation by EPA and OSHA. AWHMT stated that further clarification was needed ''on a number of points, not necessarily relevant to the fact-specific situation presented in PDs 8(R)–11(R),'' because ''there is no bright line that distinguishes the moment materials are placed in or out of transportation at consignee/consignor facilities.''

On July 24, 1996, PHMSA published a notice in the **Federal Register** announcing that it was deferring action on the petitions for reconsideration ''until the agency can complete a rulemaking, RSPA Docket HM–223, which focuses on numerous issues that are raised in the petitions for rulemaking.'' 61 FR 38513.[6] Over the next three years, PHMSA issued an advance notice of proposed rulemaking (ANPRM) (61 FR 39522 [July 29, 1996]); held public meetings in Atlanta, Sacramento, and Philadelphia; published further notices of the issues to be discussed at the public meetings (61 FR 49723 [Sept. 23, 1996], 61 FR 53483 [Oct. 11, 1996]); and issued a supplemental ANPRM (64 FR 22718 [Apr. 27, 1999]).

On August 20, 1999, The Chlorine Institute and ACC submitted a petition to ''supplement the record and for discharge'' of their March 1995 petition to PHMSA for reconsideration of the determinations in PDs 8(R)–11(R). They provided a recently-issued interpretation by EPA on the applicability of the Clean Air Act, which these petitioners contended ''is at odds'' with findings in PDs 8(R)–11(R), and stated that ''there is every reason to discharge the Petition for Reconsideration and finally decide this matter.'' In its October 19, 1999 letter, PHMSA advised these parties that it was granting their request to supplement the record in this proceeding and it had placed the August 20, 1999 petition in the docket of both the HM–223 rulemaking and the preemption proceeding. PHMSA also stated that it was denying their request to ''discharge'' the March 1995 petition for reconsideration ''pending completion of the HM–223 rulemaking,'' and that, after completion of the HM–223 rulemaking, PHMSA would reopen the docket in the preemption proceeding ''so that all participants in that proceeding may supplement the record if they wish,'' before acting on the petitions for reconsideration.

In June 2000, The Chlorine Institute and ACC formally withdrew their joint petition for reconsideration of PDs 8(R)–11(R) and filed a complaint in the United States District Court for the District of Columbia asking the court to ''reverse the holdings in the preemption determinations'' and ''such other and further relief as may be proper.'' *The Chlorine Institute, et al.* v. *U.S. Department of Transportation,* C.A. No. 00–1312 (WBB) (DDC). That complaint was dismissed on May 7, 2002, on the ground that these claims were not ripe for judicial review. The court noted that PHMSA had published a notice of proposed rulemaking (NPRM) in Docket HM–223 in the **Federal Register** on June 14, 2001 (66 FR 32420), and that it was not clear that the 1995 determinations in PDs 8(R)–11(R) reflected PHMSA's ''current position. Therefore, the Court would be in the unenviable position of having to enter its judgment on an issue that has not yet been decided by the Agency that has the expertise to make a more informed decision regarding this important issue of national policy.''

C. PHMSA's HM–223 Final Rules

After considering the extensive comments to the July 24, 1996 ANPRM, including the comments at the three public meetings, and the comments submitted in response to the April 1999 supplemental ANPRM and the June 2001 NPRM, PHMSA issued a final rule in its HM–223 rulemaking on October 30, 2003 (68 FR 61906). On April 15, 2005, PHMSA published in the **Federal Register** (70 FR 20018) amendments and corrections to its October 30, 2003 final rule in response to administrative appeals filed by fourteen companies and industry associations.[7]

In those final rules, PHMSA amended the HMR to define several terms including ''pre-transportation function,'' ''transportation,'' ''loading incidental to movement,'' ''unloading incidental to movement,'' ''storage incidental to movement,'' and ''transloading.'' 68 FR at 61907, 61940–41; 70 FR at 20021, 20033–34. PHMSA made clear that storage of hazardous materials ''at its final destination as shown on a shipping document'' is not ''storage incidental to movement'' of the materials, and

[6] This rulemaking was assigned Docket No. RSPA–1998–4952 on the Federal eRulemaking Portal at *http://www.regulations.gov.*

[7] Five additional industry associations submitted administrative appeals of PHMSA's October 30, 2003 final rule in HM–223, but withdrew those appeals and, with five other associations, filed a petition for judicial review of the HM–223 final rules.

unloading of hazardous materials after the materials have been delivered to the consignee and the carrier has departed from the consignee's facility or premises is not ''incidental to movement'' of the materials. 70 FR at 20033–34.

PHMSA amended 49 CFR 171.1 to list examples of regulated and non-regulated functions and to ''indicate that facilities at which functions are performed in accordance with the HMR may be subject to applicable standards and regulations of other Federal agencies or to applicable state or local governmental laws and regulations (except to the extent that such non-Federal requirements may be preempted under Federal hazmat law).'' 68 FR at 61907; *see also id.* at 61937–39, and 70 FR at 20021, 20032–33. With respect to rail tank car unloading, PHMSA added a new paragraph 49 CFR 173.31(g) to set forth requirements to ''assure that a tank car that is being loaded or unloaded does not inadvertently enter transportation or endanger transportation personnel (*i.e.,* posting warning signs, setting brakes, blocking wheels) are regulated under the HMR.'' 68 FR at 61931, 61941. PHMSA also revised 49 CFR 174.67 to set forth the requirements applicable to transloading operations, and clarified that ''storage of hazardous materials at transloading facilities is storage incidental to movement and subject to regulations applicable to such storage under the HMR. 70 FR at 20020; *see also id.* at 20034; 68 FR at 61931, 61941–42. Otherwise however, ''[u]nloading of rail tank cars by consignees after delivery by the carrier is not regulated under the HMR,'' and ''unloading of rail cars at a facility after delivery by and departure of the rail carrier is subject to OSHA regulations applicable to worker protection and safety.'' *Id.* at 61931.

PHMSA also specifically noted that ''DOT specification packagings, such as rail tank cars, cargo tank motor vehicles, and cylinders, are subject to DOT regulation at all times that the packaging is marked to indicate that it conforms to the applicable specification requirements.'' 70 FR at 20024. Moreover, under the HM–223 final rules, the HMR continue to apply ''to pre-transportation functions, such as filling a rail tank car and preparing shipping papers.'' *Id.* at 20025. However, Federal hazardous materials transportation law does not preclude other Federal agencies or their state counterparts from regulating workers at a facility where hazardous materials are prepared for transportation or stored incidental to movement, so long as the other Federal or non-Federal requirements governing transportation of hazardous materials are not specifically displaced or preempted. *See id.* at 20028–29. PHMSA noted that a non-Federal safety regulation affecting the transportation of hazardous materials may be preempted under the Commerce Clause of the Constitution or 49 U.S.C. 5125; 49 U.S.C. 20106 (regarding rail transportation); or 49 U.S.C. 31141 (regarding motor vehicle transportation). *Id.* at 20024, 20025.

Ten industry associations petitioned the United States Court of Appeals for the District of Columbia for review of PHMSA's October 30, 2003 and April 15, 2005 final rules. *American Chemistry Council, et al.* v. *Department of Transportation,* Nos. 03–1456, 05–1191. Five additional associations were permitted to intervene in support of the petitioners. At oral argument on March 20, 2006, the Court questioned whether these associations had ''standing'' to assert that PHMSA should be required to apply the Federal hazardous material transportation law and the HMR to unloading and storage of hazardous materials on a consignee's private property, after delivery of the materials to their final destination and departure of the carrier. Following the submission of supplemental briefs, the Court found that neither the petitioners nor intervenors had shown that PHMSA's failure to assert authority to regulate consignee unloading and storage had caused a likely actual or imminent injury to these associations. 468 F.3d 810 (D.C. Cir. 2006). The Court found that the petitioners had not shown that:

- The costs of complying with local requirements are ''fairly traceable'' to the HM–223 final rules or that, if the HM–223 final rules had not been issued, the local requirements would likely be preempted under 49 U.S.C. 5125. *Id.* at 817–18.

- They would suffer an actual or imminent injury because of an alleged ''gap'' or ''void'' in Federal, State, or local safety requirements governing the unloading of hazardous materials by a consignee. *Id.*

The Court also found that the intervenors had not provided evidence to show that ''there are inconsistent state and local regulations which a properly-issued Final Rule would have preempted'' or ''that they face increased liability risks associated with gaps in federal oversight over the safe and secure transportation of hazardous materials.'' *Id.* at 821. On February 15, 2007, the Court denied rehearing *en banc. Id.* at 810.

D. PHMSA's Further Examination of Loading and Unloading of Bulk Shipments of Hazardous Materials

PHMSA specifically recognized in PDs 8(R)–11(R) that OSHA and EPA also regulate activities involving hazardous materials ''to ensure that they are not unintentionally or intentionally released into the environment'' and ''to ensure worker safety'' in the workplace. 60 FR at 8778. In HM–223, PHMSA provided in 49 CFR 171.1(e) that: ''Each facility at which pre-transportation or transportation functions are performed in accordance with the HMR may be subject to applicable standards and regulations of other Federal agencies.'' 68 FR at 61938. PHMSA explained in the preamble to its October 30, 2003 final rule that ''unloading of rail cars at a facility after delivery by and departure of the rail carrier is subject to OSHA regulations applicable to worker protection and safety.'' *Id.* at 61931.

Nonetheless, concerns continued to be raised as to whether further Federal requirements or guidance are necessary to address the loading and unloading of shipments of hazardous materials in bulk packagings, such as rail tank cars and cargo tank motor vehicles. In recommendations I–02–1 & I–02–2, the National Transportation Safety Board had urged DOT, together with OSHA and EPA, to develop regulations ''that apply to the [certain aspects of] loading and unloading of railroad tank cars, highway cargo tanks, and other bulk containers'' and, separately in recommendation R–04–10, ''require safe operating procedures to be established before hazardous materials are heated in a railroad tank car for unloading.'' [8] In 2006, the U.S. Chemical and Safety Hazard Investigation Board (CSB) issued recommendation 2005–06 I–LA–R1 to ''Expand the scope of DOT regulatory coverage to include chlorine rail car unloading operations'' and provide specific requirements for ''remotely operated emergency isolation devices'' as part of a ''shutdown system . . . capable of stopping a chlorine release from both the rail car and the facility chlorine receiving equipment.'' [9]

During late 2006 and early 2007, PHMSA reviewed incident reports submitted during the prior decade in

[8] On November 29, 2013, the NTSB closed these three recommendations as ''Acceptable Alternative Action'' based upon the safety precautions and recommended guidance for persons responsible for unloding or transloading hazardous materials from rail tank cars, as set forth in PHMSA's July 12, 2013 safety advisory guidance. 78 FR 41853.

[9] On June 1, 2015, the CSB voted to designate this recommendation as ''Closed—No Longer Applicable'' because the board determined that the recommendation no longer applies to DOT.

accordance with the reporting requirements in 49 CFR 171.16 and concluded that ''roughly one quarter to one half of overall hazardous materials transportation incidents may be attributable to loading and unloading operations, particularly bulk packages.'' Notice of public workshop on loading/unloading practices, 72 FR 26864 (May 11, 2007). As later summarized in its notice requesting comments on ''Proposed Recommended Practices for Bulk Loading and Unloading of Hazardous Materials in Transportation,'' 73 FR 916, 917 (Jan. 4, 2008):

- During 2004–06, ''hazardous materials shipments transported by highway and rail in bulk packagings were involved in approximately 9 out of 10 high consequence events.'' *Id.*
- ''Many of the identified causes of both en route and storage incidents can be attributed to loading and unloading operations (*i.e.,* overfilled, overpressurized, loose closure, component, or device, etc.).'' *Id.*

In the January 4, 2008 notice, PHMSA also discussed the public workshop which had been held on June 14, 2007, to discuss ''the risks associated with loading and unloading bulk materials and the range of actions that could be taken by the government and industry to address those risks.'' *Id.* at 919. The participants included ''[r]epresentatives from industry, federal agencies, state and local government, standards organizations, the emergency response community, employee groups, environmental and public interest organizations, and the public.'' *Id.* At this workshop, the Interested Parties Working Group, representing thirteen industry associations including ACC, The Chlorine Institute, and NTTC, presented ''a draft operating procedures document for the loading, unloading, and storage of hazardous materials in bulk packagings having a capacity of greater than 3,000 pounds.'' *Id.* Following the workshop, PHMSA received further comments and a petition from the Dangerous Goods Advisory Group to initiate a rulemaking to adopt ''operational procedures in the HMR applicable to loading, unloading and incidental storage of hazardous materials in bulk packagings.'' *Id.*

Thereafter, PHMSA proposed to amend the HMR to require each person who engages in loading or unloading cargo tanks to perform a risk assessment of the loading and unloading operations and develop and implement safe operating procedures based upon the results of a risk assessment. NPRM, ''Cargo Tank Motor Vehicle Loading and Unloading Operations,'' 76 FR 13313 (Mar. 11, 2011); extension of comment period, 76 FR 27300 (May 11, 2011).[10] In response, however, a number of commenters ''noted confusion about the applicability of the proposed rule,'' ''expressed concern over the possibility of duplication of efforts by facilities and carriers,'' ''questioned the intent of provisions for the maintenance and testing of transfer equipment,'' and ''strongly opposed'' the proposal of an ''annual evaluation of hazmat employees performing CTMV loading and unloading operations.'' PHMSA's ''Withdrawal of notice of proposed rulemaking,'' 79 FR 10461, 10463–64 (Feb. 25, 2014). After conducting a supplementary policy analysis, PHMSA ''concluded that adopting the regulations proposed under the NPRM is not the best course of action at this time.'' *Id.* at 10465. But instead would:

- Issue ''a guidance document for CTMV loading and unloading operations;''
- Implement ''an outreach campaign to educate the regulated community on current regulatory requirements and best safety practices; and''
- Conduct ''human factors research to examine human involvement in release of hazmat and to potentially use this to support further consideration of rulemaking to address CTMV loading and unloading operations.''

During the meantime, Congress considered but failed to adopt proposals to apply the HMR to the unloading of certain packagings containing hazardous materials after delivery to the consignee. *See* S. 1813 § 34007 (as passed by the Senate on March 14, 2012), and H.R. 7 § 9005 (as reported by the Transportation and Infrastructure Committee on February 13, 2012).

II. Discussion

In its February 15, 1995 decisions in PDs 8(R)–11(R), PHMSA considered and addressed the applicability of the HMR to unloading and storage of hazardous materials in rail tank cars at a consignee's facility after a tank car has been delivered by the rail carrier and the carrier has departed. At the conclusion of its ten-year HM–223 rulemaking, after considering the many comments submitted in that rulemaking by the parties petitioning for reconsideration of PDs 8(R)–11(R), PHMSA amended the ''applicability'' provisions in the HMR to clarify that the following activities or functions are not subject to the requirements of the HMR:

- ''Unloading of a hazardous material from a transport vehicle or bulk packaging performed by a person employed by or working under contract to the consignee following delivery of the hazardous material by the carrier to its destination and departure from the consignee's premises of the carrier's personnel or, in the case of a private carrier, departure of the driver from the unloading area.'' 49 CFR 171.1(d)(2).
- Storage of a freight container, transport vehicle, or package containing a hazardous material after its delivery to the destination indicated on a shipping document, package marking, or other medium, or, in the case of a rail car, storage of a rail car on private track.'' 49 CFR 171.1(d)(3).

Since issuance of PDs 8(R)–11(R), the issues relating to post-delivery unloading and storage have been exhaustively presented and considered in rulemaking proceedings and federal court litigation. Affirmance of the fundamental holdings in the initial preemption determinations is consistent with the clarifications in the HM–223 rulemaking with regard to the scope of the definition of ''transportation'' in Federal hazardous material transportation law and the applicability of the HMR. Moreover, it is unlikely that any further submissions on the petitions for reconsideration will contain any new information or arguments. Reopening the docket on those petitions for reconsideration, as PHMSA offered to do in 1999, is no longer warranted. The time has come to close the preemption proceeding and devote future efforts to actions to reduce the safety risks in activities involved in the loading and unloading of shipments of hazardous materials, as outlined in PHMSA's February 25, 2014 withdrawal of notice of proposed rulemaking. 79 FR at 10465.

III. Ruling

For all the reasons set forth above, PHMSA finds that that Federal hazardous material transportation law does not preempt California and Los Angeles County requirements on (1) the unloading of hazardous materials from rail tank cars by a consignee and (2) the consignee's on-site storage of hazardous materials following delivery of the hazardous materials to their destination and departure of the carrier from the consignee's premises or private track adjacent to the consignee's premises.

IV. Final Agency Action

In accordance with 49 CFR 107.211(d), this decision constitutes PHMSA's final agency action on the applications by SPCMA and Hasa for

[10] In the preamble to this NPRM, PHMSA stated that it was separately ''evaluating the safety issues associated with rail tank car loading and unloading operations and may propose regulatory changes if our safety analysis concludes that such action is warranted.'' *Id.* at 13314.

administrative determinations of preemption as to certain requirements in Chapter 6.95 of the California Health and Safety Code and Titles 2 and 32 of the Los Angeles County Code relating to unloading and storage of hazardous materials.

A person who is adversely affected or aggrieved by a preemption determination may file a petition for judicial review of that determination in the United States Court of Appeals for the District of Columbia or in the Court of Appeals for the United States for the circuit in which the petitioner resides or has its principal place of business, within 60 days after the determination becomes final. 49 U.S.C. 5127(a).

Issued in Washington, DC, on November 10, 2015.

Joseph Solomey,

Senior Assistant Chief Counsel.

[FR Doc. 2015–28921 Filed 11–13–15; 8:45 am]

BILLING CODE 4910–60–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Information Collection Renewal; Submission for OMB Review; Market Risk

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

ACTION: Notice and request for comment.

SUMMARY: The OCC, 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 continuing information collection, as required by the Paperwork Reduction Act of 1995 (PRA).

In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and the respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The OCC is soliciting comment concerning the renewal of its information collection titled, ''Market Risk.'' The OCC also is giving notice that it has sent the collection to OMB for review.

DATES: You should submit written comments by: December 16, 2015.

ADDRESSES: Because paper mail in the Washington, DC area and at the OCC is subject to delay, commenters are encouraged to submit comments by email, if possible. Comments may be sent to: Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, Attention: 1557–0247, 400 7th Street SW., Suite 3E–218, Mail Stop 9W–11, Washington, DC 20219. In addition, comments may be sent by fax to (571) 465–4326 or by electronic mail to *prainfo@occ.treas.gov.* You may personally inspect and photocopy comments at the OCC, 400 7th Street SW., Washington, DC 20219. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700 or, for persons who are deaf or hard of hearing, TTY, (202) 649–5597. Upon arrival, visitors will be required to present valid government-issued photo identification and submit to security screening in order to inspect and photocopy comments.

All comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

Additionally, please send a copy of your comments by mail to: OCC Desk Officer, 1557–0247, U.S. Office of Management and Budget, 725 17th Street NW., #10235, Washington, DC 20503, or by email to: oira *submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, Clearance Officer, (202) 649–5490 or, for persons who are deaf or hard of hearing, TTY, (202) 649–5597, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 400 7th Street SW., Washington, DC 20219.

SUPPLEMENTARY INFORMATION: The OCC is requesting extension of OMB approval for this collection. There have been no changes to the requirements of the regulations.

Title: Market Risk.

OMB Control No.: 1557–0247.

Description: The Office of the Comptroller of the Currency's (OCC) market risk capital rules (12 CFR part 3, subpart F) capture positions for which the market risk capital rules are appropriate; reduce procyclicality in market risk capital requirements; enhance the rules' sensitivity to risks that are not adequately captured under the current regulatory measurement methodologies; and increase transparency through enhanced disclosures.

The information collection requirements are located at 12 CFR 3.203 through 3.212. The rules enhance risk sensitivity and include requirements for the public disclosure of certain qualitative and quantitative information about the market risk of national banks and Federal savings associations. The collection of information is necessary to ensure capital adequacy appropriate for the level of market risk.

Section 3.203 sets forth the requirements for applying the market risk framework. Section 3.203(a)(1) requires national banks and Federal savings associations to have clearly defined policies and procedures for determining which trading assets and trading liabilities are trading positions and specifies the factors a national bank or Federal savings association must take into account in drafting those policies and procedures. Section 3.203(a)(2) requires national banks and Federal savings associations to have clearly defined trading and hedging strategies for trading positions that are approved by senior management and specifies what the strategies must articulate. Section 3.203(b)(1) requires national banks and Federal savings associations to have clearly defined policies and procedures for actively managing all covered positions and specifies the minimum requirements for those policies and procedures. Sections 3.203(c)(4) through 3.203(c)(10) require the annual review of internal models and specify certain requirements for those models. Section 3.203(d) requires the internal audit group of a national bank or Federal savings association to prepare an annual report to the board of directors on the effectiveness of controls supporting the market risk measurement systems.

Section 3.204(b) requires national banks and Federal savings associations to conduct quarterly backtesting. Section 3.205(a)(5) requires institutions to demonstrate to the OCC the appropriateness of proxies used to capture risks within value-at-risk models. Section 3.205(c) requires institutions to develop, retain, and make available to the OCC value-at-risk and profit and loss information on sub-portfolios for two years. Section 3.206(b)(3) requires national banks and Federal savings associations to have policies and procedures that describe how they determine the period of significant financial stress used to calculate the institution's stressed value-at-risk models and to obtain prior OCC approval for any material changes to these policies and procedures.

Section 3.207(b)(1) details requirements applicable to a national bank or Federal savings association when the national bank or Federal savings association uses internal models

to measure the specific risk of certain covered positions. Section 3.208 requires national banks and Federal savings associations to obtain prior written OCC approval for incremental risk modeling. Section 3.209(a) requires prior OCC approval for the use of a comprehensive risk measure. Section 3.209(c)(2) requires national banks and Federal savings associations to retain and report the results of supervisory stress testing. Section 3.210(f)(2)(i) requires national banks and Federal savings associations to document an internal analysis of the risk characteristics of each securitization position in order to demonstrate an understanding of the position. Section 3.212 requires quarterly quantitative disclosures, annual qualitative disclosures, and a formal disclosure policy approved by the board of directors that addresses the approach for determining the market risk disclosures it makes.

Type of Review: Regular.

Affected Public: Businesses or other for-profit.

Number of Respondents: 13.

Estimated Burden per Respondent: 1,964 hours.

Total Estimated Annual Burden: 25,532 hours.

The OCC issued a notice for 60 days of comment on August 10, 2015, 80 FR 47987. No comments were received. Comments continue to be invited on:

(a) Whether the collection of information is necessary for the proper performance of the functions of the OCC, including whether the information has practical utility;

(b) The accuracy of the OCC'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 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: November 9, 2015.

Mary H. Gottlieb,

Regulatory Specialist, Legislative and Regulatory Activities Division.

[FR Doc. 2015–28914 Filed 11–13–15; 8:45 a.m.]

BILLING CODE 4810–33–P

DEPARTMENT OF THE TREASURY

Office of the Comptroller of the Currency

Agency Information Collection Activities: Information Collection Revision; Comment Request; Domestic First Lien Residential Mortgage Data

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

ACTION: Notice and request for comment.

SUMMARY: The OCC, 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 revision to an information collection, as required by the Paperwork Reduction Act of 1995 (PRA).

Under the PRA, Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of or revision to an existing collection of information, and to allow 60 days for public comment in response to the notice.

In accordance with the requirements of the PRA, the OCC may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid Office of Management and Budget (OMB) control number. The OCC is soliciting comment concerning a revision to its information collection titled, ''Domestic First Lien Residential Mortgage Data.''

DATES: You should submit written comments by: January 15, 2016.

ADDRESSES: Because paper mail in the Washington, DC area and at the OCC is subject to delay, commenters are encouraged to submit comments by email, if possible. Comments may be sent to: Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, Attention: 1557–0331, 400 7th Street SW., Suite 3E–218, Mail Stop 9W–11, Washington, DC 20219. In addition, comments may be sent by fax to (571) 465–4326 or by electronic mail to *prainfo@occ.treas.gov.* You may personally inspect and photocopy comments at the OCC, 400 7th Street SW., Washington, DC 20219. For security reasons, the OCC requires that visitors make an appointment to inspect comments. You may do so by calling (202) 649–6700 or, for persons who are deaf or hard of hearing, TTY, (202) 649–5597. Upon arrival, visitors will be required to present valid government-issued photo identification and submit to security screening in order to inspect and photocopy comments.

All comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Do not include any information in your comment or supporting materials that you consider confidential or inappropriate for public disclosure.

FOR FURTHER INFORMATION CONTACT: Shaquita Merritt, Clearance Officer, (202) 649–5490 or, for persons who are deaf or hard of hearing, TTY, (202) 649–5597, Legislative and Regulatory Activities Division, Office of the Comptroller of the Currency, 400 7th Street SW., Washington, DC 20219.

SUPPLEMENTARY INFORMATION: The OCC is requesting OMB approval for the following information collection:

Title: Domestic First Lien Residential Mortgage Data.

OMB Control Number: 1557–0331.

Description:

Comprehensive mortgage data is vital to assessing and monitoring credit quality and loss mitigation activities in the residential mortgage market and the federal banking system. This data is important and necessary to support supervisory activities to ensure the safety and soundness of the federal banking system.

The Dodd-Frank Wall Street Reform and Regulatory Improvement Act of 2010 requires that this data be collected. 12 U.S.C. 1715z–25.

This data collection is being revised to include aggregate values to be calculated from data that is currently reported in loan level format. These aggregate values will be industry standard measures of portfolio performance, including but not limited to: Outstanding loan count and unpaid principal balance; delinquency and liquidation ratios; and the number of loss mitigation actions completed. Aggregate values generally will be reported at the total portfolio level, with some values also reported by portfolio segments including, but not limited to: borrower credit class and type and execution date of loss mitigation action.

The reported data items will still be calculated from loan level data that includes: Bankruptcy or foreclosure status; and other detailed loan information. Banks would not be required to report this data to the OCC monthly, but would be required to provide it upon OCC's request.

Type of Review: Regular review.

Affected Public: Businesses or other for-profit.

Burden Estimate:

Estimated Number of Respondents: 61.

Estimated Annual Responses per Respondent: 12 per year.

Estimated Burden per Response: 40 hours per month/per bank.

Estimated Total Annual Burden: 29,280 hours.

Comments submitted in response to this notice will be summarized and included in the request for OMB approval. All comments 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 OCC, including whether the information shall have practical utility;

(b) The accuracy of the OCC'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 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: November 9, 2015.

Stuart E. Feldstein,

Director, Legislative & Regulatory Activities Division.

[FR Doc. 2015–28896 Filed 11–13–15; 8:45 am]

BILLING CODE 4810–33–P

DEPARTMENT OF THE TREASURY

Fiscal Service

Bureau of the Fiscal Service

Fee Schedule for the Transfer of U.S. Treasury Book-Entry Securities Held on the National Book-Entry System

Authority: 31 CFR 357.45.

AGENCY: Bureau of the Fiscal Service, Fiscal Service, Treasury.

ACTION: Notice.

SUMMARY: The Department of the Treasury (Treasury) is announcing a new fee schedule applicable to transfers of U.S. Treasury book-entry securities maintained on the National Book-Entry System (NBES) that occur on or after January 4, 2016.

DATES: Effective January 4, 2016.

FOR FURTHER INFORMATION CONTACT: Brandon Taylor or Janeene Wilson, Bureau of the Fiscal Service, 202–504–3550.

SUPPLEMENTARY INFORMATION: Treasury has established a fee structure for the transfer of Treasury book-entry securities maintained on NBES. Treasury reassesses this fee structure periodically based on its review of the latest book-entry costs and volumes.

For each transfer or reversal of Treasury securities sent or received on or after January 4, 2016, the basic fee will increase from $0.75 to $0.81. The Board of Governors of the Federal Reserve System (Federal Reserve) will maintain its fee for Federal Reserve funds movement at $0.11. The funds movement fee is not a Treasury fee, but is charged by the Federal Reserve for the cost of moving funds associated with the transfer of a Treasury book-entry security. The two fees will result in a combined fee of $0.92 for each transfer of Treasury book-entry securities. The surcharge for an off-line Treasury book-entry securities transfer will remain at $50.00. Off-line refers to the sending and receiving of transfer messages to or from a Federal Reserve Bank by means other than on-line access, such as by written, facsimile, or telephone voice instruction. The basic transfer fee assessed to both sends and receives is reflective of costs associated with the processing of securities transfers. The off-line surcharge reflects the additional processing costs associated with the manual processing of off-line securities transfers.

Treasury does not charge a fee for account maintenance, the stripping and reconstitution of Treasury securities, the wires associated with original issues, or interest and redemption payments. Treasury currently absorbs these costs.

The fees described in this notice apply only to the transfer of Treasury book-entry securities held on NBES. Information concerning fees for book-entry transfers of Government Agency securities, which are priced by the Federal Reserve, is set out in a separate **Federal Register** notice published by the Federal Reserve.

The following is the Treasury fee schedule that will take effect on January 4, 2016, for book-entry transfers on NBES:

TREASURY—NBES FEE SCHEDULE—EFFECTIVE JANUARY 4, 2016

[In dollars]

Transfer type	Basic fee	Off-line surcharge	Funds movement fee	Total fee
On-line transfer originated	0.81	N/A	0.11	0.92
On-line transfer received	0.81	N/A	0.11	0.92
On-line reversal transfer originated	0.81	N/A	0.11	0.92
On-line reversal transfer received	0.81	N/A	0.11	0.92
Off-line transfer originated	0.81	50.00	0.11	50.92
Off-line transfer received	0.81	50.00	0.11	50.92
Off-line account switch received	0.81	0.00	0.11	0.92
Off-line reversal transfer originated	0.81	50.00	0.11	50.92
Off-line reversal transfer received	0.81	50.00	0.11	50.92

Dated: October 22, 2015.

David A. Lebryk,

Fiscal Assistant Secretary.

[FR Doc. 2015–29194 Filed 11–13–15; 8:45 am]

BILLING CODE 4810–AS–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 8611

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 8611, Recapture of Low-Income Housing Credit.

DATES: Written comments should be received on or before January 15, 2016 to be assured of consideration.

ADDRESSES: Direct all written comments to Michael Joplin, 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 Sara Covington at Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the internet at *Sara.L.Covington@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Recapture of Low-Income Housing Credit.

OMB Number: 1545–1035.

Form Number: 8611.

Abstract: IRC section 42 permits owners of residential rental projects providing low-income housing to claim a credit against their income tax. If the property is disposed of or if it fails to meet certain requirements over a 15-year compliance period and a bond is not posted, the owner must recapture on Form 8611 part of the credits taken in prior years.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations and individuals.

Estimated Number of Respondents: 1,000.

Estimated Time Per Respondent: 7 hours, 50 minutes.

Estimated Total Annual Burden Hours: 7,842.

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: November 2, 2015.

Michael Joplin,

Supervisory Tax Analyst.

[FR Doc. 2015–28916 Filed 11–13–15; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 5304–SIMPLE, Form 5305–SIMPLE, and Notice 98–4

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 5304–SIMPLE, Savings Incentive Match Plan for Employees of Small Employers (SIMPLE)—Not for Use With a Designated Financial Institution; Form 5305–SIMPLE, Savings Incentive Match Plan for Employees of Small Employers (SIMPLE)—for Use With a Designated Financial Institution; Notice 98–4, Simple IRA Plan Guidance.

DATES: Written comments should be received on or before January 15, 2016 to be assured of consideration.

ADDRESSES: Direct all written comments to Michael Joplin, Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the forms, instructions, and notice should be directed to Sara Covington, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the internet at *Sara.L.Covington@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Form 5304–SIMPLE, Savings Incentive Match Plan for Employees of Small Employers (SIMPLE)—Not for Use With a Designated Financial Institution, Form 5305–SIMPLE; Savings Incentive Match Plan for Employees of Small Employers (SIMPLE)—for Use With a Designated Financial Institution; SIMPLE IRA Plan Guidance (Notice 98–4).

OMB Number: 1545–1502.

Form Number: Form 5304–SIMPLE, Form 5305–SIMPLE, and Notice 98–4.

Abstract: Form 5304–SIMPLE is a model SIMPLE IRA agreement that was created to be used by an employer to permit employees who are not using a designated financial institution to make salary reduction contributions to a SIMPLE IRA described in Internal Revenue Code section 408(p). Form 5305–SIMPLE is also a model SIMPLE IRA agreement, but it is for use with a designated financial institutions. Notice 98–4 provides guidance for employers and trustees regarding how they can comply with the requirements of Code section 408(p) in establishing and maintaining a SIMPLE IRA, including information regarding the notification and reporting requirements under Code section 408.

Current Actions: There are no changes for the forms at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations not-for-profit institutions, and individuals.

Estimated Number of Respondents: 600,000.

Estimated Time Per Respondent: 3 hours, 31 minutes.

Estimated Total Annual Burden Hours: 2,113,000.

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: November 6, 2015.

Michael Joplin,

IRS Supervisory Tax Analyst.

[FR Doc. 2015–28903 Filed 11–13–15; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 6781

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 6781, Gains and Losses From Section 1256 Contracts and Straddles.

DATES: Written comments should be received on or before January 15, 2016 to be assured of consideration.

ADDRESSES: Direct all written comments to Michael A. Joplin, 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 Sara Covington at Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the internet at *Sara.L.Covington@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Gains and Losses From Section 1256 Contracts and Straddles.

OMB Number: 1545–0644.

Form Number: Form 6781.

Abstract: Form 6781 is used by taxpayers in computing their gains and losses on Internal Revenue Code section 1256 contracts under the marked-to-market rules and gains and losses under Code section 1092 from straddle positions. The data is used to verify that the tax reported accurately reflects any such gains and losses.

Current Actions: There is no change in the paperwork burden previously approved by OMB. This form is being submitted for renewal purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Business or other for-profit organizations and individuals.

Estimated Number of Respondents: 100,000.

Estimated Time per Respondent: 9 hours, 2 minutes.

Estimated Total Annual Burden Hours: 903,237.

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: October 28, 2015.

Michael A. Joplin,

IRS Supervisory Tax Analyst.

[FR Doc. 2015–28907 Filed 11–13–15; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Schedule C–EZ (Form 1040)

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 Schedule C–EZ (Form 1040), Net Profit From Business.

DATES: Written comments should be received on or before January 15, 2016 to be assured of consideration.

ADDRESSES: Direct all written comments to Michael Joplin, 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 Sara Covington, at Internal Revenue Service, room 6129, 1111 Constitution Avenue NW., Washington, DC 20224, or through the internet at *Sara.L.Covington@irs.gov*.

SUPPLEMENTARY INFORMATION:

Title: Net Profit From Business (Sole Proprietorship).

OMB Number: 1545–1973.

Form Number: Schedule C–EZ (Form 1040).

Abstract: Schedule C–EZ (Form 1040) is used by individuals to report their Business Income. The data is used to verify that the items reported on the form are correct and also for general statistical use.

Current Actions: There is no change in the paperwork burden previously approved by OMB. This form is being submitted for renewal purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profit organizations.

Estimated Number of Respondents: 587,151.

Estimated Time per Respondent: 1 hour 45 minutes.

Estimated Total Annual Burden Hours: 1,027,515.

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: November 5, 2015.

Michael A. Joplin,

IRS Supervisory Tax Analyst.

[FR Doc. 2015–28904 Filed 11–13–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF VETERANS AFFAIRS

Notice of Meeting Cancellation—Correction

AGENCY: Department of Veterans Affairs.

The Department of Veterans Affairs gives notice under the Federal Advisory Committee Act, 5 U.S.C., App. 2, that a meeting of the National Research Advisory Council, previously scheduled to be held in Room 730, on December 9, 2015, at the Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC, is hereby postponed. The Notice of Meeting appeared in the **Federal Register** on October 30, 2015, on page 66979. The meeting will be rescheduled.

If you have any questions, please contact Pauline Cilladi-Rehrer, Designated Federal Officer, at *Pauline.Cilladi-Rehrer@va.gov,* or on (202) 443–5607.

Dated: November 10, 2015.

Rebecca Schiller,

Committee Management Officer.

[FR Doc. 2015–29166 Filed 11–13–15; 8:45 am]

BILLING CODE P



FEDERAL REGISTER

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Part II

Department of Health and Human Services

Centers for Medicare & Medicaid Services

42 CFR Part 405, 410, 411, et al.
Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2016; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, 414, 425, and 495

[CMS–1631–FC]

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: Final rule with comment period.

SUMMARY: This major final rule with comment period 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: *Effective date:* The provisions of this final rule with comment period are effective on January 1, 2016, except the definition of ''ownership or investment interest'' in § 411.362(a), which has an effective date of January 1, 2017.

Comment date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on December 29, 2015. (See the **SUPPLEMENTARY INFORMATION** section of this final rule with comment period for a list of provisions open for comment.)

ADDRESSES: In commenting, please refer to file code CMS–1631–FC. 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–FC, 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–FC, 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 issues related to pathology and ophthalmology services or any physician payment issues not identified below.

Abdihakin Abdi, (410) 786–4735, for issues related to portable X-ray transportation fees.

Gail Addis, (410) 786–4522, for issues related to the refinement panel.

Lindsey Baldwin, (410) 786–1694, for issues related to valuation of moderate sedation and colonoscopy services.

Jessica Bruton, (410) 786–5991, for issues related to potentially misvalued code lists.

Roberta Epps, (410) 786–4503, for issues related to PAMA section 218(a) policy.

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.

Geri Mondowney, (410) 786–4584, for issues related to geographic practice cost indices, malpractice RVUs, target, and phase-in provisions.

Chava Sheffield, (410) 786–2298, for issues related to the practice expense methodology, impacts, and conversion factor.

Michael Soracoe, (410) 786–6312, for issues related to the practice expense methodology and the valuation and coding of the global surgical packages.

Regina Walker-Wren, (410) 786–9160, for issues related to the ''incident to'' proposals.

Pamela West, (410) 786–2302, for issues related to therapy caps.

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.

Deborah Krauss, (410) 786–5264 and Alexandra Mugge, (410) 786–4457, 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, (410786–5663 for issues related to EHR Incentive Program-Comprehensive Primary Care (CPC) initiative and Medicare EHR Incentive Program aligned reporting.

Rabia Khan or Terri Postma, (410) 786–8084 or *ACO@cms.hhs.gov*, 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, or Matthew Edgar (410) 786–0698, for issues related to physician self-referral updates.

Christiane LaBonte, (410) 786–7234, for issues related to Comprehensive Primary Care (CPC) initiative.

JoAnna Baldwin (410) 786–7205, or Sarah Fulton (410) 786–2749, for issues

related to appropriate use criteria for advanced diagnostic imaging services.

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.

Provisions open for comment: We will consider comments that are submitted as indicated above in the **DATES** and **ADDRESSES** sections on the following subject areas discussed in this final rule with comment period: Interim final work, practice expense (PE), and malpractice (MP) RVUs (including applicable work time, direct PE inputs, and MP crosswalks) for CY 2016; interim final new, revised, potentially misvalued HCPCS codes as indicated in the Preamble text and listed in Addendum C to this final rule with comment period; and the additions and deletions to the physician self-referral list of HCPCS/CPT codes found on tables 50 and 51.

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Acronyms

In addition, because of the many organizations and terms to which we refer by acronym in this final rule with comment period, 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)
AWV Annual wellness visit
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
IPPE Initial preventive physical exam
IPPS Inpatient Prospective Payment System
IQR Inpatient Quality Reporting
ISO Insurance service office
IT Information technology
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
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 final rule with comment period 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 Final Rule with Comment Period, refer to item CMS–1631–FC. 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 final rule with comment period, 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 final rule with comment period revises payment polices under the Medicare Physician Fee Schedule (PFS) and makes other policy changes related to Medicare Part B payment. These changes are 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 final rule with comment period, 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 final rule with comment period includes discussions and proposals regarding:

- Potentially Misvalued PFS Codes.
- Telehealth Services.
- Advance Care Planning.
- 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 changes in this final rule with comment period will 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 is larger for a few specialties.

We have determined that this major final rule with comment period is economically significant. For a detailed discussion of the economic impacts, see section VII. of this final rule with comment period.

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 final rule with comment period, 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.B.2. of this final rule with comment period.

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 final rule with comment period, in accordance with section 1848(c)(2)(B)(ii)(II) of the Act, if revisions to the RVUs cause 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.

We received several comments regarding GPCIs that are not within the scope of proposals in the CY 2016 PFS proposed rule. Many of these commenters requested adjustments to GPCI values for the Puerto Rico payment locality. These commenters contend that the data used to calculate GPCIs do not accurately reflect the cost of medical practice in Puerto Rico. We have addressed some of these issues in response to specific comments in prior rulemaking, such as the CY 2014 PFS final rule with comment period (78 FR 74380 through 74391), and will further take comments into account when we next propose to update GPCIs. However, we also note that we anticipate proposing updated GPCIs during CY 2017 rulemaking, and in the context of that update, we will consider the concerns expressed by commenters and others regarding the GPCIs for the Puerto Rico locality.

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 × GPCI work) + (RVU PE × GPCI PE) + (RVU MP × GPCI MP)] × 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 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 in expenditures, 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 amendments originally made the target provisions applicable for CYs 2017 through 2020 and set the target for reduced expenditures at 0.5 percent of estimated expenditures under the PFS for each of those 4 years.

Subsequently, 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 target provisions apply for CYs 2016, 2017, and 2018; and setting a 1 percent target for reduced expenditures for CY 2016 and a 0.5 percent target for CYs 2017 and 2018. The implementation of the target legislation is discussed in section II.E. of this final rule with comment period.

Section 1848(c)(7) of the Act, as added by section 220(e) of the PAMA, specified 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. Section 220(e) of the PAMA required the phase-in of RVU reductions of 20 percent or more to begin for 2017. Section 1848(c)(7) of the Act was later amended by section 202 of the ABLE Act to require instead that the phase-in must begin in CY 2016. The implementation of the phase-in legislation is discussed in section II.F. of this final rule with comment period.

Section 218(a) of the PAMA added a new section 1834(p) of the Act. Section 1834(p) of the Act requires for certain computed tomography (CT) services 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). The CT services that are subject to the payment reduction are 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, that are 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 the amendments made by section 218(a) of the PAMA is discussed in section II.G. of this final rule with comment period.

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) Requiring that we establish a Merit-based Incentive Payment System (MIPS) under which MIPS eligible professionals (initially including physicians, physician assistants, nurse practitioners, clinical nurse specialists, and certified registered nurse anesthetists) receive annual payment adjustments (increases or decreases) based on their performance in a prior period. These and other MACRA provisions are discussions in various sections of this final rule with comment period. Please refer to the table of contents for the location of the various MACRA provision discussions.

II. Provisions of the Final Rule with Comment Period 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).

Comment: Several commenters requested that CMS include pharmacists as active qualified health care providers for purposes of calculating physician PE direct costs. The commenters stated that there are a number of ongoing Center for Medicare and Medicaid Innovation (CMMI) initiatives in which pharmacists are making substantial contributions to redesigning healthcare delivery and financing. The commenters insisted that pharmacists need to be included in the calculation of direct PE expenses as an element of the clinical labor variable relating to physician services, to ensure optimal medication therapy outcomes for beneficiaries, and the absence of these pharmacists negatively impacts the health care system.

Response: The direct PE input database contains the service-level costs in clinical labor based on the typical service furnished to Medicare beneficiaries. Commenters did not suggest that the labor costs of pharmacists are a typical resource cost in furnishing any particular physicians' service. When such costs are typically incurred in furnishing such services, we do not have any standing policies that would prohibit the inclusion of the costs in the direct PE input database used to develop PE RVUs for individual services, to the extent that inclusion of such costs would not lead to duplicative payments. Therefore, we welcome more detailed information regarding the typical clinical labor costs involving pharmacists for particular PFS services. We note, however, that in many of the CMMI initiatives, payment is provided for care management and care coordination services, including services provided by pharmacists. As such, we encourage commenters to provide information about the inclusion of additional clinical labor costs for specific services described by HCPCS codes for which payment is made under the PFS, as opposed to clinical labor costs that may be typical only under certain initiatives.

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 proposed to use a proxy PE/HR value for interventional cardiology, as there are no PPIS data for this specialty, by crosswalking the PE/HR from Cardiology, since the specialties furnish similar services in the Medicare claims data. The 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.*

Comment: One commenter expressed support for the new proposal to use a proxy PE per hour for interventional cardiology by crosswalking to the PE/HR for cardiology.

Response: We appreciate the commenter's support and are finalizing the crosswalk as proposed.

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 final rule with comment period 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 used 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. That is, 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 added 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 incorporated 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 proposed a technical improvement to step 2a of this calculation. In place of the step 2a calculation described above, we proposed 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. Although this 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 final rule with comment period reflect this refinement to the PE methodology.

We did not receive any comments on this proposed refinement of the methodology. Therefore, we are finalizing this refinement as proposed.

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. Although 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 proposed 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 refinement to the PE methodology.

Comment: We received several comments supporting this proposed refinement of the methodology. Several commenters also urged us to override the utilization data for low-volume codes using a recommended list of expected specialty or dominant specialty, consistent with our previous approach.

Response: We appreciate the support for the use of the 3-year average of claims utilization for purposes of determining the specialty mix for individual service. As we stated in our proposal, we believe that the 3-year average will mitigate the need to use dominant or expected specialty instead of the claims data. However, we also understand that the hypothesis will be tested as soon as a new year of claims data is incorporated into the PFS ratesetting methodology. Because we anticipate incorporating CY 2015 claims data for use in CY 2017 ratesetting, we believe that the proposed PE RVUs associated with the CY 2017 PFS proposed rule will provide the best opportunity to determine whether service-level overrides of claims data are necessary. Therefore, we are finalizing the policy as proposed for CY 2016 but will seek comment on the proposed CY 2017 PFS rates and whether or not the incorporation a new year of utilization data mitigates the need for service-level overrides. At that time, we would reconsider whether or not to use a claims-based approach (dominant specialty) or stakeholder-recommended approach (expected specialty) in the development of PE RVUs for low-volume codes.

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 labor 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%.

TABLE 2—APPLICATION OF PAYMENT MODIFIERS TO UTILIZATION FILES—Continued

Modifier	Description	Volume adjustment	Time adjustment
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%.
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 final rule with comment period.

The following is a summary of the comments we received regarding PE RVU methodology.

Comment: We received several comments in response to our proposal to use the 3 most recent years of Medicare claims data to determine the specialty mix assigned to each code. All commenters broadly supported the proposal to use a 3-year average to increase stability of PE RVUs and mitigate code-level fluctuations. Some commenters, including the RUC, also stated that for codes which are very low volume in the Medicare population, the dominant specialty(ies) should be assigned. These commenters stressed that CMS should continue to utilize the expertise of the RUC when making these assignments.

Response: For services that are newly created or very low volume, we will continue to explore different methods to ensure the utilization of the most accurate specialty mix.

(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.H.6.b of this final rule with comment period for a discussion of our 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. After reviewing the comments received, 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, 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 solicited comments 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 noted 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 noted 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.

Comment: Many commenters stated that the current 5 percent equipment maintenance factor does not account for expensive maintenance contracts on pieces of highly technical equipment. Most commenters were supportive of the idea of adding an item-specific maintenance variable for equipment costs, which they stated would likely increase the accuracy of the PE RVUs across the PFS. These commenters stated that specialty societies and other stakeholders should be allowed to provide documentation to CMS, as they

currently do for pricing new supplies and equipment, to apply for an increase in maintenance costs. Other commenters requested that if a fixed maintenance factor remains in place, it should be increased from 5 percent to 10 percent. One commenter expressed concern that CMS would entertain making a change in this aspect of the equipment cost per minute formula based on a few invoices when a change would impact every service in the fee schedule. The commenter expressed concerns with the possibility that CMS might adopt a variable maintenance factor based on the submission of individual invoices. Another commenter stated that without a systematic data collection methodology for determining maintenance factors, they had concerns that any invoices CMS received might not accurately capture the true costs of equipment maintenance.

Although most commenters were supportive of adopting a variable maintenance factor for equipment items, commenters also stated that they were unaware of any publicly available data source containing this information. One commenter agreed that there is no comprehensive data source for the maintenance information and therefore it would be difficult to implement a variable maintenance formula. Multiple other commenters concurred that they were unaware of any such public dataset. Several commenters encouraged CMS to work with stakeholders to define service contracts/maintenance contracts, collect data on their associated costs and update the equipment maintenance adjustment factor as necessary.

Response: We appreciate the submission of extensive comments regarding the subject of equipment maintenance factor. We agree with commenters that we do not believe the annual maintenance factor for all equipment is exactly 5 percent, and we concur that the current rate likely understates the true cost of maintaining some equipment. We also believe it likely overstates the maintenance costs for other equipment. However, in the absence of publicly available datasets regarding equipment maintenance costs or another systematic data collection methodology for determining maintenance factor, we do not believe that we have sufficient information at present to adopt a variable maintenance factor for equipment cost per minute pricing. While we believe that these costs ideally should be incorporated into the PE methodology, we also have serious concerns about the problems that result from incorporating anecdotal data based solely on voluntarily submitted pricing information. In establishing prices for equipment and supplies, in many cases we have found that the submitted invoices often overstate the costs for individual items relative to publically available prices. We believe that the incentives related to voluntarily submitted limited invoices for maintenance costs would likely produce information subject to similar limitations. However, in contrast to prices, where we have identified no feasible alternative, our alternative for determining maintenance rates is a long-established default maintenance rate. We also note that the amount of costs for maintenance under the current methodology is directly proportional to the equipment prices, largely determined by the voluntarily submitted invoices for particular equipment items. Therefore, we believe that absent an auditable, robust data source, using anecdotal data for maintenance costs is likely to compound the current problems of pricing equipment costs accurately, not increase accuracy.

We will continue to investigate potential avenues for determining equipment maintenance costs across a broad range of equipment items.

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.) We did not propose any changes to these interest rates for CY 2016.

TABLE 3A—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 nonfacility	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, nonfacility	93005 ECG, tracing nonfacility	93010 ECG, report nonfacility
(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*		0.5957	0.5957	0.5957	0.5957	0.5957	0.5957	0.5957	0.5957
(6) Adjusted Labor	Steps 2–4		=(1)*(5)	7.93	46.18	3.42	3.42	0	3.04	3.04	0
(7) Adjusted Supplies	Steps 2–4	=Eqp * Dir Adj	=(2)*(5)	1.78	4.37	0.32	0.32	0	0.71	0.71	0
(8) Adjusted Equipment	Steps 2–4	=Sup * Dir Adj	=(3)*(5)	0.1	0.35	4.22	4.22	0	0.05	0.05	0
(9) Adjusted Direct	Steps 2–4		=(6)+(7)+(8)	9.82	50.9	7.96	7.96	0	3.8	3.8	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	1.29	0.1	0.1	0	0.08	0.08	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)	0.27	1.42	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	6.7	0.54	0.54	0	0.26	0.26	0
(20) Ind. Alloc. Formula (2nd pt).	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	0.25	0.08	0.17
(22) Indirect Allocator (1st + 2nd).	Step 8		=(19)+(21)	1.8	40.45	0.85	0.63	0.22	0.52	0.35	0.17
(23) Indirect Adjustment (Ind Adj).	Steps 9–11	See Footnote**		0.3816	0.3816	0.3816	0.3816	0.3816	0.3816	0.3816	0.3816
(24) Adjusted Indirect Allocator.	Steps 9–11	=Ind Alloc * Ind Adj		0.69	15.44	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	11.71	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	13.16	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

This section focusses on specific PE inputs that we addressed in the proposed rule. The direct PE inputs are included in the CY 2016 direct PE input database, which is available on the CMS Web site under downloads for the CY 2016 PFS final 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 proposed 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 TC of the services, a stakeholder also submitted more detailed information regarding a workstation used by the practitioner interpreting the image in furnishing the PC 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 PC 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 solicited comments 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.

Comment: Many commenters supported the equipment price increase to $5,557 for the PACS workstation. Commenters stated that this is a more accurate amount than the current price of $2,501. However, many commenters, including the RUC, stated that this price did not capture the appropriate pricing for the PC of the PACS workstation. One commenter expressed concerns with the method that CMS employed to establish the proposed price for the PACS workstation, disregarded the invoices and accompanying explanations submitted by several stakeholders and instead relying on the information submitted by a single group.

Response: We acknowledge and appreciate that several stakeholders provided information intended to facilitate our pricing of the equipment related to PACS. However, much of that submitted information included costs that are considered indirect PE under the established methodology. We considered all of the submitted information and used the submitted prices that were consistent with the principles established under the PE methodology.

Comment: Many commenters, including the RUC, stated that the proposed price did not capture the appropriate pricing for the PC of the PACS workstation. Several commenters indicated that the professional workstation was a direct PE item due to the fact that it is used for individual studies (one at a time) in the non-facility setting, and its use involves a bi-directional exchange between a technologist and a radiologist while the TC is being provided. These commenters also suggested that the professional PACS workstation was a direct proxy for the film alternators, film processors, and view-boxes previously considered direct PE inputs for many of these services prior to the film to digital conversion. Several commenters suggested that the true cost of the PACS workstation was significantly higher than the proposed $5,557 due to these professional expenses.

Response: We appreciate the extensive feedback regarding the potential addition of a PC to the PACS workstation. We agree that the costs of the professional workstation may be analogous to costs previously incorporated as direct PE inputs for these services. Therefore, we are seeking comments and recommendations from stakeholders, including the RUC, regarding which codes would require the professional PACS workstation and for how many minutes the professional equipment workstation would be used relative to the work time or clinical labor tasks associated with individual codes. We would address any such recommendations in future rulemaking.

Comment: One commenter stated that the CMS' attempt to analogize elements of a PACS workstation to the historic inputs associated with film technology was inherently flawed. This commenter stated that CMS should not characterize critical elements of the PACS workstation as indirect costs because film technology is fundamentally distinct from digital technology. The commenter indicated that the PACS workstation requires specific software to function, and the costs associated with training, maintenance, and warranties for the PACS workstation have not been factored into the cost of the equipment. The commenter suggested that not including these as direct costs reflects a mistaken assumption that a PACS workstation has functionality for non-imaging services, such as patient

scheduling, billing, or electronic medical records capability.

Response: We believe that maintaining consistent treatment of PE costs is of central importance in the resource-based relative value system. Since the PE RVUs for individual services are relative to all other PFS services, we believe that we must categorize typical costs for individual services into the direct and indirect categories using the same definitions that apply to all PFS services. We believe it would be inconsistent with cost-based relative value principles to change the definition of those categories for particular procedures or tests, even when technology changes. Centralized record keeping systems, containing clinical or billing information are considered indirect expenses across the PFS. Due to technological changes, some of these systems are well-integrated into equipment items with clinical functionality, while others remain completely distinct. In pricing and categorizing these costs, we have aimed to separate these costs where possible and believe we have maintained relativity among PFS services to the greatest extent possible. We remind commenters that indirect PE RVUs are included for every nationally priced PFS service and that these RVUs contribute to payment for each and every service. We also note that over time, indirect costs change as direct costs change. For example, changes in technology might result in particular items using more or less office space, or using more or less electricity. We do not believe it would be appropriate to redefine indirect costs as direct costs whenever we have reason to believe that indirect costs have changed due to changes in technology. Instead, we acknowledge that indirect costs change over time for all those who are paid through the Medicare PFS, making it even more important to follow the established principles of relativity in establishing direct PE inputs.

After consideration of comments received, we are finalizing our proposal to update the price for the PACS workstation to $5,557 from the current price of $2,501.

As we noted in the proposed rule, one commenter 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. Therefore, we sought comment from stakeholders, including the RUC, about whether or not the PACS workstation used in imaging codes is the same workstation that is used in the post-processing described by CPT code 76377, or if a more specific workstation should be incorporated in the direct PE input database.

Comment: Multiple commenters indicated that CPT code 76377 requires image post-processing on an independent workstation. Commenters stated that the ''computer workstation, 3D reconstruction CT–MR'' equipment (ED014), which was removed by the RUC from the equipment list for this procedure, is separate from the PACS workstation and performs a different function. The commenters requested that ED014 be restored to the equipment inputs for CPT code 76377 and assigned 38 minutes of equipment time. The commenters also suggested that the PACS workstation should remain as a separate direct PE expense as well, since there are additional PACS related activities specific to the 3–D images after they have been created on the computer workstation.

Response: We appreciate the additional information regarding the use of the 3D reconstruction computer workstation for CPT code 76377. After consideration of comments received, we agree that the ''computer workstation, 3D reconstruction CT–MR'' equipment (ED014) should be restored to the equipment list and assigned to CPT code 76377 with an equipment time of 38 minutes. However, we do not believe that the typical service for CPT code 76377 would also use the PACS workstation. Therefore, we substituted ED014 in place of the PACS workstation.

(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.

Although 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 solicited comments 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 final 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.

The following is a summary of the comments we received regarding whether these standard times accurately reflect the typical time it takes to perform these clinical labor tasks associated with digital imaging.

Comment: Many commenters supported CMS' efforts to recognize the advances in digital technology and take them into account through updated RVUs. Several commenters agreed that the clinical labor tasks outlined in Table 5 reflected the PE Subcommittee's film to digital workgroup recommendations. The commenters suggested that the staff types in the tasks should be made more generalized and less specific (such as technologist to clinical staff or radiologist to physician), and stated that specialty societies should be afforded the opportunity to request deviations (that is, increases) from the standard times.

Response: We believe that providing specific guidelines for the staff types associated with these tasks will aid in determining the most accurate value for each service. We also agree that specialties should be afforded the opportunity to request deviations from the standard times for unusual situations, when supported with the presentation of additional justification for the added time.

Comment: The RUC commented that it had not supported standard times for clinical staff activities related to digital imaging in the past, as the RUC had recommended that the specialties should have an opportunity to determine the appropriate inputs at the individual distinct service level and there was too much variability across imaging modalities to propose standards. While the RUC continued to hold to its previous position on this subject, it also agreed that four of the five clinical labor activities proposed by CMS in Table 5 are representative across imaging and could appropriately be used as standard times. The one exception was the clinical labor task ''Technologist QC's images in PACS, checking for all images, reformats, and dose page'', in which the RUC stated the number of minutes would vary significantly depending on the procedure in question. For example, a cardiac MR with hundreds of images would require more quality control time than a single view X-ray of the chest. The RUC recommended that this line item remain nonstandard, and that specialties should continue to have the opportunity to make a recommendation on the appropriate number of minutes based on clinical judgment.

Another commenter also supported standard clinical labor times for four out of the five tasks associated with digital technology, again excepting the activity ''Technologist QC's images in PACS, checking for all images, reformats, and dose page.'' This commenter stated that a survey of imaging providers had been conducted which suggested that the median time required to perform this clinical labor task was 10 minutes. The commenter stated that CMS did not have any data to support its belief in the standard time of 2 minutes, and recommended considering the commenter's data and information from other stakeholders regarding the appropriate standard minutes for the clinical labor tasks associated digital imaging.

Response: With regard to the activity ''Technologist QC's images in PACS, checking for all images, reformats, and dose page'', we agree that this task may require a variable length of time depending on the number of images to be reviewed. We believe that it may be appropriate to establish several different standard times for this clinical labor task for a low/medium/high quantity of images to be reviewed, in the same fashion that the clinical labor assigned to clean a surgical instrument package has two different standard times depending on the use of a basic pack (10 minutes) or a medium pack (30 minutes). We are interested in soliciting public comment and feedback on this subject, with the anticipation of including a proposal in next year's proposed rule.

After consideration of comments received, we are finalizing standard times for clinical labor tasks associated with digital imaging at 2 minutes for ''Availability of prior images confirmed'', 2 minutes for ''Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist'', 2 minutes for ''Review examination with interpreting MD'', and 1 minute for ''Exam documents scanned into PACS. Exam completed in RIS system to generate billing process and to populate images into Radiologist work queue.'' We are not finalizing a standard time for clinical labor task ''Technologist QC's images in PACS, checking for all images, reformats, and dose page'' at this time, pending consideration of any additional public comment and future rulemaking, as described above.

(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 supports 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.

Therefore, we developed standard times that we have used in finalizing 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 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 solicited comments 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 (minutes)
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

Comment: Many commenters stated that they did not support the standardization of clinical labor activities across pathology services. Commenters stated that a single standard time for each clinical labor task was infeasible due to the differences in batch size or number of blocks across different pathology procedures. Several commenters indicated that it may be possible to standardize across codes with the same batch sizes, and urged CMS to consider pathology-specific details, such as batch size and block number, in the creation of any future standard times for clinical labor tasks. One commenter stated that the CMS clinical labor times were uniformly too low, and that CMS did not provide enough information about how it arrived at these revised standard times. The commenter provided five examples of inadequate labor times, and stated that CMS should provide stakeholders with information about the source of its data and why it rejected the RUC recommendations for these clinical labor tasks.

Response: We appreciate the extensive feedback provided by commenters on the standard times for clinical labor tasks associated with pathology services. As we stated in the CY 2016 PFS proposed rule, we developed the proposed standard times based on our review and assessment of the current times included for these clinical labor tasks in the direct PE input database. We believe that clinical labor tasks with the same work description are comparable across different pathology procedures. We concur with commenters that accurate clinical labor times for pathology codes may be dependent on the number of blocks or batch size typically used for each individual service. However, we believe that it is possible to establish ''per block'' standards or standards varied by batch size assumptions for many clinical labor activities that will be comparable across a wide range of individual services. We have received detailed information regarding batch size and number of blocks during review of individual pathology services on an intermittent basis in the past. We request regular submission of these details on the PE worksheets as part of the review process for pathology procedures, as a means to assist in the determination of the most accurate direct PE inputs. Were we to receive this information as part of standard recommendations, we would include these assumptions as part of the information open for comment in proposed revaluations. We are also seeking comment regarding how to best establish clinical labor standards for pathology services on a ''per block'' or ''per batch size'' basis.

We also believe that many of the clinical labor activities that we discussed in Table 6 are tasks that do not depend on number of blocks or batch size. Clinical labor activities such as ''Clean room/equipment following procedure'' and ''Dispose of remaining specimens'' would typically remain standard across different services without varying by block number or batch size, with the understanding of occasional allowance for additional time for clinical labor tasks of unusual difficulty.

After consideration of comments received, we are finalizing standard times for clinical labor tasks associated with pathology services at 4 minutes for

''Accession specimen/prepare for examination'', 0.5 minutes for ''Assemble and deliver slides with paperwork to pathologists'', 0.5 minutes for ''Assemble other light microscopy slides, open nerve biopsy slides, and clinical history, and present to pathologist to prepare clinical pathologic interpretation'', 1 minute for ''Clean room/equipment following procedure'', 1 minute for ''Dispose of remaining specimens, spent chemicals/other consumables, and hazardous waste'', and 1 minute for ''Prepare, pack and transport specimens and records for in-house storage and external storage (where applicable).'' We do not believe these activities would be dependent on number of blocks or batch size, and we believe that these values accurately reflect the typical time it takes to perform these clinical labor tasks. For the rest of the clinical labor tasks associated with pathology services, we are interested in soliciting further public comment and feedback on this subject as part of this final rule with comment period, with the anticipation of including a proposal in next year's proposed rule.

(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 proposed 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.

The following is a summary of the comments we received regarding the clinical labor task ''complete botox log.''

Comment: Several commenters, including the RUC, did not agree with the proposal to eliminate the minutes associated with this clinical labor task. Commenters maintained that the clinical labor task of completing the botox log was a medically reasonable direct resource cost. One commenter stated that it was critical for clinical staff to maintain accurate bookkeeping of split botox vials, and that documentation must reflect the exact dosage of the drug given to patients and a statement that the unused portion of the drug was discarded.

Response: We continue to believe that the clinical labor assigned for the task ''complete botox log'' is a form of indirect PE that is not allocated to individual services. We believe that this is a quality control issue for clinical staff. Maintaining accurate administrative records, even for public safety, is not a task we generally allocate to individual services, instead we consider these costs as attributable across a range of services, and therefore, as an indirect PE. After consideration of comments received, we are finalizing the proposal to eliminate the minutes assigned for the task ''complete botox log'' from the 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 proposed 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 proposed 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'') we proposed 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 (*e.g.,* kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; lumbar), we proposed 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.

The following is a summary of the comments we received regarding clinical labor input inconsistencies.

Comment: Two commenters indicated that although they appreciated CMS' efforts to clean up errors in the direct PE database, they had specific concerns regarding the proposed changes. The commenters stated that for CPT code 22510, it appeared that the direct PE clinical time file had the second technologist listed at 90 minutes for the ''Assist physician'' task, not 45 minutes as recommended. The commenters indicated that CMS stated an intention to include 5 minutes for ''Check dressings & wound'' but this time did not appear to be included in the direct PE input labor file. The commenters also noted that the postoperative E/M visit for CPT code 22510 was also not listed in the CMS file.

The commenters stated that for CPT code 22511, the CMS direct PE labor file correctly included the 45 minutes of ''Assist physician'' time for the second technologist, however, the 5 minutes for the RN/LPN/MTA blend (L037D) to ''Check dressings & wound'' was still not included in the CMS file. The commenter indicated that the postoperative E/M visit was also not included for this code. The commenters also stated that for CPT code 22514, CMS was proposing to include the 5 minutes for ''Check dressings & wound'' in the intraservice time for this service. The commenters indicated that this did not appear to be consistent with how CMS was proposing to handle the same clinical labor task in the prior two codes discussed. The commenters requested that CMS outline specifically which line items (from the PE spreadsheet) it proposed to change and the effects these changes would have on the direct inputs for these three codes.

Response: We appreciate the detailed feedback from the commenters on the clinical labor inconsistencies in these three codes. We agree with the commenters that there were remaining clinical labor errors in these procedures beyond those detailed in the CY 2016 PFS proposed rule, and appreciate the opportunity to clarify the discrepancies

in clinical labor for these three procedures.

For CPT code 22510, we agree with the commenters that the clinical labor assigned to the RadTech (L041B) for ''Assist Physician'' was incorrectly listed twice in our direct PE input database. The clinical labor staff type was also incorrectly entered as L041C, which is priced at the same rate but refers to a second Radiologic Technologist for Vertebroplasty. We will remove the duplicative clinical labor and assign type L041B to the ''Assist Physician'' activity. We do not agree with the commenters that the time for clinical labor task ''Check dressings & wound'' was missing, as it is present in the database. We agree with the commenters that the clinical labor time for the office visit was missing from CPT code 22510, and we will add it to the direct PE database.

For CPT code 22511, the commenters are correct that the time for clinical labor task ''Assist physician'' was entered at the correct value of 45 minutes, and the 5 minutes of clinical labor for ''Check dressings & wound'' does not appear in the non-facility setting. This clinical labor time appears to have been incorrectly entered for the facility setting instead; we will remove this time and add it to its proper non-facility setting. We agree with the commenters that the clinical labor time for the office visit was again missing from CPT code 22511, and we will add it to the direct PE input database.

For CPT code 22514, the time for clinical labor task ''Assist physician'' has been refined to 50 minutes as detailed in the CY 2016 PFS proposed rule. We agree with the commenters that the 5 minutes of clinical labor time for ''Check dressings & wound'' is missing from the direct PE input database. We agree that the clinical labor for this activity should not be treated differently from the rest of the codes in the family, and therefore these 5 minutes are included in the direct PE input database. The postoperative office visit is included in the direct PE input database for CPT code 22514.

After consideration of comments received, we are finalizing our proposed changes to clinical labor along with the additional corrections described above.

(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 proposed 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.

We did not receive comments on this proposal, and therefore, we are finalizing as proposed.

(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 proposed 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.

Comment: Several commenters strongly supported the CMS proposal to create a new supply code for Spherusol that reflects the current price for the antigen and to update the direct inputs for CPT code 86490 to include this item. However, commenters noted that the public use files included in the CY 2016 PFS proposed rule continue to reflect the prior supply code SH006 with a price of $4.10. Commenters asked whether this was a technical error and urged CMS to correct the input files to be consistent with the proposal described in the regulation preamble.

Response: We appreciate support for our proposal and acknowledge our inadvertent omission of this change in the proposed direct PE input database. After consideration of comments received, we are finalizing our proposal to create a supply item for Spherusol and it is included as a direct PE input for CPT code 86490.

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.

In the proposed rule, we stated that we 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 proposed 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.

Comment: One commenter supported the CMS proposal regarding the Patient Worn Telemetry System (EQ340). The commenter agreed with the proposed increase in the price of the equipment

from $21,757 to $23,537, and the reason for this increase. We did not receive any comments opposing the proposal.

Response: After consideration of comments received, we are finalizing our proposal regarding the Patient Worn Telemetry System equipment.

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, in the CY 2015 proposed rule, 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 solicited comments 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 solicited 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.

Comment: Several commenters disagreed with the CMS proposal regarding the updated price for the supply item ''kit, HER–2/neu DNA Probe'' (SL196). One commenter stated that the price of $94 reflected a volume discount that could not be obtained by the typical provider. The lowered price referenced in the CY 2016 PFS proposed rule indicated that the purchaser may be receiving a competitive contractually arranged price. The commenter stated that the lowered price referenced is what might be expected to be acquired by the largest hospitals, which would be expected to buy supplies in greater volume than a small community hospital or mid-sized laboratory, and the price indicated does not reflect the prices for a laboratory of typical size.

Other commenters stated that they were unable to find this pricing information through publicly available sources, suggesting that it may not reflect typical transactions. The commenters also stated that it was unclear as to whether the proposed price referred to FDA-approved kits, which are more expensive than non-approved kits. The commenters further indicated that a number of new morphometric analysis, multiplex quantitative/semi-quantitative ISH tests are in use today with probe kit costs that are higher than those of HER–2/neu probe kits. The commenters suggested that CMS should adopt a weighted-average of the probe kit prices for the probe kits currently used to perform these procedures.

Response: Without robust, auditable information regarding the actual prices paid by a range of practitioners that would allow us to reasonably determine a recommended price to be typical, we believe that we should assume that the best publicly available price is typical. Generally speaking, we do not believe vendors are likely to allow public display of pricing that is not broadly available to potential customers since that would present significant competitive disadvantages in the market. Therefore, given the options between the best publicly available price or prices on invoices selected for the distinct purpose of pricing individual services, we believe the best publicly available price is more likely to be typical. Therefore, we are not making any changes to the price of this supply item at this time.

Comment: The RUC commented that in the CMS direct PE database the unit of measure for SL196 is listed as ''kit'', while on the submitted PE spreadsheet the unit is listed as ''kit assay.'' The RUC recommended that the unit of measure be changed to ''kit assay'' to correlate correctly with the cost shown in the database.

Response: We appreciate this additional information, and will change the unit of measure of SL196 to ''kit assay'' in the direct PE database.

Comment: Several commenters stated CMS's estimated per-minute labor cost inputs are too low for laboratory technicians (L033A), cytotechnologists (L045A) and histotechnologists (L037B). The commenters stated that the complexity of many laboratory services demands highly-skilled, highly-trained, certified, and experienced personnel who typically must be paid higher wages than the current rates provided by CMS. Commenters stated that CMS has underestimated the actual labor costs associated with the work that these more specialized laboratory personnel perform by 20 to 30 percent, after accounting for costs related to benefits, taxes, and training.

Response: The clinical labor costs per minute are based on data from the Bureau of Labor Statistics. We believe that it is important to update that information uniformly among clinical labor types and will consider updating the clinical labor costs per minute in the direct PE database in future rulemaking.

(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.H. 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.

Comment: Several commenters addressed the number of blocks and batch size for prostate biopsies in particular. We direct readers to section II.H. of this final rule with comment period for a more detailed discussion of the resource costs for these services. We continue to seek stakeholder input regarding the best sources of information for typical number of blocks and batch sizes for pathology services.

d. Developing Nonfacility Rates

We noted 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 noted 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). We have 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. As discussed in the proposed rule, we believe that it now may be 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 also noted in the proposed rule that we believe 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 solicited comments from ophthalmologists and other stakeholders on office-based surgical suite cataract surgery. In addition, we solicited comments from the RUC and other stakeholders on the direct PE inputs involved in furnishing cataract surgery in the nonfacility setting in conjunction with our consideration of information regarding the possibility of development of nonfacility cataract surgery PE RVUs.

We received 138 comments from stakeholders including professional medical societies, the RUC, ambulatory surgical centers (ASCs), practitioners, and the general public. The RUC deferred to the specialty societies regarding the appropriateness of performing these services in the nonfacility setting.

Comment: A few commenters suggested that development of PE RVUs would allow for greater flexibility regarding scheduling and location where services are performed. Commenters provided information about clinical considerations related to furnishing these services in a nonfacility setting, with many commenters citing safety concerns involved in furnishing cataract surgery in the office setting.

Response: We will use this information as we consider whether to proceed with development of nonfacility PE RVUs for cataract surgery.

(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 solicited input from stakeholders, including the RUC, about the appropriate direct PE inputs for these services.

We received 53 comments from stakeholders including specialty societies, device manufacturers, medical centers, and physician practices (otolaryngology, allergy, facial, and plastics specialists).

Comment: The RUC indicated an intention to review direct PE inputs at the January 2016 RUC meeting. One specialty society representing otolaryngology head and neck surgeons indicated that endoscopic sinus surgery services have been identified by the CPT/RUC workgroup for development of bundled codes for this code family and inputs will likely be reviewed as part of this process. Some commenters submitted information about their respective PEs related to CPT codes 31254, 31255, 31267, 31276, 31287, and 31288. Other commenters limited their comments to CPT codes 31254 and 31255, noting clinical concerns about performance of other sinus surgery procedures in the nonfacility setting. A few commenters did not support development of nonfacility direct PE RVUs for endoscopic sinus surgery due to clinical considerations such as patient safety, possible complications, use of anesthesia, and need for establishment of standards and oversight of in-office surgical suites.

Response: We appreciate the feedback we received from all commenters. We will use this information as we consider whether to proceed with development of nonfacility PE RVUs or functional endoscopic sinus surgery 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 composed 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 were 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 RVU (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 proposed to continue our current approach for determining MP RVUs for new/revised codes. For the new and revised codes for which we proposed work RVUs and PE inputs, we also published the proposed MP crosswalks used to determine their MP RVUs. The MP crosswalks for those new and revised codes were subject to public comment and we are responding to comments and finalizing them in section II.H. of this CY 2016 PFS final rule with comment period. The MP crosswalks for new and revised codes with interim final values established in this CY 2016 final rule with comment period will be implemented for CY 2016 and subject to public comment. We will then respond to comments and finalize them 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 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 proposed 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 5 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 also proposed 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 proposed 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 that we are finalizing for 2016.) To determine the specialty mix assigned to each code, we also proposed to use the same process used in the PE methodology, described in section II.2.b.(6) of this final rule with comment period. We note that for CY 2016, we proposed and are finalizing a policy 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. 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 also proposed 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 did not propose 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 serve to balance the advantages of using annually updated information with the need for year-to-year stability in values. We solicited comments 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 solicited comments 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.

The following is a summary of the comments we received regarding our current approach for determining malpractice RVUs for new/revised codes.

Comment: Several commenters, including the RUC, generally supported CMS' proposal to update the MP RVUs on an annual basis. Commenters, including the RUC, stated a preference for the annual collection of professional liability insurance (PLI) premium data to insure the MP RVUs for every service is accurate, as opposed to only collecting these data every five years.

Response: We appreciate commenters' support of our proposal to update the MP RVUs on an annual basis. We also appreciate the comments from stakeholders regarding the frequency that we currently collect premium data. We will continue to consider the appropriate frequency for doing so, and we would address any potential changes in future rulemaking.

Comment: Commenters, including the RUC, support CMS's proposal to use the 3 most recent years of available data for the specialty mix assignment.

Response: We appreciate the commenters' support.

Comment: Commenters supported CMS' proposal to maintain the code-specific overrides established in previous rulemaking for codes where the claims data are inconsistent with a specialty that could be reasonably expected to furnish the service. Commenters also requested that CMS publish the list of overrides annually to receive stakeholder feedback related to necessary modification to the list, and in an effort to be as transparent as possible.

Response: We appreciate the comments and agree that we should increase the transparency regarding the list of services with MP RVU overrides. Publication of this list will also allow commenters to alert us to any discrepancies between MP RVUs developed annually under the new methodology and previously established overrides. Therefore, we have posted a public use file containing the overrides.

The file is available on the CMS Web site under the supporting data files for the CY 2016 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*.

Comment: One commenter stated that CMS should be particularly mindful of using the specialty mix in the Medicare claims data for services with low Medicare volume but high volume in the United States health care system more generally, such as pediatric procedures; and that CMS' MP RVU methodology needs to differentiate between services that are truly low volume and those that occur frequently, but not among Medicare beneficiaries.

Response: We believe that the list of overrides we are making available as a public use file on the CMS Web site will help address the commenter's concern since the purpose of the code-specific overrides is to address circumstances where the claims data are inconsistent with the specialty that could be reasonably expected to furnish the service. We have previously accepted comment on services like those identified by the commenter and will continue to consider comments regarding the need to use overrides for particular services, especially for high volume services outside the Medicare population.

Comment: One commenter requested that CMS continue to use the dominant specialty for low volume codes.

Response: We acknowledge the concern about using the dominant specialty for low volume codes, and will continue to monitor the resulting RVUs to determine if adjustments become necessary. In general, we believe the 3-year average mitigates the need to apply the dominant specialty for low volume services. However, we have a long history of applying the dominant specialty for low volume services in instances where the specialty indicated by the claims data is inconsistent with the specialty that could be reasonably expected to furnish the service, and we are maintaining that practice.

Comment: Some commenters requested more information on how specialty impacts were determined. Two commenters expressed concerns about the estimated impact of the several proposed changes in the MP methodology on some specialties—particularly gastroenterology, colon and rectal surgery, and neurosurgery. Those commenters state that they appreciate the assertion that it may be difficult to obtain premium data for some specialties, such as neurosurgery, and state that CMS must thoroughly vet the methodology used by its contractor to determine MP premiums for such specialties. The commenters urge CMS to review the data, continue to try to obtain premium data in as many states as possible, and to share the data with the public for the agency and specialties to determine its accuracy.

Response: Specialty impacts are determined by comparing the estimated overall payment for each specialty that would result from the proposed RVUs and policies to the estimated overall payment for each specialty under the current year RVUs and policies, using the most recent year of available claims data as a constant. We note that for MP RVUs, there were several refinements that resulted in minor impacts to particular specialties, especially those at the higher end of specialty risk factors. We believe that these impacts are consistent with the general tendency of greater change in MP RVUs for specialties with risk factors of greater magnitude. We agree with the commenters regarding of the importance of making certain that the collection of premium data and the methodology of calculating MP RVUs are as accurate as possible. This is the reason we continue to examine the methodology and develop technical improvements such as the ones described in this section of the final rule. Additionally, we believe that annual calibration of MP RVUs will be likely to reduce the risk of irregularities, since we will regularly compare MP RVUs for individual codes and for specialties between consecutive years instead of only comparing MP RVUs update years.

After consideration of the public comments received, we are finalizing the policies as proposed. That is, we are finalizing the proposal to conduct annual MP RVU updates to reflect changes in the mix of practitioners providing services and to adjust MP RVUs for risk, and 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. We note that we will continue to maintain the code-specific overrides where the claims data are inconsistent with a specialty that would reasonable be expected to furnish the services.

We also proposed 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 proposed 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 only proposed to allow the MP RVUs for add-on codes to round to 0.00 where the calculated MP RVU is less than 0.005.

Comment: Several commenters, including the RUC, opposed CMS' proposal to remove the MP RVU floor of 0.01 for add-on services. These commenters suggested that the incremental risk associated with performing an additional procedure is not mitigated by the risk inherent in the base procedure. Another commenter stated that each service should be considered separately for the purposes of calculating MP RVUs, and therefore, each service should be given the 0.01 floor regardless of base or add-on status.

Response: We appreciate commenters' feedback, but note that we do not believe the comments respond to the rationale for the proposed refinement. We agree that the incremental risk in procedures described by add-on codes is not mitigated by the risk inherent in the base procedure. That is why we did not propose to eliminate MP RVUs for add-on codes generally. Instead, we believe that when the incremental risk is calculated to be a number closer to 0.00 than 0.01, we do not believe that rounding such a number to 0.01 accurately reflects the risk of the service that is described by two codes (base code and add-on) relative to the risks associated with other PFS services. We continue to believe that this refinement is the most appropriate approach, since we would continue to account for the incremental risk associated with add-on codes without overestimating the risk in circumstances where the MP RVU falls below 0.005. Therefore, we are finalizing the policy as proposed.

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, to appropriately update the MP resource costs for anesthesia, we proposed to make adjustments to the anesthesia conversion factor to reflect the updated premium information collected for the 5 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 final rule with comment period for the Anesthesia Fee Schedule Conversion Factors for CY 2016. We invited public comments regarding this proposal.

The following is a summary of the comments we received regarding this proposal.

Comment: We received few comments with regard to our proposal; commenters expressed appreciation that CMS recognized the unique aspects involved in updating the MP component associated with anesthesia services, and therefore, delayed the anesthesia MP update until the CY 2016 PFS.

Response: We appreciate the commenters' feedback, and we are finalizing the policy as proposed.

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 the CY 2016 PFS proposed rule, we identified a necessary refinement to way we 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 proposed 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 proposed 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 final MP RVUs, as displayed in Addendum B of this final rule with comment period, reflect MP RVUs calculated following our established methodology, with the inclusion of the proposals and refinements described above.

Comment: Commenters generally supported the technical changes to the MP RVU methodology and found them reasonable. One commenter stated that such refinements will increase stability of MP RVUs and does a better role of capturing the role of each local area's premium in the ''national'' premium for each specialty.

Response: We appreciate the commenters' support, and we are finalizing the policy as proposed.

Comment: One commenter stated that the MP RVU for cataract and other ophthalmic surgeries is deflated significantly because CMS assumes that optometry is providing the actual surgical portion of the procedure, when there is no state that allows optometrists to perform cataract surgery or any other major ophthalmic procedure. The commenter states that the clinical reality is that optometry is involved only during the pre- or post- procedure time period, and CMS should not allow optometric utilization of those codes with co-management modifiers to be included in the calculations for any major ophthalmic surgical procedures. The commenter suggested that if CMS does not agree to remove optometry from the calculation of MP RVUs for ophthalmic surgery, that CMS should use a much lower percentage of utilization to accurately reflect the true risk that optometrists encounter during this limited portion of the service. The commenter also disagreed that all providers who pay for malpractice insurance should have their premiums taken into consideration, and stated that when CMS looks at the dominant specialty for a given service, it must ensure that the claims reported—particularly by non-physician providers such as optometrists, are for the surgical portion of the procedure for which the MP RVU is being considered.

Response: We would clarify for the commenter that we apply the risk factor(s) of all specialties involved with furnishing services to calculate the service level risk factors for all PFS codes. Our methodology already accounts for codes with longer global periods or codes where two different practitioners report different parts of the service, weighing the volume differentially among the kinds of practitioners that report the service depending on which portion of the service each reports. We also remind commenters that, to determine the raw MP RVU for a given service, we consider the greater of the work RVU or clinical labor RVU for the service. Since the time and intensity of the pre-service and post-service period are incorporated into the work RVUs for these services and the work RVUs are used in the development of MP RVUs, we believe it is methodologically consistent to incorporate the portion of the overall services that is furnished by practitioners other than those that furnish the procedure itself in the calculation of MP RVUs. If we were to exclude the risk factors of some specialties that bill a specific code from the calculation of the service level risk factor, the resulting MP RVU would not reflect all utilization. Likewise, we also disagree with the suggestion that the pre- and post- utilization should be removed from determining MP RVUs for ophthalmic surgical services. The resources associated with pre- and post-operative periods for ophthalmic surgery are included in the total RVUs for the global surgical package. Accordingly, if we did not include the portion of utilization attributed to pre- and post-operative visits in the calculation of service level risk factors, the MP RVUs for global surgery would overstate the relative MP costs.

Comment: One commenter identified three low volume codes typically performed by cardiac surgery or thoracic surgery that have anomalous MP RVU values: CPT code 31766 (carinal reconstruction), the commenter requested that the MP risk factor associated with Thoracic surgery be assigned; CPT Code 33420 (valvotomy, mitral valve; closed heart), the commenter requests that the MP risk factor associated with Cardiac Surgery be assigned; and for 32654 (thorascoscopy, surgical; with control of traumatic hemorrhage), the commenter requests that the MP risk factor associated with Thoracic surgery be assigned.

Response: We agree with the commenters and have added these services to the list of those with specialty overrides for CY 2016. We hope to identify such anomalies more regularly in the future now that the public use file listing the overrides is available on the CMS Web site as indicated above.

5. 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). Members of the public including direct 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 is not limited to, the following:

- Documentation in the peer reviewed medical literature or other reliable data that there have been changes in 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 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 periods for 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 that the labor costs for nursing staff were 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. Based on the requestor's comment, we proposed this code as a potentially misvalued code. We also noted 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).

Comment: Several commenters stated that they do not believe CPT code 36516 is potentially misvalued because they found no indication that the clinical staff time, indirect expenses, or work was misvalued. All commenters requested that this code be removed from the potentially misvalued list.

Response: We appreciate the comments, but we believe that the nominator presented some concerns that may have merit, and review of the code is the best way to determine the validity of the concerns articulated by the original requestor. Therefore, we are adding CPT code 36516 to the list of potentially misvalued codes and anticipate reviewing recommendations from the RUC and other stakeholders.

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 PE inputs were inaccurate, including the cost of the implant. We proposed these services as potentially misvalued codes.

Comment: Some commenters disagreed that the commenter intended to nominate CPT codes 52441 and 52442 as potentially misvalued.

Response: After reviewing the original comment, we agree with these commenters' perspective that the intention was not to nominate the codes as potentially misvalued. Therefore, we are not finalizing our proposal to review these codes under the potentially misvalued code initiative.

b. Electronic Analysis of Implanted Neurostimulator (CPT Codes 95970–95982)

In the CY 2015 final rule with comment period (79 FR 67670), we reviewed and valued all of the inputs for the following CPT codes: 95971 (Electronic analysis of implanted neurostimulator pulse generator system (*e.g.,* 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 (*i.e.,* peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming); 95972 (Electronic analysis of implanted neurostimulator pulse generator system (*e.g.,* 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 (*i.e.,* 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 (*e.g.,* 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 (*i.e.,* 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)). Due to significant time changes in the base codes, we believe the entire family detailed in Table 7 is potentially misvalued and should be reviewed in a manner consistent with our review of CPT codes 95971, 95972 and 95973.

TABLE 7—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.

Comment: One commenter agreed with the review of CPT codes 95970–95982 as potentially misvalued services.

Response: We are adding CPT codes 95970–95982 to the list of potentially misvalued codes and anticipate reviewing recommendations from the AMA RUC and other stakeholders.

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).

As detailed in the CY 2016 PFS proposed rule (80 FR 41706), we believed that our current resources will not necessitate further delay in proceeding with the high expenditure screen for CY 2016. Therefore, we re-ran the screen with the same criteria finalized in last year's final rule. However, in developing this CY 2016 proposed list, we also 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 described in section II.B.6. of this final rule with comment period.

We proposed 118 codes 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 the list, we followed the same approach taken last year except we excluded codes with 10- and 90-day global periods. Specifically, we identified the top 20 codes by specialty (using the specialties used in Table 64 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 described 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).

Comment: Some commenters did not believe that high expenditure/high volume was an appropriate criterion for us to use to identify the codes for the potentially misvalued codes initiative. These commenters stated that high expenditure is not an objective gauge of potential misvaluation. Additionally, commenters believed that selecting codes that have not been reviewed in the past 5 years insinuates that the delivery of these services and procedures has changed radically over that time span, which many doubted. Other commenters believed CMS should provide justification for the revaluation by providing evidence and/or data to show how the delivery of a service or procedure has changed within 5 years. While many disagreed with our use of the high expenditure screen, some commenters specifically suggested use of different types of screens; some of which would screen for services for which volume has increased a certain percentage over a set period or screen for changes in the predominate site of service.

Response: We appreciate commenters' perspective on the proposed list of potentially misvalued codes based on the high expenditure screen. It is clear that over time the resources involved in furnishing particular services can often change and, therefore, many services that have not recently been evaluated may become *potentially* misvalued. Under section 1848(c)(2)(B) of the Act, we are mandated to review relative values for codes for all physicians' services at least every 5 years. The purpose of specifically identifying potentially misvalued codes through particular screens established through rulemaking is to prioritize the review of individual codes since comprehensive, annual review of all codes for physicians' services is not practical and, due to the need to maintain relativity, changes in values for individual services can have an impact across the PFS. We identify *potentially* misvalued codes in order to prioritize review of subsets of PFS services. We prioritize review of individual services based on indications that a particular code is likely to be misvalued and on the impact that the potential misvaluation of the code would have on the valuation of PFS services broadly. Our high expenditure screen is largely intended to address the latter situation where improved valuation would have the most significant impact on the valuation of PFS services more broadly. This approach is also consistent with another category of codes identified for screening by statute: Codes with high PE relative value units. In proposing to prioritize this list of high expenditure codes, we stated that the reason we identified these codes is because they have significant impact on PFS payment on a specialty level and have not been recently reviewed.

Comment: A few commenters suggested that E/M services should not be exempt from review as potentially misvalued codes.

Response: In the CY 2012 final rule (76 FR 73063), we explained the concerns expressed by commenters that informed our decision to refrain from finalizing our proposal to review 91 E/M codes as potentially misvalued. We believe that those concerns remain valid. We also believe that it is best to exempt E/M codes from our review of potentially misvalued codes since we are continuously exploring valuations of E/M services, potential refinements to the PFS, and other options for policies that may contribute to improved valuation of E/M services.

Comment: Many commenters also stated that the review of codes over such a short time span puts significant burden on the specialty societies. Many commenters agreed that high expenditure codes should be reviewed on a periodic basis over multiple years. Some commenters specifically suggested that the periodic basis should be 10 years while others suggested delaying any review of the codes until after the misvalued code target has been met.

Response: Because of the concerns expressed by commenters about the burden associated with code reviews, we continue to believe that it is appropriate to prioritize review of codes to a manageable subset that also have a high impact on the PFS and work with the specialty society to spread review of the remaining codes identified as potentially misvalued over a reasonable timeframe. Therefore, we do not believe it would be appropriate to remove codes from the high expenditure list unless we find that we have reviewed both the work RVUs and direct PE inputs for the code during the specified time period.

Also, we believe that the resources involved in furnishing a service can evolve over time, including the time and technology used to furnish the service, and such efficiencies could easily develop in a time span as short as 5 years. As a result, we continue to believe that the review of these high expenditure codes is necessary to ensure that the services are appropriately valued. Additionally, not only do we believe that regular monitoring of codes with high impact on the PFS will produce a more accurate and equitable payment system, but we have a statutory obligation under

section 1848(c)(2)(B) of the Act to review code values at least every 5 years (although we do not always conduct a review that involves the AMA RUC). Therefore, we do not agree with the commenter that suggested that changes in technology and practice can be effectively accounted for through review of code values every 10 years.

Comment: Commenters stated that the following codes were reviewed since CY 2010 and, as a result, do not fit the criteria for the high expenditure screen and should be removed: CPT codes 51728 (Insertion of electronic device into bladder with voiding pressure studies), 51729 (Insertion of electronic device into bladder with voiding and bladder canal (urethra) pressure studies), 76536 (Ultrasound of head and neck), 78452 (Nuclear medicine study of vessels of heart using drugs or exercise multiple studies), 92557 (Air and bone conduction assessment of hearing loss and speech recognition), 92567 (Eardrum testing using ear probe), 93350 (Ultrasound examination of the heart performed during rest, exercise, and/or drug-induced stress with interpretation and report) and 94010 (Measurement and graphic recording of total and timed exhaled air capacity).

Response: We agree with commenters that the codes identified do not fit the criteria for review based on the high expenditure screen. Therefore, we are not proposing to review CPT codes 51728, 51729, 76536, 78452, 92557, 92567, 93350, and 94010 under the potentially misvalued code initiative.

Comment: Commenters believed that services that are add-ons to the excluded 10- and 90-day global services should be removed from the list of codes identified through the high expenditure screen in order to maintain relativity. The specific codes suggested for removal were: CPT codes 22614 (Fusion of spine bones, posterior or posterolateral approach); 22840 (Insertion of posterior spinal instrumentation at base of neck for stabilization, 1 interspace); 22842 (Insertion of posterior spinal instrumentation for spinal stabilization, 3 to 6 vertebral segments); 22845 (Insertion of anterior spinal instrumentation for spinal stabilization, 2 to 3 vertebral segments); and 33518 (Combined multiple vein and artery heart artery bypasses).

Response: We agree with the commenters that the codes identified should be removed from the list of codes identified for review through the high expenditure screen due to their relationship to the 10- and 90-day global services that were excluded from our screen. Although we agree that these codes should be removed from this screen, we think it is worthwhile to note that for similar reasons, we believe we should consider these and similar add-on codes in conjunction with efforts to improve the valuation and the global surgery packages as described in section II.B.6. of this final rule with comment period. Therefore, we are not including CPT codes 22614, 22840, 22842, 22845 on the list of codes identified for review through the high expenditure screen.

Comment: Commenters believed that CPT code 92002 (Eye and medical examination for diagnosis and treatment, new patient) is considered an ophthalmological evaluation and management (E/M) service and as a result, should be excluded for all the same reasons we excluded other E/M codes.

Response: We agree with commenters that CPT code 92002 is considered an E/M and, as a result, should be excluded from the screen as were other E/Ms. Therefore, we are not including CPT code 92002 on the list of codes identified for review through the high expenditure screen.

Comment: A few commenters requested that codes with a work RVU equal to 0.00 (CPT codes 51798 (Ultrasound measurement of bladder capacity after voiding), 88185 (Flow cytometry technique for DNA or cell analysis), 93296 (Remote evaluations of single, dual, or multiple lead pacemaker or cardioverter-defibrillator transmissions, technician review, support, and distribution of results up to 90 days), 96567 (Application of light to aid destruction of premalignant and/or malignant skin growths, each session), and 96910 (Skin application of tar and ultraviolet B or petrolatum and ultraviolet B)) or equal to 0.01 (CPT codes 95004 (Injection of allergenic extracts into skin, accessed through the skin)) be removed from the list of codes identified for review through the high expenditure screen. Commenters stated that historically, services with 0.00 work RVUs were excluded from screens and that re-reviewing a service with a 0.01 work RVU would most likely not lower the work component unless work was completely removed from the code.

Response: We continue to believe that codes with 0.00 work RVUs or very low work RVUs of 0.01, should still be reviewed and can still be considered potentially misvalued. As stated earlier, we do not believe it would be appropriate to remove codes from the high expenditure list unless we find that we have reviewed both the work RVUs and direct PE inputs. Therefore, we are maintaining CPT codes 51798, 88185, 93296, 96567, 96910 and 95004 as potentially misvalued codes and anticipate reviewing recommendations from the AMA RUC and other stakeholders.

Comment: Various commenters objected to the presence of individual codes that met the high expenditure screen criteria based on absence of clinical evidence that the individual services are misvalued.

Response: We reviewed each of these comments, and believe that these kinds of assessments are best addressed through the misvalued code review process. As we describe in this section, the criteria for many misvalued code screens, including this one, are designed to prioritize codes that may be misvalued not to identify codes that are misvalued. Therefore, we believe that supporting evidence for the accuracy of current values for particular codes is best considered as part of the review of individual codes through the misvalued code process.

Comment: Several commenters believed that codes that are currently scheduled to be considered by either the CPT Editorial Panel for new coding or the RUC for revised valuations (for work RVUs and/or PE inputs) at an upcoming meeting should be removed from the screen. Commenters also believed that it was best to allow these codes to go through the RUC code review process rather than identifying the codes as potentially misvalued through this screen.

Response: Although a number of codes have been or will be considered through the RUC review process, until we receive recommendations and review the codes for both work and direct PE inputs, we will continue to include these codes on the high expenditure list. We reiterate that we do not believe that the presence of a code on a misvalued code list signals that a particular code necessarily is misvalued. Instead, the lists are intended to prioritize codes to be reviewed under the misvalued code initiative. If any code on the list finalized here is already being reviewed by the RUC through its process, we will receive a recommendation regarding valuation for the code, and the presence or absence of the code in this particular list is immaterial. However, if subsequent to the removal of a code from the high expenditure code list, the RUC decides not to review the code, we would still want to consider the code as potentially misvalued based on its meeting the criteria established for the screen. Therefore, we do not agree that we should remove individual codes from a potentially misvalued code list because the RUC already anticipates

reviewing the code. However, we want to be clear that when we receive RUC recommendations regarding a code, we generally remove that code from misvalued code lists, regardless of whether or not the RUC reviewed the code on the basis of that particular screen.

Accordingly, we are finalizing the 103 codes in Table 8 as potentially misvalued services under the high expenditure screen and seek recommended values for these codes from the RUC and other interested stakeholders.

TABLE 8—LIST OF 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/>.
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.
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.
51702	Insert temp bladder cath.
51720	Treatment of bladder lesion.
51784	Anal/urinary muscle study.
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.
77059	Mri both breasts.
77263	Radiation therapy planning.
77334	Radiation treatment aid(s).
77470	Special radiation treatment.
78306	Bone imaging whole body.
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.
92136	Ophthalmic biometry.
92240	Icg angiography.
92250	Eye exam with photos.
92275	Electroretinography.
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.
93351	Stress tte complete.
93503	Insert/place heart catheter.
93613	Electrophys map 3d add-on.
93965	Extremity study.
94620	Pulmonary stress test/simple.
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.

6. 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 the CPT Editorial Committee has determined that moderate sedation is an inherent part of furnishing the procedure. For these diagnostic and therapeutic procedures, only the procedure code is reported by the practitioner who conducts the procedure, without separate billing by the same practitioner for anesthesia services, and, in developing RVUs for these services, we include the resource costs associated with moderate sedation in the valuation. 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 appropriate. In the CY 2015 PFS proposed rule (79 FR 40349), we noted that it appeared 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, broad-based information about the provision of moderate sedation, 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 code 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 to which each code may be misvalued. 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 involved in these services 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, in the CY 2016 PFS proposed rule, we solicited recommendations from the RUC and other interested stakeholders on the 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, in the CY 2016 PFS proposed rule, we proposed to identify CPT codes 00740 and 00810 as potentially misvalued. We welcomed comments on both of these issues.

Comment: Several commenters noted that they support CMS' decision to seek input from the medical community prior to proposing a method for reporting and valuing moderate sedation as well as adjusting existing valuations to remove these services. One commenter also encouraged CMS to seek and consider recommendations from societies that represent members who provide dialysis vascular access interventional care, such as the American Society of Diagnostic and Interventional Nephrology.

Response: We thank the commenters for their support. Through notice and comment rulemaking, we will review and consider any recommendations from the public, including those from any interested specialty societies.

Comment: In response to CMS' proposal to identify anesthesia procedure codes 00740 and 00810 as potentially misvalued, the RUC stated that the committee anticipated reviewing CPT codes 00740 and 00810 as potentially misvalued codes.

Response: We appreciate the RUC's responsiveness to the proposal.

Comment: One commenter disagreed that the increase in utilization of anesthesia is indicative of potential misvaluation of the codes in Appendix G. This commenter noted that the policy adopted by CMS in the CY 2015 final rule to eliminate cost-sharing for anesthesia furnished in conjunction with screening colonoscopies encourages patients to undergo these screenings. The commenter also noted that use of anesthesia with upper endoscopy procedures not only decreases patient discomfort, but also decreases complications and creates more optimal conditions for efficiency during the procedure as well as reduced recovery time as compared to the use of narcotics and sedative hypnotic agents. The commenter believes that this results in savings that offset the costs of anesthesia services. The commenter also expressed the view that the work involved in these services has not changed.

Response: We thank the commenters for their input. Since the pool of beneficiaries that receive anesthesia in conjunction with these Appendix G services has grown, we believe it is possible that the typical circumstances under which patients receive these services have changed since the services were last reviewed. Therefore, we continue to seek recommendations regarding appropriate approaches to valuation for these services.

Comment: A few commenters noted that there are a variety of services in Appendix G and stated their view that practitioners who furnish services for which there are claims data supporting the inherent nature of moderate sedation should not have to report moderate sedation separately, as they believe they would be faced with administrative burden and costs. They recommended that CMS conduct ongoing analysis of claims data to determine which codes may require unbundling of moderate sedation and to refer only those codes as potentially misvalued. One commenter noted that they opposed the use of any ''blanket approach'' to valuing moderate sedation such as removing the standard packages for the direct PE inputs associated with moderate sedation. The commenter recommended instead that we look at codes by family or specialty in order to ensure that reimbursements are fair and accurate. One commenter also noted the difference in the work involved with moderate sedation when it is furnished by the same physician who is furnishing the procedure compared with when it is furnished by another clinician, and requested that this be considered when valuing the moderate sedation services. Another commenter suggested that CMS create a modifier to be used by surgeons providing moderate sedation. They also suggested that CMS consider the expenses involved with using a registered nurse or CRNA, the medications and delivery systems, patient monitoring equipment, and lengthened postoperative recovery period when valuing moderate sedation services.

Response: We thank the commenters for their input. We will consider input from the medical community on this issue through evaluation of CPT coding changes and associated RUC recommendations, as well as feedback received through public comments, as we value these services through future notice and comment rulemaking.

7. 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 periods in order to improve the accuracy of valuation and payment for the various components of global surgical packages, including pre- and postoperative visits and the surgical procedure itself. Although in previous rulemaking we have marginally addressed some of the concerns we identified with global packages, we believe there is still a need to address other fundamental issues with the 10- and 90-day postoperative global packages. We believe it is critical that the RVUs we use 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.

In the rulemaking for CY 2015, 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 postoperative 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 postoperative physicians' services in the 0-day global code; 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 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 that 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 sought input from stakeholders on various aspects of this task. We solicited 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 postoperative periods) needed to increase the accuracy of the values for surgical services. We also solicited comment on the most efficient means of acquiring these data as accurately and efficiently as possible. For example, we sought information on the extent to which individual practitioners or practices may currently maintain their own data on services, including those furnished during the postoperative 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 received many comments regarding the kinds of auditable, objective data needed to increase the accuracy of the values for surgical services and the most efficient means of acquiring these data. Commenters had several suggestions for the approach that CMS should take, including the following:

- Collect and examine large group practice data for CPT code 99024 (postoperative follow-up visit).
- Review Medicare Part A claims data to determine the length of stay of surgical services performed in the hospital facility setting.
- Prioritize services that the Agency has identified as high concern subjects.
- Review postoperative visit and length of stay data for outliers.

In general, commenters were supportive of the need to identify auditable, objective, representative data, but many were not able to identify a specific source for such data. We appreciate the comments we received and we will consider these suggestions for purposes of future rulemaking.

As noted above, 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 sought public comment on potential methods of valuing the individual components of the global surgical package, including the procedure itself, and the pre- and postoperative care, including the follow-up care during postoperative days. We were also interested in stakeholder input on what other items and services related to the surgery, aside from postoperative visits, are furnished to beneficiaries during postoperative care.

We received many comments regarding potential methods of valuing the individual components of the global surgical package, including the following:

- Use a measured approach to valuing the individual components of the global surgical package rather than implementing a blanket data collection policy.
- Examine and consider the level of the postoperative E/M visits, including differences between specialties.
- Consider the interaction between the valuing the global surgery package and the multiple procedure payment reduction (MPPR) policy.

We will consider these comments regarding the best means to develop and implement the process to gather information needed to value surgical services and will provide further opportunity for public comment through future rulemaking.

Comment: We received many comments expressing strong support for the CMS proposal to hold an open door forum or town hall meetings with the public.

Response: We appreciate the extensive comments we received from the public regarding the global surgical package. We have noted the positive feedback from commenters about holding potential open forums or town hall meetings to discuss this process. We will consider these comments regarding the best means to develop and implement the process to gather information needed to value surgical services as we develop proposals for inclusion in next year's PFS proposed rule.

C. Elimination of the 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 RVUs 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

We proposed to permanently eliminate the refinement panel beginning in CY 2016, and instead, publish the proposed rates for all interim final codes in the PFS proposed rule for the subsequent year. For example, we would 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 were published in the CY 2016 PFS proposed rule. As explained in the CY 2015 final rule with comment period, a smaller 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. Under our proposal, 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 *http://www.regulations.gov.* We welcomed comments on this proposed change to eliminate the use of refinement panels in our process for establishing final values for interim final codes.

The following is a summary of the comments we received on this proposed change to eliminate the use of refinement panels in our process for establishing final values for interim final codes.

Comment: The majority of commenters, including the American Medical Association/Specialty Society Relative (Value) Update Committee, opposed the proposal to eliminate the refinement panel. Commenters expressed concern that the complete elimination of the refinement process decreases CMS's accountability to its stakeholders who do not agree with the Agency's decisions. They urged CMS to provide detailed guidance on how to seek a change in previously finalized RVUs including the process to initiate a meeting with CMS staff to share and discuss new information or clarify previously shared information, as well as any key timelines or dates that may impact CMS's ability to initiate a change in previously finalized RVUs. Commenters also urged CMS to maintain a transparent appeal process. Another stated that, as CY 2017 will be the first full year using the new process for establishing final values for interim final codes, it is possible that unforeseen needs for the continuation of the refinement panel could arise.

Several commenters agreed with the proposal to eliminate the refinement panel. One commenter supported the permanent elimination of the refinement panel since CMS's display of interim final values in the subsequent year's proposed rule will provide another opportunity for public input. Another believed the new process will provide more timely input on the codes and stated that publishing interim final values for these in the proposed rule versus the final rule should allow adequate time for public comment and for physicians to prepare for changes that would have an impact on their practices and patients. Another commenter welcomed the increased opportunity to review and comment on interim values, especially given that CMS has not been obligated to accept recommendations of the refinement panels and has frequently rejected those recommendations.

Response: We appreciate all of the comments on the proposal. We understand that commenters have an interest in a transparent process to review CMS's assignment of RVUs to individual PFS services. We also understand that some commenters believe that the purpose of the refinement panel process is to provide for reconsideration of the agency's previous decisions. However, the refinement panel was established to assist us in reviewing the public comments on CPT codes with interim final work RVUs and in balancing 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. Therefore, we do not believe that the refinement panel has generally served as the kind of ''appeals'' or reconsideration process that some stakeholders envision in their comments. We also have come to believe that the refinement panel is not achieving its intended purpose. Rather than providing us with additional information, balanced across specialty interests, to assist us in establishing work RVUs, the refinement panel process generally serves to rehash the issues raised and information already discussed at the RUC meetings and considered by CMS.

We also appreciate commenters' interest in CMS maintaining a transparent process with public accountability in establishing values for physicians' services. In contrast to the prior process of establishing interim final values and using a refinement panel process that generally is not observed by members of the public, we believe that the new process of proposing the majority of code values in the proposed rule and making sure that those proposed values are open for comment prior to their taking effect for payment inherently represents greater transparency and accountability. We will also continue to work towards greater transparency in describing in rulemaking how we develop our proposed values for individual codes. We believe that focusing our resources on notice and comment rulemaking would facilitate greater transparency.

Given that the timing for valuation of PFS services under the new process will in large part mitigate the need to establish values on an interim final basis and will provide two opportunities for notice and public comment, we do not believe that the refinement panel would necessarily provide value as an avenue for input, for either CMS or stakeholders, beyond that intrinsic in the notice and comment rulemaking process. However, we appreciate commenters' concerns that the new process has not been fully implemented and there may be unanticipated needs for additional input like the kind made available through the refinement panels. We agree that it may be advisable to preserve existing avenues for public input beyond the rulemaking process, like the refinement panel.

Therefore, after consideration of all of the comments and the issues described in this section, we are not finalizing our proposal to eliminate the refinement panel process at this time. Instead, we will retain the ability to convene refinement panels for codes with interim final values under circumstances where additional input provided by the panel is likely to add value as a supplement to notice and comment rulemaking. We will make the determination on whether to convene refinement panels on an annual basis, based on review of comments received on interim final values. We remind stakeholders that CY 2016 is the final year for which we anticipate establishing interim final values for existing services.

We also want to remind stakeholders that we have established an annual process for the public nomination of potentially misvalued codes. This process, described in the CY 2012 PFS final rule (76 FR 73058), provides an annual means for those who believe that values for individual services are inaccurate and should be readdressed through notice and comment rulemaking to bring those codes to our attention.

D. Improving Payment Accuracy for Primary Care and Care Management Services

In the CY 2016 PFS proposed rule, we sought public comment on a number of issues regarding payment for primary care and care coordination under the PFS. 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) model, 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 and 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 qualifying 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 our comment solicitation and the public comments we received regarding 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. Commenters stated that the time and intensity of the cognitive efforts associated with such planning 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 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, in the CY 2016 PFS proposed rule we solicited 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. To appropriately recognize the different resource costs for this additional cognitive work within the structure of PFS resource-based payments, we were particularly interested in codes that could be used in addition to, not instead of, the current E/M codes.

In our comment solicitation, we stated that, 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 E/M 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 stated that we were 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 were 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 encouraged stakeholders to comment on this topic to assist us in developing potential proposals to address these issues through rulemaking in CY 2016 for implementation in CY 2017. We anticipated using an approach similar to our multi-year approach for implementing CCM and TCM services, to facilitate broader input from stakeholders regarding details of implementing such codes, including their structure and description, valuation, and any requirements for reporting.

Comment: We received many comments on these potential policy and coding refinements that will be useful in the development of potential future policy proposals. We note that the American Medical Association and others urged us to make separate Medicare payment for existing CPT codes that are not separately paid under the PFS, but that describe similar services and for which we have RUC-recommended values. These codes describe a broad range of services, some of which involve non face-to-face care management over a period of time.

Response: We will take the comments into consideration in developing any potential policy proposals in future PFS rulemaking.

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 includes payment 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, in the CY 2016 PFS proposed rule we also sought 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 were 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 expressed interest 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 were 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 under the PFS. We also expressed interest 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 solicited comments 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 solicited comments 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 encouraged stakeholders to comment on this topic to assist us in developing potential proposals to address these issues through rulemaking in CY 2016 for implementation in CY 2017. We anticipated using an approach similar to our multi-year approach for implementing CCM and TCM services, to facilitate broader input from stakeholders regarding details of implementing such codes, including their structure and description, valuation, and any requirements for reporting.

Comment: We received many comments on these potential policy and coding refinements that will be useful in the development of potential future policy proposals.

Response: We will take the comments into consideration in developing any potential policy proposals in future PFS rulemaking.

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, in the proposed rule, we were particularly interested in comments 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 would evaluate potential refinements to the PFS to account for the provision of services through such a model. We solicited information to assist us in considering refinements to coding and payment to address this model in particular. We also sought comments on the potential application of the collaborative care model for other diagnoses and treatment modalities. For example, we solicited 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 requested 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 comment solicitation on interprofessional consultation, since the patient may not have direct contact with the psychiatric consultant we solicited comments 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 also solicited comments 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.

In addition, we solicited comments on whether this kind of care model should be implemented through a CMMI model 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 encouraged stakeholders to comment on this topic to assist us in developing potential proposals to address these issues through rulemaking in CY 2016 for implementation in CY 2017.

Comment: We received many positive comments regarding the possibility of implementing new payment codes that would allow more accurate reporting and payment when these services are furnished to Medicare beneficiaries.

Response: We appreciate commenters' interest in appropriate coding and payment for these services. We will take all comments into consideration as we consider the development of proposals in future rulemaking.

We took particular note that several commenters identified resource inputs CMS might use to value these services under the PFS, including defined time elements. As we consider those comments, we encourage stakeholders to consider whether there are alternatives to time elements that would account for the range in intensity of services delivered in accordance with beneficiary need. In addition, since the

collaborative care models described in the proposed rule include primary care-based care management, as well as psychiatric consulting, we encourage further input including comments on this final rule with comment period, from a broad group of stakeholders, including the community of primary care providers, who are critical in the successful provision of these Services.

3. CCM and TCM Services

a. Reducing Administrative Burden for CCM and TCM Services

In CY 2013, we implemented separate payment for TCM services under CPT codes 99495 and 99496, and in CY 2015, we implemented separate payment for CCM services under CPT code 99490. We established many service elements and billing requirements that the physician or nonphysician practitioner must satisfy to fully furnish these services and to report these codes (77 FR 68989, 79 FR 67728). Particularly because of the significant amount of non face-to-face work involved in CCM and TCM services, these elements and requirements were relatively extensive and generally exceeded 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 solicited 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. In the CY 2016 PFS proposed rule, we solicited stakeholder input on how we could 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 recognized 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 sought information regarding the circumstances under which CCM services are furnished. This information would include 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 were interested in examining such information 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 also solicited objective data regarding the resource costs associated with furnishing the services described by this code. We stated that as we review that information, in addition to our own claims data, we would 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.

Comment: We received several comments recommending various changes in the billing requirements for CCM and TCM services. Some commenters sought significant changes to the CCM scope of service elements, such as eliminating the requirement to use certified electronic health record technology (CEHRT); suspending the electronic care plan sharing requirement until such time that electronic health records (EHRs) have the ability to support such capabilities; or having CMS provide a model patient consent form. Other commenters recommended more minor changes such as clarifying the application of CCM rules regarding fax transmission from certified EHRs, and changing the reporting rules for TCM services (required date of service and when the claim can be submitted). Many commenters stated the current payment amounts are not adequate to cover the resources required to furnish CCM or TCM services and urged CMS to increase payments, for example by creating an add-on code to CPT code 99490, increasing the clinical labor PE input for CPT code 99490 to the RUC recommended 60 minutes, and/or paying separately for the complex CCM codes (CPT codes 99487 and 99489). Commenters also noted that since CY 2015 is the first year of separate payment for CCM, there is little utilization data available to assess average time spent in furnishing CCM services and similar issues. One commenter planned to share data with CMS next spring upon completion of a study on the cost and value associated with care management.

Response: We will take these comments into consideration in the development of potential proposals for future PFS rulemaking. We will develop subregulatory guidance clarifying the intersection of fax transmission and CEHRT for purposes of CCM billing. Regarding TCM services, we are adopting the commenters' suggestions that the required date of service reported on the claim be the date of the face-to-face visit, and to allow (but not require) submission of the claim when the face-to-face visit is completed, consistent with current policy governing the reporting of global surgery and other bundles of services under the PFS. We will revise the existing subregulatory guidance for TCM services accordingly.

E. 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)(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 estimated net reduction in expenditures for a year as a result of adjustments to the relative values for misvalued codes is equal to or greater than the target for that 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 difference between the target for the year and 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 applies to calendar years (CYs) 2017 through 2020 and sets 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 the CY 2016 PFS proposed rule, we proposed 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 identified several aspects of our approach for which we specifically solicited comments. We organized this discussion by identifying and explaining these aspects in particular but we solicited comments 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 updated 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 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.H.2. of this final rule with comment period, 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 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 generates challenges in 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 final rule with comment period, we are finalizing values for a significant portion of misvalued codes during one calendar year. Therefore, CY 2015 will include a significant 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 proposed 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 changes for CY 2016 included under this definition of ''adjustments to RVUs for misvalued codes'' is available on the CMS Web site under downloads for the CY 2016 PFS final rule with comment period at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

The following is a summary of the comments we received regarding this aspect of the proposal to implement the statutory provision:

Comment: Several commenters, including the RUC, supported CMS' proposal to include all services that receive revised input values even if the specific codes were not identified on a misvalued services list for review; the commenters' stated that this is a reasonable and fair approach.

Response: We appreciate the commenters' feedback and support.

Comment: A few commenters stated that the selection of codes to be included for review beyond the codes identified by the screens should be determined by the pertinent specialty societies as they are the best determiners of which codes make up a family of codes. Another commenter stated that CMS should include the E/M services in the list of codes that are potentially misvalued.

Response: We note that the process for selection of codes to be reviewed as potentially misvalued is addressed in section II.H. of this final rule with comment period and has also been addressed in prior rulemaking. Our proposal to implement section 1848(c)(2)(O) of the Act does not address how codes are identified to be reviewed under the misvalued code initiative. Instead, it addresses how to identify the changes in expenditures that result from such reviews in the calculation of the target amount.

Comment: Several commenters, including the RUC, also supported CMS' proposal to exclude code level input changes for CY 2015 interim final values from the calculation of the target. The commenters concur that the year 2 and year 3 changes in values represent an incomplete picture of the redistributive effects for a particular year resulting from the review of the misvalued services, and the vast majority of redistribution happens between year 1 and year 2.

Response: We appreciate the commenters' support and feedback.

Comment: One commenter disagreed with CMS' proposal to exclude code-level input changes for 2015 interim final values stating that it means organized medicine does not get credit for any net decreases associated with such codes and is therefore being penalized. The commenter requested that CMS consider including 2015 interim final values in the calculation of the 2016 misvalued code target even though the misvalued change occurred over multiple years. Another commenter stated that the proposed net reduction in expenditures of 0.25 percent, as opposed to 1.00, means that the 0.75 percent difference will come from the conversion factor, and doing so would more than negate the 0.5 percent increase physicians were promised under MACRA, and therefore the commenter requested that CMS help mitigate this result by including 2015 interim final values in the calculation of the target.

Response: With regard to the commenters who disagreed with the exclusion of code-level input changes for 2015 interim final values, we cannot determine if the commenters intended to suggest that CMS was not including decreases that would help towards the achievement of the misvalued code target by excluding changes for 2015 interim final values, or that CMS should include the changes between years 1 and 3. As stated in the CY 2016 proposed rule (80 FR 41712 through 41713), 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 code values 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). Additionally, the statute requires comparison between 2 years, and therefore, we do not believe we have the authority to include changes between year 1 and year 3. Since our remaining options were to include changes between year 2 and year 3 which, as indicated above, generally results in an increase, or to exclude code-level input changes for CY 2015 interim final values, and the commenters express interest in moving closer to achievement of the target, we do not believe it would be in the commenters' interest to include the changes between years 2 and 3.

With regard to the commenter who stated that the net reduction in expenditures under the PFS if CMS does not achieve the target reduction would negate the 0.5 percent increase physicians were promised under MACRA, we note that both of these provisions continue to apply under current law.

Comment: Some commenters, including the RUC, suggested that CMS should be sure to include existing codes that are either being deleted or will have utilization changes as a result of the misvalued code project and/or the CPT Editorial Panel process. Another commenter stated that CMS was excluding existing codes with large volume changes, and recommended that such codes be included in the calculation of the target. Some commenters recommended that CMS conduct a procedure-to-procedure comparison and then calculate the net reduction in RVUs, including the values of new and deleted CPT codes prompted by the misvalued code initiative. The commenters stated that this is an area where the specialty societies and CMS need to work together to determine the comparisons for calculating the net reduction.

Response: We agree that changes in coding often contribute to improved valuation of PFS services. We note that we included these changes in our methodology in the proposed rule and explained that we would include services directly affected by changes to coding for related services. We did not propose to exclude existing codes with large volume changes; changes for such codes have been included. To clarify, we are including changes in values for any codes for which changes in coding or policies may result in differences in how a given service is reported from one year to the next. Under our current ratesetting methodologies, we already consider how coding revisions change the way services are reported from one year to the next. The crosswalk we use to incorporate such changes in our methodology is based on RUC and specialty society recommendations that explicitly address the kinds of procedure-to-procedure comparisons suggested by the commenter. This file is available in the ''downloads'' section of the PFS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html* under ''Analytic Crosswalk from CY 2015 to CY 2016.'' Since it reflects the best information available, we used the same crosswalk to account for coding changes in the calculation of the target. We also refer readers to the list of HCPCS defined as misvalued for purposes of the target which is available on the CMS Web site under downloads for the CY 2016 PFS final rule with comment period.

Comment: One commenter recommended that CMS include the review of all individual codes and broader adjustments across the PFS, as this would more accurately represent the total revaluations.

Response: As we explained in the proposed rule, our goal is to include the review of all individual codes and changes to inputs for additional codes where changes can be measured between two years. Because PFS payments are developed under the statutory requirements of relativity and budget neutrality, including all adjustments to all codes would necessarily result in a net of zero.

Comment: A few commenters raised objections to the statutory provision. For example, one commenter stated that the legislation is penalizing physicians and other healthcare professionals for already having taken on the task of identifying and revaluating potentially misvalued codes over the past 10 years. Other commenters stated that since the RUC and specialty societies have been addressing potentially misvalued codes since 2006, there should be a way to include revaluations made back to 2006 in the calculation of the target. Another commenter stated that CMS should hold primary care and E/M services harmless in this process, since these services are not over-valued but rather under-valued. One commenter requested more time to evaluate the proposed process to identify yearly targets, and encouraged CMS to work with the AMA to discuss this issue at future RUC Panel meetings prior to implementing the provision. One commenter requested that CMS review its approach to determine if there are other methods that will come closer to reaching the target. One commenter stated that this new requirement creates a potential incentive to target codes that offer the greatest likelihood of savings, not those that are actually misvalued.

Response: We appreciate the commenters' feedback and have considered these concerns to the extent possible in light of the requirements of section 1848(c)(2)(O) of the Act.

After consideration of the public comments received, we are finalizing the approach of defining 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, including any codes for which changes in coding or policies might result in differences in how a given service is reported from one year to the next. We are also finalizing our proposal to exclude code-level input changes for CY 2015 interim final values from the calculation of the CY 2016 misvalued code target. After considering all comments, we continue to believe this approach is appropriate and compliant with statutory directives.

2. Calculating ''Net Reduction''

Once the RVU adjustments attributable to misvalued codes are identified, estimated net reductions in PFS expenditures resulting from those adjustments would be calculated by determining the sum of all decreases and offsetting them against any applicable increases in valuation within the changes that we defined as misvalued, as described above. Because section 1848(c)(2)(O)(i) of the Act only explicitly addresses reductions in expenditures, and we recognize that 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 proposed 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.

The following is a summary of the comments we received regarding our proposal.

Comment: One commenter stated that the proposal for calculating net reduction is consistent with the plain reading of the statute.

Response: We appreciate the commenter's feedback and support.

Comment: Several commenters, including the RUC, requested that CMS use a more transparent process for calculation of the target, suggesting that the discussion in the CY 2016 PFS proposed rule was not sufficiently detailed to allow for replication by external stakeholders. Commenters requested that CMS provide a comprehensive methodological description of how CMS will calculate the target, including publication of dollar figure estimates, and information about individual service level estimated impacts on the net reduction. Commenters further requested that we provide the impact on the net reduction either per CPT code, or that we identify a family of services and publish a combined impact for that family. Another commenter expressed concern with how CMS will operationalize this policy, noting that the language in the CY 2016 PFS proposed rule did not outline where the adjustments would be made. The commenter further questioned how CMS planned to track the ''savings'' from the revaluation of services, and requested that CMS clarify how new technology will be handled, as well as new codes that are a restructuring of existing codes.

Response: We appreciate the commenters' feedback. In response to the request for greater transparency, we have posted a public use file that provides a comprehensive description of how the target is calculated as well as the estimated impact by code family on the CMS Web site under the supporting data files for the CY 2016 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*.

In response to the commenter who asked for clarification on how new technology will be handled, we assume the commenter intends to ask about how new codes for new services would be addressed under our proposed methodology. Under our proposal, we would include adjustments to values for all deleted, new, and revised codes under our calculations of changes from one year to the next. We would also weight the changes in the values for those codes by the utilization for those services in order to calculate the net reduction in expenditures. If a new code describes a new service (new technology as opposed to recoding of an existing service), then there would be no utilization for that code in the calculation. Without utilization, the value for a new service would have no impact on the calculation of the target. In response to the commenter who expressed concern about how CMS would operationalize this policy, and stated that CMS did not explain where the adjustments would be, we note that if the estimated net reduction in expenditures is less than the target for the year, then there would be an overall reduction to the PFS conversion factor as described in section VI. of this final rule with comment period.

Comment: One commenter disagreed that all increases should be incorporated into the net reduction calculation and requested that CMS consider an approach that would maximize the overall magnitude of the measured reductions in order to prevent an overall reduction to the PFS conversion factor as a result of failure to achieve the target for reductions. Specifically, the commenter stated that codes identified as potentially misvalued for which there is compelling evidence based on the RUC recommendations to support an increase in RVUs based on a change in work should not be defined as misvalued for the purposes of calculating the target.

Response: We believe the requirement that we calculate the net reduction in expenditures indicates that we must account for adjustments in values including both increases and decreases and therefore, believe our proposal comports with the plain reading of the statute. We recognize that the RUC internal deliberations include rules that govern under what circumstances individual specialties can request that the RUC recommend CMS increase values for particular services. As observers to the RUC process, we appreciate having an understanding of these rules in the context of our review of RUC-recommended values. However, we do not believe that the internal RUC standards for developing recommendations are relevant in determining whether the statutory provision applies to adjustments to values for individual codes.

Comment: Some commenters requested that CMS review its administrative authority to achieve a target recapture amount in a selective manner, rather than by an across-the-board adjustment to the conversion factor. A commenter stated that codes already sustaining reductions in 2016, and consequently contributing to the target, should not be subjected to additional across-the-board cuts to achieve the statutory target.

Response: We do not believe that section 1848(c)(2)(O)(iii) of the Act provides us authority to insulate particular services from the effects of the budget neutrality adjustment for the target recapture amount that is required if the estimated net reduction in expenditures is less than the target for the year. The statute specifies that an amount equal to the target recapture amount is not to be taken into account in applying the PFS budget neutrality requirement under section 1848(c)(2)(B)(ii)(II) of the Act. This PFS budget neutrality adjustment has been in place since the outset of the PFS, and we have consistently interpreted and implemented it as an adjustment that is made across the entire PFS. Therefore, we do not believe we can apply the budget neutrality adjustments in a selective manner.

Comment: Several commenters, including the RUC, stated that when considering the net impact of service-level input changes in a given year, it is important for CMS to understand specific scenarios in which codes under review should not be included in the net reduction target calculation. The commenters requested that CMS not include particular payment initiatives, such as Advance Care Planning (ACP), in the target definition. Instead, since the payment rates for these services require budget neutrality and relativity adjustments to all other PFS services and these reductions are not otherwise accounted for in the target calculation, CMS should count the payments for ACP services as ''redistribution'' (or, in other words, reductions) from other services for CY 2016. Commenters urged CMS to use the same approach for care management services valued under the PFS in the future. Generally, the commenters stated that these and similar new codes could not possibly be misvalued and therefore, should not only be excluded from the target, but the reductions to other services due to separate payment for these services should be counted as net reductions toward achievement of the misvalued code target.

Response: Because we believe that all of our intended revaluations of services under the PFS are intended to improve the accuracy of the relative value units for PFS services, we do not believe we should exclude increases and decreases to particular services in the target calculation. Therefore, we do not agree with commenters' suggestions that codes describing one kind of service (e.g. care management) as opposed to another (for example, procedures or

diagnostic tests) should be excluded from the target under the statutory provision. Similarly, we do not agree that counting the relativity and budget neutrality redistributions that result from care management services as part of the net ''reduction'' would be consistent with a reasonable understanding of ''net reduction'' in allowed expenditures as a result of changes to misvalued codes.

However, in considering the points raised by commenters, we do agree that the increases in value for new codes like ACP or Chronic Care Management (CCM) are not the same as increases to other services. In general, new codes describe new services that would not have been reported with particular codes in the previous years or new codes describe existing services that were reported using other codes in the prior year. In other cases, however, new codes describe services that were previously included in the payment for other codes. When those services become separately payable through new codes, we generally make adjustments to other relevant codes to adjust for the value of the services that will be separately reported. In general, new codes describing care management services fall into this latter category, since the associated resource costs for these services were previously bundled into payment for other services. However, unlike many other PFS services, the resource costs for these kinds of services were bundled into a set of broadly reported E/M codes and services that include E/M visits. Since these codes are so broadly reported across nearly all PFS specialties, to the extent that it would be impracticable to make adjustments to individual codes, we have not made corresponding adjustments to E/M visits to account for the status of the new codes as separately billable. Instead, when unbundling new separately reported services such as these, we have allowed our general budget neutrality adjustment to account for these types of changes, since budget neutrality adjustments apply broadly to the full range of PFS services, including both codes that specifically describe E/M visits and those with E/M services as components of the service, such as all codes with global periods. In terms of calculating the net reduction in expenditures for purposes of section 1848(c)(2)(O)(i) of the Act, this means that the shift in payment to these new separately reportable services, unlike the adjustments to values for other new services, is not offset by adjustments to any other individual codes. Therefore, under the methodology we proposed, the increase in payment for these new separately reportable services would be counted in the net reduction calculations since the adjustments to values for these services are reflected in values for individual codes, but the corresponding decreases would not be counted, since the corresponding decreases are not attributable to any particular codes. Under the methodology we proposed, the change to make these types of codes separately reported would be counted against achievement of the target even though the increases in value for these codes are fully offset by budget-neutrality adjustments to all other PFS services.

As we have reflected on the comments and on this particular circumstance, we do not believe that the change to separate payment for these kinds of services should be counted as increases that are included in calculating the ''net reductions'' in expenditures attributable to adjustments for misvalued codes. Instead, we think that the adjustments to value these services should be considered in the context of the budget neutrality adjustments that are applied broadly to PFS services. This would be consistent with our treatment of the increase in values for other new codes since the reductions or deletion of predecessor codes are counted as offsets in our calculation. Since, under the established ratesetting methodology, the increases in new separately reportable services and the corresponding budget neutrality decreases fully offset one another and net to zero, we believe that the easiest way to account for the adjustments associated with valuing these services is to exclude altogether the changes for these types of codes from the list of codes included in the target. This will effectively make the creation and valuation of such codes neutral in the calculation of the misvalued code target.

After considering public comments, we are finalizing our policy as proposed with a modification to exclude from the calculation of the ''net reduction'' in expenditures changes in coding and valuation for services, such as ACP for CY 2016, that are newly reportable, but for which no corresponding reduction is made to existing codes and instead reductions are taken exclusively through a budget neutrality adjustment.

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 had the advantage of being intuitive and readily replicable.

However, there are several issues related to the potential imprecision of this method. 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. Although we believe that this approach would be transparent and external stakeholders could replicate this method, it might be difficult and time-consuming for stakeholders to do so. We also noted that when we modeled the interaction of the statutory phase-in requirement under section 220(e) of the PAMA 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 years, we found that both approaches generally resulted in similar estimated net reductions. After considering these options, we proposed to use the simpler 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 solicited comments 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.

The following is a summary of the comments we received regarding our proposal.

Comment: A few commenters supported CMS' selection of the simpler formula to calculate the target over the more precise but more complex formula since it is simpler and easier to understand. One commenter stated that CMS did not indicate exactly how similar the two proposals are or which method estimated the larger reduction, and stated that CMS should make this information available in the final rule and consider revising the approach in CY 2017 rulemaking and use the method that results in the larger reduction.

Response: We do not agree that CMS should do both calculations and determine which to use based solely on which results in the higher amount. We note that the target for net reductions in expenditures from adjustments to values for misvalued codes is a multi-year provision and we believe neither of the two methodologies is assured to produce a consistently higher result from year to year. Since the majority of commenters agree that the more intuitive approach to estimating the net reduction in expenditures is preferable to the more precisely accurate approach, we are finalizing our approach as proposed.

Comment: One commenter requested that CMS count the full reduction in payment for codes subject to the phase-in required under section 1848(c)(7) of the Act as discussed in section II.F. of this final rule with comment period, toward the target in the first year. Another commenter stated that CMS used the fully reduced RVUs in calculating the target, not the first year phase-in RVUs, and therefore, CMS should include the full impact of the change in the equipment utilization rate for linear accelerators toward the target calculation. Similarly, the commenter requested that any future multi-year phase-in proposals should similarly be counted toward the target in the first year.

Response: The target provision requires the calculation of an estimated net reduction measure between 2 years of PFS expenditures. As we have detailed in the above paragraphs, we believe that under certain specific circumstances, changes should be excluded from that estimate; but we do not believe we can include changes that would occur in future years based solely on the rulemaking cycle during which policies are established. Therefore we will not count the full reduction in payment for codes that are subject to the phase-in toward the calculation of the net reduction in expenditures for the first year. With regard to the commenter that stated that CMS used the fully reduced RVUs in calculating the target, we note that we only used the first year phase-in RVUs and, for the reasons stated above, believe that we are limited to including only the changes in the immediate year in the calculation of the target.

After consideration of the public comments received, we are finalizing the policy to calculate the net reduction using the simpler method as proposed.

4. Target Achievement for CY 2016

We refer readers to the regulatory impact analysis section of this final rule with comment period for our final estimate of the net reduction in expenditures relative to the 1 percent target for CY 2016, and the resulting adjustment required to be made to the conversion factor. Additionally, we refer readers to the public use file that provides a comprehensive description of how the target is calculated as well as the estimated impact by code family on the CMS Web site under the supporting data files for the CY 2016 PFS final rule at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*.

F. 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 the CY 2016 PFS proposed rule, we proposed a methodology to implement this statutory provision. In developing this methodology, we identified several aspects of our approach for which we specifically solicited comments, given the challenges inherent in implementing this provision in a manner consistent with the broader statutory construct of the PFS. We organized this discussion by identifying and explaining these aspects in particular but we solicited comments on all aspects of our proposal.

1. Identifying Services That Are Not New or Revised Codes

As described in this final rule with comment period, 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 changes to RVUs that occur as a result of a coding change for a particular service over 2 years 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 proposed 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 excludes 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 also are excluding 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 application of the phase-in is also 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 also excluded 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.

We received few comments regarding this aspect of our proposal, and some of the comments suggested changes that would require changes to the statutory provision that requires the phase-in of significant changes in RVUs. The following is a summary of the comments that we received.

Comment: One commenter agreed with CMS' broad definition of new or revised.

Response: We appreciate the commenter's feedback and support.

Comment: One commenter did not agree that new and revised services should be excluded from the phase-in, and suggested that the phase-in be applied more broadly.

Response: Section 1848(c)(7) of the Act specifies that services described by new or revised codes are not subject to the phase-in of significant reductions in RVUs. Additionally, because RVUs are assigned to individual codes, we do not believe there would be a straightforward or transparent way to phase in reductions for services that are described by new or revised codes between the years for which a phase-in would apply.

Comment: One commenter urged CMS to include in the phase-in codes that had interim Final values for CY 2015 and have substantial reductions of 20 percent or greater as compared to the 2014 values.

Response: We do not believe it would be consistent with the statutory provision to phase in changes in values between 2015 and 2016 based on 2014 values. Section 1848(c)(7) of the Act, as amended, specifies that the phase-in of significant reductions in values begins for fee schedules established beginning with 2016.

Comment: One commenter stated that any code that has a decrease in value of over 20 percent due to repricing of expensive supplies (for example, over $500) should be excluded from the phase-in provision.

Response: We appreciate the commenter's feedback and understand the rationale for the request; however, we do not believe that we have the discretion to exempt codes from the phase-in, regardless of the reason for the reduction.

After consideration of the public comments received on this aspect of our proposal to implement the phase-in of significant changes in RVUs, we are finalizing the implementation of the phase-in for significant (20 percent or greater) reductions in RVUs as proposed.

2. Estimating the 20 Percent Threshold

Because the phase-in of significant reductions in RVUs falls within the budget neutrality requirements specified in section 1848(c)(2)(B)(ii)(II) of the Act, we proposed 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.

The following is a summary of the comments we received regarding this proposal.

Comment: One commenter supported CMS' proposal for estimating the 20 percent threshold.

Response: We appreciate the commenter's support.

Comment: Another commenter did not agree with the proposal to estimate total RVUs for a service prior to the budget-neutrality redistributions that result from implementing phase-in values. The commenter stated that the methodology should not give inequitable treatment to any particular specialty, and instead it should apply to all codes that are cut greater than 20 percent in the final analysis.

Response: We appreciate that our proposed methodology could, in the end, result in no phase-in for some codes that ultimately do have a 20 percent or greater reduction in value after application of required budget neutrality adjustment. However, we have no reason to believe that this situation, resulting from using initial unadjusted RVUs to identify significant RVU reductions, would disadvantage one specialty more than the next. Therefore, we also do not believe that our proposed approach is likely to result in unequitable treatment to any one specialty over another.

After consideration of the public comments received on this aspect of our proposal, we are finalizing without modification our proposal to identify significant reductions in RVUs based on a comparison of RVUs before application of budget neutrality adjustment.

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 not take place in the first year of the phase-in.

After considering both of these options, we proposed 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 solicited comments on this proposal.

The following is a summary of the comments we received regarding this proposal.

Comment: Several commenters supported CMS' proposal 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.

Response: We appreciate the commenters' feedback and support.

Comment: Several commenters did not support CMS' proposal, and instead stated that CMS should spread the transition evenly over both years—meaning a 50 percent phase-in for year one and year two. One commenter stated that this would lead to a more equitable payment system and allow physicians more time to make changes in their practices to accommodate for reductions. Another commenter acknowledged that codes with reductions that are less than 20 percent and not phased-in may experience greater reductions in the first year, however the commenter stated that a more gradual phase-in for practices facing steeper cuts should be the paramount principle for any policy to transition cuts at or greater than 20 percent.

Response: We have considered the comments and understand the commenters' concerns. We acknowledge some commenters' views that the gradual phase-in of reductions for services that would experience reductions above the threshold (20 percent) is an important principle in determining the best way to implement the phase-in provision. However, we note that the 19 percent reduction maximum also has the advantage of applying the most gradual reduction to services with the greatest reductions (greater than 40 percent). Furthermore, we remain concerned about several practical problems that could arise from utilizing the 50 percent approach. The first of these problems would occur whenever some codes within the same family of services would meet threshold reductions while others do not. For example if two codes in a four code family would be reduced by an estimated 20 percent while the other two were estimated to be reduced by 19 percent, then the first two would be reduced by 10 percent while the remaining two would be reduced by 19 percent. Such a scenario could easily create rank order anomalies within families of codes. The risks of such anomalies is associated with the financial incentives toward inaccurate downward coding that could not only jeopardize Medicare claims data as an accurate source of information, but more directly could have serious consequences within our ratesetting methodologies for both purposes of budget neutrality and for allocation of PE and MP RVUs. The second practical issue with the 50 percent approach would be that the impact of using the estimated reduction instead of the final reduction to determine whether or not particular codes qualify for the phase-in would be significant. Under the 19 percent approach, values for codes with reductions estimated to be very close to 19 percent would be similar regardless of whether or not we engage in various iterations of budget neutrality adjustments to determine whether or not the phase-in applies. Under the 50 percent approach, determinations that result from repeated iterations of ratesetting calculations and budget neutrality adjustments could decide significant changes in the rates for individual codes (up to 10 percent of the total payment.)

In order to avoid these circumstances and apply the most gradual phase-in possible to codes with the most significant reductions, we continue to believe that a 19 percent reduction as the maximum 1-year reduction is the better approach to determining the phase-in amount.

Comment: One commenter requested that the phase-in period be extended to a greater number of years when entire code groupings are impacted, and when multiple codes are identified within a code grouping and they significantly impact revenue to a specialist or specific provider.

Response: The statute specifies a 2-year phase-in period and does not provide authority to extend the phase-in period as described by the commenter.

After consideration of the comments, we are finalizing the policy to phase in 19 percent of the reduction in value in the first year, and the remainder of the reduction in the second year, as proposed.

4. Applicable Adjustments to RVUs

Section 1848(c)(7) of the Act provides that the applicable adjustments in work, PE, and MP RVUs be phased-in over 2 years for any service for which total RVUs 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 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 professional/technical (PC/TC) component. 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 proposed, therefore, to estimate whether a particular code met 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 professional or technical 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 implementing the phase-in of the RVUs for the component codes billed globally by comparing the global value in the prior year versus the global value in the current year and applying the phase-in to the global value for the current year and letting the results flow through to the PC and TC for each code, irrespective of their respective changes in value. Similarly, for the codes with site of service differentials, we considered developing an overall, blended set of overall PE RVUs using a weighted average of site of service volume in the Medicare claims data and then comparing that blended value in the prior year versus the blended value in the current year and applying the phase-in to the value for the current year before re-allocating the blended value to the respective PE RVUs in each setting, regardless of the changes in value for nonfacility or facility values. 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 all individual codes in order to effect the appropriate phase-in amount is the most straightforward and fair approach to implementing the 2-year phase-in of significant reductions of total RVUs.

The following is a summary of the comments we received regarding this proposal.

Comment: One commenter requested that CMS confirm that it would apply all adjustments for the phase-in to the PE RVUs only in situations in which just one site of service, or just one component is subject to the phase-in. That is, if both sites of service or both components of a code were subject to the phase-in, then any adjustments would be applied to work and malpractice RVUs as well.

Response: As discussed in the proposal, all adjustments for the phase-in, including for codes with facility and nonfacility RVUs and PC/TC splits, will be applied to the PE RVUs only. We acknowledge that for some codes it would be hypothetically possible to phase in the reductions proportionally across all three RVU components. As we explained in the proposed rule, it would not be practical to do so for services with site of service differentials since each of the three RVU components represent a different proportion of overall nonfacility or facility RVUs. Therefore, we believe this alternative approach could only work for codes without site of service differentials and those without PC/TC splits, which represents a minority of PFS services. We believe that applying the phase-in for these large categories of codes differently than for the rest of PFS codes would be confusing to the public and make adjustments unpredictable since they would be based on whether or not the service priced in the opposite setting met the phase-in threshold. Furthermore, we remind commenters that because the work RVU is an important allocator of indirect PE in the established methodology, the overall payment impact of any changes in work RVUs is also automatically reflected in corresponding changes to the PE RVUs, whereas changes to direct PE inputs do not have a parallel impact on work RVUs. Therefore, even for individual codes for which it might be possible to establish phase-in values for work RVUs, the necessary adjustments would necessarily be weighted more heavily in PE RVUs.

Comment: With regard to CMS' proposal to consider the RVUs for different sites of service and components independently for the purposes of identifying when and how the phase-in applies, one commenter expressed concerns that the proposed approach ignores the spirit of section 220(e) of the PAMA to benefit physician practices by dampening the year to year impact of large payment reductions. The commenter stated that if CMS adjusts only the PE RVUs, then a large number of codes with greater than 20 percent work RVU reductions could be excluded. The commenter urged CMS to clarify its intent to dampen the effects of year to year reductions to both work RVUs and PE RVUs independently, even for codes with separate facility and non-facility PE RVUs.

Response: We appreciate the commenter's feedback and we acknowledge that our proposed approach would not dampen the year to year reductions in work RVUs. However, our approach would dampen the effect of any payment reductions for all codes, including those reductions that would result from reductions to work RVUs when such reductions contributed to an overall reduction of 20 percent or greater, consistent with the statutory provision. As a practical matter, we believe that practitioners reporting services furnished to Medicare beneficiaries and paid through the PFS would be paid very similar amounts regardless of which approach we implemented. We also note that the commenter did not provide any information that would help us to understand how the suggested phase-in could be applied to services with site of service differentials.

After consideration of the comments received, we are finalizing this aspect of the phase-in methodology as proposed.

The list of codes subject to the phase-in and the associated RVUs that result from this methodology are available on the CMS Web site under downloads for the CY 2016 PFS final rule with comment period at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html.*

G. Changes for Computed Tomography (CT) Under the Protecting Access to Medicare Act of 2014 (PAMA)

Section 218(a)(1) of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93) amended section 1834 of the Act by establishing a new subsection 1834(p). Effective for services furnished on or after January 1, 2016, new section 1834(p) of the Act reduces payment for the technical component (TC) of applicable CT services paid under the Medicare PFS and applicable CT services paid under the OPPS (a 5-percent reduction in 2016 and a 15-percent reduction in 2017 and subsequent years). The applicable CT services are identified by HCPCS codes 70450 through 70498; 71250 through 71275; 72125 through 72133; 72191 through 72194; 73200 through 73206; 73700 through 73706; 74150 through 74178; 74261 through 74263; and 75571 through 75574 (and any succeeding codes). As specified in section 1834(p)(4) of the Act, the reduction applies for applicable services 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.'' Section 1834(p)(4) of the Act also specifies that the Secretary may apply successor standards through rulemaking.

Section 1834(p)(6)(A) of the Act 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 standard set forth in section 1834(p)(4) of the Act (currently the NEMA CT equipment standard) and that such information may be included on a claim and may be a modifier. Section 1834(p)(6)(A) of the Act also provides that such information must 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. Section 218(a)(2) of the PAMA made a conforming amendment to section 1848 (c)(2)(B)(v) of the Act by adding a new subclause (VIII), which provides that, effective for fee schedules established beginning with 2016, reduced expenditures attributable to the application of the quality incentives for computed tomography under section 1834(p) of the Act shall not be taken into account for purposes of the budget neutrality calculation under the PFS.

To implement this provision, in the CY 2016 PFS proposed rule (80 FR 41716), we proposed to establish a new modifier to be used on claims that describes CT services furnished using equipment that does not meet each of the attributes of the NEMA Standard XR–29–2013. We proposed that, beginning January 1, 2016, hospitals and suppliers would be required to use this modifier on claims for CT scans described by any of the CPT codes identified in this section (and any successor codes) that are furnished on non-NEMA Standard XR–29–2013-compliant CT scans. We stated that the use of this proposed modifier would result in the applicable payment reduction for the CT service, as specified under section 1834(p) of the Act. We received the following comments on our proposal to require the modifier to be used on claims:

Many commenters endorsed the use of quality incentives to improve patient safety and optimize the use of radiation when providing CT diagnostic imaging services. Several commenters were supportive of the proposal to establish the modifier to identify CT services furnished using equipment that does not meet each of the attributes of the NEMA Standard XR–29–2013.

Comment: Several commenters requested that we delay implementation of section 1834(p) of the Act so that they have additional time to comply before the payment reduction becomes effective.

Response: The statute requires that we apply the payment adjustment for computed tomography services furnished on or after January 1, 2016. Given this language, we believe that we must implement this provision beginning January 1, 2016. Therefore, we are not delaying implementation of this provision. We note that the payment reduction for 2016 is 5 percent, and it then increases to 15 percent in subsequent years. Hospitals and suppliers that furnish services that do not meet the equipment standard as of January 1, 2016, will receive this 5 percent payment reduction during 2016, but will have an opportunity to upgrade their CT scanners before the larger payment adjustment that takes effect beginning in CY 2017.

Comment: One commenter cited section 1834 (p)(4) of the Act, which specifies that through rulemaking, the Secretary may apply successor standards for CT equipment. The commenter indicated that CMS should develop successor standards that exempt CT scans performed on cone beam CT (CBCT) scanners that are FDA cleared only for imaging of the head from the requirement for Automatic Exposure Control (AEC) capability. This request was based on the AEC capability being unavailable on CBCT scanners.

Response: Although we agree with the commenter that the Secretary has authority to apply successor standards for CT equipment through notice and comment rulemaking, we would like to gain some experience with the NEMA Standard XR–29–2013 before adopting a successor standard. Therefore, we are not adopting a successor standard to the NEMA Standard XR–29–2013 in this final rule with comment period, but may consider doing so in future rulemaking.

After consideration of the public comments we received, we are finalizing the establishment of new modifier, ''CT.'' This 2-digit modifier will be added to the HCPCS annual file as of January 1, 2016, with the label ''CT,'' and the long descriptor ''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 January 1, 2016, hospitals and suppliers will be required to report the modifier ''CT'' on claims for CT scans described by any of the CPT codes identified in this section (and any successor codes) that are furnished on non-NEMA Standard XR–29–2013-compliant CT scanners. The use of this modifier will result in the applicable payment reduction for the CT service, as specified under section 1834(p) of the Act.

H. 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.B.5. of this final rule with comment period. 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 proposed new values in the CY 2016 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 the CY 2016 proposed rule, we are establishing interim final values in this final rule with comment period, consistent with previous practice. In this final rule with comment period, we considered all comments received in response to proposed values for codes in our proposed rule, including alternative recommendations to those used in developing the proposed rule.

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 are establishing final values for those codes in this final rule with comment period. However, the RUC recommendations included CPT tracking codes instead of the actual 2016 CPT codes, which were first made available to the public subsequent to the publication of the CY 2016 proposed rule with comment period. 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 developed and used alternative 5-character placeholder codes for use in the proposed rule. The final CPT codes are included and used for purposes of discussion in this final rule with comment period. Table 9 lists the CPT tracking codes, the CMS placeholder codes, and the final CPT codes for all new CPT codes included in the CY 2016 PFS proposed rule.

TABLE 9—2016 FINAL RULE HCPCS PLACEHOLDER TO CPT CODE NUMBERS

CPT Tracking code	CMS Placeholder code	CPT 2016	Short descriptor
3160X1	3160A	31652	Bronch ebus samplng 1/2 node.
3160X2	3160B	31653	Bronch ebus samplng 3/> node.
3160X3	3160C	31654	Bronch ebus ivntj perph les.
3347X1	3347A	33477	Implant tcat pulm vlv perq.
3725X1	3725A	37252	Intrvasc us noncoronary 1st.
3725X2	3725B	37253	Intrvasc us noncoronary addl.
3940X1	3940A	39401	Mediastinoscpy w/medstnl bx.
3940X2	3940B	39402	Mediastinoscpy w/lmph nod bx.
5039X1	5039A	50430	Njx px nfrosgrm &/urtrgrm.
5039X2	5039B	50431	Njx px nfrosgrm &/urtrgrm.
5039X3	5039C	50432	Plmt nephrostomy catheter.
5039X4	5039D	50433	Plmt nephroureteral catheter.
5039X13	5039M	50434	Convert nephrostomy catheter.
5039X5	5039E	50435	Exchange nephrostomy cath.
5069X7	5069G	50693	Plmt ureteral stent prq.
5069X8	5069H	50694	Plmt ureteral stent prq.
5069X9	5069I	50695	Plmt ureteral stent prq.
5443X1	5443A	54437	Repair corporeal tear.
5443X2	5443B	54438	Replantation of penis.
657XX7	657XG	65785	Impltj ntrstrml crnl rng seg.
692XXX	692XX	69209	Remove impacted ear wax uni.
7208X1	7208A	72081	X-ray exam entire spi 1 vw.
7208X2	7208B	72082	X-ray exam entire spi 2/3 vw.
7208X3	7208C	72083	X-ray exam entire spi 4/5 vw.
7208X4	7208D	72084	X-ray exam entire spi 6/> vw.
7778X1	7778A	77767	Hdr rdncl skn surf brachytx.
7778X2	7778B	77768	Hdr rdncl skn surf brachytx.
7778X3	7778C	77770	Hdr rdncl ntrstl/icav brchtx.
7778X4	7778D	77771	Hdr rdncl ntrstl/icav brchtx.
7778X5	7778E	77772	Hdr rdncl ntrstl/icav brchtx.
8835X0	8835X	88350	Immunofluor antb addl stain.
9254X1	9254A	92537	Caloric vstblr test w/rec.
9254X2	9254B	92538	Caloric vstblr test w/rec.
99176X	9917X	99177	Ocular instrumnt screen bil.
9935XX1	9935A	99415	Prolong clincl staff svc.
9935XX2	9935B	99416	Prolong clincl staff svc add.
GXXX1	GXXX1	G0296	Visit to determ ldct elig.
GXXX2	GXXX2	G0297	Ldct for lung ca screen.

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 RVU, 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 work that determines the appropriate work RVU for a service by gauging the total amount of work for that service relative to the work for a similar service across the PFS without explicitly valuing the components of that work. In addition to these methodologies, CMS has frequently utilized an incremental methodology in which we value a code based upon its incremental difference between another code or another family of codes. Since the statute specifically defines the work component as the resources in time and intensity required in furnishing the service and the published literature on valuing work has recognized the key role of time in overall work, we have also refined the work RVUs for particular codes in direct proportion to the changes in the best information regarding the time resources involved in furnishing particular services, either considering the total time or the intra-service time.

Comment: Several commenters objected to CMS' use of these methodologies as unprecedented and invalid in the context of the development of PFS RVUs.

Response: We appreciate that many commenters, including the RUC, have maintained that magnitude estimation, informed by survey results, is the only appropriate method for valuation of PFS services. However, we have observed that the approaches used by the RUC in developing recommended work RVUs have resulted in recommended values that do not adequately address significant changes in assumptions regarding the amount of time required to furnish particular PFS services. Since section 1848(c)(1)(A) of the Act explicitly identifies time as one of the two kinds of resources that comprise the work component of PFS payment, we do not believe that our use of the above methodologies is inconsistent with the statutory requirements related to the maintenance of work RVUs, and we have regularly used these and other methodologies in developing values for PFS services. 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. In our review of RUC-recommended values, we have noted that the RUC also uses a variety of methodologies to develop work RVUs for individual services, and subsequently validates the results of these approaches through magnitude estimation. We believe that our discrete use of methodologies that compare the time resources among PFS codes is fundamentally similar to that approach, but better facilitates our ability to identify the most accurate work RVU for individual services by explicitly considering the significance of time in the estimate of total work.

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 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 multiplied by 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, now addresses the overlap in time and work when a service is typically provided on the same day as an E/M service.

Table 13 contains a list of codes for which we proposed work RVUs; this includes all RUC recommendations received by February 10, 2015. When the proposed work RVUs varied from those recommended by the RUC or for which we do not have RUC

recommendations, we address those codes 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. Addendum B is available on the CMS Web site under downloads for the CY 2016 PFS final rule with comment period at *http://www.cms.gov/physicianfeesched/downloads/.* The 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 final rule with comment period 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 inputs includes many refinements that are common across codes as well as refinements that are specific to particular services. Table 16 details our refinements of the RUC's direct PE recommendations at the code-specific level. In this final rule with comment period, 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 note 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 interim 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 14 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 final direct PE inputs for CY 2016 are displayed in the final CY 2016 direct PE input database, available on the CMS Web site under the downloads for the CY 2016 final 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 final 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 interim final direct PE inputs. In other cases, CMS refinement of RUC-recommended work times prompts necessary adjustments in the direct PE inputs.

We proposed to remove the 6 minutes of clinical labor time allotted to ''discharge management, same day (0.5 × 99238)'' in the facility setting from a number of procedures under review. We proposed to align the clinical labor for discharge day management to align the work time assigned in the work time file. We made these proposed refinements under the belief that we should not allocate clinical labor staff time for discharge day management if there is no discharge visit included in the procedure's global period.

Comment: Several commenters, including the RUC, disagreed with CMS and suggested that the clinical staff time in the facility setting may not conform with work time for discharge day management in a given code. Commenters stated that the work discharge time reflects the work involved in discharging from a facility setting. Therefore, if the service is typically performed in the nonfacility setting, the post-service time for a CPT code 99238 discharge visit would not be included. However, since the inputs for PE are differentiated by site of service, the time for discharge day might be included in the facility inputs, even if the service is infrequently provided in the facility setting overall. Although the commenters agreed that there should not be clinical staff time for discharge management assigned to 0-day global procedures, the commenters requested that this clinical staff time be restored for the nine 10-day global procedures under review. Commenters stressed that clinical staff must instruct the patient regarding home care prior to the post-operative visit and call in any necessary prescriptions. Commenters also requested that this clinical labor time be included as two, 3-minute phone calls under the task ''Conduct phone calls/call in prescriptions.''

Response: We understand and agree that when cases typically performed in the non-facility setting are performed in the facility setting, discharge day management may not be typical for the code overall even if discharge day management activities may be typical when the service is furnished in the facility setting. However, we also believe that if a patient's conditions are serious enough to warrant treatment in the facility setting, then it is likely that the patient will also be receiving additional services that already include the resource costs involved with clinical labor tasks associated with discharge day management. Therefore, we do not believe that it is appropriate to include the additional time for staff phone calls for these services generally furnished in the office setting.

We have thus far been addressing the subject of discharge day management on a code-by-code basis. Based on the comments received, we believe there is a need for a broader policy concerning the proper treatment of this issue. We will consider this subject for future rulemaking.

After consideration of the comments received, we are finalizing our current

refinements to discharge day management clinical labor time.

(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 the 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 and have reiterated these objections in comments regarding the proposed direct PE inputs. We are responding to these comments by referring the commenters to our extensive discussion in response to the same 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 conform to 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, we review 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 16 in section II.A.3. of this final rule with comment period for a discussion of these standards.

Comment: Several commenters stated that our standard clinical labor inputs for digital imaging inputs for many different codes do not reflect the accurate number of minutes associated with clinical labor tasks for individual services.

Response: In the CY 2015 PFS final rule with comment period (79 FR 67561), we finalized the transition from film-based to digital direct PE inputs for imaging services. In the CY 2016 PFS proposed rule, we sought comment on the appropriate values for the clinical labor tasks associated with digital imaging. Please see section II.B. of this rule for a discussion of those policies. We believe that adherence to these standards produces the most accurate estimate of the resource costs for these kinds of tasks and supports relativity within the development of PE RVUs. For these reasons, absent extenuating factors for specific codes, we are finalizing interim final direct PE inputs that adhere to these standards.

(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

Over several rulemaking cycles, we have proposed and finalized a standard package of direct PE inputs for services where moderate sedation is considered inherent in the procedure (76 FR 73043 through 73049). Our CY 2016 proposed direct PE inputs conform to these policies. This includes not

incorporating the recommended power table (EF031) where it was included during the intraservice period, since a stretcher is the standard item in the moderate sedation package. These refinements are reflected in the final CY 2016 PFS direct PE input database and detailed in Table 16.

Comment: One commenter agreed with CMS' proposal to include the use of a stretcher in the standard moderate sedation package, and that the time allocated for the stretcher should be the entire post procedure recovery period. The commenter recommended that CMS work with the RUC and specialty groups before removing the power table input from the service period of any codes.

Response: We appreciate the commenter's support for the standard moderate sedation package, but we do not believe we should consult with the RUC prior to implementing the standards in developing or finalizing direct PE inputs. However, will consider the appropriate direct PE inputs for each code under review.

(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 that a new item be created and has facilitated our pricing of that item by working with the specialty societies to provide us copies of sales invoices. For CY 2016, we received invoices for several new supply and equipment items. We have accepted the majority of these items and added them to the direct PE input database. Tables 18 and 19 detail the invoices received for new and existing items in the direct PE database. As discussed in section II.A. of this final rule with comment period, 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 18 and 19 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 use 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.

The following is a summary of the comments we received regarding new supply and equipment items.

Comment: Several commenters stated that they had concerns regarding the process of pricing new supply and equipment items for the PFS. The current process requires the submission of recently paid invoices for CMS to consider pricing a new direct PE item. The commenters asked CMS to develop a new pathway to submit pricing information that will protect physicians and vendors, since publishing copies of paid invoices, even when redacted, does not sufficiently protect private identities.

Response: We share commenters' concerns about protecting the privacy of practitioners and vendors during invoice submission. We welcome and will consider additional feedback and suggestions submitted by stakeholders regarding alternate avenues to provide updated pricing information for individual supplies and equipment.

Comment: A commenter stated that although the commenter understands that CMS cannot accurately value the typical cost of a supply or equipment if the agency is not provided with sufficient pricing information, they disagreed with CMS' decision to list the item in question in the direct PE database without assigning any value to it, as this can significantly affect the overall PE value for that service. The commenter requested that CMS highlight those cases where the price of a supply or equipment item is not being finalized due to inadequate documentation, so that there is an opportunity to provide additional resources that might assist in assigning an accurate value.

Response: We agree with the commenter that a lack of sufficient pricing information can often be problematic in assigning an accurate value to new supplies and equipment. Although we do not specifically identify all such items in the preamble to PFS rules, we note that stakeholders can easily identify items without prices in the direct PE input database files that are included as downloads with each PFS rule. We urge the public to submit a comment alerting us to items without a price that appear to be errors in the database. As detailed above, we also encourage the submission of invoices to help provide up-to-date, accurate pricing information for medical supplies and equipment.

Comment: A commenter wrote to express concern with the pricing of three supplies: Probe, radiofrequency, three array (StarBurstSDE) (SD109) from $1995 to $353.44; gas, helium (SD079) from 25 cents per cubic foot to one cent per cubic foot; and gas, argon (SD227) from 25 cents per cubic foot to less than one cent per cubic foot. The commenter added that there was no evidence that supported lower prices for these supplies, and urged CMS to retain the existing pricing for these supply items. The commenter stated that CMS' concerns regarding the price of these supplies were not addressed in the proposed rule, which did not allow opportunity for public comment.

Response: The prices of these three supplies were updated in response to invoices received during the previous calendar year. We appreciate the commenters' feedback and we recognize that it would have been easier for stakeholders to identify the prices had they been included on the Invoices

Received for Existing Direct PE Inputs table in the proposed rule. We believe that the commenter may have been mistaken about the pricing of supplies SD079 and SD227. Both of these supplies have increased in price, from 25 cents per cubic foot to 57 cents and 32 cents per cubic foot, respectively. Neither supply has been lowered in price to one cent per cubic foot. Absent better data sources, we continue to believe that the supply prices listed in the public use files for the CY 2016 PFS proposed rule are the most accurate values for these items.

Comment: Many commenters wrote to express their concern over the pricing of the radiofrequency generator (NEURO) (EQ214) equipment affecting CPT codes 41530, 43228, 43229, 43270, 64633, 64634, 64635 and 64636. Commenters indicated that the invoice for this new equipment item was submitted in relation to CPT code 41530, and the equipment is not the same radiofrequency generator used to perform the services described by CPT codes 64633, 64634, 64635 and 64636. Commenters requested that the equipment input represented in the invoice be assigned an equipment code separate from existing code EQ214 and that CMS maintain the current price of $32,900 for EQ214.

Response: We appreciate the additional information provided by commenters regarding the pricing of the radiofrequency generator equipment. After consideration of comments received, we will create a new equipment code for the radiofrequency generator described in the submitted invoice, and assign this equipment to CPT codes 41530, 43228, 43229, and 43270. For CPT codes 64633, 64634, 64635, and 64636, we will maintain the current price of $32,900 for EQ214 and maintain this equipment.

Comment: One commenter submitted additional invoices regarding the pricing of the PrePen (SH103) supply. The commenter requested that CMS update the price of the PrePen to $92 based on an average of the four invoices submitted.

Response: We appreciate the commenter's submission of additional pricing information regarding the PrePen supply. We note that three of the four submitted invoices reported a price of $86 for supply item ''PrePen'' (SH103); we believe that this represents the typical price of this supply.

Therefore, after consideration of the comments received, we are increasing the price of supply SH103 from $83 to $86.

(7) Service Period Clinical Labor Time in the Facility Setting

Several of the PE worksheets included in RUC recommendations contained clinical labor minutes assigned to the service period in the facility setting. Our proposed inputs did 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. We received no general comments that addressed this issue; we will address code-specific refinements to clinical labor in the individual code sections.

(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 by the RUC, we did not propose to include the time for this equipment item from these services. In the proposed rule, we solicited comments on whether there is a rationale for including this additional light source as a direct PE input for these procedures.

The following is a summary of the comments we received.

Comment: One commenter stated that if CMS believes two light sources are duplicative for these procedures, the commenter recommended retaining input EQ167 and removing input EQ170 (the fiberoptic headlight), as the xenon light source is compatible with various items and can serve as the light source throughout the procedures.

Response: We appreciate the additional information from the commenter regarding the appropriate use of these two light sources.

After consideration of comments received, we are restoring input EQ167 and removing input EQ170 with the same number of equipment minutes for CPT codes 30300, 31295, 31296, 31297, and 92511.

(9) Identification of Database Errors

Several commenters identified possible errors in the direct PE database that did not apply to CPT codes under review. The following is a summary of the comments we received regarding potential database entry errors.

Comment: A commenter located a potential error for CPT code 33262 (Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; single lead system) where the PE RVU dropped from 3.68 in 2015 to 2.35 in the CY 2016 PFS proposed rule. The commenter pointed out that no changes were made to the direct PE inputs for the code, and similar codes within the same family retained the same PE value. The commenter recommended that CMS review this PE RVU and make a correction in the final rule.

Response: For CPT code 33262, the pre-existing direct PE inputs for this code were inadvertently not included in the development of the CY 2016 PFS proposed direct PE input database . We believe this was the result of a data error, and therefore, we are restoring the direct PE inputs to this service.

Comment: One commenter indicated that the underlying line item direct inputs for a series of CPT codes were missing from the individual labor, equipment, and supply public use files. The commenter provided a list of the ten codes affected by this issue, and asked whether this was the result of a technical error.

Response: The ten codes in question were all procedures that the CPT Editorial Panel has assigned for deletion in CY 2016. These codes appeared in error in our public use files for the CY 2016 PFS proposed rule. We have identified the technical issue that was causing this error and corrected it in the CY 2016 final direct PE input database.

Comment: One commenter identified a group of codes where the calculated clinical labor costs (based on the underlying direct input labor file) differed from the CMS summary labor findings. The commenter asked if there were instances where CMS was applying different labor inputs from those published in the files released with the rule.

Response: We appreciate the commenter bringing this issue regarding conflicting information in the CY 2016 PFS proposed rule public use files to our attention. This discrepancy was caused by an error in the creation of the public use files that undercounted the number of clinical labor minutes assigned to the postoperative E/M visits assigned to codes with 10-day and 90-day global periods. This error did not affect the proposed rates in the proposed rule, only the displayed values in the ''labor task detail'' public use file. We have corrected this issue in the public use files for the CY 2016 final direct PE input database.

Comment: A commenter indicated that for several codes, the CMS file for work times did not appear to be updated

with the RUC-approved times. In particular, the pre-evaluation time and immediate post-service time appeared to be missing from the CMS file.

Response: These incorrect work times have been corrected in the CY 2016 final direct PE input database.

(10) Procedures Subject to the Multiple Procedure Payment Reduction (MPPR) and the OPPS Cap

We note that services subject to the MPPR lists on diagnostic cardiovascular services, diagnostic imaging services, diagnostic ophthalmology services and therapy services, and the list of procedures that meet the definition of imaging under section 5102(b) of the DRA and are therefore subject to the OPPS cap for the upcoming calendar year are displayed in the public use files for the PFS proposed and final rules for each year. The public use files for CY 2016 are available on the CMS Web site under downloads for the CY 2016 PFS final rule with comment period at *http://www.cms.gov/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFSFederal-Regulation-Notices.html.*

5. Methodology for Establishing Malpractice RVUs

As discussed in section II.B. of this final rule with comment period, our malpractice methodology uses a crosswalk to establish risk factors for new services until utilization data becomes available. Table 10 lists the CY 2016 HCPCS codes and their respective source codes used to set the CY 2016 MP RVUs. The MP RVUs for these services are reflected in Addendum B on the CMS Web site at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/.*

TABLE 10—CY 2016 MALPRACTICE CROSSWALK

CY 2016 new, revised or misvalued code		Malpractice risk factor crosswalk code	
10035	Perq Dev Soft Tiss 1St Imag	19285	Perq dev breast 1st us imag
10036	Perq Dev Soft Tiss Add Imag	19286	Perq dev breast add us imag
26356	Repair finger/hand tendon	26356	Repair finger/hand tendon
26357	Repair finger/hand tendon	26357	Repair finger/hand tendon
26358	Repair/graft hand tendon	26358	Repair/graft hand tendon
41530	Tongue base vol reduction	41530	Tongue base vol reduction
43210	Egd esophagogastrc fndoplsty	43276	Ercp stent exchange w/dilate
47531	Injection For Cholangiogram	49450	Replace g/c tube perc
47540	Perq Plmt Bile Duct Stent	47556	Biliary endoscopy thru skin
47541	Plmt Access Bil Tree Sm Bwl	47500	Injection for liver x-rays
47542	Dilate Biliary Duct/Ampulla	47550	Bile duct endoscopy add-on
47543	Endoluminal Bx Biliary Tree	47550	Bile duct endoscopy add-on
47544	Removal Duct Glbldr Calculi	47630	Remove bile duct stone
47532	Injection For Cholangiogram	49407	Image cath fluid trns/vgnl
47533	Plmt Biliary Drainage Cath	47510	Insert catheter bile duct
47534	Plmt Biliary Drainage Cath	47511	Insert bile duct drain
47535	Conversion Ext Bil Drg Cath	47505	Injection for liver x-rays
47536	Exchange Biliary Drg Cath	49452	Replace g-j tube perc
47537	Removal Biliary Drg Cath	47505	Injection for liver x-rays
47538	Perq Plmt Bile Duct Stent	47556	Biliary endoscopy thru skin
47539	Perq Plmt Bile Duct Stent	47556	Biliary endoscopy thru skin
49185	Sclerotx Fluid Collection	49407	Image cath fluid trns/vgnl
50606	Endoluminal Bx Urtr Rnl Plvs	50955	Ureter endoscopy & biopsy
50705	Ureteral Embolization/Occl	50393	Insert ureteral tube
50706	Balloon Dilate Urtrl Strix	50395	Create passage to kidney
55866	Laparo radical prostatectomy	55866	Laparo radical prostatectomy
61645	Perq Art M-Thrombect &/Nfs	37218	Stent placemt ante carotid
61650	Evasc Prlng Admn Rx Agnt 1St	37202	Transcatheter therapy infuse
61651	Evasc Prlng Admn Rx Agnt Add	37202	Transcatheter therapy infuse
64461	Pvb Thoracic Single Inj Site	64490	Inj paravert f jnt c/t 1 lev
64462	Pvb Thoracic 2Nd+ Inj Site	64480	Inj foramen epidural add-on
64463	Pvb Thoracic Cont Infusion	64446	N blk inj sciatic cont inf
64553	Implant neuroelectrodes	64553	Implant neuroelectrodes
64555	Implant neuroelectrodes	64555	Implant neuroelectrodes
64566	Neuroeltrd stim post tibial	64566	Neuroeltrd stim post tibial
65778	Cover eye w/membrane	65778	Cover eye w/membrane
65779	Cover eye w/membrane suture	65779	Cover eye w/membrane suture
65780	Ocular reconst transplant	65780	Ocular reconst transplant
65855	Trabeculoplasty Laser Surg	65855	Laser surgery of eye
66170	Glaucoma surgery	66170	Glaucoma surgery
66172	Incision of eye	66172	Incision of eye
67107	Repair Detached Retina	67107	Repair detached retina
67108	Repair Detached Retina	67108	Repair detached retina
67110	Repair detached retina	67110	Repair detached retina
67113	Repair Retinal Detach Cplx	67113	Repair retinal detach cplx
67227	Dstrj Extensive Retinopathy	67227	Treatment of retinal lesion
67228	Treatment X10Sv Retinopathy	67228	Treatment of retinal lesion
72170	X-ray exam of pelvis	72170	X-ray exam of pelvis
73501	X-Ray Exam Hip Uni 1 View	72170	X-ray exam of pelvis
73502	X-Ray Exam Hip Uni 2–3 Views	72170	X-ray exam of pelvis
73503	X-Ray Exam Hip Uni 4/> Views	72170	X-ray exam of pelvis
73521	X-Ray Exam Hips Bi 2 Views	72170	X-ray exam of pelvis
73522	X-Ray Exam Hips Bi 3–4 Views	72170	X-ray exam of pelvis
73523	X-Ray Exam Hips Bi 5/> Views	72170	X-ray exam of pelvis
73551	X-Ray Exam Of Femur 1	72170	X-ray exam of pelvis
73552	X-Ray Exam Of Femur 2/>	72170	X-ray exam of pelvis
74712	Mri Fetal Sngl/1St Gestation	72195	Mri pelvis w/o dye

TABLE 10—CY 2016 MALPRACTICE CROSSWALK—Continued

CY 2016 new, revised or misvalued code		Malpractice risk factor crosswalk code	
74713	Mri Fetal Ea Addl Gestation	72195	Mri pelvis w/o dye
77778	Apply Interstit Radiat Compl	77778	Apply interstit radiat compl
77790	Radiation handling	77790	Radiation handling
78264	Gastric Emptying Imag Study	78264	Gastric emptying study
78265	Gastric Emptying Imag Study	78264	Gastric emptying study
78266	Gastric Emptying Imag Study	78264	Gastric emptying study
91200	Liver elastography	91133	Electrogastrography w/test
93050	Art pressure waveform analys	93784	Ambulatory bp monitoring
95971	Analyze neurostim simple	95971	Analyze neurostim simple
95972	Analyze Neurostim Complex	95972	Analyze neurostim complex

6. CY 2016 Valuation of Specific Codes

TABLE 11—CY 2016 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES WITH PROPOSED VALUES IN THE CY 2016 PFS PROPOSED RULE

HCPCS Code	Long descriptor	CY 2015 WRVU	Proposed CY 2016 work RVU	Final CY 2016 work RVU
11750	Excision of nail and nail matrix, partial or complete (eg, ingrown or deformed nail), for permanent removal;.	2.50	1.58	1.58
20240	Biopsy, bone, open; superficial (eg, ilium, sternum, spinous process, ribs, trochanter of femur).	3.28	2.61	2.61
27280	Arthrodesis, open, sacroiliac joint, including obtaining bone graft, including instrumentation, when performed.	14.64	20.00	20.00
31652	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	4.71	4.71
31653	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	5.21	5.21
31654	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	1.40	1.40
31622	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with cell washing, when performed (separate procedure).	2.78	2.78	2.78
31625	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial or endobronchial biopsy(s), single or multiple sites.	3.36	3.36	3.36
31626	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with placement of fiducial markers, single or multiple.	4.16	4.16	4.16
31628	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial lung biopsy(s), single lobe.	3.80	3.80	3.80
31629	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial needle aspiration biopsy(s), trachea, main stem and/or lobar bronchus(i).	4.09	4.00	4.00
31632	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial lung biopsy(s), each additional lobe (List separately in addition to code for primary procedure).	1.03	1.03	1.03
31633	Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with transbronchial needle aspiration biopsy(s), each additional lobe (List separately in addition to code for primary procedure).	1.32	1.32	1.32
33477	Transcatheter pulmonary valve implantation, percutaneous approach, including pre-stenting of the valve delivery site, when performed.	NEW	25.00	25.00
37215	Transcatheter placement of intravascular stent(s), cervical carotid artery, open or percutaneous, including angioplasty, when performed, and radiological supervision and interpretation; with distal embolic protection.	19.68	18.00	18.00
37252	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	1.80	1.80
37253	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
38570	Laparoscopy, surgical; with retroperitoneal lymph node sampling (biopsy), single or multiple.	9.34	8.49	8.49

TABLE 11—CY 2016 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES WITH PROPOSED VALUES IN THE CY 2016 PFS PROPOSED RULE—Continued

HCPCS Code	Long descriptor	CY 2015 WRVU	Proposed CY 2016 work RVU	Final CY 2016 work RVU
38571	Laparoscopy, surgical; with bilateral total pelvic lymphadenectomy	14.76	12.00	12.00
38572	Laparoscopy, surgical; with bilateral total pelvic lymphadenectomy and periaortic lymph node sampling (biopsy), single or multiple.	16.94	15.60	15.60
39401	Mediastinoscopy; includes biopsy(ies) of mediastinal mass (eg, lymphoma), when performed.	NEW	5.44	5.44
39402	Mediastinoscopy; with lymph node biopsy(ies) (eg, lung cancer staging)	NEW	7.25	7.25
43775	Laparoscopy, surgical, gastric restrictive procedure; longitudinal gastrectomy (ie, sleeve gastrectomy).	C	20.38	20.38
44380	Ileoscopy, through stoma; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure).	1.05	0.90	0.97
44381	Ileoscopy, through stoma; with transendoscopic balloon dilation	I	1.48	1.48
44382	Ileoscopy, through stoma; with biopsy, single or multiple	1.27	1.20	1.27
44384	Ileoscopy, through stoma; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed).	I	2.88	2.95
44385	Endoscopic evaluation of small intestinal pouch (e.g., Kock pouch, ileal reservoir [S or J]); diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure).	1.82	1.23	1.30
44386	Endoscopic evaluation of small intestinal pouch (eg, Kock pouch, ileal reservoir [S or J]); with biopsy, single or multiple.	2.12	1.53	1.60
44388	Colonoscopy through stoma; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure).	2.82	2.75	2.82
44389	Colonoscopy through stoma; with biopsy, single or multiple	3.13	3.05	3.12
44390	Colonoscopy through stoma; with removal of foreign body(s)	3.82	3.77	3.84
44391	Colonoscopy through stoma; with control of bleeding, any method	4.31	4.22	4.22
44392	Colonoscopy through stoma; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps.	3.81	3.63	3.63
44394	Colonoscopy through stoma; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique.	4.42	4.13	4.13
44401	Colonoscopy through stoma; with ablation of tumor(s), polyp(s), or other lesion(s) (includes pre-and post-dilation and guide wire passage, when performed).	I	4.44	4.44
44402	Colonoscopy through stoma; with endoscopic stent placement (including pre- and post-dilation and guide wire passage, when performed).	I	4.73	4.80
44403	Colonoscopy through stoma; with endoscopic mucosal resection	I	5.53	5.60
44404	Colonoscopy through stoma; with directed submucosal injection(s), any substance.	I	3.05	3.12
44405	Colonoscopy through stoma; with transendoscopic balloon dilation	I	3.33	3.33
44406	Colonoscopy through stoma; with endoscopic ultrasound examination, limited to the sigmoid, descending, transverse, or ascending colon and cecum and adjacent structures.	I	4.13	4.20
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 adjacent structures.	I	5.06	5.06
44408	Colonoscopy through stoma; with decompression (for pathologic distention) (eg, volvulus, megacolon), including placement of decompression tube, when performed.	I	4.24	4.24
45330	Sigmoidoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure).	0.96	0.77	0.84
45331	Sigmoidoscopy, flexible; with biopsy, single or multiple	1.15	1.07	1.14
45332	Sigmoidoscopy, flexible; with removal of foreign body(s)	1.79	1.79	1.86
45333	Sigmoidoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps.	1.79	1.65	1.65
45334	Sigmoidoscopy, flexible; with control of bleeding, any method	2.73	2.10	2.10
45335	Sigmoidoscopy, flexible; with directed submucosal injection(s), any substance.	1.46	1.07	1.14
45337	Sigmoidoscopy, flexible; with decompression (for pathologic distention) (*e.g.,* volvulus, megacolon), including placement of decompression tube, when performed.	2.36	2.20	2.20
45338	Sigmoidoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique.	2.34	2.15	2.15
45340	Sigmoidoscopy, flexible; with transendoscopic balloon dilation	1.89	1.35	1.35
45341	Sigmoidoscopy, flexible; with endoscopic ultrasound examination	2.60	2.15	2.22
45342	Sigmoidoscopy, flexible; with transendoscopic ultrasound guided intramural or transmural fine needle aspiration/biopsy(s).	4.05	3.08	3.08
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).	I	2.84	2.91
45347	Sigmoidoscopy, flexible; with placement of endoscopic stent (includes pre- and post-dilation and guide wire passage, when performed).	I	2.75	2.82

TABLE 11—CY 2016 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES WITH PROPOSED VALUES IN THE CY 2016 PFS PROPOSED RULE—Continued

HCPCS Code	Long descriptor	CY 2015 WRVU	Proposed CY 2016 work RVU	Final CY 2016 work RVU
45349	Sigmoidoscopy, flexible; with endoscopic mucosal resection	I	3.55	3.62
45350	Sigmoidoscopy, flexible; with band ligation(s) (*e.g.,* hemorrhoids)	I	1.78	1.78
45378	Colonoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed (separate procedure).	3.69	3.29	3.36
45379	Colonoscopy, flexible; with removal of foreign body(s)	4.68	4.31	4.38
45380	Colonoscopy, flexible; with biopsy, single or multiple	4.43	3.59	3.66
45381	Colonoscopy, flexible; with directed submucosal injection(s), any substance	4.19	3.59	3.66
45382	Colonoscopy, flexible; with control of bleeding, any method	5.68	4.76	4.76
45384	Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by hot biopsy forceps.	4.69	4.17	4.17
45385	Colonoscopy, flexible; with removal of tumor(s), polyp(s), or other lesion(s) by snare technique.	5.30	4.67	4.67
45386	Colonoscopy, flexible; with transendoscopic balloon dilation	4.57	3.87	3.87
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).	I	4.98	4.98
45389	Colonoscopy, flexible; with endoscopic stent placement (includes pre- and post-dilation and guide wire passage, when performed).	I	5.27	5.34
45390	Colonoscopy, flexible; with endoscopic mucosal resection	I	6.07	6.14
45391	Colonoscopy, flexible; with endoscopic ultrasound examination limited to the rectum, sigmoid, descending, transverse, or ascending colon and cecum, and adjacent structures.	5.09	4.67	4.74
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 adjacent structures.	6.54	5.60	5.60
45393	Colonoscopy, flexible; with decompression (for pathologic distention) (*e.g.,* volvulus, megacolon), including placement of decompression tube, when performed.	I	4.78	4.78
45398	Colonoscopy, flexible; with band ligation(s) (*e.g.,* hemorrhoids)	I	4.30	4.30
46500	Injection of sclerosing solution, hemorrhoids	1.69	1.42	1.42
46601	Anoscopy; diagnostic, with high-resolution magnification (HRA) (*e.g.,* colposcope, operating microscope) and chemical agent enhancement, including collection of specimen(s) by brushing or washing, when performed.	I	1.60	1.60
46607	Anoscopy; with high-resolution magnification (HRA) (*e.g.,* colposcope, operating microscope) and chemical agent enhancement, with biopsy, single or multiple.	I	2.20	2.20
47135	Liver allotransplantation; orthotopic, partial or whole, from cadaver or living donor, any age.	83.64	90.00	90.00
50430	Injection procedure for antegrade nephrostogram and/or ureterogram, complete diagnostic procedure including imaging guidance (*e.g.,* ultrasound and fluoroscopy) and all associated radiological supervision and interpretation; new access.	NEW	3.15	3.15
50431	Injection procedure for antegrade nephrostogram and/or ureterogram, complete diagnostic procedure including imaging guidance (*e.g.,* ultrasound and fluoroscopy) and all associated radiological supervision and interpretation; existing access.	NEW	1.10	1.10
50432	Placement of nephrostomy catheter, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (*e.g.,* ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation.	NEW	4.25	4.25
50433	Placement of nephroureteral catheter, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (*e.g.,* ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation, new access.	NEW	5.30	5.30
50435	Exchange nephrostomy catheter, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (*e.g.,* ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation.	NEW	1.82	1.82
50434	Convert nephrostomy catheter to nephroureteral catheter, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (*e.g.,* ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation.	NEW	4.00	4.00
50693	Placement of ureteral stent, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (*e.g.,* ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; pre-existing nephrostomy.	NEW	4.21	4.21

TABLE 11—CY 2016 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES WITH PROPOSED VALUES IN THE CY 2016 PFS PROPOSED RULE—Continued

HCPCS Code	Long descriptor	CY 2015 WRVU	Proposed CY 2016 work RVU	Final CY 2016 work RVU
50694	Placement of ureteral stent, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (*e.g.,* ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; new access, without separ.	NEW	5.50	5.50
50695	Placement of ureteral stent, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (*e.g.,* ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; new access, with separate.	NEW	7.05	7.05
54437	Repair of traumatic corporeal tear(s)	NEW	11.50	11.50
54438	Replantation, penis, complete amputation including urethral repair	NEW	22.10	24.50
63045	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; cervical.	17.95	17.95	17.95
63046	Laminectomy, facetectomy and foraminotomy (unilateral or bilateral with decompression of spinal cord, cauda equina and/or nerve root[s], [eg, spinal or lateral recess stenosis]), single vertebral segment; thoracic.	17.25	17.25	17.25
65785	Implantation of intrastromal corneal ring segments	NEW	5.39	5.39
68801	Dilation of lacrimal punctum, with or without irrigation	1.00	0.82	0.82
68810	Probing of nasolacrimal duct, with or without irrigation	2.15	1.54	1.54
68811	Probing of nasolacrimal duct, with or without irrigation; requiring general anesthesia.	2.45	1.74	1.74
68815	Probing of nasolacrimal duct, with or without irrigation; with insertion of tube or stent.	3.30	2.70	2.70
68816	Probing of nasolacrimal duct, with or without irrigation; with transluminal balloon catheter dilation.	3.06	2.10	2.10
71100	Radiologic examination, ribs, unilateral; 2 views	0.22	0.22	0.22
72070	Radiologic examination, spine; thoracic, 2 views	0.22	0.22	0.22
72081	Entire spine x ray, one view	NEW	0.26	0.26
72082	Entire spine x-ray; 2 or 3 views	NEW	0.31	0.31
72083	Entire spine x-ray; 4 or 5 views	NEW	0.35	0.35
72084	Entire spine x-ray; min 6 views	NEW	0.41	0.41
73060	Radiologic examination; humerus, minimum of 2 views	0.17	0.16	0.16
73560	Radiologic examination, knee; 1 or 2 views	0.17	0.16	0.16
73562	Radiologic examination, knee; 3 views	0.18	0.18	0.18
73564	Radiologic examination, knee; complete, 4 or more views	0.22	0.22	0.22
73565	Radiologic examination, knee; both knees, standing, anteroposterior	0.17	0.16	0.16
73590	Radiologic examination; tibia and fibula, 2 views	0.17	0.16	0.16
73600	Radiologic examination, ankle; 2 views	0.16	0.16	0.16
76999	Unlisted ultrasound procedure (*e.g.,* diagnostic, interventional)	C	C	C
77385	Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; simple.	I	0.00	I
77386	Intensity modulated radiation treatment delivery (IMRT), includes guidance and tracking, when performed; complex.	I	0.00	I
77387	Guidance for localization of target volume for delivery of radiation treatment delivery, includes intrafraction tracking, when performed.	I	0.58	I
77402	Radiation treatment delivery, >= 1 MeV; simple	I	0.00	I
77407	Radiation treatment delivery, >= 1 MeV; intermediate	I	0.00	I
77412	Radiation treatment delivery, >= 1 MeV; complex	I	0.00	I
77767	Remote afterloading high dose rate radionuclide skin surface brachytherapy, includes basic dosimetry, when performed; lesion diameter up to 2.0 cm or 1 channel.	NEW	1.05	1.05
77768	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	1.40	1.40
77770	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; 1 channel.	NEW	1.95	1.95
77771	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; 2–12 channels.	NEW	3.80	3.80
77772	Remote afterloading high dose rate radionuclide interstitial or intracavitary brachytherapy, includes basic dosimetry, when performed; over 12 channels.	NEW	5.40	5.40
88346	Immunofluorescent study, each antibody; direct method	0.86	0.74	0.74
88350	Immunofluorescence, per specimen; each additional single antibody stain procedure (List separately in addition to code for primary procedure).	NEW	0.56	0.56
88367	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), using computer-assisted technology, per specimen; initial single probe stain procedure.	0.73	0.73	0.73
88368	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), manual, per specimen; initial single probe stain procedure.	0.88	0.88	0.88

TABLE 11—CY 2016 WORK RVUS FOR NEW, REVISED AND POTENTIALLY MISVALUED CODES WITH PROPOSED VALUES IN THE CY 2016 PFS PROPOSED RULE—Continued

HCPCS Code	Long descriptor	CY 2015 WRVU	Proposed CY 2016 work RVU	Final CY 2016 work RVU
91299	Unlisted diagnostic gastroenterology procedure	C	C	C
92537	Caloric vestibular test with recording, bilateral; bithermal (ie, one warm and one cool irrigation in each ear for a total of four irrigations).	NEW	0.60	0.60
92538	Caloric vestibular test with recording, bilateral; monothermal (ie, one irrigation in each ear for a total of two irrigations).	NEW	0.30	0.30
99174	Instrument-based ocular screening (*e.g.,* photoscreening, automated-refraction), bilateral.	N	N	N
99177	Instrument-based ocular screening (*e.g.,* photoscreening, automated-refraction), bilateral; with on-site analysis.	NEW	N	N
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 care professional; first 30 minutes, face-to-face with the patient, family member(s), and/or surrogate.	I	1.50	1.50
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 care professional; each additional 30 minutes (List separately in addition to code for primary procedure).	I	1.40	1.40
G0104	Colorectal cancer screening; flexible sigmoidoscopy	0.96	0.77	0.84
G0105	Colorectal cancer screening; colonoscopy on individual at high risk	3.69	3.29	3.36
G0121	Colorectal cancer screening; colonoscopy on individual not meeting criteria for high risk.	3.69	3.29	3.36

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. In the CY 2016 PFS proposed rule, we made use of similar methodologies in establishing the proposed 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 12 reflects how we applied this methodology and the values we proposed. 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 code 43235 of 2.19 to arrive at our proposed work RVU for the base colonoscopy CPT code 45378 of 3.29. We used this value as the base code in the incremental methodology for establishing the proposed work RVU for the other base codes in the colonoscopy subfamilies which were then used to value the other codes in that subfamily.

Comment: Many commenters expressed concerns that the proposed values for the lower GI code set will hinder efforts to reduce the incidence of colorectal cancer through detection and treatment by limiting access to screenings. Comments stated,

''According to a poll of more than 550 gastroenterologists, more than half of the respondents plan to limit new Medicare patients if the proposed cuts are implemented; 55 percent plan to limit procedures to Medicare patients; and 15 percent are considering opting out of Medicare entirely. These findings suggest that GI physicians may not be able to maintain the current mix of Medicare patients and protect the financial viability of their practices.'' Some commenters specifically disagreed with CMS' methodology of applying an incremental difference between the base procedure for upper GI and lower GI, stating they believe that is a misapplication of the incremental approach and some noted that they believe that the upper and lower GI services are clinically distinct. Additionally, many commenters expressed disappointment that CMS did not consider the survey results, which they believe are the most reliable indicator of the work involved in colonoscopy. These commenters suggested that CMS adopt the RUC-recommended values for the lower GI code set. Additionally, the affected specialty societies suggested that we accept their original recommendations (a work RVU of 3.51 for the base colonoscopy code, CPT code 45378). Some commenters stated that new colorectal cancer screening protocols have resulted in increased work due to the attention required to identify and remove precancerous lesions.

Response: In developing the proposed work RVUs, we did consider the survey data. However, we considered the survey data in the context of the work RVUs for services within the broader endoscopy family. While we continue to believe that relativity among families of codes is important and view the upper and lower endoscopy codes as one code family, in the context of receiving many comments urging us to accept the RUC-recommended value for diagnostic colonoscopy (and thus the screening colonoscopy), we reconsidered the differences between the RUC-recommended value and our proposed RVUs. We do not believe the relatively small difference between these two values is itself likely to present significant issues in PFS relativity. Therefore, we agree with commenters that the RUC-recommended values generally reflect the work resources involved in furnishing the service and we are finalizing the RUC-recommended value of 3.36 RVUs for the base colonoscopy code, CPT code 45378, and are adjusting the valuation of all the other codes in the lower GI code set using that base with the incremental difference methodology. We also note that while we appreciate and share commenters' interest in maintaining beneficiaries' access to screening colonoscopies where appropriate under the current benefit, we believe that establishing RVUs that most accurately reflect the relative resource costs involved in furnishing services paid under the PFS is not only required by the statute, but also important to preserve and promote beneficiary access to all PFS services.

Comment: A few commenters requested that CMS delay finalizing values for the lower GI codes until codes that are used to report moderate sedation are separately valued, since implementation of those codes will require a methodology for removing the work RVUs for moderate sedation from the endoscopy codes.

Response: We will review and consider recommendations from the medical community about the work RVUs associated with moderate sedation and will address the valuation of moderation sedation separately. Since moderate sedation is a broad, cross-cutting issue that affects many specialties and code families, we do not believe that it is appropriate to delay finalizing values for all codes with moderate sedation, and therefore, will not do so for the GI codes.

Comment: A few commenters stated disagreement with CMS' proposed PE refinement to remove the mobile instrument table (EF027) from codes 45330 and 45331on the basis that the procedures do not include moderate sedation. The commenter noted that, ''while the mobile instrument table is part of the moderate sedation standard package and moderate sedation is not inherent in the procedure, it is still a necessary part of flexible sigmoidoscopy codes 45330 and 45331.''

Response: We agree with the commenter that the mobile instrument table is typically involved in furnishing these services, even though moderate sedation may not be inherent in the procedure. Therefore, we have included the mobile instrument table (EF027) in the direct PE input database for codes 45330 and 45331.

Comment: We received a comment on the proposed PE refinements made to CPT code 45330, stating that the RUC approved sterile water for CPT code 43450 instead of distilled water due to the risk of infections and potential for contamination. The commenter stated an expectation that all GI endoscopy codes that currently contain distilled water should be revised to include sterile water instead.

Response: We have considered the comment; however, we re-examined the RUC-recommended direct PE inputs, and we did not identify the sterile water as part of that recommendation. Additionally, the commenter did not provide a detailed rationale for the use of sterile water over distilled water. Therefore, for CY 2016, we are finalizing the inputs for code 45330 as proposed. However, we are seeking additional information regarding these inputs (including rationale and explanation for the use of the commenter's recommended inputs) and we will consider this issue for future rulemaking.

TABLE 12—APPLICATION OF THE INCREMENTAL DIFFERENCE METHODOLOGY

HCPCS	Descriptor	Current WRVU	RUC WRVU	Base procedure	Base RVU	Increment	Increment value	Proposed WRVU	Finalized WRVU (using 3.36 RVUs for the base)
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	0.97
44382	Ileoscopy, through stoma; with biopsy, single or multiple.	1.27	1.27	Ileoscopy	0.9	Biopsy	0.3	1.2	1.27

TABLE 12—APPLICATION OF THE INCREMENTAL DIFFERENCE METHODOLOGY—Continued

HCPCS	Descriptor	Current WRVU	RUC WRVU	Base procedure	Base RVU	Increment	Increment value	Proposed WRVU	Finalized WRVU (using 3.36 RVUs for the base)
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	2.95
44385	Endoscopic evaluation of small intestinal pouch (*e.g.*, 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	1.3
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	1.6
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	2.82
44389	Colonoscopy through stoma; with biopsy, single or multiple.	3.13	3.12	Colonoscopy through stoma.	2.75	Biopsy	0.3	3.05	3.12
44390	Colonoscopy through stoma; with removal of foreign body.	3.82	3.82	Colonoscopy through stoma.	2.75	Foreign body ...	1.02	3.77	3.84
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	4.8
44403	Colonoscopy through stoma; with endoscopic mucosal resection.	NA	5.81	Colonoscopy through stoma.	2.75	Endoscopic mucosal resection.	2.78	5.53	5.6
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	3.12
44406	Colonoscopy through stoma; with endoscopic ultrasound examination, limited to the sigmoid, descending, transverse, or ascending colon and cecum and adjacent structures.	NA	4.41	Colonoscopy through stoma.	2.75	Endoscopic ultrasound.	1.38	4.13	4.2
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	0.84
45331	Sigmoidoscopy, flexible; with biopsy, single or multiple.	1.15	1.14	Sigmoidoscopy	0.77	Biopsy	0.3	1.07	1.14
45332	Sigmoidoscopy, flexible; with removal of foreign body.	1.79	1.85	Sigmoidoscopy	0.77	Foreign body ...	1.02	1.79	1.86

TABLE 12—APPLICATION OF THE INCREMENTAL DIFFERENCE METHODOLOGY—Continued

HCPCS	Descriptor	Current WRVU	RUC WRVU	Base procedure	Base RVU	Increment	Increment value	Proposed WRVU	Finalized WRVU (using 3.36 RVUs for the base)
45335	Sigmoidoscopy, flexible; with directed submucosal injection(s), any substance.	1.46	1.15	Sigmoidoscopy	0.77	Submucosal injection.	0.3	1.07	1.14
45341	Sigmoidoscopy, flexible; with endoscopic ultrasound examination.	2.6	2.43	Sigmoidoscopy	0.77	Endoscopic ultrasound.	1.38	2.15	2.22
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	2.91
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	2.82
45349	Sigmoidoscopy, flexible; with endoscopic mucosal resection.	NA	3.83	Sigmoidoscopy	0.77	Endoscopic mucosal resection.	2.78	3.55	3.62
45378	Colonoscopy, flexible; diagnostic, including collection of specimen(s) by brushing or washing, when performed, (separate procedure).	3.69	3.36	Colonoscopy	3.29				3.36
45379	Colonoscopy, flexible; with removal of foreign body.	4.68	4.37	Colonoscopy	3.29	Foreign body ...	1.02	4.31	4.38
45380	Colonoscopy, flexible, proximal to splenic flexure; with biopsy, single or multiple.	4.43	3.66	Colonoscopy	3.29	Biopsy	0.3	3.59	3.66
45381	Colonoscopy, flexible; with directed submucosal injection(s), any substance.	4.19	3.67	Colonoscopy	3.29	Submucosal injection.	0.3	3.59	3.66
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	5.34
45390	Colonoscopy, flexible; with endoscopic mucosal resection.	NA	6.35	Colonoscopy	3.29	Endoscopic mucosal resection.	2.78	6.07	6.14
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	4.74

(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. In the CY 2016 PFS proposed rule, we proposed to establish national pricing for CPT code 43775. To establish a work RVU, we crosswalked the work RVUs for this code from 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 proposed a work RVU of 20.38 for CPT code 43775.

Comment: Some commenters noted that CPT code 43775 was reviewed at the April 2009 RUC meeting and that the RUC submitted recommendations to CMS for CY 2010, including a recommendation of 21.40 work RVUs for CPT code 43775. The commenters stated that those recommendations are still valid and requested that CMS accept the RUC recommended work RVU of 21.40 for CPT code 43775.

Response: We thank the commenters for pointing out the previous RUC recommendations from April 2009. We continue to believe that the proposed work RVU is appropriate based on the reasons stated in the proposed rule, and therefore, for CY 2016, we are finalizing a work RVU of 20.38 for CPT code 43775.

Comment: A few commenters noted that they believe the crosswalk code used by CMS (CPT code 37217) does encourage relativity, but because it is an endovascular procedural code, does not accurately capture all aspects of a bariatric surgical patient in the pre-service, intra-service, or post-service periods. Commenters stated that they believed a comparison within the code family would provide an assessment that is more accurate. The commenters urged CMS to accept the previous valuation of 21.56.

Response: After consideration of the comments, we continue to believe that the proposed work RVU is appropriate based on the reasons stated in the proposed rule, and that it maintains relativity within its family of codes. Therefore, for CY 2016, we are finalizing 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 proposed 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 proposed 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 change in input values, we also solicited comments 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 solicited comments 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 solicited 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 splenic flexure. 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.

Comment: Some commenters agreed with the proposed policy of using the–53 modifier to identify the reduced work involved with an incomplete colonoscopy and a reimbursement that is 50 percent of the full procedure. However, some noted that instances where the cecum is not reached immediately would be associated with greater PE than sigmoidoscopy, noting that the endoscopist will have utilized a colonoscope for the procedure requiring greater work for staff to clean and also noted that the endoscopist will commonly obtain a pediatric endoscope to navigate the narrowed sigmoid. Commenters also stated that sigmoidoscopy is a procedure commonly performed without moderate sedation. One commenter recommended that CMS establish a new modifier for instances in which the colonoscope has passed beyond the splenic flexure but has not reached the cecum or small bowel—large bowel anastomosis due to inadequate preparation precluding high-quality examination of the lumen of the bowel or technical limitations that preclude the ability of the physician to safely complete the examination of the colon. The commenter also recommended that payment for the professional services for colonoscopy in these circumstances be adjusted to 75 percent of the payment for the colonoscopy procedure, noting that appending this new modifier to the professional services for the procedure would allow the same or other physician to bring the patient back for another colonoscopy examination within 2 months without triggering the frequency limitation under the Act, and that facility payment for the procedure would not be adjusted when this modifier is reported with codes 45378, G0105 or G0121.

Response: We appreciate the commenters' support for the proposed policy of using the–53 modifier. We also appreciate the additional feedback regarding the resource costs of incomplete colonoscopies and will consider whether further changes to valuation or the coding structure are necessary in future rulemaking.

(4) Malpractice (MP) Crosswalk

We examined the RUC-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 final rule with comment period 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-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-recommended MP crosswalks for these codes were likely to be more accurate than the RUC-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 those 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 are available, we proposed to use the specialty mix of the source code(s) in the RUC-recommended utilization crosswalk 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.

Comment: The RUC commented that they support CMS' decision to use the utilization crosswalk in determining the malpractice crosswalk for CPT code 43775 given that there are newer data since the RUC last reviewed this code in 2009. However, the RUC commented that it did not agree with this proposed decision for the other four services, CPT codes 44407, 44408, 46601, and 46607, stating that its MP crosswalks for these codes were based on the intended specialty mix.

Response: We continue to believe 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. Therefore, for CY 2016, we are finalizing these malpractice crosswalk codes as proposed.

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 on 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 proposed to establish values for the new codes based on RUC recommendations, subject to standard CMS refinements. We also note that because the invoices used to price the capital equipment included ''on-board imaging,'' and based on our review of the information used to price the equipment, we considered the costs of that equipment already to be reflected in the price per minute associated with the capital equipment. Therefore, we did not propose to include it as a separate item in the 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 proposed direct PE inputs for those codes were displayed 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 direct PE inputs (and work RVUs and work time, as applicable) were displayed in proposed rule Addendum B on the CMS Web site.

We received many comments regarding various aspects of our proposal to implement the new CPT codes for radiation treatment services based on our refinement of RUC-recommended input values. Some commenters addressed issues for which we explicitly sought comment, while several commenters brought other issues to our attention. We address these comments in the following paragraphs.

(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 indicated that stereotactic guidance for radiation treatment services was furnished more frequently than CT guidance. The RUC recommended a work RVU of 0.58 and associated work times of three pre-service minutes, 10 intraservice minutes, and three 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. We solicited comments as to the appropriate work time associated with CPT code 77387.

Comment: Commenters provided feedback that work time of 16 minutes is accurate for 77387, consistent with the RUC recommendation without explaining why the work time associated with image guidance has changed significantly.

Response: We appreciate that commenters responded to our solicitation but the commenters did not provide a rationale for why the recommended work time for the new code would be significantly different than the current work time for the most frequently reported predecessor code. Absent an explanation, we remain concerned that the aspects of the recommended values for the new single modality code were developed based on erroneous assumptions regarding what imaging modality is most frequently used to provide guidance for radiation treatment services.

Although CPT codes 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). The RUC recommendation stated that the CPT editorial panel maintained CPT code 77014 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 included a statement that utilization of this code was expected to drop to negligible levels in 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.

Comment: Several commenters stated that, while they believe that the volume for 77014 will fall to negligible levels, they support CMS' adoption of the decision to continue to monitor and review this code.

Response: We appreciate commenters support and the stakeholder interest in making certain that the codes accurately describe the services furnished to Medicare beneficiaries.

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 CPT 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, stereotactic radiosurgery (SRS) or stereotactic body radiation therapy (SBRT) treatment delivery codes. The RUC recommendation, however, incorporated the same capital cost of image guidance equipment (a linear accelerator, or linac), for the conventional radiation treatment delivery codes and the the codes that describe IMRT treatment delivery services. The RUC explained that 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 for the proposed rule, we assumed 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 this 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, SRS, and SBRT treatment delivery codes as CPT guidance would suggest.

In order to avoid incorporating the cost of this equipment into both the treatment delivery codes (CPT codes 77402, 77407, and 77412) and the technical component of the new imaging guidance code (CPT code 77387–TC), we considered valuing CPT code 77387 as a professional service only and not creating the professional/technical component splits envisioned by CPT. In the proposed rule we stated that in the context of the budget neutral PFS, incorporating a duplicative direct input with a cost of more than six dollars per minute would have significant impacts on the PE RVUs for all other services. However, we also noted that the RUC did not address this issue in its recommendation and proposed that not all of the recommended direct PE inputs for the

technical component of CPT code 77387 are capital equipment costs. Therefore, we proposed to allow for professional and technical component billing for these services, as reflected in CPT guidance, and to use the RUC-recommended direct PE inputs for these services (refined as described in Table 13 of the proposed rule (80 FR 41725–41764). We solicited comments on the technical component billing for image guidance in the context of the inclusion of a single linac and the RUC-recommended integration of imaging guidance technology for all external beam treatment codes.

Comment: Many commenters stated that it was necessary for CPT code 77387 to include both a technical and professional component because the current price of the linear accelerator used in radiation treatment delivery services does not include the additional costs of an integrated image guidance system. These commenters urged CMS to retain the technical and professional components for CPT code 77387 on the basis that there are equipment and labor costs associated with image guidance that are not reflected in a professional-only code.

Some other commenters were concerned that the new coding structure for image guidance did not accurately reflect the way that image guidance is typically furnished. These commenters stated that multiple modalities of image guidance can be used in a single procedure, and that this heterogeneity is not reflected through a single image guidance code.

Response: We appreciate that many commenters addressed the bundling in the new CPT codes of the technical component of image guidance for IMRT, SRS, and SBRT, but not for conventional radiation treatment delivery codes. However, in reviewing the comments, we did not identify any that address the fundamental issues we identified in the proposed rule. We understand that commenters generally agreed that image guidance was not necessarily typically used for conventional radiation treatment delivery services, so the related costs should not be embedded in the RVUs for the treatment delivery codes. We also understand that commenters recommended that we assume that image guidance costs, while integrated into the functionality of the linear accelerator, represent additional capital costs and should be used in the development of PE RVUs for these services. Despite these comments, we were unable to reconcile the inconsistencies and potential rank order anomalies associated with including the image guidance costs in the IMRT treatment delivery codes but not including the image guidance costs in the conventional radiation treatment delivery codes even though both use the same capital equipment. Based on the RUC recommendations and the information from the commenters, we understand that the same linear accelerator is typically used for all of these services, and that the image guidance is integrated into the only linear accelerator that is currently being manufactured and that, therefore, the image guidance costs should always be included in the RVUs for the IMRT treatment delivery codes. Based on these comments and the RUC-recommended values, it appears that when the same machine (with integrated image guidance) is used for intermediate and complex conventional treatment, the combination of the treatment costs and image guidance costs is significantly higher than the technical costs associated with IMRT treatment delivery furnished with image guidance. As a result, the PE RVUs for these services include higher overall payment for intermediate and complex conventional radiation treatment with imaging guidance than for simple IMRT treatment delivery with imaging guidance. After review of the comments, we continue to believe that this creates problematic rank order anomalies, both relative to the accuracy of the assumed costs and the financial incentives associated with Medicare paying more overall for conventional radiation treatment than for IMRT services.

Comment: Many commenters, including equipment manufacturers, suggested that linacs that include integrated image guidance are significantly more expensive than the $2.6 million CMS proposed in the direct practice expense input database. One commenter, a manufacturer of linear accelerators, submitted several invoices intended to indicate that the price of a new linear accelerator is significantly higher than the current price in the direct PE input database. This commenter suggested that this higher price was due in part to the integrated image guidance, inherent in all new linear accelerators. The commenter also submitted invoices intended to illustrate the price of upgrading an older linear accelerator with image guidance capability.

Response: We appreciate the submission of invoices that indicate prices for linear accelerators with image guidance and the price associated with updating existing linacs with image guidance. In our analysis of these documents, however, we identified several aspects that make us hesitant to use the documents to change the price of the equipment in the direct PE input database. First, many of the invoices listed a total contract value that was distinct from the sum of total prices listed on the invoice. The documents themselves did not include any explanation regarding the significant differences in value between these two prices and whether or not the differences in value represent costs related to other direct PE input equipment items, factors already incorporated into the equipment cost per minute calculation, or items included in the allocation of indirect PE. For example, some line items included the description of items such as ''travel and lodging,'' ''education,'' and treatment planning software or software upgrades that are already accounted for in the allocation of indirect PE. In many cases line-item prices were not included, making it difficult to identify the portion of the total invoice price attributable to direct equipment costs, which is necessary under the established PE methodology. Therefore, we will maintain the current equipment price for CY 2016 while we seek accurate information regarding the price of this capital equipment.

(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 would be 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 percent, 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 by the RUC, 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, we suggested in the proposed rule that 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. As we noted in the proposed rule, 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 proposed 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 proposed 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 how often the equipment is used in comparison to the previous assumption. In the proposed rule, we noted 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.

Comment: Several commenters objected to our analysis specifically because we described it as a ''rough reconciliation.''

Response: We appreciate commenters' interest in our use of the best data available in determining what values to assign to necessary assumptions. We regret the use of the term ''rough reconciliation'' and clarify that our analysis relied on two somewhat imprecise data points: The RUC procedure time assumptions for individual services and the current 50 percent utilization assumption. Because both of these assumptions directly determine how capital equipment costs are translated into PE RVUs, they were essential to our analysis. However, we recognize that these assumptions are round figures, reflecting assumptions about what is typical. Therefore, when we combined these numbers with precise Medicare claims data in order to develop a more accurate assumption, we arrived at a very specific number that might have appeared to be very precise. Recognizing that the calculation was based on assumptions as noted above, we subsequently proposed to round the number to 70 percent instead of using the fractional result of the calculation. We continue to believe rounding to 70 percent is appropriate for the reasons stated above.

Given the best available information, we believe that the 70 percent utilization assumption based on the changes in direct PE input recommendations and Medicare claims

data 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 are 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 assumptions (7 hours out of 10 available business hours per day).

For advanced diagnostic imaging services, we finalized a policy for CY 2010 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 noted in the proposed rule 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 assumed that the transition to use of a single kind of capital equipment would likely take place over seven years as individual pieces of equipment age into obsolescence. However, in the case of this transition in capital equipment, we have reason 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 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 proposed to use the 2013 recommendations for the CY 2016 PFS payment rates, we believed 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 recognized 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 the RUC and that the useful life of the newest generation of linear accelerator is seven 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 proposed to use a 60 percent utilization rate assumption for CY 2016 and a 70 percent utilization rate assumption for CY 2017. The proposed 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 proposed 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.

Comment: Most commenters were opposed to changing the default utilization assumption for linear accelerators. Many of these commenters stated that the rationale CMS used to support the change in default utilization assumption was inadequate and anecdotal. Several commenters performed and submitted their own data analyses.

Response: We continue to believe a reconciliation of Medicare claims data with the RUC-recommended procedure times results in the most accurate equipment utilization rate assumption. We also believe that whenever possible we should use the Medicare claims data to test the validity and internal consistency of our ratesetting assumptions. We do not agree with the commenters that such an approach is anecdotal. While CMS appreciates the analyses performed by some commenters, no additional data were submitted to substantiate these analyses.

Comment: One commenter conducted an analysis somewhat similar to ours, but used three data sets: Medicare claims data, the ASRT staffing survey CMS referenced in the proposed rule, and data from the CMS physician billing public use database. Based on this analysis, the commenter suggested that 50 percent is a more accurate utilization assumption.

Response: We appreciate the commenter's analysis, and found it to be very useful in considering whether or not to finalize our proposal. However, the commenter's conclusion of a 50 percent utilization rate is entirely dependent on what we believe is an overestimate of the number of linacs used to deliver radiation treatment. In order to determine the number of linacs overall, the commenter multiplied the 2.3 linacs per center statistic cited in the ASRT staffing survey by the number of individual billing entities reporting treatment services in the Medicare claims data as a proxy for the number of freestanding centers. That approach would count two radiation oncologists reporting services in the same center as if they were practicing in two centers, not one, and therefore overestimate the number of machines. Were the same analysis conducted using the number of centers included in the same ASRT staffing survey, the result of the analysis would be an approximately 70 percent equipment utilization rate. Therefore, we did not find the commenter's analysis persuasive.

Comment: Many commenters stated that a 70 percent utilization rate assumption did not take into account events beyond the control of the facility that could impact how long any given linear accelerator might be used over the course of time. These commenters suggested that issues such as time necessary to warm up the treatment machine, maintenance, patient preferences, missed appointments, and multiple treatment devices contributed to a lower utilization rate that CMS proposed to assume.

Response: We understand that the day-to-day operation and utilization of capital equipment will vary, and that is precisely why the equipment cost per minute calculation does not assume that the equipment is used for the full amount of time possible (100 percent rate). Instead, the utilization rate assumption is used to allocate the total cost of the equipment relative to other

direct PE costs on a per-minute basis. Therefore, the assumptions are intended to reflect the percentage of total time (assuming a 50-hour work week) payment is made for services on the machine. In assigning minutes to individual codes, we generally assign minutes for preparing and cleaning the equipment; therefore, these minutes would contribute to the 70 percent portion, or 35 hours per week. In contrast, minutes for a missed appointment would count toward the 30 percent of the 50 hours, or 15 hours per week, that the equipment is not being used.

Comment: Many commenters were concerned that a higher utilization rate assumption would have a negative effect on rural treatment centers and treatment centers in medically disadvantaged areas.

Response: We believe it is important to preserve access to care for all Medicare beneficiaries. However, we believe we are obligated under the statute to use accurate assumptions in developing RVUs for individual services under the PFS. Under the statutory construct of the PFS, we believe that accurate valuation for all PFS services is important in maintaining access to care for all Medicare beneficiaries.

Comment: A few commenters suggested that CMS should phase in the utilization rate change over four years or delay implementing the change until 2017.

Response: We appreciate the commenters' suggestions. We did consider these suggested alternatives as part of our rulemaking process. Although both a longer phase-in and a delay would temporarily mitigate the payment reductions for these services, especially in the context of other proposed payment reductions, we did not identify any persuasive rationale for delaying implementation or phasing in implementation over more than 2 years.

Comment: Many commenters were concerned that the change in utilization rate assumption was affecting all equipment items in the radiation treatment delivery codes, and argued that it should only apply to the linac. Commenters urged CMS to use a 50 percent utilization rate assumption for the other equipment items. Some commenters argued that this was contradictory to the utilization assumption for advanced diagnostic imaging.

Response: We applied the increased utilization rate assumption across all equipment items under the assumption that items generally located in the same room as the linear accelerator could not be used to furnish other services while the linear accelerator was in use, and therefore, would be subject to the same utilization assumptions. This approach is consistent with the application of the equipment utilization assumption for advanced diagnostic imaging.

Comment: MedPAC expressed support for CMS' proposal to change the equipment utilization rate assumption for linear accelerators. MedPAC agreed that CMS should develop a normative standard based on the assumption that those who purchase an expensive piece of capital equipment would use it at a higher utilization rate.

Response: We appreciate MedPAC's support for the proposal.

(3) Other Equipment Cost Variables

Comment: A few commenters suggested that CMS update the price for the radiation treatment vault to approximately $800,000 and reduce the useful life assumption from 15 to 7 years. Several other commenters suggested that CMS update the variable maintenance rate from the default five percent assumption to between 10 and 15 percent.

Response: We appreciate the commenter's feedback, and acknowledge our longstanding concerns regarding obtaining accurate, objective information regarding the pricing of direct PE inputs, particularly the prices for expensive equipment. In the case of the radiation treatment vault, we believe that at least some portions of the costs associated with the vault construction are indirect PE under the established methodology. We will continue to consider this issue, including these commenters' suggestion to use increased pricing for the item.

Comment: Many commenters disagreed with the classification of ''intercom'' as an indirect PE. These commenters stated that the intercom is specifically for the practitioner to communicate directly with the patient and, as such, it constitutes a direct PE.

Response: We remind the commenter that under the established methodology, direct PE inputs are defined as clinical labor, disposable supplies, and medical equipment. Other items are incorporated as indirect costs, regardless of how the items are used.

Comment: Several commenters, including the AMA RUC, stated that CMS should include 2 minutes for the clinical labor task ''dose output and verification'' as it is performed on the equipment items associated with these codes.

Response: ''Dose output and verification'' occurs during the ''pre-service'' period and pre-service minutes are generally not allocated to the equipment items, under our established methodology.

(4) Specialty Impacts

Comment: One commenter stated that CMS should no longer display specialty level impacts for ''radiation therapy centers'' in the proposed and final rule. The commenter argued that since the PFS allowed charges associated with ''Radiation Therapy Centers'' represent only a small portion of radiation oncology services overall, displaying the impacts separately is misleading to the interested public.

Response: We appreciate the commenter's concerns and agree with commenters that the PFS allowed charges associated with ''radiation therapy centers'' is only a small portion of overall payments for radiation oncology services, including the total amount of those furnished outside of the hospital setting. Because we think it is important to maintain a consistent display of specialty-level impacts between a proposed and final rule, we are not making a change for this year's final rule. However, we are seeking additional comment regarding how the impacts for these services should be displayed in future rulemaking.

(5) Implementation of New Coding

Comment: Several commenters expressed concerns about the two new treatment delivery codes describing simple and complex IMRT treatment delivery in contrast to the current single code. Specifically, these commenters were concerned that that the CPT instruction that requires treatment for prostate and breast cancer to be reported using the simple IMRT treatment delivery code would have a negative impact on overall treatment for patients with prostate and breast cancer. These commenters suggested that that the new coding structure did not allow radiation therapy providers to accurately report prostate and breast cancer treatment services that are more resource intensive than those described in the simple IMRT code. These commenters also stated that the coding change including CMS' proposed valuations would have a widespread negative impact on access to care, including reduction in the number of freestanding centers offering radiation treatment for breast and prostate cancer, and therefore limit patients' access to care outside of the higher cost hospital setting.

Response: We believe that increased specificity in coding for such a resource-intensive, high-volume group of services is a significant improvement compared to the use of a single code to describe all IMRT treatment services, regardless

of their relative resource costs. However, we understand the commenters' concerns about the potential negative impact of implementing the new code set for payment of treatment for breast and prostate cancers. The primary resource cost for these services is represented by the capital equipment, so we believe that for purposes of most accurate payment, the optimal coding for these services would group them based on how long the capital equipment is being used per service, so that payment is linked to the resource costs of furnishing particular services. Under the current set of codes, payment would be made based on the assumptions regarding the typical resource costs for the treatment of particular diseases, instead of the resource costs based on the length of treatment time.

Comment: Several commenters pointed out a rank order anomaly in the PE RVUs among codes CPT codes 77402, 77407, and 77412 that describe simple, intermediate, and complex radiation treatment codes, respectively. The commenters stated that it was illogical for the intermediate radiation treatment delivery code to have higher PE RVUs and overall payment compared to the complex radiation treatment delivery. Commenters suggested that this anomaly may be the result of the allocation of indirect PE because the specialty reporting the utilization for the intermediate code is more frequently dermatology than radiation oncology and dermatology is allocated more indirect PE within the PE methodology.

Response: We agree with commenters that this rank order anomaly is due to the difference in the mix of specialties in the utilization for these services. We also agree with the commenters that such rank order anomalies within families should be avoided when possible. We believe these kinds of rank order anomalies generally suggest inaccurate valuations and present risks to accurate billing and overall ratesetting. The risks are associated with incentives toward inaccurate downward coding. For example, in this case, individual practitioners would have the financial incentive to report radiation treatment delivery services using the intermediate code, even when the complex code would be more accurate. If practitioners acted on such an incentive, there would be serious consequences within our ratesetting methodologies for both purposes of budget neutrality and for allocation of PE RVUs. The increased utilization of the higher paying intermediate code would result in inappropriately low budge neutrality adjustment across the PFS. The rank order anomaly might also result in cyclical fluctuations in the year-to-year allocation of PE. This would happen if the inappropriate reporting of the intermediate code itself resulted in a concentration of most of the overall volume (including radiation oncology at a greater volume than dermatology) in the intermediate code. Then, once the claims data reflecting this concentration were incorporated into PFS ratesetting, the rank order anomaly would recur and the cycle would begin again. In considering these comments in the context of our proposal to implement these codes, we considered how we might eliminate this anomaly. We concluded that the best approach would be to maintain the total number of PE RVUs for these services overall, but to redistribute them among the three codes in order to eliminate the rank order anomaly. In order to do this, we would calculate the PE RVUs for these services under the established methodology and multiply these RVUs by the volume associated with each code. We would then reallocate the total number of PE RVUs among the three codes based on the weights of their direct costs included in the direct PE input database, since the total direct costs for these codes reflect appropriate valuation. We are seeking comment on this approach or other possible ways to mitigate the impact of the rank order anomaly among these codes.

Comment: One commenter stated that, in light of the significant negative impact of the coding changes and the proposed change in the default utilization rate assumption, CMS should delay implementation of the new codes for another year and work with stakeholders to gather information on the appropriate pricing of equipment items, utilization of equipment, and coding structure. A few commenters also stated that CMS should consider pricing radiation treatment delivery through the OPPS. And finally, several commenters noted that the proliferation of TC-only codes had a negative impact on the overall allocation of PE RVUs for radiation oncology services.

Response: We agree with commenters regarding the magnitude of changes that would result from the new code set. In general, we believe that significant changes in coding can improve the valuation and payment for PFS services. In the case of this set of new codes, we believe increased granularity in IMRT treatment delivery codes would benefit payment accuracy. We also believe that it is generally preferable for CMS to use CPT codes to describe physicians' services paid under the PFS and that, when possible, we should use consistent coding between the PFS and OPPS.

In consideration of comments from stakeholders and our concerns as described above, however, we do not believe that, on balance, we should finalize the new code set for CY 2016. Therefore, for CY 2016, we are not finalizing our proposal to implement the new set of codes. We will continue the use of the current G-codes and values for CY 2016 while we seek more information, including public comments and recommendations regarding new codes to be developed either through the CPT process or through future PFS rulemaking. We believe that significant changes to the codes need to be made before we can develop accurate payment rates under the PFS for these services. These changes would include: developing a code set that recognizes the difference in costs between kinds of imaging guidance modalities; making sure that this code set facilitates valuation that incorporates the cost of imaging based on how frequently it is actually provided; and developing treatment delivery codes that are structured to differentiate payment based on the equipment resources used.

While we are not finalizing the new code set for these services, we are finalizing our proposals to include the single linear accelerator for radiation treatment delivery services as recommended by the RUC, and to update the default utilization rate assumption for linear accelerators used in radiation treatment services from 50 to 70 percent, phased in over 2 years. Under either set of codes, it is clear that the 50 percent utilization assumption is incompatible with the times used to develop payment rates for individual procedures, given that the same linear accelerator is used for the services.

Finally, because the costs of capital equipment are the primary drivers of RVUs and payment amounts for these services, and we acknowledge significant difficult in obtaining quality information regarding the actual costs of such equipment across the wide range of practitioners and suppliers that furnish these services, we will be engaging in market research to develop independent estimates of utilization and pricing for linear accelerators and image guidance used in furnishing radiation treatment services. We will also consider ways in which data collected from hospitals under the OPPS may be helpful in establishing rates for these and other technical component services. We will consider this information, including public comment, as we develop proposals for inclusion in future notice and comment rulemaking.

(6) Superficial Radiation Treatment Delivery

In the CY 2015 PFS final rule with comment period, we noted that changes to the CPT prefatory language modified the services that are appropriately billed using 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 CPT code 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 work and PE components for CPT 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 CPT code 77401, and practitioners were precluded from reporting these activities separately, additional 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 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. Finally, stakeholders 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.

In response, we solicited recommendations from 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. We believe it would be appropriate to address the clinical labor assigned to the code in the context of the information regarding the work that might be associated with the service. We also solicited information on the possible inclusion of nurse time for this service as part of the comments and/or recommendations regarding work for the service. Lastly, we reviewed the invoices submitted in response to our request to update the capital equipment for the service.

We proposed to update the equipment item ER045 ''orthovoltage radiotherapy system'' by renaming it ''SRT–100 superficial radiation therapy system'' and update the price from $140,000 to $216,000, on the basis of the submitted invoices. The proposed PE RVUs displayed in Addendum B on the CMS Web site were calculated with this proposed modification that was displayed in the CY 2016 direct PE input database.

Comment: Multiple commenters from various specialty societies responded to our request for comment. Several stated that there was work in 77401, while other commenters stated that there was not. One commenter suggested that CMS create a G-code to account for work, while another commenter stated that 77401 should be resurveyed by the RUC.

Response: Given the disagreement among commenters on the work involved in furnishing CPT code 77401, we are considering the possibility of creating a code to describe total work associated with the course of treatment for these services and are seeking additional information on alternatives descriptions and valuations for a code describing this work for consideration in future rulemaking.

Comment: A few commenters pointed out that the description of equipment item ER045 as proposed, ''SRT–100 superficial radiation therapy system,'' is a particular item that might better be identified generically as ''superficial radiation therapy system.''

Response: We agree with the commenter's suggestion and have updated the direct PE input database accordingly.

Comment: A few commenters thanked CMS for updating the price of the superficial radiation therapy system.

Response: We appreciate the support for our proposal.

After considering the comments, we are finalizing the update to ER045 as proposed.

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.

In the CY 2016 PFS proposed rule, for CY 2016 we proposed 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 proposed to adopt the RUC-recommended values (work RVUs, time, and direct PE inputs) for CPT codes 99497 and 99498 beginning in CY 2016. The services could be paid on the same day or a different day as other E/M services. Physicians' services are covered and paid by Medicare in accordance with section 1862(a)(1)(A) of the Act. Therefore, under our proposal CPT code 99497 (and CPT code 99498 when applicable) would 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 E/M of these two

diseases, including adjusting medications as appropriate. In addition to discussing the patient's short-term treatment options, the patient may express 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 solicited comment on this proposal, including whether payment is needed and what type of incentives the proposal might create. In addition, we solicited 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.

We received approximately 725 public comments to the proposed rule regarding payment for ACP services. We received comments from individual citizens; several coalitions; professional associations; professional and community-based organizations focusing on end-of-life health care; healthcare systems; major employers; and many individual healthcare professionals working in primary care, geriatrics, hospice/palliative medicine, critical care, emergency medicine and other settings. We also received comments from chaplains, ethicists, advanced illness counseling companies and other interested parties. The majority of commenters expressed support for the proposal, providing recommendations on valuation, the types of professionals who should able to furnish or bill for the services and the appropriate setting of care, intersection with existing codes, the establishment of standards or specialized training, and beneficiary cost sharing and education. Some commenters opposed or expressed provisional support for the proposal because they believed it might create perverse financial incentives relating to termination of patient care. We summarize all of the comments below.

Valuation

Comment: Many commenters supported the separate identification and payment for ACP, either by adopting CPT codes 99497 and 99498 or other unique code(s). Many commenters supported the proposal broadly, advocating for improved Medicare coverage and payment of ACP. Several commenters supported our proposal to adopt the RUC-recommended payment inputs. Several other commenters stated the proposed payment amount was insufficient, and one of these commenters recommended a payment rate equal to the payment for CPT code 99215 (Office or other outpatient visit for the E/M of an established patient) in order to appropriately account for the physician's time.

Response: We appreciate the commenters' support for separate identification and payment for voluntary ACP services. We believe the RUC-recommended inputs accurately reflect the resource costs involved in furnishing the services described by CPT codes 99497 and 99498, and therefore, are finalizing our proposal to adopt the RUC-recommended values for both codes.

Comment: Regarding the time required to furnish ACP services, the commenters cited times ranging from 10 minutes to several hours over multiple encounters, depending on the setting and the patient's condition. Several commenters requested payment for increments of time of less than 30 minutes (for example, 10–15 minutes). One said the services typically require 30–45 minutes of face-to-face time with the patient and family. Several commenters recommended payment for services lasting less than 30 minutes, for example, by pro-rating the add-on code.

Response: We believe the CPT codes describe time increments that are appropriate for furnishing ACP services in various settings. Therefore we are finalizing our proposal to adopt the CPT codes and CPT provisions regarding the reporting of timed services.

Comment: Many commenters recommended that CMS issue a national coverage decision to avoid any local variation in coverage.

Response: We believe it may be advantageous to allow time for implementation and experience with ACP services, including identification of any variation in utilization, prior to considering a controlling national coverage policy through the National Coverage Determination process (see 78 FR 48164, August 7, 2013). By including ACP services as an optional element of the AWV (for both the first visit and subsequent visits), as discussed below, this rule creates an annual opportunity for beneficiaries to access ACP services should they elect to do so.

Comment: Many commenters recommended limits on utilization to prevent abuse, while others recommended no utilization limits in order to increase access and ensure periodic updates to advance care plans. Several commenters were concerned that the lack of utilization limits would lead to practitioners harassing patients.

Response: In general, we do not agree with the commenters who suggested that this service is more likely to be subject to overutilization or abuse than other PFS services without our adoption of explicit frequency limitations. We believe the CPT codes describe time increments that are appropriate for furnishing ACP services in various settings. Therefore, we are finalizing our proposal to adopt the CPT codes and CPT provisions regarding the reporting of timed services. Since the services are by definition voluntary, Medicare beneficiaries may decline to receive them. When a beneficiary elects to receive ACP services, we encourage practitioners to notify the beneficiary that Part B cost sharing will apply as it does for other physicians' services (except when ACP is furnished as part of the AWV, see the discussion below). We plan to monitor utilization of the new CPT codes over time to ensure that they are used appropriately.

Intersection With Other Services

Comment: Many commenters supported our proposal to pay for ACP services when furnished either on the same day or a different day than other E/M services. Several commenters asked CMS to specify whether and how the ACP codes could be billed in conjunction with E/M visits or services that span a given time period, such as 10- or 90-day global codes or Transitional Care Management (TCM) and Chronic Care Management (CCM) services. One commenter recommended that CMS unbundle ACP services from critical care services and pay at a higher rate, but did not suggest an alternative payment amount.

Response: We believe that CPT guidance for these codes is consistent with the description and recommended valuation of the described services. When adopting CPT codes for payment, we generally also adopt CPT coding guidance. In this case, CPT instructs that CPT codes 99497 and 99498 may be billed on the same day or a different day as other E/M services, and during the same service period as TCM or CCM services and within global surgical periods. We are also are adopting the CPT guidance prohibiting the reporting of CPT codes 99497 and 99498 on the same date of service as certain critical care services including neonatal and pediatric critical care.

Who Can Furnish/Setting of Care

Comment: Many commenters who supported the proposal provided recommendations regarding which practitioners and support staff should be able to provide or be paid for ACP services. Many commenters sought clarification regarding who would qualify as the ''other health care professionals'' described by or able to bill the CPT codes. Many commenters described ACP services as being routinely provided by a multidisciplinary team under physician supervision. For example, they stated that ACP is routinely provided by physicians, non-physician practitioners and other staff under the order and medical management of the beneficiary's treating provider. They stated that often a team approach is used, involving coordination between the beneficiary's physicians, non-physician practitioners (such as licensed clinical social workers or clinical nurse specialists) and other licensed and credentialed hospital staff such as registered nurses.

Similarly, other commenters described social workers, clinical psychologists, registered nurses, chaplains and other individuals as appropriate providers of ACP services, either alone or together with a physician, and recommended payment for the services of these individuals. For example, one commenter stated that a significant portion of ACP discussions occur between patients and registered nurses or allied health professionals functioning as care coordinators, care navigators or similar roles; that a growing proportion are performed at home; and that CMS should enable care coordinators and navigators to bill the ACP codes either by defining them as ''other qualified health professionals'' or under ''incident to'' provisions.

Some commenters specifically recommended allowing social workers and chaplains qualified under the hospice benefit to bill the ACP codes. One community oncologist association stated that best practices have evolved to include a multi-disciplinary approach utilizing trained physician, advanced practice provider and social worker skill sets, and that nearly half of their oncology network's ACP is performed by licensed clinical social workers. This commenter stated that while it is typical for a physician to initiate the ACP discussion with patients, ACP usually occurs with a mid-level provider or social worker and therefore the association requested that CMS allow clinical social workers to bill for these services. Another national association stated that it was working towards the development of new CPT codes for practitioners such as social workers who the commenter believed would not be able to directly bill the proposed codes.

Some commenters argued that such non-medically trained individuals are qualified and have special training and expertise (whether psychosocial, spiritual or legal) that are needed on ACP care teams. Some believed that ACP is sometimes appropriate for physicians to perform, but that physicians do not have enough time to supply all of the demand for ACP services. Some commenters similarly argued that inclusion of social workers and other non-medically trained individuals including Spiritual Directors, Chaplains, Clinical Pastoral Counselors and others would alleviate concerns about undue influence over patient decisions. These commenters stated that part of the ACP conversation is emotional and spiritual and not merely clinical, so it is important to include individuals who can address the non-clinical aspect of ACP. Some commenters argued that widening the field of professionals who can initiate these conversations within their scope of practice will further encourage appropriate and frequent ACP. Several commenters stated that physicians should not be paid for ACP services due to an ethical or financial conflict of interest, and that communities should take more responsibility for these services.

In contrast, several commenters were concerned that allowing ACP to be paid to certain trained facilitators would undermine physician authority in treating patients. These commenters described the use of trained facilitators in certain community models that offer group discussions by trained lay and health professionals. These commenters were concerned that such facilitators would qualify as ''other qualified professionals'' under the CPT code descriptor and be given control over ACP, shaping physician behavior. One commenter stated that to prevent coercion of patients, it would be better if payment was limited to non-employees of hospitals.

Response: We appreciate the many comments we received on existing or recommended practice patterns for the provision of ACP services. We acknowledge the broad range of commenters that stated that the services described by CPT codes 99497 and 99498 are appropriately provided by physicians or using a team-based approach provided by physicians, non-physician practitioners and other staff under the order and medical management of the beneficiary's treating physician. We note that the CPT code descriptors describe the services as furnished by physicians or other qualified health professionals, which for Medicare purposes is consistent with allowing these codes to be billed by the physicians and NPPs whose scope of practice and Medicare benefit category include the services described by the CPT codes and who are authorized to independently bill Medicare for those services. Therefore only these practitioners may report CPT codes 99497 or 99498. We note that as a physicians' service, ''incident to'' rules apply when these services are furnished incident to the services of the billing practitioner, including a minimum of direct supervision. We agree with commenters that advance care planning as described by the proposed CPT codes is primarily the provenance of patients and physicians. Accordingly we expect the billing physician or NPP to manage, participate and meaningfully contribute to the provision of the services, in addition to providing a minimum of direct supervision. We also note that the usual PFS payment rules regarding ''incident to'' services apply, so that all applicable state law and scope of practice requirements must be met in order to bill ACP services.

Comment: Several commenters recommended that CMS not require direct supervision for ACP services or allow it to be furnished ''incident to'' under general supervision.

Response: As discussed above, we understand that the services described by CPT codes 99497 and 99498 can be provided by physicians or using a team-based approach where, in addition to providing a minimum of direct supervision, the billing physician or NPP manages, participates and meaningfully contributes to the provision of the services. We note that the ''incident to'' rules apply when these services are provided incident to the billing practitioner, including direct supervision. We do not believe it would be appropriate to create an exception to allow these services to be furnished incident to a physician or NPP's professional services under less than direct supervision because the billing practitioner must participate and meaningfully contribute to the provision of these face-to-face services.

Comment: Many commenters made recommendations regarding the settings of care that would be appropriate for payment of ACP services. Some of these commenters specified that payment should be made in both ambulatory and inpatient settings. Many commenters stated that ACP is ideally performed in

a primary care setting, where the patient has a longstanding relationship with a physician and can engage in planning prior to illness, at which time they may be most receptive and most likely to have full decision making capacity. However many commenters believed payment was also appropriate in inpatient and other acute care settings. A few commenters recommended payment for an outpatient code or a code that would not be payable in the intensive care setting. Some commenters recommended that ACP should only be payable in clinical settings and that CMS should explicitly exclude group information sessions and similar offerings. Commenters stated that patients should be able to choose any location for ACP services including at home; in community-based settings; or via telehealth, telephone or other remote technologies. A few commenters were concerned that CMS might limit payment to certain specialists and recommended against such a policy.

Response: We agree with commenters that ACP services are appropriately furnished in a variety of settings, depending on the condition of the patient. These codes will be separately payable to the billing physician or practitioner in both facility and non-facility settings and are not limited to particular physician specialties. We refer commenters to the CY 2016 hospital outpatient prospective payment system final rule with comment period for a discussion of how payment will be made to hospitals for ACP services furnished in hospital outpatient departments.

Comment: Many commenters supported payment for ACP along the entire health continuum, in advance of acute illness, and revisiting the advance care plan with changes in the patient's condition. These commenters stated ACP is a routine service that should be regularly performed like preventive services. These commenters responded affirmatively to our solicitation as to whether or not ACP services should be included as an optional element, at the beneficiary's discretion, of the annual wellness visit (AWV) under section 1861(hhh)(2)(G) of the Act. Several of these commenters specified that ACP should remain separately paid even if included as an optional element of the AWV.

Response: We appreciate the response of commenters regarding our request for comment on whether or not we should include ACP as an optional element, at the beneficiary's discretion, of the annual wellness visit (AWV) under section 1861(hhh)(2)(G) of the Act. Based on the commenters' positive response to this solicitation, we are adding ACP as a voluntary, separately payable element of the AWV. We are instructing that when ACP is furnished as an optional element of AWV as part of the same visit with the same date of service, CPT codes 99497 and 99498 should be reported and will be payable in full in addition to payment that is made for the AWV under HCPCS code G0438 or G0439, when the parameters for billing those CPT codes are separately met, including requirements for the duration of the ACP services. Under these circumstances, ACP should be reported with modifier -33 and there will be no Part B coinsurance or deductible, consistent with the AWV.

Regarding who can furnish ACP when it is furnished as an optional element of the AWV, we note that AWV cannot be furnished as an ''incident to'' service since the AWV has a separate, distinct benefit category from ''incident to'' services. However, the current regulations for the AWV allow the AWV to be furnished under a team approach by physicians or other health professionals under direct supervision. Therefore, the rules that apply to the AWV will also apply to ACP services when furnished as an optional element of the AWV, including the requirement for direct supervision.

Comment: We received several comments requesting that ACP be added as a billable visit for FQHCs, and several comments requesting that we ensure that Medicare Administrative Contractors (MACs) are aware that a standalone ACP counseling session with an FQHC billable provider qualifies as a ''billable visit'' under Medicare's Prospective Payment System (PPS) for FQHCs.

Response: RHCs and FQHCs furnish Medicare Part B services and are paid in accordance with the RHC all-inclusive rate system or the FQHC PPS. Beginning on January 1, 2016, ACP will be a stand-alone billable visit in a RHC or FQHC, when furnished by a RHC or FQHC practitioner and all other program requirements are met. If furnished on the same day as another billable visit, only one visit will be paid. Coinsurance will be applied for ACP when furnished in an FQHC, and coinsurance and deductibles will be applied for ACP when furnished in an RHC. Coinsurance and deductibles will be waived when ACP is furnished as part of an AWV. Additional information on RHC and FQHC billing of ACP will be available in sub-regulatory guidance.

Standards/Training

Comment: Many commenters recommended that CMS establish standards or require specialized training as a condition of payment for ACP services. Many commenters recommended standards or special training in relevant state law and advance planning documents; content and time; communication, representation, counseling, shared decision making and skills outside the scope of physician training. Several commenters recommended standards regarding the use of certified electronic health record technology; contractual or employment relationships with nurses, social workers and other clinical staff working as part of an ACP team; use of written protocols and workflows to make ACP part of routine care; and working with professional societies and other organizations including the National Quality Forum and the Agency for Healthcare Research & Quality to establish quality standards for clinician-patient communication and ACP that would be tied to payment. Many commenters recommended policies to ensure documentation and transmission of the results of ACP among health care providers. Some of these commenters encouraged CMS to use technology to enhance the use and portability of advance directives across care settings and state lines, or recommended a universal registry.

Several commenters were concerned about the nature of the services that would be payable under the proposed codes, noting that ACP should extend beyond education about advance directives and completing forms. Several recommended the development of content criteria or quality measures to ensure that ACP services are meaningful and of value to patients. Some commenters expressed concern about ensuring appropriate services were furnished as part of ACP. For example, they expressed concern that payable services would include mere group information sessions, filling out forms or similar offerings. One commenter recommended that CMS require some minimal element like one personal real-time encounter, whether face-to-face or by phone or telemedicine.

Response: Since CPT codes 99497 and 99498 describe face-to-face services, we do not believe it would be appropriate at this time to apply additional payment standards as we have for certain non-face-to-face services such as CCM services. We will continue to consider whether additional standards, special training or quality measures may be appropriate in the future as a condition of Medicare payment for ACP services. We note that we did not propose to add ACP services to the list of Medicare telehealth services, so the face-to-face

services described by the codes need to be furnished in-person in order to be reported to Medicare.

Comment: Several commenters supported advance care planning between patients and clinicians, but expressed concern about the potential for bias against choosing treatment options involving living with disability, requiring physicians to discuss questionable treatment options (such as physician assisted suicide or other patient choices that might violate individual physician ethics) and similar issues. Some commenters were concerned that patients might change their decisions once care was actually needed and be unable to override previous advance directives; or that the government would be making healthcare decisions instead of patients, physicians, and families.

Response: As discussed above, based on public comments we received, we believe the services described by CPT codes 99497 and 99498 are appropriately provided by physicians or using a team-based approach where ACP is provided by physicians, non-physician practitioners and other staff under the order and medical management of the beneficiary's treating physician. We also note that the CPT code descriptors describe the services as furnished by physicians or other qualified health professionals, which for Medicare purposes, is consistent with allowing these codes to be billed by the physicians and NPPs whose scope of practice and Medicare benefit category include the services described by the CPT codes and who are authorized to independently bill Medicare for those services. Therefore only these practitioners may report CPT codes 99497 or 99498, and ''incident to'' rules apply when these services are provided incident to the services of the billing practitioner under a minimum of direct supervision. We agree with commenters that advance care planning as described by the new CPT codes is primarily the provenance of patients and physicians. Accordingly we expect the billing physician or NPP, in addition to providing a minimum of direct supervision, to manage, participate and meaningfully contribute to the provision of the services. Also, we note that PFS payment rules apply when ACP is furnished incident to other physicians' services, including where applicable, that state law and scope of practice must be met. Since the ACP services are by definition voluntary, we believe Medicare beneficiaries should be given a clear opportunity to decline to receive them. We note that beneficiaries may receive assistance for completing legal documents from other non-clinical assisters outside the scope of the Medicare program. Nothing in this final rule with comment period prohibits beneficiaries from seeking independent counseling from other individuals outside the Medicare program—either in addition to, or separately from, their physician or NPP.

Beneficiary Considerations

Comment: Several commenters suggested that CMS pursue waivers of cost sharing for ACP services or that cost sharing should vary by the condition of the patient.

Response: We lack statutory authority to waive beneficiary cost sharing for ACP services generally because they are not preventive services assigned a grade of A or B by the United States Preventive Services Task Force (USPSTF); nor may CMS vary cost sharing according to the patient's diagnosis. Under current law, the Part B cost sharing (deductible and coinsurance) will be waived when ACP is provided as part of the AWV, but we lack authority to waive cost sharing in other circumstances. We would recommend that practitioners inform beneficiaries that the ACP service will be subject to separate cost sharing.

Comment: One commenter recommended beneficiary education through *Medicare & You*, partnerships with senior advocacy groups and other means.

Response: We agree that beneficiary education about ACP services, especially the voluntary nature of the services, is important. We welcome such efforts by beneficiary advocacy and community-based organizations and will consider whether additional material should be added to the *Medicare & You* handbook to highlight new payment provisions for these voluntary services.

In summary, we are finalizing our proposal to assign CPT codes 99497 and 99498 PFS status indicator ''A'' with RVUs developed based on the RUC-recommended values. We are also adding ACP as an optional element, at the beneficiary's discretion, of the AWV. We are also making the conforming changes to our regulations at § 410.15 that describe the conditions for and limitations on coverage for the AWV.

We note that while some public commenters were opposed to Medicare paying for ACP services, the vast majority of comments indicate that most patients desire access to ACP services as they prepare for important medical decisions.

d. Valuation of Other Codes for CY 2016

(1) Excision of Nail Bed (CPT Code 11750)

CPT code 11750 appeared on the RUC's misvalued code screen of 10-day global services with greater than 1.5 office visits and utilization over 1,000. The Health Care Professional Advisory Committee (HCPAC) reviewed the survey results for valuing this code and determined that 1.99 work RVUs, corresponding to the 25th percentile survey result, was the appropriate value for this service. As discussed in the proposed rule, we indicated that we believed the recommendation for this service overstated the work involved in performing this procedure, specifically, given the decrease in post-operative visits. Due to similarity in service and time, we indicated that we believed a direct crosswalk from the work RVU for CPT code 10140 (Drainage of blood or fluid accumulation), which is also a 10-day global service with one post-operative visit, more accurately reflects the time and intensity of furnishing the service. Therefore, for CY 2016 we proposed a work RVU of 1.58 for CPT code 11750.

The following is a summary of the comments we received on our proposal.

Comment: One commenter disagreed with CMS' direct crosswalk of the work RVU from CPT code 10140 to CPT code 11750. The commenters suggested that CMS establish the RVU for this procedure consistent with the recommendation. Additionally, the commenter stated that the HCPAC recommendation accounted for the removal of one post-operative visit from the global period. The commenter also stated that CMS' proposed work RVU would have an intraservice work intensity similar to a level one E/M visit (99211), which suggests that the value is too low.

Response: In developing our proposed RVUs for this service, we reviewed codes with similar intra-service and total times, and identified CPT code 11760 (Repair of nail bed) and CPT code 11765 (Excision of nail fold toe). Since we believe that the crosswalk for CPT code 11750 has similar intensity, and our proposed RVU is consistent with these similar services, we do not agree with the commenter who states that the proposed work RVU is inaccurate.

After consideration of comments received, we are finalizing a work RVU of 1.58 for CPT code 11750, as proposed.

(2) Bone Biopsy Excisional (CPT Code 20240)

In its review of 10-day global services, the RUC identified CPT code 20240 as potentially misvalued. Subsequent to this identification, the RUC requested that CMS change this code from a 10-day global period to a 0-day global period for this procedure. Based on 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. In the proposed rule, we stated that we did not believe the RUC recommendation accurately reflected the work involved in this procedure, especially given the decrease in intraservice time and post-operative visits relative to the previous assumptions used in valuing the service. Therefore, for CY 2016, we proposed a work RVU of 2.61 for CPT code 20240 based on the reductions in time for the service.

The following is a summary of the comments we received on our proposal.

Comment: Several commenters, including the RUC, recommended that CMS reconsider its decision not to accept the RUC's recommendation for CPT code 20240. The commenters noted that the service was last valued by the Harvard study over 20 years ago and the assumptions made at the time no longer reflect current practice as the survey respondents included fewer than 10 non-orthopedic surgeons. Commenters stated that podiatry is currently the dominant provider of the service. Commenters also stated that deriving a new proposed work RVU based on existing work RVUs would be misguided in this case.

The commenters also suggested that using a reverse building block methodology to convert a 10-day global code to 0-day global code by removing the bundled E/M services is inappropriate since magnitude estimation was used initially when establishing the work RVUs for surgical codes. Several commenters indicated that CMS' proposed work RVU has inappropriately low work intensity and expressed concern about CMS' approach to global code conversion.

Additionally, the RUC expressed disagreement with CMS' decision to remove 6 minutes of clinical labor minutes for discharge management time from 0-day global services stating there is clinical staff time that needs to be accounted for; the commenter requested we include the 6 minutes of clinical labor time based on the standard clinical labor task ''conduct phone calls/call in prescriptions.''

Response: In proposing what we believed to be a more accurate value for CPT code 20240, we considered applying the intra-service ratio, which yielded a value of 2.52 RVUs; however we believed that value would have inadequately reflected the work involved in furnishing the service. Instead, we opted to use the reverse building block methodology to remove the post-operative visits, acknowledging the transition from a 10-day to a 0-day global period. We removed the RVUs associated with the visits (1.12 RVUs) from the RUC-recommended value of 3.73 RVUs and arrived at an RVU of 2.61, which we continue to believe accurately accounts for work involved in furnishing the service. While we generally understand that the work RVUs may not have been developed using a building-block methodology, and that the reverse building block methodology may not always be the best approach to valuing services, we do not agree that significant changes in the post-operative period should be ignored, especially since we note that the RUC uses magnitude estimation to develop recommended work RVUs in the context of survey data regarding the number and level of visits in the post-operative periods.

In terms of the clinical labor minutes associated with the discharge day management, we do not agree that the typical discharge work associated for this service or for others without work time for discharge day management would typically involve clinical staff conducting phone calls regarding prescriptions. We are aware that some codes include the clinical labor minutes for discharge management even though the work time for these codes do not include time for discharge management. We are seeking comment on how we might address this discrepancy in future rulemaking.

After consideration of comments received, we are finalizing the proposed work RVU of 2.61 for CPT code 20240.

(3) Endobronchial Ultrasound (CPT Codes 31622, 31652, 31653, 31625, 31626, 31628, 31629, 31654, 31632 and 31633)

For CY 2016, the CPT Editorial Panel deleted one code, CPT code 31620 (Ultrasound of lung airways using an endoscope), and created three new codes, CPT codes 31652–31654, 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 RVUs 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 proposed to use those work RVUs for CY 2016.

For the newly created codes, the RUC recommended work RVUs of 5.00 for CPT code 31652, 5.50 for CPT code 31653 and 1.70 for CPT code 31654. In the proposed rule, we stated that we believe the RUC-recommended work RVUs for these services overstate the work involved in furnishing the procedures. In order to develop proposed work RVUs for CPT code 31652, we compared the service described by the code descriptor to deleted CPT codes 31620 and 31629, because this new code describes a service that combines services described by CPT code 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 31652's RUC-recommended intraservice time (INTRA = 60 minutes) and the sum of CPT codes 31620 and 31629's current and CY 2015 intraservice times (INTRA = 70 minutes), respectively. This resulted in a proposed work RVU of 4.71. To value CPT code 31653, we used the RUC-recommended increment of 0.5 work RVUs between this service and CPT code 31652 to calculate for CPT code 31653 our proposed work RVUs of 5.21. Lastly, because the service described by new CPT code 31654 is very similar to deleted CPT code 31620, we stated that we believed a direct crosswalk of the previous values for CPT code 31620 accurately reflected the time and intensity of furnishing the service described by CPT code 31654. Therefore, we proposed a work RVU of 1.40 for CPT code 31654.

The following is a summary of the comments we received on our proposals.

Comment: Several commenters, including the RUC, stated they did not agree with CMS' calculations or methodology utilized in valuing these services. The commenters suggested that CMS' calculations were based on inconsistent data. One commenter stated the methodology outlined in the proposed rule had several flaws in the understanding of the new and deleted bronchoscopy codes and questioned what purpose the creation of the new bundled codes were designed to address.

Response: As we have addressed more broadly, when we do not believe that

the RUC-recommended values adequately address changes in the time resources required to furnish particular services, we have used several methodologies to identify potential work RVUs. We examine the results of such approaches and consider whether or not these results appropriately account for the total work of the service. We continue to believe that the methodology used to calculate the proposed work RVU is the most appropriate methodology to use for these procedures.

Specifically, in considering CPT code 31652 in the context of similar codes, including CPT code 31638 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with revision of tracheal or bronchial stent inserted at previous session (includes tracheal/bronchial dilation as required)) and CPT code 31661(Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; with bronchial thermoplasty, 2 or more lobes) both of which have 60 minutes of intraservice time and RVUs of 4.88 and 4.50, we continue to believe that a work RVU of 4.71 is the most accurate valuation. For CPT code 31653, we continue to believe that maintaining the RUC-recommended 0.5 work RVU increment between 31652 and 31653 yields the most accurate value for CPT code 31653. For CPT code 31654, we note the direct crosswalk preserves the work RVU of 1.40 from the previous CPT code 31620, which was also an add-on code, and had more intraservice time. Therefore, after consideration of comments received, we are finalizing the work RVUs for CPT codes 31622, 31652, 31653, 31625, 31626, 31628, 31629, 31654, 31632 and 31633 for CY 2016 as proposed.

Comment: One commenter also expressed appreciation of CMS' acceptance of the RUC's PE recommendation for several codes in this family.

Response: We appreciate the support of the commenter.

Comment: In its comment, the RUC indicated that equipment items ES045 and ES016 were incorrectly included for 31652, 31653, and 31654 and that these items were replaced with new equipment codes. In the CY 2015 Technical Correction Notice (CMS–1612–F2), equipment item ES015 was included in 31654, and the clinical labor direct PE inputs for 31654 were omitted from the direct PE input database. Similarly, for CPT code 31629, the RUC indicated that CMS proposed 30 minutes for clinical labor tasks ''assist physician in performing procedure'' and ''assist physician for moderate sedation'', as included in the CY 2016 proposed direct PE input database, while the RUC had recommended 35 minutes. The RUC opined that since the 30 minutes displayed for CPT code 31629 was incorrect, all of the corresponding equipment times included discrepancies of 5 minutes. The RUC suggested that all equipment times should increase by 5 minutes, excluding the stretcher, which should remain 89 minutes as that equipment is not needed during the intraservice portion of the procedure. In addition, the RUC suggested that the calculation of supply item ''gas, oxygen'' (SD084) would also be affected by the ''assist physician'' time and should be 105 liters, rather than 90 liters as currently indicated in the supply direct PE input CMS file.

Response: We agree with the RUC's comments regarding the proposed direct PE inputs for these procedures; the resulting changes appear in the final direct PE input database for CY 2016.

(4) Intravascular Ultrasound (CPT Codes 37252 and 37253)

In the CY 2015 PFS proposed rule, a stakeholder requested that CMS establish non-facility PE RVUs for CPT codes 37250 and 37251. CMS sought comment regarding the setting and valuation of these services. In September 2014, these codes were referred to the CPT Editorial Panel. The CPT Editorial Panel deleted CPT codes 37250 and 37251 and created new bundled codes 37252 and 37253 to describe intravascular ultrasound (IVUS). The RUC recommended 1.80 RVUs for CPT code 37252 and 1.44 RVUs for CPT code 37253. The RUC also recommended new direct PE inputs for an IVUS catheter and IVUS system. CMS proposed to accept the RUC-recommended work RVUs for intravascular ultrasound.

Comment: Commenters expressed support for CMS' proposed work and time values, as well as for updating the direct PE inputs.

Response: We appreciate commenters' support, and we are finalizing these values as proposed.

(5) 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 surveyed 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 used the RUC recommendations to propose values for CPT codes 38571 and 38572, since the RUC recommended reductions in the work RVUs that correspond with marked decreases in intraservice time and decreases in total time. As discussed in the proposed rule, we did 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 proposed a work RVU for CPT code 38570 of 8.49, which reflects the proportional reduction in total time for this code and maintains the rank order among the three codes.

The following is a summary of the comments we received on our proposals.

Comment: Several commenters, including the RUC, indicated that CMS should use the recommended work RVU of 9.34 for CPT code 38570. Commenters stated that CMS used an erroneous calculation to derive the proposed work RVU of 8.49, with the use of time ratios being methodologically flawed due to an assumption that the existing time is correct, that physician intensity would remain constant for a service over a period of many years, and that different components of total time consisting of differing levels of physician intensity cannot be measured together. Commenters stated that using this rationale as the basis for not accepting the RUC recommendation was unprecedented and misguided.

Commenters also stated that the recommended work RVU of 9.34 was based on work time and a comparison to CPT codes 31239 (Nasal/sinus endoscopy, surgical; with dacryocystorhinostomy) and 50590 (Lithotripsy, extracorporeal shock wave). Commenters indicated that the comparison to these codes confirmed

that maintaining the current value for CPT code 38570 would be appropriate. A different commenter stated that the survey time for this procedure had increased to 280 minutes and included a hospital inpatient visit. This commenter also urged CMS to maintain the current work RVUs of 9.34 for CPT code 38570.

Response: We refer the reader to our earlier discussion about time ratios. We continue to believe that the use of time ratios is one of several reasonable methods for identifying potential work RVUs for particular PFS services, particularly when the alternative values do not account for information that suggests the amount of time involved in furnishing the procedure has changed significantly. In the case of CPT code 38570, we noted that the intraservice time was reduced by 50 percent, from 120 minutes to 60 minutes, and the total time was also reduced from 242 minutes to 220 minutes. We also noted that the other codes in the same family, CPT codes 38571 and 38572, reflected similar time reductions and consequently had reduced recommended work RVUs. We believe that in order to maintain relativity, it is appropriate to apply a similar reduction to the work RVUs of CPT code 38570.

We were unable to find mention of CPT code 31239 in the RUC recommendations for 38570. Therefore, we considered the values for the code as a potential rationale for using the RUC-recommended value for CPT code 38570. We concluded that CPT code 31239 has limited utility as a comparison, since its values appear to be an outlier among codes with similar characteristics. For example, all 25 of the other 10-day global codes with 60 minutes of intraservice time have a lower work RVU than CPT code 38570, most of them substantially lower, with CPT code 49429 (Removal of peritoneal-venous shunt) having the next highest work RVU of 7.44. We also do not agree with the comparison to CPT code 50590, since that code describes all of the work within a 90-day global period, and we do not believe that relativity between services would be preserved if we were to make direct work RVU comparisons between 10-day and 90-day global codes.

After consideration of comments received, we are finalizing our proposed work RVUs of 8.49 for CPT code 38570, 12.00 for CPT code 38571, and 15.60 for CPT code 38572.

(6) Mediastinoscopy With Biopsy (CPT Codes 39401 and 39402)

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, = the CPT Editorial Panel concluded that the code had 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 39401 and 39402 to describe each of the two mediastinoscopy procedures.

We proposed to accept the RUC-recommended work RVU of 5.44 for code 39401 and to use the RUC-recommended crosswalk from CPT code 52235 (Cystourethroscopy, with fulguration), which accurately estimates the overall work for CPT code 39401. In the proposed rule, we disagreed with the RUC-recommended work RVU of 7.50 for CPT code 39402. We stated that the work RVU for CPT code 39401 establishes an accurate baseline for this family of codes, so we proposed to scale the work RVU of CPT code 39402 in accordance with the change in the intraservice times between CPT codes 39401 and 39402. We indicated that applying this ratio in the intraservice time to the work RVU of CPT code 39401 yielded a total work RVU of 7.25 for CPT code 39402. We also noted that the RUC recommendation for CPT code 39401 represented 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 39402 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 proposed a work RVU of 7.25 for CPT code 39402.

The following is a summary of the comments we received on our proposals.

Comment: Several commenters stated that the use of intraservice time ratios was inappropriate for valuation of CPT codes. They indicated that CMS should instead use the RUC's recommended work RVU of 7.50, due to the difference in technical skill, physical/mental effort, and additional stress involved in the performance of CPT code 39402 relative to CPT code 39401. Commenters expressed the importance of using physician survey data and magnitude estimation to arrive at work RVUs.

Response: We refer the reader to our earlier discussions about the utility of time ratios in identifying potential work RVUs for PFS services. We note that when comparing the work RVUs for CPT codes 39401 and 39402, the work RVU for CPT code 39402 was higher than would be expected based on the difference in time between these two procedures, even considering the more difficult clinical nature of CPT code 39402. We continue to believe that the use of intraservice time ratios is one of several different methods that can be effectively employed for valuation of CPT codes. For this particular mediastinoscopy family, CPT codes 39401 and 39402 share identical preservice time, postservice time, and office visits. Based on this information, we continue to believe that the intraservice time ratio between the two codes is the most accurate method for determining the work RVU for this procedure.

Comment: Several commenters suggested that CMS should use the RUC-recommended work RVU of 7.50 for CPT code 39402 based on the use of a building block methodology. Commenters stated that the RUC arrived at this value by adding the work RVU of CPT code 39401 (5.44 RVUs) to one half of the work RVU of CPT code 32674 (4.12 RVUs). The resulting calculation of 5.44 plus 2.06 equaled 7.50 RVUs, exactly the same value recommended by the RUC and a proof of the accuracy of magnitude estimation.

Response: We believe that the use of the reverse building block methodology would result in a significantly lower valuation for CPT code 39402. The current CPT code used for a mediastinoscopy with lymph node biopsy is 39400, which has a work RVU of 8.05, and includes three postoperative visits in its global period (a 99231 hospital inpatient visit, a 99238 hospital discharge visit, and a 99213 office visit). CPT code 39402 does not include the hospital inpatient visit (0.76 RVUs) or the office visit (0.97 RVUs), and includes only half of the discharge visit (0.64 RVUs). If the work of these visits were removed from CPT code 39400, the result would be a work RVU of 8.05 − 2.37 = 5.68. We believe that this work RVU understates the work of CPT code 39402, which is why we believe that a building block methodology would be less accurate than the use of the intraservice time ratio for this code family.

After consideration of comments received, we are finalizing our proposed work RVU of 5.44 for CPT code 39401 and 7.25 for 39402.

(7) Hemorrhoid(s) Injection (CPT Code 46500)

The RUC 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 maintain the current work RVU of 1.69 in spite of the reductions in intraservice and total times. We proposed to reduce the work RVU to 1.42, which reduces the work RVU by the same ratio as the reduction in total time.

We also proposed to refine the RUC-recommended direct PE inputs by removing the inputs associated with cleaning the scope.

The following is a summary of the comments we received on our proposals.

Comment: The RUC disagreed with the methodology CMS used to develop the proposed work RVUs stating that CMS' proposed methodology did not account for differences in pre-service or post-service time. The RUC also stated that different components of total time (preservice time, intra-service time, post-service time, and post-operative visits) consist of differing levels of physician intensity and CMS' calculations did not appear to have been based on any clinical information or any measure of physician intensity.

Another commenter supported our efforts to identify and address such incongruities between work times and work RVUs, stating that when work time decreases, work RVUs should decrease comparatively, absent a compelling argument that the intensity of the service has increased sufficiently to offset the decrease in work time.

One commenter disagreed with CMS' proposed PE refinements for CPT code 46500 regarding the pre-service clinical labor time for the facility setting, clinical labor time related to setting up endoscopy equipment, clinical labor time and supplies related to cleaning endoscopy equipment, equipment time for item ES002, and clinical labor time associated with clinical labor task ''follow-up phone calls and prescriptions''. The commenter also disagreed with CMS' refinement of not including setup and clean-up time for the scope at the post-operative visit.

Response: We believe the total time ratio produces an RVU that is comparable with other 10-day global services. We note that CPT code 41825 (Excision of lesion or tumor (except listed above), dentoalveolar structures; without repair) and CPT code 10160 (Puncture aspiration of abscess, hematoma, bulla, or cyst) are similar 10-day global services that have comparable work RVUs. For CY 2016, we are finalizing our proposed value of 1.42 RVUs for CPT code 46500.

After reviewing the public comments that were submitted regarding direct PE inputs, we recognize that we mistakenly believed that a disposable scope was included as a direct PE input, when a reusable equipment item was actually included. As a result, we removed the clinical labor time associated with setting up and cleaning the scope. Since we made this refinement in error, we will restore the clinical labor time associated with setting up and cleaning the scope. We also agree with commenters regarding the time for clinical labor task ''follow-up phone calls and prescriptions''. Therefore, we are restoring the RUC-recommended clinical labor times for ''follow-up phone calls & prescriptions'', ''setup scope (non-facility setting only)'', and ''clean scope''. As a result of including the previously removed clinical labor time associated with the equipment input ES002 (anoscope with light source), we are increasing the equipment time for this code from 60 minutes to 70 minutes. We did not add the set-up and clean scope time to the post-operative visits, however, since the clinical labor time for post-operative visits across PFS services match the clinical labor for the associated E/M visits. We are seeking comment regarding whether or not we should reconsider that practice broadly before making an exception in this particular case.

(8) Liver Allotransplantation (CPT Code 47135)

The RUC 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 results 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 corresponds to the survey median result, as well as the exact work RVU for CPT code 33935 (Heart-lung transplant with recipient cardiectomy-pneumonectomy). In the proposed rule, we stated that we did not believe the RUC-recommended crosswalk was the most accurate from among the group of transplant codes. We noted that 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 corresponds to the 25th percentile survey result for CPT code 47135. Therefore, we proposed to increase the work RVU of CPT code 47135 to 90.00.

The following is a summary of the comments we received on our proposal.

Comment: The RUC stated that its original reference code is the most appropriate comparator for this service and revising the work RVU for CPT code 47135 to 1.9 percent below the RUC's recommendation would be arbitrary and punitive. Another commenter stated that while they believed the RUC proposed valuation more accurately reflected the work involved, they appreciated the proposal to increase the work RVUs associated with liver transplants, and suggested that CMS accept the RUC-recommended direct PE valuations.

Response: As we stated in the proposed rule, CPT code 32854(Lung transplant, double (bilateral sequential or en bloc); with cardiopulmonary bypass) has very similar intra-service and total times, in addition to an identical work RVU (90.00) to the 25th percentile survey result. We continue to believe the proposed direct crosswalk from CPT code 32854 (Lung transplant, double (bilateral sequential or en bloc); with cardiopulmonary bypass) to CPT code 47135 results in the most accurate valuation. Therefore, for CY 2016 we are finalizing without modification our proposed work RVU of 90.00 for CPT code 47135.

(9) Genitourinary Catheter Procedures (CPT Codes 50430, 50431, 50432, 50433, 50434, 50435, 50693, 50694, and 50695)

For CY 2016, the CPT Editorial Panel deleted six CPT codes (50392, 50393, 50394, 50398, 74475, and 74480) that were commonly reported together, and created 12 new CPT codes, both to describe these genitourinary catheter procedures more accurately and to bundle inherent imaging guidance. Three of these CPT 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 proposed to use the RUC-recommended work RVU of 3.15 for CPT code 50430. We agreed 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. We began by making comparisons between the service times of CPT code 50430 and the other codes in the family in order to determine the appropriate proposed work RVU of each procedure.

In our proposal for CPT code 50431, we stated that we disagreed with the RUC-recommended work RVU of 1.42; we instead proposed a work RVU of 1.10, based on three separate data points. First, the RUC recommendation stated that CPT code 50431 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 suggested that this value reflected the total work for the service. Accordingly, we proposed 1.10 as the work RVU for CPT code 50431.

We employed a similar methodology to develop a proposed work RVU of 4.25 for CPT code 50432. The three previously established codes were combined in CPT code 50432; these had respective work RVUs 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 examined the valuation of this service relative to other codes in the family. The ratio of the intraservice time of 35 minutes for CPT code 50430 and the intraservice time of 48 minutes for CPT code 50432, applied to the work RVU of base code 50430 (3.15), results in a potential work RVU of 4.32. The total time for CPT code 50432 is higher than CPT code 50430 (107 minutes relative to 91 minutes); applying this ratio to the base work RVU results in a work RVU of 3.70. We utilized these data to inform our proposed crosswalk. In valuing CPT code 50432, we considered CPT code 31660 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance), which has an intraservice time of 50 minutes, total time of 105 minutes, and a work RVU of 4.25. Therefore, we proposed to establish the work RVU for CPT code 50432 at the crosswalked value of 4.25 work RVUs.

In the proposed rule, we stated that according to the RUC recommendations, CPT codes 50432 and 50433 are very similar procedures, with CPT code 50433 making use of a nephroureteral catheter instead of a nephrostomy catheter. The RUC valued the added difficulty of CPT code 50433 at 1.05 work RVUs compared to CPT code 50432. We proposed to maintain the relative difference in work between these two codes by proposing a work RVU of 5.30 for CPT code 50433 (4.25 + 1.05). Additionally, we considered CPT code 57155 (Insertion of uterine tandem and/or vaginal ovoids for clinical brachytherapy), which has a work RVU of 5.40 and an identical intraservice time of 60 minutes, but 14 additional minutes of total time (133 minutes compared to 119 minutes for CPT code 50433), which supported the difference of 0.10 RVUs. For these reasons, we proposed a work RVU of 5.30 for CPT code 50433.

As with the other genitourinary codes, we developed the proposed work RVU of CPT code 50434 in order to preserve relativity within the family. In the proposed rule, we stated that CPT code 50434 has 15 fewer minutes of intraservice time compared to CPT code 50433 (45 minutes compared to 60 minutes). We proposed to apply this ratio of 0.75 to the base work RVU of CPT code 50433 (5.30), which resulted in a potential work RVU of 3.98. We also considered CPT code 50432 as another similar service within this family of services, with three more minutes of intraservice time compared to CPT code 50434 (48 minutes of intraservice time instead of 45 minutes). We noted that applying this ratio (0.94) to the base work RVU of CPT code 50432 (4.25) 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 direct crosswalk, and proposed a work RVU of 4.00 for CPT code 50434. 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 50435, we considered how the code and work RVU would fit within the family in comparison to our proposed values for CPT codes 50430 and 50432. CPT code 50430 serves as the base code for this group; it has 35 minutes of intraservice time in comparison to 20 minutes for CPT code 50435. This intraservice time ratio of 0.57 (20/35) resulted in a potential work RVU of 1.80 for CPT code 50435 when applied to the work RVU of CPT code 50430 (3.15). Similarly, CPT code 50432 is the most clinically similar procedure to CPT code 50435. CPT code 50432 has 48 minutes of intraservice time compared to 20 minutes of intraservice time for CPT code 50435. This ratio of 0.42 (20/48) applied to the base work RVU of CPT code 50432 (4.25) results in a potential work RVU of 1.77. We also considered two additional procedures to determine a proposed value for CPT code 50435. 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 50435, with a work RVU of 1.82. Accordingly, we proposed a work RVU of 1.82, a direct crosswalk from CPT code 36569.

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 50693, we proposed a work RVU of 4.21, which corresponds to the 25th percentile survey result. We stated in the proposed rule that we believed that the work RVU corresponding to the 25th percentile survey result provided a more accurate value for CPT code 50693 based on the work involved in the procedure and within the context of other codes in the family. We also indicated that 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, was an accurate crosswalk for CPT code 50693.

For CPT code 50694, we compared its intraservice time to the code within the family that had the most similar duration, CPT code 50433. This code has 60 minutes of intraservice time compared to 62 minutes for CPT code 50694. This is a ratio of 1.03; when applied to the base work RVU of CPT code 50433 (5.30), we arrived at a potential work RVU of 5.48. We also looked to procedures with similar times, in particular CPT code 50382 (Removal and replacement of internally dwelling ureteral stent), which has 60 minutes of intraservice time, 125 minutes of total time, and a work RVU of 5.50. We proposed a work RVU of 5.50, a direct crosswalk from CPT code 50382.

Finally, we developed the proposed work RVU for CPT code 50695 using three related methods. In the proposed rule, we stated that CPT codes 50694 and 50695 describe very similar procedures, with 50695 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 50695 than for CPT code 50694. Maintaining the 1.55 work RVUs increment, we noted that adding 1.55 to our proposed work RVU for CPT code 50694 (5.50)

would produce a work RVU of 7.05 for CPT code 50695. We also examined the ratio of intraservice times for CPT code 50695 (75 minutes) and the base code in the subfamily, CPT code 50693 (45 minutes). The intraservice time ratio between these two codes is 1.67; when applied to the base work RVU of CPT code 50693 (4.21), we calculated a potential work RVU of 7.02. We also noted that CPT code 36481 (Percutaneous portal vein catheterization by any method) shares the same intraservice time as CPT code 50695 and has a work RVU of 6.98. Accordingly, to maintain relativity among this subfamily of codes, we proposed a work RVU of 7.05 for CPT code 50695 based on an incremental increase of 1.55 RVUs from CPT code 50694.

In reviewing the direct PE inputs for this family of codes, we refined a series of the RUC- recommended direct PE inputs in order to maintain relativity with other codes in the direct PE database. All of the following refinements refer to the non-facility setting for this family of codes. Under the clinical labor inputs, we proposed to remove the RN/LPN/MTA (L037D) (intraservice time for assisting physician in performing procedure) for CPT codes 50431 and 50435. This amounts to 15 minutes for CPT code 50431 and 20 minutes for CPT code 50435. Moderate sedation is not inherent in these procedures and, therefore, we indicated that we did not believe that this clinical labor task would typically be completed in the course of this procedure. We also reduced the RadTech (L041B) intraservice time for acquiring images from 47 minutes to 46 minutes for CPT code 50694. This procedure contains 62 minutes of intraservice time, with clinical labor assigned for acquiring images (75 percent) and a circulator (25 percent). The time for these clinical labor tasks is 46.5 minutes and 15.5 minutes, respectively. The RUC recommendation for CPT code 50694 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 reduced the time for clinical labor tasks ''acquire images'' to 46 minutes to preserve the 62 minutes of total intraservice time for CPT code 50694.

With respect to the post-service portion of the clinical labor service period, we proposed to change the labor type for the task ''patient monitoring following service/check tubes, monitors, drains (not related to moderate sedation)''. There are 45 minutes of clinical labor time assigned under this category to CPT codes 50430, 50432, 50433, 50434, 50693, 50694, and 50695. Although we agreed that the 45 minutes are accurate for these procedures as part of moderate sedation, we proposed to change the clinical labor type from the RUC-recommended RN (L051A) to RN/LPN/MTA (L037D) to reflect the staff that would typically be doing the monitoring for these procedures. Even though the CPT Editorial Committee's description of post-service work for CPT code 50435 included a recovery period for sedation, we recognized in our proposal that according to the RUC recommendation, CPT codes 50431 and 50435 did not use moderate sedation; therefore, we did not propose to include moderate sedation inputs for these codes.

The RUC recommendation for CPT code 50433 included a nephroureteral catheter as a new supply input with an included invoice. However, the RUC recommendation did not discuss the use of a nephroureteral catheter in the intraservice work description. CPT code 50433 did 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 asked for feedback from stakeholders regarding the use of the nephroureteral catheter for CPT code 50433, but did not propose to add the nephroureteral catheter as a supply item for CPT code 50433 pending this information. We also requested stakeholder feedback regarding the intraservice work description in 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. In our proposal we stated that we did 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 therefore proposed to replace equipment item ''room, angiography'' (EL011) with equipment item ''room, radiographic-fluoroscopic'' (EL014) for the same number of minutes. We requested 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. In the proposed rule, we stated that we believed that such a recommendation from the RUC concerning all of these codes could be useful in ensuring relativity across the PFS.

The following is a summary of the comments we received on our proposals.

Comment: Several commenters, including the RUC, stated that the CMS proposed work RVUs were based on a flawed methodology. Commenters stated that CMS ignored intensity measures, differences in patient population, and risk profile considerations between the genitourinary codes. These commenters indicated that they did not agree with the use of intraservice time ratios as a methodology for establishing work RVUs.

Response: We refer the reader to our earlier discussion about the utility of time ratios in identifying potential work RVUs. For this particular group of codes, we believe that establishing CPT code 50430 as the baseline value and then using intraservice time ratios to maintain relativity of work RVUs results in accurate work RVUs for these services. We note that these refined work RVUs were supported in all cases by the use of crosswalks to existing CPT codes which we believe reflect similar intensity, which further supported the refined work RVUs

Comment: Several commenters indicated that the compelling evidence standard applied by the RUC for requiring an increase in valuation had been met for this code family, and therefore increased work RVUs were acceptable when compared to the previous group of genitourinary catheter procedures.

Response: We recognize that the RUC internal deliberations include rules that govern under what circumstances individual specialties can request that the RUC recommend CMS increase values for particular services. As observers to the RUC process, we appreciate having an understanding of these rules in the context of our review of RUC-recommended values. However, we remind the commenters that we are aware of such rules when we initially consider RUC recommendations. We are committed to preserving relativity between services across the entirety of the PFS, and believe that our proposed values best achieve that aim.

Comment: Several commenters disagreed with the use of crosswalks to other CPT codes provided by CMS. Commenters stated that the work

between the codes was not comparable due to clinical differences between the genitourinary catheter codes and the procedures described in the crosswalk codes. Commenters specifically referenced the crosswalk that CMS selected for CPT code 50431 and stated that the CMS chosen crosswalk code does not have the same infectious considerations (bacteremia) or the magnitude of diagnostic considerations as CPT code 50431.

Response: In the resource-based relative value system, services do not have to be clinically similar in order to be comparable. Relative value units (RVUs) are comparable across services furnished by different medical specialties. We note as well that the crosswalk codes referenced by the RUC in its recommendations are frequently not clinically similar to the CPT code under review. In the case of 50431, we note that our crosswalk to CPT code 49460 has identical intraservice time and total time with CPT code 50431, along with similar clinical intensity, suggesting that it has value as a point of comparison for this code. Furthermore, we did not establish a direct crosswalk between the work of these two codes, only using CPT code 49460 (which has a work RVU of 0.96 RVUs) as one of three separate data points. For our second data point, we wrote that the recommendation for CPT code 50431 stated that the new code described work previously performed 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. For our third data point, we observed that the minimum survey result had a work RVU of 1.10, which we believe accurately reflects the total work for this service. The survey minimum value of 1.10 RVUs was the method used to establish our proposed work RVU for this code. We refer readers to the discussion above in the Methodology for Establishing Work RVUs section for more information regarding the crosswalks used in developing values for this procedure.

After consideration of comments received, we are finalizing our proposed work RVU of 1.10 for CPT code 50431.

Comment: Several commenters disagreed with the CMS proposed work RVU of 4.25 for CPT code 50432 and suggested that CMS accept the RUC-recommended RVU of 4.70. They indicated that CMS used a clinically dissimilar crosswalk, CPT code 31660, which consists of very different work, patient populations, and potential complications. Commenters also stated that CMS used a different combination of existing CPT codes in its building block valuation of the new code 50432, leaving out CPT code 50390. Commenters indicated that this was a mistake and the use of CPT code 50390 would be typical.

Response: As we mentioned previously, in the resource-based relative value system, services do not have to be clinically similar to be comparable. CPT code 31660 shares intraservice time and total time values that are nearly identical to CPT code 50432, along with similar clinical intensity, so we continue to believe that it is an accurate crosswalk. We also do not believe that the use of CPT code 50390 would be typical in constructing a building block methodology for CPT code 50432. The new code is assembled through a combination of genitourinary catheter CPT code 50392 with injection CPT codes 74425 and 74475. We do not believe that CPT code 50390 would typically be included in this group as well, since the code descriptors for both 50390 and 50392 also include drainage and this service would not be performed twice. We believe that the new CPT code 50432 would be used for either the previously reported CPT codes 50390 or 50392 service, but not for both of them at once. In addition, the RUC has recommended that we assume that most of the procedures previously reported using CPT code 50392 would be reported using new CPT code 50432.

We note as well that our proposed work RVU for CPT code 50432 was supported by the use of two time ratios with CPT code 50430. Both the intraservice time ratio and the total time ratio suggested that a value below the RUC recommendation of 4.70 RVUs would be more accurate. After consideration of comments received, we are finalizing our proposed work RVU of 4.25 for CPT code 50432.

Comment: Several commenters stated that CMS should accept the RUC-recommended work RVU of 5.75 for CPT code 50433. While they agreed with CMS' use of the RUC-recommended increment of 1.05 RVUs relative to CPT code 50432, they did not agree with the CMS refined work RVU of CPT code 50432 itself. Some commenters also did not support the CMS crosswalk to CPT code 57155, which they stated had very different work, patient population, and potential complications.

Response: We agree that CPT code 50433 is accurately valued at 1.05 RVUs greater than CPT code 50432, which describes the additional work performed by placing a nephroureteral catheter relative to the work of placing a nephrostomy catheter. However, we continue to believe that our proposed work RVU for CPT code 50432 is an accurate value for the reasons detailed above. With regard to our crosswalk, we maintain that relative value units are comparable across different medical specialties. CPT code 57155 (Insertion of uterine tandem and/or vaginal ovoids for clinical brachytherapy) has an identical intraservice time of 60 minutes and 14 additional minutes of total time, along with similar clinical intensity, which support the difference of 0.10 RVUs when compared to CPT code 50433. After consideration of the comments received, we are finalizing a work RVU of 5.30 for CPT code 50433.

Comment: Several commenters requested that CMS adopt the RUC-recommended work RVU of 4.20 for CPT code 50434. Commenters disagreed with the methodology that CMS used to arrive at the proposed value of 4.00 RVUs, in particular the use of intraservice time ratios, and stated that the CMS crosswalk to CPT code 31634 (Bronchoscopy, rigid or flexible, with balloon occlusion) was inappropriate due to clinical dissimilarity.

Response: We refer the reader to our earlier discussion about intraservice time ratios. We found the identical result of 3.98 work RVUs for CPT code 50434 when we applied the intraservice time ratio to CPT codes 50432 and 50433. This lent further support to our proposed work RVU. With regard to our crosswalk, we note that in the resource-based relative value system, CPT codes do not have to be clinically similar to be comparable. CPT code 31634 shares the identical intraservice time with CPT code 50434 and serves as a direct crosswalk. After consideration of comments received, we are finalizing our proposed work RVU of 4.00 for CPT code 50434.

Comment: Several commenters made similar statements regarding the proposed work RVU for CPT code 50435, criticizing the use of intraservice time ratios with other codes in the genitourinary catheter family and disagreeing with the crosswalked CPT codes for being medically dissimilar.

Response: We refer the reader to our earlier discussion about intraservice time ratios and continue to believe that their use results in accurate work RVUs for this family of codes. We made use of an intraservice time ratio with both CPT code 50430 (the base code for the family) and CPT code 50432 (the most clinically similar code), which produced results of 1.80 and 1.77 RVUs, respectively. We also found two different crosswalks with identical intraservice time and very similar work RVUs, including CPT code 36569, with identical intraservice time, identical

total time, and a work RVU of 1.82 RVUs. Although we maintain that relative value units are comparable across different medical specialties, CPT code 36569 does in fact describe a medically related procedure, with the insertion of a central venous catheter. After consideration of comments received, we are finalizing our proposed work RVU of 1.82 for CPT code 50435.

Comment: Commenters urged CMS to adopt the RUC-recommended work RVU, corresponding to the median survey work RVU of 4.60 RVUs for CPT code 50693. They stated that the placement of a ureteral stent requires more work than the placement of a nephroureteral catheter, and the 0.21 RVU differential proposed by CMS is insufficient to reflect the additional work difficulty of CPT code 50693.

Response: We are uncertain about which codes are being compared by the commenters, since the 0.21 RVU differential referenced by the commenters does not exist in the codes that appear to be discussed in the comment (50433). Since the commenters did not include the five digit CPT designation in their comparison, we are uncertain which code the commenters intended to discuss.

We continue to believe that a work RVU of 4.21, corresponding to the 25th percentile survey result, is the most accurate value for CPT code 50693. We believe that the ureteral stent procedures are clinically similar to the rest of the genitourinary catheter family, and the use of intraservice time ratios with these procedures provides an accurate method for determining relative values. We continue to believe that the work RVU of 4.21, corresponding to the 25th percentile survey result, is further supported through our crosswalk to CPT code 31648 (Bronchoscopy, rigid or flexible, with removal of bronchial valve) which has similar times and a work RVU of 4.20. After consideration of comments received, we are finalizing our proposed work RVU of 4.21 for CPT code 50693.

Comment: Several commenters made statements similar to those mentioned previously regarding the work RVU for CPT code 50694, criticizing the use of intraservice time ratios with other codes in the genitourinary catheter family and disagreeing with the crosswalked CPT codes for being medically dissimilar.

Response: We refer the reader to our earlier discussion about intraservice time ratios and continue to believe that their use results in accurate work RVUs for this family of codes. We compared CPT code 50694 with 50433, the code within the family with the most similar intraservice time, which resulted in a potential work RVU of 5.48. We also found that CPT code 50382 had nearly identical intraservice time and total time, and a work RVU of 5.50. While we maintain that relative value units are comparable across different medical specialties, we do not agree with the commenters that CPT code 50382 is medically dissimilar from CPT code 50694. The former refers to the removal and replacement of a ureteral stent, while the latter refers to the placement of a ureteral stent. We believe that these codes describe very similar procedures, share the same patient population, and can serve as a direct crosswalk for the work RVU of each other. After consideration of comments received, we are finalizing our proposed work RVU of 5.50 for CPT code 50694.

Comment: A few commenters stated that their comments on CPT code 50695 are similar to those they had made previously about CPT code 50433. While they agreed that CMS was correct to maintain the RUC-recommended increment of 1.55 RVUs greater than the value of CPT code 50694, they did not agree with the CMS refined work RVU of 50694 itself. Commenters also did not support the CMS crosswalk to CPT code 36481, which they stated had very different work, patient population, and potential complications.

Response: We agree that CPT code 50695 is accurately valued at 1.55 RVUs greater than CPT code 50694, which describes the additional work performed by the use of a nephrostomy tube. However, we continue to believe that the proposed work RVU for CPT code 50694 is an accurate value for the reasons detailed above. With regard to our crosswalk, we continue to believe that relative value units are comparable across services furnished by different medical specialties. CPT code 36481 (Percutaneous portal vein catheterization by any method) has an identical intraservice time of 75 minutes and 18 additional minutes of total time, but a lower work RVU (6.98 RVUs) than the one suggested by our incremental method. Commenters also did not discuss our use of an intraservice time ratio with the base code in this subfamily, CPT code 50693, which suggested a work RVU of 7.02. After consideration of comments received, we are finalizing our proposed work RVU of 7.05 for CPT code 50695.

Comment: Several commenters disagreed with the CMS proposal to eliminate the RN/LPN/MTA blend (L037D) of clinical labor for assisting the physician during procedures 50431 and 50435. The CMS rationale was based on the lack of moderate sedation taking place in these two procedures. However, commenters argued that these procedures do require monitoring for patient stability that the attending physician cannot provide. They urged that the RN/LPN/MTA blend would be most appropriate for these procedures.

Response: We are not aware of any other procedures in which there is a third assistant in the procedure room when moderate sedation is not being provided. We believe that the standard use of clinical labor staff would be typical when performing these procedures.

Comment: Commenters also disagreed with the CMS proposal to change the labor type for patient monitoring following service (not related to moderate sedation) from the RUC-recommended RN (L051A) to the RN/LPN/MTA blend (L037D). Commenters stated that although use of the RN/LPN/MTA blend is standard for this clinical labor task, the RUC allows specialty groups to use an RN with justification, and that was the case here for these procedures since they involve invasive percutaneous solid organ interventions.

Response: After consideration of comments, we agree that the use of the RN (L051A) clinical labor is typical for patient monitoring following service (not related to moderate sedation) for these particular specialty groups. We will restore the recommended L051A labor type for this clinical labor task for CPT codes 50430, 50432, 50433, 50434, 50693, 50694, and 50695. We will also consider making a formal proposal regarding the most suitable type of clinical labor staff for this monitoring in future rulemaking.

Comment: CMS sought clarification regarding the use of the nephroureteral catheter (SD306) for CPT code 50433. CMS removed this supply from CPT code 50433 since it was not mentioned in the information about the survey included in the RUC recommendation. Commenters wrote to explain that the phrase ''An 8 Fr nephroureteral stent is inserted with the distal pigtail in the bladder'' is included in the description of work for CPT code 50433, and in the context of genitourinary and biliary procedures, the historic term ''stent'' has been used interchangeably with the term ''catheter''. Commenters suggested that the nephroureteral catheter should be maintained as a supply item for this code and for CPT code 50434.

Response: We agree that the nephroureteral catheter should be maintained as a supply item for CPT codes 50433 and 50434, based on the presentation of this additional information. However, based on our analysis of the comments, we believe

that our review of the RUC recommendations would be facilitated by consistent use of terminology throughout the information included in the recommendations.

Comment: Several commenters, including the RUC, disagreed with the CMS decision to replace the angiography room (EL011) with a fluoroscopic room (EL014) for the genitourinary catheter family of codes. Commenters stressed that the fluoroscopic room was incapable of 3-axis rotational imaging, that it would require dangerous movement of the patient, and that it presented sterility concerns. Commenters further disagreed that use of the angiography room was typically limited to cardiovascular procedures. They suggested that looking at service utilization, rather than number of CPT codes, indicates that non-vascular interventional procedures together comprise more than 50 percent of utilization of a typical angiography room. Commenters also provided a list of the equipment found in an angiography room, and stated that everything other than the ''Injector, Provis'' would be typically utilized for the genitourinary catheter procedures. As a result, the commenters urged CMS to reverse the proposed refinement and restore the use of the angiography room for these codes.

Response: We continue to believe that the use of an angiography room would not be typical for these genitourinary catheter procedures. The new genitourinary catheter codes in this family are being constructed through the bundling of imaging guidance with previously existing genitourinary catheter procedures. With the exception of CPT code 50398, the direct PE inputs for the predecessor codes do not include the use of an angiography room. We do not have reason to believe the coding changes related to these procedures would necessitate the use of different technology in furnishing the services. While it is true that the angiography room was included as a direct PE input for some of the predecessor imaging services, such as CPT codes 77475, 77480, and 77485, the equipment times for these services were significantly shorter than the time included for the base procedures, where use of the room was not considered to be typical. Given the six fold increase in recommended time and the significantly higher expenses of the newly recommended equipment versus the equipment costs associated with the predecessor codes, we are seeking not only a rationale for the use of the angiography room, but also evidence that this room is typically used when these services are reported in the nonfacility setting.

Comment: One commenter disagreed with the CMS decision to refine the time for clinical labor task ''Clean room/equipment by physician staff'' (L041B) from 6 minutes to 3 minutes. The commenter stated that there had been a robust discussion of this topic at the RUC meeting, and the additional minutes are needed to clean fluids/equipment/etc.

Response: We continue to believe that the standard time of 3 minutes for this clinical labor task is more accurate for the genitourinary catheter family of codes. We do not believe that these procedures typically produce enough external fluids to justify 6 minutes for room cleaning.

Comment: Several commenters disagreed with the CMS refinement of supplies to remove those that were duplicative of the same supplies found in visit packs (SA048) and sedation packs (SA044). Commenters stated that the IV starter kit (SA019), endoscope cleaning and disinfecting pack (SA042), non-sterile gloves (SB022), sterile gloves (SB024), sterile surgical gown (SB028), and three-way stop cock (SC049) were not duplicative supplies, as they were used in addition to the supplies included in the packs. Commenters requested that these supplies be restored to the direct PE inputs for the genitourinary catheter codes.

Response: We agree with the commenters that three sets of sterile garments would typically be used for the three medical professionals performing the procedure. We are therefore restoring one pair of sterile gloves, one sterile surgical gown, one IV starter kit, and one three-way stop cock to these codes, consistent with the RUC recommendation. We do not believe that the use of two more pairs of non-sterile gloves (beyond the two pairs already included in the visit pack) would be typical for these procedures. With regards to the ''endoscope cleaning and disinfecting pack'', our rationale was not that this supply was duplicative, but rather that its use would not be typical because the genitourinary catheter codes do not make use of an endoscope. We did not receive comments that suggested that supply item ''endoscope cleaning and disinfecting pack'' would typically be used.

After consideration of comments received, we are finalizing the direct PE inputs as proposed, with the addition of the nephroureteral catheter for CPT code 50433, the change in clinical labor type from L037D to L051A for patient monitoring following service (not related to moderate sedation), and the additional four supplies detailed in the previous paragraph for CPT codes 50430, 50432, 50433, 50434, 50693, 50694, and 50695.

(10) Penile Trauma Repair (CPT Codes 54437 and 54438)

The CPT Editorial Panel 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 54437 describes a repair of traumatic corporeal tear(s), while CPT code 54438 describes a replantation, penis, complete amputation.

In the proposed rule, we stated that we disagreed with the RUC recommendation of 24.50 work RVUs for CPT code 54438. We indicated that a work RVU of 22.10, corresponding to the 25th percentile survey result, was 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 54437 was also valued using the 25th percentile. We found 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 proposed a work RVU of 22.10 for CPT code 54438.

Because CPT codes 54437 and 54438 are typically performed on an emergency basis, in the proposed rule, we questioned the accuracy of the standard 60 minutes of preservice clinical labor in the facility setting, as we suggested that the typical procedure would not make use of office-based clinical labor. We suggested, for example, the typical case would require 8 minutes to schedule space in the facility for an emergency procedure, or 20 minutes to obtain consent. We solicited further public comment on this issue from the RUC and other stakeholders.

The following is a summary of the comments we received on our proposals.

Comment: One commenter urged CMS to accept the RUC-recommended value for CPT code 54438 at 24.50 RVUs. This commenter argued that the RUC regularly accepts the median survey work RVU for one service and the 25th percentile survey result work RVU for another when both are in the same code family, particularly when they diverge in length of time. The commenter also suggested that reducing the intensity of CPT code 54438 below its RUC-recommended value of 0.071

was inappropriate for such a complex and difficult procedure, with an unusual patient population that is often schizophrenic and prone to self-injury. This commenter emphasized using the RUC-supplied reference of CPT code 53448 as justification for the RUC-recommended work RVU.

Response: We appreciate the presentation of this additional information concerning the complexity and intensity of CPT code 54438. We agree that the unusual patient population for this procedure justifies a higher work RVU than the proposed value. After consideration of comments received, we are finalizing our proposed work RVU of 11.50 for CPT code 54437, and assigning the RUC-recommended work RVU of 24.50 for CPT code 54438.

(11) Intrastromal Corneal Ring Implantation (CPT Code 65785)

CPT code 65785 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.

In the proposed rule, we stated that we disagreed with the RUC recommendation of a work RVU of 5.93 for CPT code 65785. Although we appreciated the extensive list of other codes the RUC provided as references, we expressed concern that the recommended value for CPT code 65785 overestimated the work involved in furnishing this service relative to other PFS services. We did not find any codes 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 unlikely to be accurate.

As a result, we proposed a work RVU for CPT code 65785 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 65785. 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, 7 additional minutes of total time, and a work RVU of 5.28. In the proposed rule, we stated that we believed that CPT code 58605 was a more accurate direct crosswalk because it shares the same intraservice time of 30 minutes with CPT code 65785. Accordingly, we proposed a work RVU of 5.39 for CPT code 65785.

The RUC recommendation for CPT code 65785 included 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 believed were more likely to be typical since we assumed 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 proposed to establish a new supply code for ''suture, nylon 10–0'' and price that item at $12.17 each. We welcomed comments from stakeholders regarding this supply item.

The following is a summary of the comments we received on our proposals.

Comment: Several commenters indicated that CMS should reconsider its decision and accept the RUC-recommended work RVU of 5.93. These commenters stated that the intraservice time ratio used by CMS did not account for differences in preservice time, postservice time, or levels of physician intensity. Commenters also disagreed with CMS' statement that there were no services with a comparable intraservice and total time that had a higher work RVU than the RUC-recommended value of 5.93 for CPT code 65785. The commenters supplied a list of seven CPT codes that have a work RVU higher than 5.93 RVUs.

Response: We continue to believe that the use of intraservice time ratios is one of several different methods that can be used to identify potential work RVUs. For this particular code, the RUC used a direct crosswalk to CPT code 67917 (Repair of ectropion; extensive) to set their recommended work RVU at 5.93 RVUs. We do not believe that that direct crosswalk was the most accurate way to value CPT code 65785, since code 67917 has an intraservice time that is 10 percent longer than the intraservice time of CPT code 65785 (33 minutes to 30 minutes). CPT code 67917 is a clinically similar code which the RUC used for its own valuation of CPT code 65785, making it an especially good choice for comparative purposes after applying a ratio to normalize the intraservice times. We continue to believe that the use of an intraservice time ratio resulted in the most accurate value, given the difference in time between the two codes.

As discussed in the proposed rule, all CPT codes with comparable time values and the same global period had lower work RVUs than the RUC-recommended work RVU of 5.93. While it is true that the seven codes provided by the commenters have work RVUs higher than 5.93 RVUs, we do not agree that these CPT codes are appropriate for comparative purposes with code 65785. CPT code 33768 is an add-on code (global ZZZ) that cannot be compared to a code with a 90-day global period such as 65785. CPT code 59830 is a Harvard-valued code that has not been subject to RUC review, has low utilization (2013 = 7 reported services), and 20 minutes fewer total time than CPT code 65785. CPT codes 66770 and 67145 are also Harvard codes which have not been RUC reviewed, and both have different intraservice times than 65785, 5 minutes and 10 minutes, respectively. CPT codes 67210 and 67220 are the only codes supplied by the commenters to be recently reviewed by the RUC, but both of them have only 15 minutes intraservice time, limiting their utility for comparative purposes with the 30 minutes intraservice time assumed for CPT code 65785. Although we accept the commenters' point that other codes with work RVUs above 5.93 RVUs do exist, we do not agree that codes referenced by commenters have ''comparable intraservice and total time'' with CPT code 65785. We continue to believe that scaling the RUC's key reference code of 67917 by the intraservice time ratio between the two codes provides the most accurate value for CPT code 65785.

After consideration of comments received, we are finalizing the work RVU and the direct PE inputs for CPT code 65785 as proposed.

(12) Dilation and Probing of Lacrimal and Nasolacrimal Duct (CPT Codes 66801, 68810, 68811, 68815 and 68816)

The RUC reviewed 10-day global services and 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. The RUC requested surveys and reviews of these services for CY 2016.

As discussed in the proposed rule, the RUC recommended a work RVU of 1.00

for CPT code 68801 and a work RVU of 1.54 for CPT code 68810. Although we proposed to use the RUC-recommended work RVU for CPT code 68810, we stated that the recommendation for CPT code 68801 did not best reflect 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. We proposed to accept the RUC's recommendation to remove the 99211 visit from the service but proposed to further reduce the work RVU for CPT code 68801 by removing the RVUs associated with CPT code 99211. Therefore, for CY 2016, we proposed 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. In the proposed rule, we stated that the RUC recommendations for these services do not appear to best reflect the work involved in performing these procedures. To value these services for the proposed rule, 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 produced the proposed work RVUs of 1.74, 2.70, and 2.10 for CPT codes 68811, 68815, and 68816, respectively.

The following is a summary of the comments we received on our proposals.

Comment: Several commenters, including the RUC, suggested that CMS reconsider its decision to not accept the RUC recommendations. The commenters believe that using a reverse building block methodology to reduce a work RVU for this service is inappropriate since magnitude estimation was used to establish the recommended work RVUs for this series of codes. Commenters also believe that CMS did not provide detailed rationale for the rejection of the RUC-recommended work RVUs for CPT codes 68811, 68815 and 68816. Finally, commenters noted that the existing IWPUT for each of these three surgical services is below 0.03, which the commenters believe calls into question the accuracy of the existing work time and its usage in deriving a new work RVU.

Response: We appreciate the commenters' perspectives, but reiterate that our proposed values accounted for the changes in the time resources assumed to be involved in furnishing these services since they were previously valued. We note that the validity of the IWPUT alone as a measure of intensity is reliant on the accuracy of the assumption regarding the number and level of visits for services in the global period for individual services. Therefore, we do not generally agree that a low IWPUT itself indicates misvaluation, particularly for services with global periods. After considering the comments received, we continue to believe that the work RVUs proposed for these codes accurately reflect the work involved in furnishing these services.

Therefore, for CY 2016 we are finalizing work RVUs for CPT codes 68801, 68810, 68811, 68815, and 68816, as proposed.

(13) Spinal Instability (CPT Codes 72081, 72082, 72083, and 72084)

For CY 2015, the CPT Editorial Panel deleted codes 72010 (radiologic examination, spine, entire, survey study, anteroposterior and lateral), 72069 (radiologic examination, spine, thoracolumbar, 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 72081, two to three views in 72082, four to five views in 72083, and minimum of six views in 72084.

In the proposed rule, we stated that we did not agree with the RUC's recommended work RVUs for the four new codes. For 72081, 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 RVUs in the source code and comparing that to the time and work RVU ratio in the new code. Using the relationship between time and RVUs from deleted CPT code 72069, we proposed a work RVU of 0.26 for CPT code 72081, 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 proposed to adjust the RUC-recommended work RVUs for CPT codes 72082, 72083 and 72084 to 0.31, 0.35, and 0.41, respectively.

The following is a summary of the comments we received on our proposals.

Comment: Many commenters, including the RUC, disagreed with CMS' proposed crosswalk for 72081 and urged CMS to use the RUC recommendation. The commenters stated that since CPT code 72069 is being deleted due to changes in technology and patient population, it is a poor comparison. Other commenters pointed out that CPT code 72081 typically includes an X-ray of skull, cervical spine, and pelvis and therefore is by definition more work than CPT code 72069. CPT code 72069 is also noted as ''CMS/other'' code in the RUC's time file and the times in that file are not divided into time periods as CPT code 72081 is. One commenter suggested that a more accurate crosswalk was CPT code 74020 (Radiologic examination, abdomen; complete, including decubitus and/or erect views,) which has a work RVU of 0.30. Using the same increments, the commenter suggested that the CMS proposed change for CPT code 72081 to 0.26 RVUs would result in an accurate increase in work across the family.

Response: We continue to believe that CPT code 72069 is an accurate crosswalk. While CPT code 72069 may not be divided into time periods, the ratio between the total time and the RVU adequately reflects the relationship between time and intensity in CPT code 72081. Although we used CPT code 72069 as a comparison to CPT code 72081, we note that CPT code 72081 has a higher work RVU, which accounts for the extra work associated with imaging the skull, cervical spine, and pelvis. We do not believe that CPT code 74020 would be an accurate crosswalk because it describes a radiological examination of the abdomen whereas CPT code 72069 refers to the same anatomical region as CPT code 72081.

Therefore, after considering the comments received, we are finalizing these work RVUs for 72081, 72082, 72083, and 72084 as proposed.

(14) 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. In the proposed rule, we stated that we had concerns about valuation of this code since it is a guidance code

used only for a single procedure, CPT code 58970 (aspiration of ova), and that these two codes are typically billed concurrently. We believe CPT codes 76948 and 58970 should be bundled to accurately reflect how the service is furnished.

We proposed 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 CPT code 58970. We proposed 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 work time of 30 minutes and an RVU of 0.56. Therefore we proposed to maintain 25 minutes of intraservice time for CPT code 76948 and proposed a work RVU of 0.56.

The following is a summary of the comments we received on our proposals.

Comment: Commenters stated that CMS should not have removed the work from the pre and post service portions of the service period and should restore the RUC-recommended work RVU of 0.85. The commenters stated that in the pre service period the physician reviews clinical history as well as prior imaging studies, and in the post service period the physician reviews and signs final report. The RUC commented that CPT codes 58970 and 76945 were billed less than 10 times each in 2014, and were not billed together in any of those instances. The RUC acknowledged that these codes may be billed together under private payers and stated they would continue to review codes billed together 75 percent of the time and bundle them when appropriate.

Response: We appreciate the commenters' feedback. However, given the definition of the codes, we continue to believe that CPT code 76945 is the image guidance code for CPT code 58970, and that these codes would not typically be billed separately. We acknowledge the anomalies in the low volume of Medicare claims data but do not believe that data likely reflects the way the services are intended to be reported. Therefore, any pre- or post-service work would be accounted for in CPT code 58970. After considering the comments received, we are finalizing a work RVU of 0.56 for CPT code 76945 as proposed.

(15) Surface Radionuclide High Dose Radiation Brachytherapy (CPT Codes 77767, 77768, 77770, 77771, and 77772)

In October 2014 the CPT Editorial Panel created five new codes to describe high dose radiation (HDR) brachytherapy. We proposed the RUC-recommended work RVUs of 1.05, 1.40, 1.95, 3.80, and 5.40 respectively, for CPT codes 77767, 77768, 77770, 77771, and 77772. The RUC also recommended a new PE input, a brachytherapy treatment vault, which we proposed to include without modification.

Comment: Commenters expressed support for CMS' proposed work and time values for this family of codes, and for CMS' proposal to add the brachytherapy vault as a PE input. Many commenters expressed concern for the overall downward trend in reimbursement for brachytherapy services, citing a sustained decrease in office-based brachytherapy procedures since 2009. The commenters encouraged CMS to enact measures to improve this.

Response: We appreciate commenters' concerns regarding accurate payment for brachytherapy services. The revaluation of services under the Potentially Misvalued Code Initiative is aimed at achieving the most appropriate relative values under the PFS. There is not an intentional ''downward trend'' for any particular family of services. We remind commenters and stakeholders that disagree with CMS values, including those based on RUC recommendations, that in addition to submitting comments on our proposed rules, they may also nominate codes as potentially misvalued through the public nomination process. We are finalizing the values for HDR brachytherapy as proposed.

(16) Immunohistochemistry (CPT Codes 88341, 88342, and 88344)

As discussed in the proposed rule, in establishing CY 2015 interim final direct PE inputs 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 recommendation 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 reexamined 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 proposed 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.

In establishing interim final work RVUs for this family of codes, we refined the RUC recommendation for CPT code 88341 to 0.42, such that the work RVU for this add-on code was 60 percent of that of the base code 88342 (0.70 work RVUs). We noted that for similar procedures in this family, the RUC had recommended work RVUs for add-on codes that were 60 percent of the base codes, and that we believed this methodology would appropriately value this add-on code. In the proposed rule, we reexamined the work RVU for this service in the context of reviewing the immunoflurescent studies procedures. In doing so, we increased the work RVU of this add-on code to 0.53, which reflected 76 percent of 0.70, the base code for this service. We discuss our rationale for this adjustment in the immunofluorescent studies section below. However, we inadvertently omitted the rationale for this revision to the work RVU in the proposed rule.

The following is a summary of the comments we received on our proposals.

Comment: Several commenters, including the RUC, stated their appreciation of CMS' reconsideration when reexamining the RUC-recommended direct PE inputs, ''UltraView Universal DAB Detection Kit'' (SL488) and equipment time for the supply item ''microscope, compound'' (EP024) for CPT codes 88341, 88342, and 88344 following feedback from the public.

A few commenters also noted that the work RVU for CPT code 88341 (Immunohistochemistry or immunocytochemistry, per specimen; each additional single antibody stain procedure (List separately in addition to code for primary procedure) as displayed in Addendum B of the proposed rule was inconsistent with the CY 2015 work RVU but was not discussed elsewhere in the proposed rule.

Response: The discussion about the rationale for the increased work RVU for CPT code 88341 was inadvertently omitted from the proposed rule. Since the proposed rule did not include this discussion, we will maintain the interim final status of the CY 2015 work RVU of 0.53 for CY 2016 and we are seeking comment on this work RVU during the comment period for this final rule with comment period.

(17) Immunofluorescent Studies (CPT Codes 88346 and 88350)

For CY 2016, the CPT Editorial Panel deleted one code, CPT code 88347

(Antibody evaluation), created a new add-on service, CPT code 88350, 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 88350. In the proposed rule, we stated that although we proposed to use the RUC recommendation for CPT code 88346, we did not believe the recommendation for CPT code 88350 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 code 37250 (Ultrasound evaluation of blood vessel during diagnosis or treatment) and CPT code 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 88350. Due to these similarities, we believed it was 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 88350. In the proposed rule, we explained that we multiplied the RVU of CPT code 88346, 0.74, by 24 percent, and then subtracted the product from 0.74, resulting in a work RVU of 0.56 for CPT code 88350. Therefore, for CY 2016, we proposed a work RVU of 0.74 for CPT code 88346 and 0.56 for CPT code 88350.

The following is a summary of the comments we received on our proposals.

Comment: Several commenters stated their disagreement with the comparison of immunofluorescent studies (CPT codes 88346 and 88350) to ultrasound evaluation of blood vessels (CPT Codes 37250 and 37251). Commenters specifically stated the ultrasound services are add-on services involving initial and additional vessels, whereas CPT codes 88346 and 88350 involve work related to initial and additional single antibody stain procedures. Commenters maintain that the level of work required to evaluate the initial stain is nearly identical to the second and that no efficiency is gained from the initial to the next and, therefore, a reduction in work RVUs for the additional slide would be inappropriate.

Response: We continue to believe that the RVUs should reflect a reduction of overall work in each additional antibody stain slide. We also note that for CY 2015, we established as interim final a 40 percent reduction for add-on codes, which we subsequently refined to a 24 percent reduction in the CY 2016 proposed rule. We have not received any alternative recommendations as to the appropriate value for CPT code 88350. Therefore, we are finalizing our proposed valuation for CPT codes 88346 and 88350.

(18) Morphometric Analysis (CPT Codes 88364, 88365, 88366, 88367, 88373, 88374, 88377, 88368, and 88369)

The RUC reviewed and developed recommendations regarding CPT codes 88367 and 88368. We reviewed and proposed values based on those recommended values as discussed in the proposed rule. Subsequently, the RUC 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 was identical to the RUC recommendation provided for CY 2015. Therefore, we proposed to retain the CY 2015 work RVUs and work time for CPT codes 88367 and 88368 for CY 2016.

For CPT codes 88364 and 88369, we refined the RUC recommendations to 0.67 for both procedures, such that the work RVUs for these add-on codes was 60 percent of the base codes. We noted that for similar procedures in this family, the RUC had previously recommended work RVUs for add-on codes that were 60 percent of the base codes, and that we believed this methodology would appropriately value these add-on codes. In the proposed rule, we reexamined the work RVUs for these services in the context of reviewing the immunofluorescent studies procedures. In doing so, we increased the work RVUs of these add-on codes to 0.67, which reflected 76 percent of 0.88, the work RVUs of the base codes for these services. We discuss our rationale for this adjustment in the immunofluorescent studies section above. However, we inadvertently omitted the rationale for this revision to the work RVU in the proposed rule.

As discussed in the proposed rule, 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.

For CY 2016, we reexamined these codes when valuing the immunofluorescence family of codes, and reviewed information received from commenters during the CY 2015 final rule's comment period that described the typical batch size for each of these services, which identified apparent inconsistencies and discrepancies in the quantity of units among the codes in the family. For CY 2016, we proposed 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. 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 proposed 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. Therefore, we proposed to include this equipment item consistent with the RUC recommendations for CPT code 88366.

In the proposed rule, we noted 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 noted 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

expressed concern 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 noted in the proposed rule 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 noted that an equipment item involved in furnishing a service 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 invited stakeholders to provide us with information about the equipment and supply inputs used in the typical case for particular pathology services.

The following is a summary of the comments we received on our proposals.

Comment: Several commenters, including the RUC, stated their disagreement with the methodology utilized in valuing CPT code 88367 and urged CMS to use survey data and magnitude estimation when proposing a work RVU. Commenters also suggested that there should be no comparison of intravascular ultrasound services to morphometric analysis, immunohistochemistry, immunofluorescence or any pathology service. One commenter noted that for CPT code 88374 (Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), using computer-assisted technology, per specimen; each multiplex probe stain procedure), using computer-assisted technology does not replace the pathologist's work; it merely refers to computer-aided selection of images for the pathologist to review and that the computer does not establish the distinction between cancer and non-cancer cells.

Response: As discussed in the CY 2015 final rule with comment period (79 FR 67669), we do not believe the RUC-recommended work RVU of 0.86 for 88367 (intraservice time = 25 minute) adequately reflects the difference in time relative to 88368 (RVU = .88, intraservice time = 30 minutes). Commenters did not address our concerns about this change in time not being reflected in the work RVU for 88367. Therefore, we continue to believe 0.73 RVUs accurately reflects the work for CPT code 88367. With regard to CPT code 88374, while we acknowledge using computer-assisted technology does not replace the pathologist's work, we continue to believe there are some efficiencies gained with the computer assistance. After considering the comments received, for CY 2016, we are finalizing the values for CPT codes 88367 and 88374 as proposed.

Comment: A commenter noted that the work RVUs for CPT codes 88364 and 88369 as displayed in Addendum B of the proposed rule were inconsistent with the CY 2015 work RVUs, but were not discussed elsewhere in the proposed rule.

Response: As noted above, the discussion about the rationale for the increased work RVU was inadvertently omitted from the proposed rule. Since the proposed rule did not include this discussion, we will maintain the interim final status of the work RVU of 0.76 for CPT codes 88464 and 88369 for CY 2016 and we are seeking comment on these work RVUs during the comment period for this final rule with comment period.

(19) Vestibular Caloric Irrigation (CPT Codes 92537 and 92538)

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, 92537 and 92538, to report caloric vestibular testing for bithermal and monothermal testing procedures, respectively. The RUC recommended a work RVU of 0.80 for CPT code 92537 and a work RVU of 0.55 for CPT code 92538. In the proposed rule, we stated that we believed that the recommendations for these services overstate the work involved in performing these procedures. Due to similarity in service and time, we proposed that a direct crosswalk of CPT code 97606 (Negative pressure wound therapy, surface area greater than 50 square centimeters, per session) to CPT code 92537 accurately reflects the total work involved in furnishing the service. To establish a proposed value for CPT code 92538, we divided the proposed work RVU for 92537 in half since the code descriptor for this procedure describes the service as having two irrigations as opposed to the four involved in CPT code 92537. Therefore, for CY 2016, we proposed work RVUs of 0.60 to CPT code 92537 and 0.30 to CPT code 92538.

The following is a summary of the comments we received on our proposals.

Comment: Several specialty societies stated their disappointment that CMS did not accept the RUC-recommended work RVUs for CPT codes 92537 and 92538. Commenters stated their objection to the rationale CMS used, stating that the rationale ignored the cogent, methodical, and thorough approach utilized by the RUC.

Response: We appreciate the commenters' feedback. However, we reiterate that CPT code 67606 has nearly identical intra-service and total times as CPT code 92537 and given the similarity in services we continue to believe the direct crosswalk from CPT code 97606 to CPT code 92537 to be the most accurate. Also, CPT code 92538 describes two irrigations which is half the work involved in furnishing the service of CPT code 92537. For that reason, we continue to believe it is appropriate to establish 92538 with half of the work RVUs of 92537. Therefore, for CY 2016 we are finalizing a work RVU of 0.60 for 92537 and 0.30 for 92538.

(20) Instrument-Based Ocular Screening (CPT Codes 99174 and 99177)

For CY 2015, the CPT Editorial Panel created a new code, CPT code 99177, 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. In the proposed rule, we stated that CPT code 99174 was currently assigned a status indicator of N (non-covered service) which we proposed should remain unchanged since this is a screening service. After review of CPT code 99177, we proposed that this service was also a screening service and should be assigned a status indicator of N (non-covered service). Therefore, for CY 2016, we proposed to assign a PFS status indicator of N (non-covered service) for CPT codes 99174 and 99177.

The following is a summary of the comments we received on our proposals.

Comment: A few commenters, including the RUC, stated their disagreement with CMS' proposal to assign a status indicator of ''N'' (non-covered service). Commenters stated there is a long-standing precedent that status indicator ''N,'' codes have had their RUC-recommended values published in the PFS.

Response: We continue to believe CPT codes 99174 and 99177 are screening

services and are therefore non-covered services under the Medicare program. Therefore, for CY 2016, we are finalizing our proposed assignment of a PFS status indicator of N (non-covered service) for CPT codes 99174 and 99177. Because we have not reviewed the recommended values for these services, we do not believe that we should develop or display RVUs for these services. In some cases in the past, we have developed and displayed RVUs for codes not separately payable by Medicare. However, we note that this practice has not been consistently applied and we have concerns about this practice since it is not apparent in the display itself that the resulting RVUs do not reflect our review or assessment of the recommendations nor do they reflect the influence of updated Medicare claims data. However, we understand that, for PFS nonpayable services, displaying RVUs that are based solely on recommendations may serve an interest for the public. Therefore, we will consider for the future how we might reconcile that interest with our interest in maintaining a clear distinction between the RVUs that result from our established methodology and RVUs that result solely from recommended input values.

(21) Lung Cancer Screening Counseling and Shared Decision Making Visit and Lung Cancer Screening With Low Dose Computed Tomography (CPT Codes G0296 and G0297)

We issued national coverage determination (NCD) for Medicare 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, effective February 5, 2015. The American College of Radiology (ACR) submitted recommendations for work and direct PE inputs.

We proposed to value CPT code G0296 (Counseling visit to discuss need for lung cancer screening (LDCT) using low dose CT scan (service is for eligibility determination and shared decision making)) using a crosswalk from the work RVU 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 one 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 G0296 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.

For CPT code G0297 (Low dose CT scan (LDCT) for lung cancer screening), the ACR recommended that CMS crosswalk CPT code G0297 to CPT code 71250 (computed tomography, thorax; without contrast material) with additional work added to account for the added intensity of the service. After reviewing this recommendation, we stated in our proposal that the work (time and intensity) was identical for both CPT code G0297 and CPT code 71250. Therefore, we proposed a work RVU of 1.02 for CPT code G0297. The following is a summary of the comments we received on our proposals.

Comment: Several commenters stated that the CMS-proposed crosswalk for G0296 (Counseling visit to discuss need for lung cancer screening (LDCT) using low dose CT scan (service is for eligibility determination and shared decision making)) did not accurately reflect the time and intensity of furnishing this service. Some commenters suggested that 15 minutes is not enough time for the practitioner to engage in a meaningful conversation with the patient and that the work and time for the shared decision making visit should reflect this.

Response: Because we continue to believe that the cognitive work for G0296 is comparable to G0443 and that there is no additional work associated with fulfilling the requirements of the NCD, we believe that the work and time for the counseling and shared decision making visit is included in the values associated with the crosswalk code.

Comment: For CPT code G0297 (Low dose CT scan (LDCT) for lung cancer screening), a few commenters expressed support for our proposed work RVUs of 1.02. Several commenters were concerned that the proposed crosswalks and work valuations did not adequately reflect the time and intensity involved in furnishing these services. The American College of Radiology suggested that a lung cancer screening low dose CT required greater technical skill and mental effort to make the correct diagnosis, and that the baseline increase of malignancy caused greater psychological stress for the provider and the additional requirements of the NCD add to the intensity of performing these services.

Response: Reading radiologists that meet the eligibility requirements of the NCD have extensive experience interpreting chest CTs. For example, the NCD states that among other things, an eligible reading radiologist must have been involved in the supervision and interpretation of at least 300 chest CT acquisitions in the past 3 years. Therefore, we do not believe that extra work is involved in furnishing the low-dose CT, as compared to CPT code 71250.

Comment: Several commenters requested CMS clarify that a medically necessary E/M visit can be billed on the same day as the lung cancer screening counseling and shared decision making visit. Some commenters also requested that the shared decision making visit be considered part of, or complementary to, the annual wellness visit. Several commenters also asked CMS to clarify that the lung cancer LDCT screening and the counseling and shared decision making visit are not subject to cost sharing since they are preventive services.

Response: As long as the NCD requirements for the counseling and shared decision making visit are met, the counseling visit may be billed on the same day as a medically necessary E/M visit or an annual wellness visit with the -25 modifier. Practitioners should refer to the NCD for information regarding the Medicare coverage requirements for the counseling and shared decision making visit. Lung cancer screening with LDCT, including a lung cancer screening counseling and shared decision making visit, is covered as an additional preventive benefit, identified for Medicare coverage through the NCD process. Therefore, this benefit meets the criteria in sections 1833(a)(1) and (b)(1) of the Act for nonapplication of the deductibles and coinsurance.

Comment: Many commenters were concerned with the fact that, although the NCD was issued in February of 2015, there are no instructions for billing services performed prior to 2016.

Response: CMS is in the process of developing claims processing, coding and billing instructions. This information is forthcoming.

Comment: One commenter asked if the imaging facility would be subject to recoupment for a CT if a hospital performed a CT believing that the required counseling had occurred, and later it was determined that it had not.

Response: We appreciate this comment. While we acknowledge the commenter's concern, we believe that this comment is outside the scope of this rulemaking.

Comment: One commenter requested that the shared decision making visit be added to the list of telehealth services.

Response: We refer readers to section II.I. of this final rule with comment period, where we discuss the process for adding services to the list of Medicare

telehealth services. In addition, we note that information about how to submit a request to add a service to the telehealth list is available on the CMS Web site at www.cms.gov/telehealth.

Comment: Commenters were concerned that there was a discrepancy in reimbursement between the PFS and the OPPS.

Response: Payments made under the PFS and the OPPS are established under different statutory provisions using different bases and methodologies, and therefore often result in differential payment amounts for similar services.

Comment: Several commenters pointed out that there were no malpractice or PE inputs for G0296 and G0297 in the downloads available with the proposed rule.

Response: We appreciate commenters' attention to detail and we have corrected these values in this final rule with comment period.

After consideration of the comments received, we are finalizing the work RVUs for G0296 and G0297 as proposed.

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 PE data that are auditable, comprehensive, and regularly updated would contribute to the accuracy of PE 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 RVUs, 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 reviewed the RUC-recommended direct PE inputs for these services and proposed to use them, with the refinements addressed in this section. However, we also identified 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 noted that while we proposed 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)

The RUC recommendation for CPT code 11760 included 22 minutes assigned to clinical labor task ''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 were also calculated based on the 22 minutes of intraservice time. We proposed to use the RUC-recommended equipment times while we solicited comments on whether or not it would be appropriate to include the full 33 minutes of work intraservice time for the equipment.

Comment: A commenter clarified that the 22 minutes of time for clinical labor task ''Assist physician in performing procedure'' was indeed intended to represent 67 percent of the physician intraservice time of 33 minutes. The commenter agreed that it is appropriate to include the full 33 minutes of intraservice time in the equipment time calculation.

Response: We appreciate the clarification of this issue from the commenter. After consideration of comments received, we will refine the equipment times for CPT code 11760 by adding 11 minutes to each item, to reflect the entire intraservice period of 33 minutes.

Comment: One commenter disagreed with the CMS decision to remove pre-service clinical labor time in the non-facility setting. The commenter stated that the service is performed more than 33 percent of the time in a facility setting, and suggested that CMS should adopt the RUC recommendation.

Response: We continue to believe that this clinical labor task would not be performed on a typical basis, as the procedure is most frequently done on an emergent basis. We also do not believe that time should be allotted for clinical labor task ''Provide pre-service education/obtain consent'' in the preservice period, since CPT code 11760 also includes time for the same clinical labor task in the service period. We note that information about the percentage of time a service is performed in one setting versus another is not factored into our assessment of PE inputs for each setting. After consideration of comments received, we are finalizing the direct PE inputs as proposed for CPT code 11760, with the additional refinements to equipment time discussed above.

b. Simple Repair of Superficial Wounds (CPT Codes 12005, 12006, 12007, 12013, 12014, 12015, and 12016)

We refined the time for clinical labor task ''Check dressings & wound/home care instructions'' to 3 minutes for each code in this family to reflect the standard time for this clinical labor task.

Comment: One commenter stated that the commenter was unaware that there was a standard time for this clinical labor task. The commenter stated that a reduction to 3 minutes was not warranted absent an identified standard in this regard.

Response: Three minutes is the generally applied number of minutes assigned to the clinical labor task ''Check dressings & wound/home care instructions''. In general, we continue to believe that this is the most accurate time for this clinical labor task.

After consideration of comments received, we are finalizing the direct PE inputs as proposed for CPT codes 12005, 12006, 12007, 12013, 12014, 12015, and 12016.

c. Intermediate Repair of Wounds (CPT Codes 12041, 12054, 12055, and 12057)

We refined the preservice clinical labor time in the non-facility setting to zero minutes, and the information in the proposed rule indicated that this refinement was because these codes are emergent procedures where certain

clinical labor tasks would not typically be performed. We also removed one of the two suture packs (SA054) from the recommended list of supplies, and adjusted the equipment time formulas to reflect the established standards.

Comment: A commenter disagreed with the CMS decision to remove the preservice clinical labor time in the non-facility setting. The commenter stated that neither the site of service nor the diagnosis codes for these services indicate that these are emergency procedures, and they are most commonly performed in a non-emergent setting. The commenter urged CMS to accept the RUC-recommended times for these clinical labor tasks.

Response: We appreciate the commenter bringing this issue to our attention. After reviewing these clinical labor activities again, we continue to believe that time for these preservice activities should not be included in the non-facility setting. However, our stated rationale for this refinement, that this is due to the emergent nature of these procedures, was incorrectly stated due to a clerical error. We intended to explain that we refined these preservice activities to zero minutes because the standard preservice clinical labor for 10-day global codes in the non-facility setting is zero minutes for all five preservice activities, and there was no additional justification to increase the value for this group of codes. We are maintaining this refinement to zero minutes.

Comment: One commenter indicated that CMS incorrectly reduced the quantity of suture packs (SA054) from two to one for CPT codes 12055 and 12057 in the facility setting. CMS stated that there was no rationale for the increase in the quantity of this supply and that sutures would only be removed one time, but the commenter stated that suture removal takes place twice for these procedures, with some of the sutures being removed at each of the two office visits. The commenter requested that CMS accept the RUC-recommended supply inputs.

Response: We appreciate the additional information regarding the use of suture packs for this procedure. After consideration of comments received and based on this presentation of new information, we agree that the second suture pack would typically be used in these procedures, and we are restoring the quantity of SA054 to two for CPT codes 12055 and 12057 in the facility setting.

After consideration of comments received, we are finalizing the direct PE inputs as proposed for CPT codes 12041, 12054, 12055, and 12057, with the additional refinement to SA054 discussed above.

d. Nasal or Sinus Surgical Endoscopy (CPT Codes 31295, 31296, and 31297)

We refined some of the preservice clinical labor times to align with standard values, as well as the fact that the decision for surgery would have been made on the previous day. We also refined the time for clinical labor task ''Sedate/apply anesthesia'' to reflect the established standard, refined the quantity of the Afrin nasal spray (SJ037) to the amount typical for the procedures, and refined the equipment times to conform to our standard policies.

Comment: A commenter disagreed with the decision by CMS to refine the time for clinical labor task ''Sedate/apply anesthesia'' from 5 minutes to 2 minutes. The commenter stated that 5 minutes would be typical for these procedures, since a topical anesthesia requires additional time to be applied, the staff typically applies a local anesthetic after the initial topical form, and a second application is necessary in the majority of patients.

Response: We continue to believe that the established standard of 2 minutes for clinical labor task ''Sedate/apply anesthesia'' is the most accurate value for these procedures. The RUC recommendations for these codes did not provide a rationale for anesthesia times in excess of the standard value.

After consideration of comments received, we are finalizing the direct PE inputs for CPT codes 31295, 31296, and 31297 as proposed.

e. Removal of Embedded Foreign Body From Mouth and Pharynx (CPT Codes 40804 and 42809)

In the proposed rule, we stated that the ENT suction and pressure cabinet (EQ234) would not typically be used during an office visit, and we refined the equipment times to remove the minutes associated with the office visit. We also refined the quantity of supply item ''suction canister'' (SD009) from two to one to reflect the amount typically used during these procedures.

Comment: One commenter indicated that the suction and pressure cabinet would be standard in ENT rooms, and would be used to store items and equipment to keep them clean. The commenter urged CMS to accept the RUC-recommended equipment time for the suction and pressure cabinet.

Response: We include direct PE inputs for items and services that are typically involved in furnishing a particular service. The presence of the suction and pressure cabinet in the same room where the procedure is being performed does not provide sufficient rationale for its inclusion in this service since it is not typically used in furnishing the service. We continue to believe that the suction and pressure cabinet would only be utilized during the intraservice portion of CPT codes 40804 and 42809, and not during the follow-up office visits.

Comment: The same commenter stated that these procedures required the use of two suction canisters. The commenter explained that one suction canister would be used during the intraservice portion of the procedure, and the other suction canister would be used during a follow-up office visit.

Response: We continue to believe that the use of a suction and pressure cabinet would not be typical for an office visit, and therefore there is only a need for one suction canister for these procedures. Furthermore, the RUC considered this issue in making its recommendations, and found that no suction canister is needed in the follow-up visit for the service when furnished in the facility setting. We therefore do not believe that the suction and pressure cabinet, with a corresponding suction canister, would be typically used during a follow-up visit when the procedure is furnished in the non-facility setting.

After consideration of comments received, we are finalizing the direct PE inputs as proposed for CPT Codes 40804 and 42809.

f. Cytopathology Fluids, Washings or Brushings and Cytopathology Smears, Screening, and Interpretation (CPT Codes 88104, 88106, 88108, 88112, 88160, 88161, and 88162)

We proposed to update the price for supply item ''Millipore filter'' (SL502) based on stakeholder submission of new information following the RUC's original recommendation. As requested, we proposed to crosswalk the price of SL502 from the cytology specimen filter (Transcyst) supply (SL041) and assign a price of $4.15. 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 final rule with comment period at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*. We also refined the time for clinical labor task ''Order, restock, and distribute specimen containers with requisition forms'' to zero minutes due to our belief that this task was not allocable to individual services and therefore an

indirect PE under our established methodology.

As discussed in the proposed rule, 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 proposed 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 no slide preparation is taking place, as the descriptor for this code suggests.

We proposed to update supply item ''protease solution'' (SL506) based on stakeholder submission of new information following the RUC's original recommendation. As requested, we proposed 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 direct PE input database, which is available on the CMS Web site under downloads for the CY 2016 final rule with comment period at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/PFS-Federal-Regulation-Notices.html*.

Subsequent to receiving these recommendations, we received additional recommendations from the RUC for this family of procedures following the publication of the CY 2016 PFS proposed rule. We will address both recommendations here.

Comment: A commenter provided an invoice for supply item ''Millipore filter'' (SL502) to replace the current supply crosswalk to the cytology specimen filter (SL041).

Response: We appreciate the submission of this supply invoice. After consideration of comments received, we will update the price of supply item ''Millipore filter'' (SL502) in our direct PE inputs database from the current value of $4.15 to the submitted invoice price of $0.75.

Comment: A commenter stated that the clinical labor task ''Order, restock, and distribute specimen containers with requisition forms'' is a direct PE as it is a variable clinical labor task. The commenter stated that this task depends on the typical laboratory volume mix for each service, and any blanket categorization cannot be justified.

Response: We continue to believe that the clinical labor task ''Order, restock, and distribute specimen containers with requisition forms'' is an indirect PE, as it is not allocated to any individual service. We have defined direct PE inputs as clinical labor, medical supplies, or medical equipment that are individually allocable to a particular patient for a particular service. For a detailed explanation of the direct PE methodology, including examples, we refer readers to the CY 2007 PFS final rule with comment period (71 FR 69629). Therefore, whether a particular cost is fixed or variable does not determine whether it is a direct PE input under the methodology. We have removed the recommended 0.5 minutes of time for clinical labor task ''Order, restock, and distribute specimen containers with requisition forms'' from all seven of these procedures. However, we have maintained 0.5 minutes of time for clinical labor task ''Prepare specimen containers/preload fixative/label containers/distribute requisition form(s) to physician'' from the previous recommendations for CPT codes 88160, 88161, and 88162, and added this 0.5 minutes to the other four codes in the family to conform with the other codes in the family.

Comment: Several commenters disagreed that there is a lack of clarity and possibility for confusion within the cytopathology smears, screening and interpretation family. These commenters stated that in CPT code 88160, the slide is received in the laboratory typically as a spray-fixed and air-dried slide that has not been stained. The slide is then stained in the laboratory with the appropriate stain per fixation prior to review and interpretation. For CPT code 88161, the laboratory must first put the patient material on the slide (that is, prepare the slide) then stain it in the laboratory with the appropriate stain per fixation prior to review and interpretation. Both codes therefore include staining, review and interpretation in the laboratory. Commenters did not agree that there was any provider confusion concerning these specialized, low volume codes, and stressed that these codes did not need to be added to the potentially misvalued code list.

Response: We appreciate the additional information clarifying the nature of the work that takes place during these two procedures.

Comment: The same commenters did not agree with the refinement to the time for clinical labor task ''Stain air dried slides with modified Wright stain'' from 5 minutes to 0 minutes for CPT code 88160 and from 5 minutes to 3 minutes for CPT code 88161. Commenters explained that for CPT code 88160, the slides are received in the laboratory typically as spray-fixed and air-dried slides that have not been stained. They must be stained prior to review and interpretation. For CPT code 88161, the laboratory must put the patient material on the slide, followed by staining for review and interpretation. Both codes therefore include staining, review and interpretation in the laboratory.

Response: We appreciate the submission of this additional information regarding the staining of slides in these procedures. After consideration of comments received and based on the submission of this additional information, we agree that there should be time for allocated for clinical labor task ''Stain air dried slides with modified Wright stain'' in CPT code 88160. We later received additional recommendations from the RUC that suggested a time of 2 minutes for the clinical labor task. We are therefore accepting the time for clinical labor task ''Stain air dried slides with modified Wright stain'' at the value of 2 minutes in the most recent set of RUC recommendations for all seven procedures; we believe that 2 minutes is an accurate standard for this clinical labor task.

Comment: One commenter disagreed with the CMS refinement to the clinical labor task ''Prepare automated stainer with solutions and load microscopic slides.'' The commenter stated that 4 minutes were recommended for this task, which applied specifically to these particular CPT codes based on the typical laboratory and efficiency assumptions.

Response: We agree with the commenter that 4 minutes is an accurate value for this clinical labor task, but note that we refined the value to 4 minutes during our initial review.

Comment: A commenter recommended that CMS refine the

equipment time of the solvent recycling system to 2 minutes. The commenter expressed the opinion that the use of this equipment is not dependent on clinical labor time.

Response: We continue to believe that the solvent recycling system is an indirect PE cost used across numerous services and not individually allocated to particular procedures. We have removed the clinical labor time associated with the solvent recycling system from all seven codes.

In addition, we have removed the time associated with clinical labor task ''Recycle xylene from stainer'' from all of the codes for similar reasons. We also noticed what appeared to be an error in the amount of non-sterile gloves (SB022), impermeable staff gowns (SB027), and eye shields (SM016) assigned to CPT codes 88108 and 88112. The recommended value of these supplies was a quantity of 0.2, which we believe was intended to be a quantity of 2. We are therefore refining the value of these supplies to 2 for CPT codes 88108 and 88112. After consideration of comments received, we are finalizing the direct PE inputs as proposed for CPT Codes 88104, 88106, 88108, 88160, 88161, and 88162 with the exception of the refinements to the clinical labor, supplies, and equipment described above.

g. Flow Cytometry, Cell Cycle or DNA Analysis (CPT Code 88182)

We refined many of the clinical labor activities in this procedure to align with the typical times included for other recently reviewed pathology codes. We requested additional information regarding the use of the desktop computer with monitor (ED021) since the RUC recommendation did not specify how it is used.

Comment: One commenter disagreed with the eight refinements that CMS made to the clinical labor time for CPT code 88182, and with the rationale of using clinical labor standards for pathology activities in general. The commenter stated that the time for these clinical labor tasks varies for each CPT code, and the RUC-recommended times only reflect the time associated with each particular CPT code. The times associated with pathology clinical labor activities vary by typical laboratory-specific efficiencies, such as batch size. The commenter stated that it was inappropriate for CMS to establish standard clinical labor times for these clinical labor activities, and urged CMS to accept the RUC recommendation for these inputs.

Response: We refer the reader to section II.A. of this final rule for our discussion about clinical labor standards for pathology codes. We continue to believe that clinical labor tasks with the same description are comparable across different pathology CPT codes. We continue to believe that our refinements to clinical labor time ensure the most accurate values for these activities, based on a comparison with other pathology codes that share these same clinical labor activities.

Comment: Several commenters provided additional information concerning the use of the desktop computer with monitor. These commenters explained that CPT code 88182 is performed using ploidy analysis, by comparing the tumor curve to normal cells. These analyses are performed using a dedicated desktop computer with a monitor, which is located in the same room and is dedicated to the patient for each use.

Response: We appreciate the submission of additional information regarding the use of the desktop computer with monitor. After consideration of comments received, we believe that the use of this equipment item is typical during this service and will retain this equipment item for CPT code 88182. After consideration of comments received, we are finalizing the direct PE inputs as proposed for CPT Code 88182.

h.. Flow Cytometry, Cytoplasmic Cell Surface (CPT Codes 88184 and 88185)

We refined many of the clinical labor activities in these procedures to align with the times typically included in other recently reviewed pathology codes. We also requested 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.

Comment: Many commenters disagreed with the decrease in direct PE inputs for these codes. Commenters emphasized that the CMS proposal for these codes reflected reductions in the PE RVUs of 38 percent to CPT code 88184 and 69 percent to CPT code 88185. Commenters stated that these reductions are unreasonable and could jeopardize patient access to care. Several commenters requested that these codes be re-reviewed by the RUC process because certain inputs were not considered in the original RUC deliberations.

Response: We agree with the commenters that there were major changes to the direct PE inputs for these two procedures. We note that almost all of the change in direct PE inputs resulted from RUC recommendations. With the exception of the equipment time for the dye sublimation color photo printer and the clinical labor activities that we refined to bring into accordance with pathology standards, we used the RUC-recommended values to develop proposed PE inputs for these codes and we believe that they provide the most accurate valuation for these services.

Comment: Several commenters indicated that the pathology specialties inadvertently left an equipment item out of their recommendation, Flow Cytometry Analytics Software. The commenters stated that this software is typically used for both CPT codes 88184 and 88185, and recommended adding 10 minutes of equipment time to CPT code 88184 along with 2 minutes of equipment time for CPT code 88185.

Response: Equipment time for flow cytometry analytics software is not currently included in CPT codes 88184 and 88185, and equipment time for this software was not included in the RUC recommendation for these procedures. We believe that if there are new direct PE inputs for these procedures, the commenter should publicly nominate CPT codes 88184 and 88185 for further review through the potentially misvalued code initiative.

Comment: Multiple commenters disagreed with the CMS decision to refine the time for clinical labor task ''Other Clinical Activity: Load specimen into flow cytometer, run specimen, monitor data acquisition, and data modeling, and unload flow cytometer.'' The commenters requested adding 10 minutes to this clinical labor task for CPT code 88184 and 2 minutes for CPT code 88185. This additional time would reflect the Cytotechnician's time spent using the Cytometry Analytics Software to analyze the data generated from the service on a designated desktop computer, w-monitor (ED021). The commenters also requested adding these additional minutes to the equipment time for the desktop computer.

Response: We continue to believe that 7 minutes is the most accurate time for this clinical labor task for CPT code 88184 based on a comparison with CPT code 88182, which is another flow cytometry code in the same family where we included the recommended 7 minutes of time for the same clinical labor task. Since we do not believe that this clinical labor time would be typical, we also do not believe that an additional 10 minutes would be typical for use of the desktop computer with monitor. We continue to believe that the recommended 20 minutes of equipment time for the desktop computer with monitor, which is shared by CPT code

88182, is the most accurate value for CPT code 88184.

Comment: Several commenters stated that the pathology specialties inadvertently miscalculated the amount of supply item ''antibody, flow cytometry'' (SL186) that are necessary for CPT codes 88184 and 88185. The commenters recommended a revised supply quantity of 1.6 for both codes instead of the quantity of 1 included in the RUC recommendation.

Response: CPT codes 88184 and 88185 currently use 1 unit of supply SL186, and the recommendation for these procedures also indicated that 1 unit of supply SL186 is typical. We continue to agree with the RUC recommendation that 1 unit of supply SL186 is the most accurate amount for these procedures. If the commenter believes that these codes are potentially misvalued, then we suggest the submission of a public comment following the publication of the CY2016 final rule with comment period to nominate CPT codes 88184 and 88185 as a potentially misvalued code that could facilitate development of new recommended values.

Comment: A commenter explained that the equipment time for the dye sublimation color photo printer (ED031) is independent of clinical labor time. The commenter suggested that CMS should therefore accept the RUC recommendation of 5 minutes of equipment time for CPT code 88184 and 2 minutes for CPT code 88185, instead of the CMS refinement of 1 minute chosen to reflect the clinical labor time assigned to printing in each procedure.

Response: We appreciate the commenter bringing this issue to our attention. Although we agree with the general principle that equipment time for printers may not align with clinical labor time assigned to printing, we do not agree that 5 minutes of equipment time would be the most accurate value for the dye sublimation color photo printer assigned to CPT code 88184. However, we did notice that we inadvertently set the equipment time of this printer to 1 minute, when it should have been 2 minutes to align with the time for clinical labor task ''Print out histograms.'' After consideration of comments received, we are refining the equipment time of the dye sublimation color photo printer to 2 minutes for CPT code 88184, and maintaining an equipment time of 1 minute for the dye sublimation color photo printer for CPT code 88185.

Comment: Several commenters disagreed with the CMS refinement to the time for clinical labor task ''Enter data into laboratory information system, multiparameter analyses and field data entry, complete quality assurance documentation.'' The commenters stated that entering this information takes additional time, that these are extremely important tasks that require technical skill, and assigning zero minutes to this clinical labor task is illogical for a service like flow cytometry.

Response: We have not recognized the laboratory information system as an equipment item that can be allocated to an individual service. We continue to believe that this is a form of indirect PE, and therefore we do not recognize the laboratory information system as a direct PE input, as we do not believe this task is typically performed by clinical labor for each service.

Comment: One commenter stated that CMS should accept the RUC recommendation of 5 minutes of clinical labor for ''Print out histograms, assemble materials with paperwork to pathologists, review histograms and gating with pathologists.'' The commenter stated that it is not reasonable to expect a cytotechnologist to print out histograms, assemble the documents and deliver them to a pathologist, and review the histograms with a pathologist, all in the span of 2 minutes. The commenter stated that a technologist would not be able to produce a high quality product and ensure its accuracy in the clinical labor time assigned to this task by CMS.

Response: We believe that in order to maintain relativity, it is important to apply standards to ensure consistency in the time for the same clinical labor task among similar procedures. In refining the time for this clinical labor task, we examined procedures that included the same task, such CPT code 88182, which include 2 minutes for this task. Therefore, we continue to believe that 2 minutes is the appropriate value for this clinical labor task.

Comment: A commenter requested that CMS maintain the current quantity of supply item ''lysing reagent'' (SL089). The commenter indicated that there are increased supply costs associated with the newer, more automated flow cytometers, such as additional costs for tandem conjugates and other fluorochromes. Although the commenter agreed that the new technology may require less lysing reagent supplies, they urged CMS to maintain the current supply quantity of SL089.

Response: We believe that the increasing use of new technology reduces the need for the same quantity of lysing reagent used in the past for these procedures. Since the commenter did not provide a rationale for us to maintain the current quantity for supply item SL089 relative to the actual use of that quantity in furnishing the service, we continue to agree that the RUC-recommended quantities of 5 ml for CPT code 88184 and 2 ml for CPT code 88185 are the most accurate amounts of lysing reagent typically required for these procedures.

After consideration of comments received, we are finalizing the direct PE inputs as proposed for CPT codes 88184 and 88185, with the additional refinements to equipment time discussed above.

i. Consultation on Referred Slides and Materials (CPT Codes 88321, 88323, and 88325)

We proposed to remove the time for clinical labor task ''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 proposed to maintain the recommended 4 minutes for this clinical labor task for CPT code 88323, since it does require slide preparation.

We proposed to refine the time for clinical labor task ''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 standard time for clinical labor task ''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 allocation of indirect PE under our established methodology.

We proposed to refine the time for clinical labor 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'' from 7 minutes to 5 minutes. Based on the description of this task, we indicated that we believe that this task would typically take 5 minutes to be performed by the Lab Technician.

We proposed to remove supply item ''eosin solution'' (SL063) from CPT code

88323. We do not agree that this supply would typically be used in this procedure, since the eosin solution is redundant when used together with supply item ''hematoxylin stain supply'' (SL135). We also refined the quantity of SL135 from 32 to 8 for CPT code 88323, to be consistent with its use in related procedures.

We proposed 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 proposed to refine the labor, supplies, and equipment inputs to align with the inputs recommended for CPT code 88321, which also does not include the preparation of slides.

Comment: One commenter disagreed with the CMS refinements and urged CMS to accept the RUC recommendations. The commenter stated that the clinical labor task ''Accession specimen/prepare for examination'' is actually far more time consuming for outside cases than accessioning inside cases, due to the need to individually identify and enter each slide and block. The commenter disagreed with the CMS proposal to remove this clinical labor time for CPT codes 88321 and 88325.

Response: According to the code descriptors, there is no slide preparation taking place in CPT codes 88321 and 88325. These services consist of the consultation and review of specimens prepared by another practitioner. We continue to believe that accession of specimens would not be typical for these procedures, and we therefore maintain that time should not be allocated for this clinical labor task. In addition, any clinical labor required for preparation of the referred slides is already included in the descriptions for other clinical labor tasks included for these codes, such as:

- Register the patient in the information system, including all demographic and billing information. In addition to standard accessioning, enter contributing physician name and address, number of slides and the outside case number, etc., into the laboratory information system. Print labels for slides, and affix labels to slides.
- Print label for outside block and affix to block.
- List and label all accompanying material (imaging on a disk, portion of chart, etc.)

Comment: The commenter also disagreed with the CMS refinement to the time for clinical labor task ''Register the patient in the information system, including all demographic and billing information.'' The commenter stated that these tasks are performed in addition to accessioning the specimen and preparing for examination.

Response: We continue to believe that the typical time for the clinical labor task ''accession of specimen'' is 4 minutes, based on comparison to other pathology services. We refined the time for this clinical labor task to 5 minutes based on our belief that the additional tasks involving label preparation would typically take 1 minute. We also continue to believe that the additional recommended time for CPT codes 88321, 88323, and 88325 likely reflects administrative tasks that are appropriately accounted for in the indirect PE methodology.

Comment: A commenter disagreed with the proposal to remove the time for clinical labor tasks ''Assemble and deliver slides with paperwork to pathologists'' and ''Clean equipment while performing service'' for CPT code 88323. The commenter stated that the assembling of slides in this task was a separate task from the clinical labor associated with preparation of materials associated with the non-frozen section processing of the specimen. The commenter also stated that for the typical laboratory setting, specific equipment must be cleaned and maintained immediately after use.

Response: We continue to believe that these are duplicative clinical labor activities. CPT code 88323 already includes time for clinical labor task ''Complete workload recording logs. Collate slides and paperwork. Deliver to pathologist'' and ''Clean room/equipment following procedure.'' We do not believe that there it would be typical to assemble slides or clean the room twice.

Comment: The commenter disagreed with the removal of the eosin solution (SL063) from CPT code 88323. The commenter stated that the eosin solution would be used for the hematoxylin stain (SL135), and elimination of this supply item would likely compromise patient care. The commenter also indicated that 32 ml of the hematoxylin stain is typical for these services in the typical laboratory setting.

Response: We appreciate the additional information regarding this supply and its importance for staining in this procedure. After consideration of comments received, we believe that this is the most accurate type of eosin supply for use in this type of slide staining because it is most similar to the eosin supply previously used in CPT code 88323. Therefore, we are replacing supply SL063 with supply SL201 (stain, eosin) and restoring a quantity of 8 ml for CPT code 88323. We are also refining our proposed quantity of 8 ml of the hematoxylin stain to 16 ml for CPT code 88323. The current supply inputs for CPT code 88323 have twice the amount of hematoxylin stain compared to eosin, 4.8 compared to 2.4, and we are maintaining the same 2:1 ratio.

Comment: The commenter disagreed with the removal of time for many clinical labor tasks in CPT code 88325, such as ''Dispose of remaining specimens'', ''Prepare, pack and transport specimens and records for in-house storage and external storage'', and several other activities related to slide preparation. The commenter objected to the standardization of clinical labor tasks across differing pathology codes, and stated that these are necessary and integral tasks for this service that cannot be eliminated without compromising standards of care.

Response: As the code descriptor indicates for CPT code 88325, we continue to believe that there is no slide preparation taking place in this procedure. Therefore, we do not believe that clinical labor tasks related to the preparation of slides or the disposal of hazardous waste materials would typically be performed.

Comment: The commenter also disagreed with the CMS decision to remove supplies and equipment unassociated with slide preparation from CPT code 88325. The commenter wrote to indicate that when hematoxylin and eosin (H&E) slides are prepared from referred blocks, all technical services are performed. The commenter urged that the recommended supplies and equipment be restored to CPT code 88325.

Response: We do not agree that referred materials require the same clinical labor, supplies, and equipment as materials prepared locally. The vignette for CPT code 88325 states that the pathologist performing the service is receiving prepared slides from another laboratory; therefore, we do not believe that the use of these supplies and equipment associated with slide preparation would be typical for the second pathologist performing this consultation.

After consideration of comments received, we are finalizing the direct PE inputs as proposed for CPT Codes 88321, 88323, and 88325, with the additional refinement to the eosin stain and hematoxylin stain supplies discussed above in CPT code 88323.

j. Pathology Consultation During Surgery (CPT Codes 88329, 88331, 88332, 88333, and 88334)

We refined many of the clinical labor activities in these procedures to align with the typical times included in recently reviewed pathology codes, in particular the clinical labor times for CPT code 88305. We also removed supply item ''H&E stain kit supply'' (SL231) and replaced it with supply item ''H&E frozen section stain supply'' (SL134) and refined the quantity of the microscope slides (SL122) for CPT codes 88333 and 88334.

Comment: A commenter disagreed with the CMS refinement of these clinical labor activities. The commenter stated that clinical labor times should not be standardized for pathology services, and that although standards may be used as a starting point, the work for pathology codes varies depending on the pathology task that is being done.

Response: We refer the reader to our earlier discussion about clinical labor standards for pathology codes. We continue to believe that clinical labor tasks with the same description are comparable across different pathology CPT codes. For these pathology consultation codes, we have refined the clinical labor times to bring them into accordance with other similar codes, in particular CPT code 88305. For example, we do not believe that the time for clinical labor task ''Assist pathologist with gross specimen examination'' for a consultation procedure (as in CPT code 88331) should require more clinical labor time than the identical clinical labor task in a tissue biopsy procedure (as in CPT code 88305).

Comment: The same commenter stated that 3 minutes of time for clinical labor task ''Clean room/equipment following procedure'' is the standard for surgical procedures, and the same clinical labor time should be applied to pathology procedures.

Response: We do not believe that clinical labor times for surgical procedures are typically applicable to pathology procedures. We believe that it is more accurate to compare clinical labor times for pathology procedures to other pathology procedures that utilize the same clinical labor tasks. In the case of the clinical labor for ''Clean room/equipment following procedure'', we continue to believe that 1 minute is the standard time for these services, based on a comparison to other recently reviewed pathology codes.

Comment: The commenter stated that the H&E stain supply kit removed by CMS is needed to perform the procedure for CPT codes 88331 and 88332, as the kit is needed to prepare the slides (that is, xylene, alcohol, bluing agent, etc). The commenter also stated that the preamble text in the CY 2016 PFS proposed rule did not state anything specific about this substitution, and that CMS must supply a better rational for this proposed change.

Response: We appreciate the opportunity to clarify our position regarding the replacement of the H&E stain supply kit with an H&E frozen section stain. We noticed that these procedures had previously been performed using 1 H&E frozen section stain, which was removed by the RUC in favor of a quantity of 0.1 of supply item ''H&E stain supply kit''. Because the RUC recommendation did not explain why the use of an H&E stain supply kit would be typical, we believed that it would be more accurate to maintain the quantity of 1 for supply item ''H&E frozen section stain'' as is currently included in these codes. We believe that this maintains relativity with other codes in the family, and maintains consistency with other related pathology procedures.

Comment: A different commenter disagreed with the CMS decision to remove the time for clinical labor task ''Prepare room. Filter and replenish stains and supplies.'' The commenter stated that this dedicated room must be prepared for the next immediate consultation after each service; stains must be filtered and changed, while cryostats and chucks must be cleaned. The commenter requested the restoration of the RUC recommended clinical labor time.

Response: We continue to believe that the preparation in this clinical labor task is duplicative with the clinical labor assigned for ''Clean room/equipment following procedure.'' We also continue to believe that the labor involved in replenishing stains and supplies is not allocated to an individual service, and therefore comprises an indirect PE.

After consideration of comments received, we are finalizing the direct PE inputs as proposed for CPT Codes 88329, 88331, 88332, 88333, and 88334.

k. Morphometric Analysis (CPT Code 88355)

We refined many of the clinical labor activities in these procedures to align with the standard times used by other recently reviewed pathology codes, in particular the clinical labor times for CPT code 88305. We also removed the equipment time for the ultradeep freezer (EP046), as we believe that items used for storage such as freezers are more accurately classified as indirect PE.

Comment: One commenter disagreed with the CMS removal of the equipment time for the ultradeep freezer. The commenter stated that the use of the ultradeep freezer is specific to CPT code 88355. While other specimens may be stored in the same freezer, freezer space is unavailable for other specimens or items during storage. Freezer space is therefore a variable direct expense dependent upon patient specimen caseloads, and should be considered a direct expense for pathology services.

Response: As we stated in the CY 2016 PFS proposed rule (80FR 41699), we do not believe that minutes should be allocated to items such as freezers since the storage of any particular specimen in a freezer for any given length of time would be unlikely to make the freezer unavailable for storing other specimens. We continue to believe that the ultradeep freezer is most accurately classified as an indirect PE since freezers can be used for many specimens at once. We refer readers to our discussion of direct PE inputs earlier in this section.

Comment: The same commenter objected to the CMS refinements to standard pathology times for clinical labor tasks ''Assemble and deliver slides with paperwork to pathologist'', ''Clean room/equipment following procedure,'' and ''Receive phone call from referring laboratory/facility with scheduled procedure to arrange special delivery of specimen procurement kit.'' The commenter indicated their disagreement with these refinements and the standardization of pathology clinical labor tasks more generally, as the time for these tasks varies for each unique service.

Response: We refer the reader to our earlier discussion about clinical labor standards for pathology codes. We continue to believe that clinical labor tasks with the same description are comparable across different pathology CPT codes. For this morphometric analysis of the skeletal muscle procedure, we have refined the clinical labor times to bring them into accordance with other similar procedures.

Comment: The commenter disagreed with the CMS refinement to the time for clinical labor task ''Prepare specimen containers/preload fixative/label containers/distribute requisition form(s) to physician.'' The commenter explained that nerves and muscle typically arrive in the laboratory on saline soaked gauze held in a clamp, and the tissue requires specialized knowledge to further prepare and

process it. The commenter stressed that the specimen preparation for these services is vastly different than for routine surgical pathology specimens where large numbers of specimen containers are prepared at one time, and therefore the typical batch size for this type of specimen would be one, necessitating the increased time.

Response: We appreciate the additional description of the clinical labor tasks taking place in CPT code 88355 provided by the commenter. Based on this presentation of further clinical information and after consideration of comments, we believe that additional time for clinical labor task ''Prepare specimen containers/preload fixative/label containers/distribute requisition form(s) to physician.'' is appropriate. We note that the original RUC recommendation included 9 minutes for this clinical labor task. However, this clinical labor task is related to clinical labor task ''Accession specimen/prepare for examination''. To avoid duplicative preparation labor, we have assigned an additional 4.5 minutes relative to our proposal, for a total of 5 minutes, of time for clinical labor task ''Prepare specimen containers/preload fixative/label containers/distribute requisition form(s) to physician'' for CPT code 88355.

Comment: The commenter requested that CMS adopt the RUC-recommended time of 4 minutes for clinical labor task for ''Prepare, pack and transport specimens and records for storage.'' The commenter explained that these specimens are quite unique and require special care and handling and the time allocated to this task is typically longer than other pathology specimens.

Response: We appreciate the commenter submission of additional information regarding this clinical labor task. After consideration of comments received, we believe that it would be more accurate to increase the time for this clinical labor task to 3 minutes for CPT code 88355, to reflect the additional preparation taking place over the typical storage of specimens in other pathology procedures.

Comment: The commenter disagreed with the CMS decision to remove the recommended time for clinical labor task ''Prepare specimen for −70 degree storage.'' The commenter stated that this task was not on the table of standard times for clinical labor tasks associated with pathology services included in the CY 2016 PFS proposed rule, and this specimen preparation task is unique to CPT code 88355.

Response: We believe that the resource costs associated with storage preparation are accurately accounted for under the minutes assigned to the clinical labor tasks ''Prepare, pack and transport specimens and records for storage'' for CPT code 88355. We believe that the clinical labor associated with preparation for −70 degree storage would be duplicative of this clinical labor task. We have also added additional time for clinical labor task ''slide storage preparation'' under the clinical labor task ''Prepare, pack and transport specimens and records for storage'' to reflect the extra storage requirements of this procedure.

Comment: The commenter also disagreed with the CMS decision to refine the time for clinical labor task ''Assist pathologist with gross examination.'' The commenter wrote that specialty knowledge is required to further process the tissue. The tag of nerve or muscle outside the clamp must be carefully trimmed by hand with the trimmings going to formalin containers. Clinical labor staff is needed to collaborate with the pathologist often to prepare the specimen and process the specimen. Tissue must be examined and, if too thick, must be further trimmed to allow penetration by glutaraldehyde. The properly trimmed, clamped tissue can then be transferred to a glutaraldehyde container, which is then transferred to a refrigerator for at least 24 hours when it can then be processed with further consultation with the pathologist.

Response: We appreciate the submission of additional clinical information regarding the clinical labor utilized in the performance of CPT code 88355. However, we do not agree that all of this labor would take place during the ''Assist pathologist with gross examination'' task. We believe that the information provided by the commenter describes several other steps in the procedure, such as ''Measure specimen and fix on muscle/nerve clamp'' and ''Process specimen for slide preparation'', each task having its own respective clinical labor time. In order to avoid the potential for duplicative clinical labor, we are maintaining the CMS refinement to 3 minutes for clinical labor task for ''Assist pathologist with gross examination'' for CPT code 88355.

After consideration of comments received, we are finalizing the direct PE inputs as proposed for CPT code 88355, with the additional clinical labor refinements discussed above.

l. Morphometric Analysis, Tumor Immunohistochemistry (CPT Codes 88360 and 88361)

We refined many of the clinical labor activities in these procedures to align with the typical times included in recently reviewed pathology codes. We also proposed 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 proposed to reclassify these two pieces of equipment as a single item with a price of $150,000, which will use equipment code EP112. CPT codes 88360 and 88361 have been valued using this new price. The equipment minutes remain unchanged.

The RUC recommendation for CPT codes 88360 and 88361 included an invoice for supply item ''Antibody Estrogen Receptor monoclonal'' (SL493). The submitted invoice had a price of $694.70 per box of 50, or $13.89 per test. We sought publicly 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 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 proposed to establish a new supply code for ''Antibody Estrogen Receptor monoclonal'' and price that item at $3.19 each. We welcomed comments from stakeholders regarding this supply item.

Comment: Several commenters disagreed with the CMS refinements to the time for clinical labor task ''Enter patient data, computational prep for antibody testing, generate and apply bar codes to slides, and enter data for automated slide stainer'', ''Verify results and complete work load recording logs'', and ''Recycle xylene from tissue processor and stainer.'' The commenters stated that entering patient data requires far longer than the 1 minute proposed by CMS, and that removing the time for clinical labor tasks related to verifying results and recycling xylene could result in laboratory disaccreditation or errors that are harmful to patients.

Response: We refer the reader to our earlier discussion about clinical labor standards for pathology codes. We continue to believe that clinical labor

tasks with the same description are comparable across different pathology CPT codes. We continue to believe it is most accurate to allocate zero minutes of time for the task ''Verify results and complete work load recording logs'', and ''Recycle xylene from tissue processor and stainer'', as we believe that these are indirect PE tasks not allocated to any individual service.

Comment: One commenter provided a list of eight additional clinical labor activities for CPT code 88360 and one additional clinical labor task for CPT code 88361. The commenter suggested that CMS should consider adding these tasks, which were not included in the RUC recommendations, into its labor estimates for the two procedures.

Response: We appreciate the suggestion from the commenter of additional tasks that can aid in the performance of IHC special stains. We believe that the tasks associated with furnishing particular PFS services could be described and categorized in various ways. We believe that particular tasks should be considered in the context of comprehensive review that allows for an assessment of overall number of minutes involved in furnishing the service. If the commenter examines the list of clinical labor tasks used by the RUC to develop recommendations for these services and finds that many tasks are missing, then we believe that the commenter may want to consider submitting the codes through the public nomination process of the misvalued code initiative to improve the accuracy of the valuations.

Comment: Another commenter disagreed with CMS' refinement to the equipment time of the compound microscope (EP024). The commenter stated that this refinement was not discussed in the preamble text, and that the time involves 35 minutes of work time plus 1 minute of clinical labor time, as described in the RUC recommendation. The commenter asked for CMS to accept the RUC recommended equipment time of 36 minutes.

Response: We note that we did not fully explain our rationale for the refinement of equipment time for the compound microscope equipment time. We observed that the description of the intraservice work for the physician includes many tasks that do not use the microscope. As a result, we do not believe that use of the compound microscope would be typical for the entire intraservice period. We continue to believe that the most accurate equipment time for the compound microscope is 25 minutes: 24 Minutes for the work time (66 percent of 35 minutes) plus 1 minute for the technician.

Comment: Many commenters disagreed with the CMS proposal to price supply item ''monoclonal antibody estrogen receptor'' (SL493) at $3.19. Commenters stated that this was substantially lower than the submitted invoice of $13.89; CMS instead referenced the Estrogen Receptor Antibody (h-151) [DyLight 405] for its price of $3.19. Commenters stated that this supply is for research use only, and that it is not approved for use in humans or in clinical diagnosis. According to the commenters, this item is not an alternate reagent for CPT codes 88360 and 88361, and would not be used for these services.

Response: We appreciate all of the additional information provided by the commenter. The only pricing information that we received for SL493 was an invoice that included a hand-written price over redacted information. We were unable to verify the accuracy of this invoice. In order to price SL493 appropriately, we believe that we need additional information. We will use the publicly available price of $3.19 as a proxy value pending the submission of additional pricing information. We welcome the submission of updated pricing information regarding SL493 through valid invoices from commenters and other stakeholders.

After consideration of comments received, we are finalizing the direct PE inputs as proposed for CPT Codes 88360 and 88361.

m. Nerve Teasing Preparations (CPT Code 88362)

We proposed to refine the recommended time for clinical labor task ''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 noted that the 5 minutes includes 3 minutes for assisting the pathologist with the gross specimen examination (as listed in Table 6 of the proposed rule (80 FR 41698) and an additional 2 minutes for the additional tasks due to the work taking place on a fresh specimen.

Comment: Several commenters disagreed with the CMS decision to refine the time for clinical labor task ''Assist pathologist with gross specimen examination'' from 10 minutes to 5 minutes. The commenters stated that the pathologist must work together with clinical labor staff during the gross specimen work, and the clinical labor could not be performed in 5 minutes due to the number of specimens involved.

Response: We continue to believe that the 5 minutes for this clinical labor task included 3 minutes for assisting the pathologist with the gross specimen examination and an additional 2 minutes for the additional tasks due to the work taking place on a fresh specimen. We also continue to believe that this is the most accurate value for this clinical labor task in the absence of additional data supporting an increase in the time for this clinical labor task.

Comment: These commenters also expressed their disagreement with the CMS removal of the recommended time for clinical labor task ''Consult with pathologist regarding representation needed, block selection and appropriate technique.'' Commenters stated that clinical labor staff must collaborate with the pathologist in the preservice time, and the unique technical protocols required for nerve teasing pathology services requires the clinical labor staff to have a complete understanding of what is necessary for each individual specimen case. Commenters emphasized that nerve teasing pathology services cannot be batched as they are complex, low volume unusual studies requiring special handling, preparation, and storage.

Response: We continue to believe that the clinical labor described in this clinical labor task constitutes basic knowledge for a practicing Histotechnologist. We noted that this clinical labor task appears to be unique to CPT code 88362, and does not appear in other pathology services. We do not believe it maintains relativity to include increasingly specialized clinical labor tasks that are not included in similar procedures. We also do not believe that it would be typical for the Histotechnologist to require this kind of extensive consultation with the pathologist before performing each individual procedure, since the technician would have prior knowledge of what he or she will be doing.

Comment: One commenter disagreed with the CMS refinements to clinical labor tasks associated with slide preparation. For the clinical labor tasks ''Assemble and deliver cedar mounted slides with paperwork to pathologists'', ''Assemble other light microscopy slides, epon nerve biopsy slides, and clinical history, and present to pathologist to prepare clinical pathologic interpretation'', and ''Dispose of remaining specimens, spent chemicals/other consumables, and hazardous waste'', the commenter indicated that there are less batch size

efficiencies with these specimens compared to other typical surgical pathology services, and the recommendation for extra clinical labor time reflected the need for careful handling of materials.

Response: We refer the reader to our earlier discussion about clinical labor standards for pathology codes. We continue to believe that clinical labor tasks with the same description are comparable across different pathology CPT codes. The proposed refinement to 0.5 minutes for these clinical labor tasks reflects the time typically included for slide preparation established across many different pathology procedures.

Comment: The same commenter disagreed with the CMS refinement to the time for clinical labor tasks ''Preparation: labeling of blocks and containers and document location and processor used'' and ''Accession specimen and prepare for examination.'' The commenter stated that although they agreed with the reduction in time, they disagreed with the refinement rationale and the standardization of pathology clinical labor tasks, as the time for each task varies for each CPT code.

Response: We appreciate that the commenter's support for our proposal to reduce the clinical labor for these activities. We continue to believe that clinical labor tasks with the same description are comparable across different pathology CPT codes assuming similar batch sizes, and we appreciate further comments as we work to establish clinical labor standards across pathology services.

Comment: The commenter did not agree with the CMS refinement to the time for clinical labor task ''Prepare specimen containers preload fixative label containers distribute requisition form(s) to physician.'' The commenter explained that nerves and muscle typically arrive in the laboratory on saline soaked gauze for this procedure. Specialty knowledge is required to further prepare and process the tissue, and as a result the specimen preparation for CPT code 88362 is different from routine surgical pathology specimens where large numbers of specimen containers are prepared at one time. The commenter stated that the typical batch size for this type of specimen would be one, which necessitates the increased time.

Response: We appreciate the additional description of the clinical labor taking place in CPT code 88362 provided by the commenter. Based on this presentation of further clinical information, and in order to maintain consistency with our refinements to CPT code 88355, we believe that additional clinical labor time is appropriate. Since this is the same clinical labor task taking place in CPT code 88355, we will also assign 5 minutes for ''Prepare specimen containers/preload fixative/label containers/distribute requisition form(s) to physician'' for CPT code 88362 using the same rationale as described for 88355.

Comment: The commenter also disagreed with the CMS refinements to the time for clinical labor task ''Prepare, pack and transport specimens and records for in-house storage and external storage'' and ''Prepare, pack and transport cedar oiled glass slides and records for in-house special storage.'' The commenter stressed that the specimens used in these labor tasks were unique to CPT code 88362, and therefore they cannot be standardized as part of a wider set of clinical labor activities for the field of pathology. However, the commenter did agree that the clinical labor task ''Prepare, pack and transport specimens and records for in-house storage and external storage'' would typically take 1 minute, although the typical time in the commenter's specialized laboratory would be higher.

Response: We appreciate the commenter's support for our proposal to refine the time for clinical labor task ''Prepare, pack and transport specimens and records for in-house storage and external storage''. We continue to believe that this and other pathology clinical labor tasks more generally, can be standardized across different services. We do not believe that there should be time allocated for clinical labor task ''Prepare, pack and transport cedar oiled glass slides and records for in-house special storage'' for this procedure, since there is already time for clinical labor tasks related to preparing, packing, and transportation of materials.

Comment: The commenter also did not agree with the CMS removal of the recommended time for clinical labor task ''Storage remaining specimen. (Osmicated nerve strands, potential for additional teased specimens).'' The commenter stated that this clinical labor task was not listed anywhere in the proposed rule to explain why CMS believes this is a standard clinical labor task. This storage clinical labor task is unique to CPT code 88362 and its removal could potentially compromise patient care.

Response: We appreciate this opportunity to clarify our rationale regarding the refinement to this clinical labor task. We believe that the clinical labor described in this clinical labor task is duplicative of the clinical labor described in the task ''Prepare, pack and transport specimens and records for in-house storage and external storage.'' We do not believe that the use of three different clinical labor activities for storage of specimens would be typical for CPT code 88362.

After consideration of comments received, we are finalizing the direct PE inputs as proposed for CPT code 88362, with the additional clinical labor refinements discussed above.

n. Nasopharyngoscopy With Endoscope (CPT Code 92511)

We proposed to remove the endosheath (SD070) from this procedure, because we indicated that 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 stated we believed it would be appropriate to remove all of the clinical labor and equipment time currently assigned to cleaning the scope. We sought public comment regarding the proper use of the endosheath supply and the clinical labor associated with scope cleaning.

Comment: Several commenters agreed that the endosheath is not typically used for CPT code 92511 and was inadvertently included from past direct PE inputs for the service. The commenters stated that after removing the endosheath, it was appropriate to retain all the clinical labor and equipment time assigned to cleaning the scope. In addition, in order to clean the equipment and to be consistent with other codes in the family, commenters requested adding four supplies to the code associated with scope cleaning, which were excluded previously because the endosheath was retained.

Response: We appreciate the additional clarification from the commenters regarding the use of supply item ''endosheath'' for this procedure. After consideration of comments received, we agree that it is appropriate to retain the clinical labor and equipment time assigned to cleaning the scope, as well as include the additional requested cleaning supplies. Based on this additional information, we are refining the direct PE inputs to include the following supply items: 2 Endoscope cleaning brushes (SM010), 4 oz. of enzymatic detergent (SM015), 4 oz. of glutaraldehyde 3.4% (SM018), and 1 glutaraldehyde test strip (SM019).

Comment: One commenter disagreed with the CMS decision to remove the recommended surgical masks,

impervious staff gowns, and non-sterile drape sheet from the procedure. The commenter stated that these supplies were necessary, with one mask and gown needed for the physician and one mask and gown needed for the staff, since the procedure produces a lot of secretion transmission. Therefore, these were not duplicative supplies.

Response: We appreciate the additional clarification regarding the use of these supplies. After consideration of comments received, we are restoring these supplies and adding 2 surgical masks (SB033), 2 impervious staff gowns (SB027), and 1 non-sterile sheet drape (SB006) to CPT code 92511 in the non-facility setting.

After consideration of comments received, we are finalizing the direct PE inputs for CPT code 92511, with the additional supply refinements described above.

o. EEG Extended Monitoring (CPT Codes 95812 and 95813)

We refined several of the clinical labor times for CPT codes 95812 and 95813 to align them with our proposed standards, including refining the time for clinical labor task ''Assist physician in performing procedure'' to align with the intraservice time of each procedure. We also removed the service period time for clinical labor task ''Provide pre-service education/obtain consent'' to avoid duplicative clinical labor with the same task in the preservice period, and refined several of the equipment times to align with the standard equipment times for non-highly technical equipment.

Comment: Some commenters did not agree with the CMS refinement of the time for clinical labor task ''Assist physician in performing procedure.'' The commenters stated that the practitioner reads the patient record subsequently without the technologist present, and that the intraservice work time is not temporally equivalent with the tech's assist physician clinical labor time. The line ''Assist physician in performing procedure'' was used as a surrogate data entry line for where to place the technologist's service in performing the testing, and it was not meant to be taken literally. The commenter therefore requested that CMS adopt the RUC-recommended time for both procedures.

Response: The RUC recommendation for these procedures explicitly stated that CPT code 95812 requires 50 minutes of time for clinical labor task ''EEG recording'', and CPT code 95813 requires 80 minutes of clinical labor time for the same clinical labor task. We do not believe that existing clinical labor tasks should be used as data entry surrogates for other tasks, and we do not believe that clinical labor time should be allocated to tasks that are not described in the submitted recommendations. We continue to believe that this represents the clinical labor time which would be spent assisting the physician in performing the procedure.

After consideration of comments received, we are finalizing the direct PE inputs as proposed for CPT codes 95812 and 95813.

p. Testing of Autonomic Nervous System Function (CPT Code 95923)

We proposed to reduce the quantity of supply item ''iontophoresis electrode kit'' (SA014) from 4 to 3. According to the description of this code, the procedure typically uses 2–4 electrodes, and we indicated that we therefore believe that a supply quantity of 3 would better reflect the typical case. We requested 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 recommended that the code descriptor be referred to CPT for further clarification.

Comment: Several commenters pointed out that CMS incorrectly labeled this section of the CY 2016 PFS proposed rule under the heading of ''Needle Electromyography'' with associated CPT codes 95863, 95864, 95869, and 95870. Commenters inferred that CMS intended to reference CPT code 95923 instead of the needle electromyography procedures.

Response: The commenters are correct, and we agree that we included the wrong heading for this part of the CY 2016 PFS proposed rule (80 FR 41781). We apologize for any confusion caused by this error.

Comment: The commenters also explained that the use of 4 iontophoresis electrode kits would be typical for CPT code 95923. According to the commenters, several experts in the field of autonomic testing confirmed that when providing this service they always, without exception, used at least 4 sites of iontophoresis: forearm, proximal leg, distal leg, and foot. The commenters therefore maintained that 4 units of the iontophoresis electrode kit would be the appropriate quantity.

Response: We appreciate the submission of this additional clinical information regarding the use of the iontophoresis electrodes. After consideration of comments received, we are increasing the quantity of the iontophoresis electrode kit (SA014) to 4 for CPT code 95923 in line with the recommended value.

After consideration of comments received, we are finalizing the direct PE inputs as proposed for CPT Code 95923, with the additional refinement to SA014 discussed above.

q. Central Motor Evoked Study (CPT Codes 95928 and 95929)

We refined portions of the clinical labor time for CPT codes 95928 and 95929 as duplicative with other tasks, and refined the time for clinical labor task ''Assist physician in performing procedure'' to align with the intraservice work duration. We also removed a minimum multi-specialty visit pack (SA048) from CPT code 95928 due to the fact that it is typically billed with a same-day E/M service, and we refined some of the equipment times for both procedures to conform to the standard equipment formulas.

Comment: One commenter disagreed with the CMS decision to refine the time for clinical labor task ''Assist physician in performing procedure'' to align with the intraservice work time. This commenter stated that the technologist sets up the service without the physician present, after which the physician enters the room for the main portion of the testing. Afterwards, the physician leaves the room and the technologist completes the last portion of the procedure without the physician present. The commenter indicated that the time for clinical labor task ''Assist physician in performing procedure'' and the physician intraservice work time were not temporally equivalent, and that this clinical labor task was only used as a surrogate data entry line for where to place the technologist's service in performing the testing, not meant to be taken literally.

Response: The RUC recommendation for CPT codes 95928 and 95929 states that the technologist will ''Assist physician in conducting the test.'' As a result, we do not believe that the clinical labor assigned to ''Assist physician in performing procedure'' was merely a surrogate data entry line that was not meant to be taken literally. We do not agree that existing clinical labor tasks should be used as data entry surrogates for other tasks, and we do not believe that clinical labor time should be allocated to tasks that are not described in the submitted recommendations. We continue to believe that this clinical labor task should align with the intraservice work time, and we are maintaining durations of 40 minutes for CPT code 95928 and 95929.

After consideration of comments received, we are finalizing the direct PE inputs as proposed for CPT codes 95928 and 95929.

r. Blink Reflex Test (CPT Code 95933)

We added 2 minutes of time for clinical labor task ''Prepare room, equipment, supplies'' to CPT code 95933 and refined the time for clinical labor task ''Clean room/equipment by physician staff'' to 3 minutes, in both cases conforming to the established standards for these clinical labor tasks.

Comment: One commenter indicated that the CY 2016 PFS proposed rule summary showed a net reduction in PE relative value units for CPT code 95933, from a 2015 PE RVU of 1.75 to a proposed 2016 PE RVU of 1.50. The commenter disagreed with this reduction and stated that they were unable identify the source for the proposed reductions.

Response: To clarify the proposed change in PE for CPT code 95933, we note that we believe this reduction is due to two changes in the recommended values. We accepted the RUC recommendation to reduce the time for clinical labor task ''Assist physician in cleaning area, relaxing patient. Take notes from physician'' from 30 minutes to 25 minutes. We also accepted the RUC recommendation to reduce the quantity of supply item ''electrode skin prep gel (NuPrep)'' (SJ022) from 100 ml to 10 ml. These two reductions likely account for the reduction in PE RVUs.

After consideration of comments received, we are finalizing the direct PE inputs as proposed for CPT code 95933.

8. CY 2015 Interim Final Codes

In this section, we discuss each code for which we received a comment on the CY 2015 interim final work RVU or work time during the comment period for the CY 2015 final rule or for which we are modifying the CY 2015 interim final work RVU, work time or procedure status indicator for CY 2016. If a code in Table 15 is not discussed in this section, we did not receive any comments on that code or received only comment(s) in support of the CY 2015 interim final status; for those, we are finalizing the interim final work RVU and time without modification for CY 2016.

A comprehensive list of all interim final values for which public comments were sought in the comment period for the CY 2015 PFS final rule is contained in Addendum C to the CY 2015 PFS final rule with comment period. We note that the values for some codes with interim final values were addressed in the CY 2016 PFS proposed rule (see: *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeeSched/index.html*), and therefore, are addressed in section II.H. of this final rule with comment period. A comprehensive list of all CY 2016 RVUs is in Addendum B. All Addenda to the PFS final rule with comment period are available on the CMS Web site under downloads at *http://www.cms.gov/physicianfeesched/PFSFederalRegulationNotices.html/.* The time values and direct PE inputs for all codes are listed files called ''CY 2016 PFS Work Time,'' and ''CY 2016 Direct PE Inputs,'' available on the CMS Web site under downloads for the CY 2016 PFS final rule with comment period at *http://www.cms.gov/physicianfeesched/downloads/.*

TABLE 13—CY 2016 ACTIONS ON CODES WITH CY 2015 INTERIM FINAL RVUS

HCPCS code	Long descriptor	CY 2015 interim final work RVU	CY 2016 work RVU	CY 2016 action
11980	Subcutaneous hormone pellet implantation (implantation of estradiol and/or testosterone pellets beneath the skin).	1.10	1.10	Finalize.
20604	Arthrocentesis, aspiration and/or injection, small joint or bursa (*e.g.,* fingers, toes); with ultrasound guidance, with permanent recording and reporting.	0.89	0.89	Finalize.
20606	Arthrocentesis, aspiration and/or injection, intermediate joint or bursa (*e.g.,* temporomandibular, acromioclavicular, wrist, elbow or ankle, olecranon bursa); with ultrasound guidance, with permanent recording and reporting.	1.00	1.00	Finalize.
20611	Arthrocentesis, aspiration and/or injection, major joint or bursa (*e.g.,* shoulder, hip, knee, subacromial bursa); with ultrasound guidance, with permanent recording and reporting.	1.10	1.10	Finalize.
20983	Ablation therapy for reduction or eradication of 1 or more bone tumors (*e.g.,* metastasis) including adjacent soft tissue when involved by tumor extension, percutaneous, including imaging guidance when performed; cryoablation.	7.13	7.13	Finalize.
21811	Open treatment of rib fracture(s) with internal fixation, includes thoracoscopic visualization when performed, unilateral; 1–3 ribs.	10.79	10.79	Finalize.
21812	Open treatment of rib fracture(s) with internal fixation, includes thoracoscopic visualization when performed, unilateral; 4–6 ribs.	13.00	13.00	Finalize.
21813	Open treatment of rib fracture(s) with internal fixation, includes thoracoscopic visualization when performed, unilateral; 7 or more ribs.	17.61	17.61	Finalize.
22510	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; cervicothoracic.	8.15	8.15	Finalize.
22511	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; lumbosacral.	7.58	7.58	Finalize.
22512	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; each additional cervicothoracic or lumbosacral vertebral body (List separately in addition to code for primary procedure).	4.00	4.00	Finalize.
22513	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (*e.g.,* kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; thoracic.	8.90	8.90	Finalize.

TABLE 13—CY 2016 ACTIONS ON CODES WITH CY 2015 INTERIM FINAL RVUS—Continued

HCPCS code	Long descriptor	CY 2015 interim final work RVU	CY 2016 work RVU	CY 2016 action
22514	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (*e.g.,* kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; lumbar.	8.24	8.24	Finalize.
22515	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (*e.g.,* kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; each additional thoracic or lumbar vertebral body (List separately in addition to code for primary procedure).	4.00	4.00	Finalize.
22856	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); single interspace, cervical.	24.05	24.05	Finalize.
22858	Total disc arthroplasty (artificial disc), anterior approach, including discectomy with end plate preparation (includes osteophytectomy for nerve root or spinal cord decompression and microdissection); second level, cervical (List separately in addition to code for primary procedure).	8.40	8.40	Finalize.
27279	Arthrodesis, sacroiliac joint, percutaneous or minimally invasive (indirect visualization), with image guidance, includes obtaining bone graft when performed, and placement of transfixing device.	9.03	9.03	See II.J.5.a.
29200	Strapping; thorax	0.39	0.39	Finalize.
29240	Strapping; shoulder (*e.g.,* Velpeau)	0.39	0.39	Finalize.
29260	Strapping; elbow or wrist	0.39	0.39	Finalize.
29280	Strapping; hand or finger	0.39	0.39	Finalize.
29520	Strapping; hip	0.39	0.39	Finalize.
29530	Strapping; knee	0.39	0.39	Finalize.
31620	Endobronchial ultrasound (EBUS) during bronchoscopic diagnostic or therapeutic intervention(s) (List separately in addition to code for primary procedure[s]).	1.40	.....	Deleted.
33215	Repositioning of previously implanted transvenous pacemaker or implantable defibrillator (right atrial or right ventricular) electrode.	4.92	4.92	Finalize.
33216	Insertion of a single transvenous electrode, permanent pacemaker or implantable defibrillator.	5.87	5.87	Finalize.
33217	Insertion of 2 transvenous electrodes, permanent pacemaker or implantable defibrillator.	5.84	5.84	Finalize.
33218	Repair of single transvenous electrode, permanent pacemaker or implantable defibrillator.	6.07	6.07	Finalize.
33220	Repair of 2 transvenous electrodes for permanent pacemaker or implantable defibrillator.	6.15	6.15	Finalize.
33223	Relocation of skin pocket for implantable defibrillator	6.55	6.55	Finalize.
33224	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, with attachment to previously placed pacemaker or implantable defibrillator pulse generator (including revision of pocket, removal, insertion, and/or replacement of existing generator).	9.04	9.04	Finalize.
33225	Insertion of pacing electrode, cardiac venous system, for left ventricular pacing, at time of insertion of implantable defibrillator or pacemaker pulse generator (*e.g.,* for upgrade to dual chamber system) (List separately in addition to code for primary procedure).	8.33	8.33	Finalize.
33240	Insertion of implantable defibrillator pulse generator only; with existing single lead.	6.05	6.05	Finalize.
33241	Removal of implantable defibrillator pulse generator only	3.29	3.29	Finalize.
33243	Removal of single or dual chamber implantable defibrillator electrode(s); by thoracotomy.	23.57	23.57	Finalize.
33244	Removal of single or dual chamber implantable defibrillator electrode(s); by transvenous extraction.	13.99	13.99	Finalize.
33249	Insertion or replacement of permanent implantable defibrillator system, with transvenous lead(s), single or dual chamber.	15.17	15.17	Finalize.
33262	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; single lead system.	6.06	6.06	Finalize.
33263	Removal of implantable defibrillator pulse generator with replacement of implantable defibrillator pulse generator; dual lead system.	6.33	6.33	Finalize.
33270	Insertion or replacement of permanent subcutaneous implantable defibrillator system, with subcutaneous electrode, including defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters, when performed.	9.10	9.10	Finalize.
33271	Insertion of subcutaneous implantable defibrillator electrode	7.50	7.50	Finalize.
33272	Removal of subcutaneous implantable defibrillator electrode	5.42	5.42	Finalize.

TABLE 13—CY 2016 ACTIONS ON CODES WITH CY 2015 INTERIM FINAL RVUS—Continued

HCPCS code	Long descriptor	CY 2015 interim final work RVU	CY 2016 work RVU	CY 2016 action
33273	Repositioning of previously implanted subcutaneous implantable defibrillator electrode.	6.50	6.50	Finalize.
33418	Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; initial prosthesis.	32.25	32.25	Finalize.
33419	Transcatheter mitral valve repair, percutaneous approach, including transseptal puncture when performed; additional prosthesis(es) during same session (List separately in addition to code for primary procedure).	7.93	7.93	Finalize.
33946	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; initiation, veno-venous.	6.00	6.00	Finalize.
33947	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; initiation, veno-arterial.	6.63	6.63	Finalize.
33949	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; daily management, each day, veno-arterial.	4.60	4.60	Finalize.
33951	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; insertion of peripheral (arterial and/or venous) cannula(e), percutaneous, birth through 5 years of age (includes fluoroscopic guidance, when performed).	8.15	8.15	Finalize.
33952	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; insertion of peripheral (arterial and/or venous) cannula(e), percutaneous, 6 years and older (includes fluoroscopic guidance, when performed).	8.15	8.15	Finalize.
33953	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; insertion of peripheral (arterial and/or venous) cannula(e), open, birth through 5 years of age.	9.11	9.11	Finalize.
33954	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; insertion of peripheral (arterial and/or venous) cannula(e), open, 6 years and older.	9.11	9.11	Finalize.
33955	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; insertion of central cannula(e) by sternotomy or thoracotomy, birth through 5 years of age.	16.00	16.00	Finalize.
33956	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; insertion of central cannula(e) by sternotomy or thoracotomy, 6 years and older.	16.00	16.00	Finalize.
33957	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition peripheral (arterial and/or venous) cannula(e), percutaneous, birth through 5 years of age (includes fluoroscopic guidance, when performed).	3.51	3.51	Finalize.
33958	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition peripheral (arterial and/or venous) cannula(e), percutaneous, 6 years and older (includes fluoroscopic guidance, when performed).	3.51	3.51	Finalize.
33959	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition peripheral (arterial and/or venous) cannula(e), open, birth through 5 years of age (includes fluoroscopic guidance, when performed).	4.47	4.47	Finalize.
33962	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition peripheral (arterial and/or venous) cannula(e), open, 6 years and older (includes fluoroscopic guidance, when performed).	4.47	4.47	Finalize.
33963	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition of central cannula(e) by sternotomy or thoracotomy, birth through 5 years of age (includes fluoroscopic guidance, when performed).	9.00	9.00	Finalize.
33964	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; reposition central cannula(e) by sternotomy or thoracotomy, 6 years and older (includes fluoroscopic guidance, when performed).	9.50	9.50	Finalize.
33965	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; removal of peripheral (arterial and/or venous) cannula(e), percutaneous, birth through 5 years of age.	3.51	3.51	Finalize.
33966	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; removal of peripheral (arterial and/or venous) cannula(e), percutaneous, 6 years and older.	4.50	4.50	Finalize.
33969	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; removal of peripheral (arterial and/or venous) cannula(e), open, birth through 5 years of age.	5.22	5.22	Finalize.

TABLE 13—CY 2016 ACTIONS ON CODES WITH CY 2015 INTERIM FINAL RVUS—Continued

HCPCS code	Long descriptor	CY 2015 interim final work RVU	CY 2016 work RVU	CY 2016 action
33984	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; removal of peripheral (arterial and/or venous) cannula(e), open, 6 years and older.	5.46	5.46	Finalize.
33985	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; removal of central cannula(e) by sternotomy or thoracotomy, birth through 5 years of age.	9.89	9.89	Finalize.
33986	Extracorporeal membrane oxygenation (ECMO)/extracorporeal life support (ECLS) provided by physician; removal of central cannula(e) by sternotomy or thoracotomy, 6 years and older.	10.00	10.00	Finalize.
33987	Arterial exposure with creation of graft conduit (*e.g.,* chimney graft) to facilitate arterial perfusion for ECMO/ECLS (List separately in addition to code for primary procedure).	4.04	4.04	Finalize.
33988	Insertion of left heart vent by thoracic incision (*e.g.,* sternotomy, thoracotomy) for ECMO/ECLS.	15.00	15.00	Finalize.
33989	Removal of left heart vent by thoracic incision (*e.g.,* sternotomy, thoracotomy) for ECMO/ECLS.	9.50	9.50	Finalize.
34839	Physician planning of a patient-specific fenestrated visceral aortic endograft requiring a minimum of 90 minutes of physician time.	B	B	Finalize.
34841	Endovascular repair of visceral aorta (*e.g.,* aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including one visceral artery endoprosthesis (superior mesenteric, celiac or renal artery).	C	C	Finalize.
34842	Endovascular repair of visceral aorta (*e.g.,* aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including two visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s]).	C	C	Finalize.
34843	Endovascular repair of visceral aorta (*e.g.,* aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including three visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s]).	C	C	Finalize.
34844	Endovascular repair of visceral aorta (*e.g.,* aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) by deployment of a fenestrated visceral aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including four or more visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s]).	C	C	Finalize.
34845	Endovascular repair of visceral aorta and infrarenal abdominal aorta (*e.g.,* aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including one visceral artery endoprosthesis (superior mesenteric, celiac or renal artery).	C	C	Finalize.
34846	Endovascular repair of visceral aorta and infrarenal abdominal aorta (*e.g.,* aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including two visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s]).	C	C	Finalize.
34847	Endovascular repair of visceral aorta and infrarenal abdominal aorta (*e.g.,* aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including three visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s]).	C	C	Finalize.

TABLE 13—CY 2016 ACTIONS ON CODES WITH CY 2015 INTERIM FINAL RVUS—Continued

HCPCS code	Long descriptor	CY 2015 interim final work RVU	CY 2016 work RVU	CY 2016 action
34848	Endovascular repair of visceral aorta and infrarenal abdominal aorta (*e.g.,* aneurysm, pseudoaneurysm, dissection, penetrating ulcer, intramural hematoma, or traumatic disruption) with a fenestrated visceral aortic endograft and concomitant unibody or modular infrarenal aortic endograft and all associated radiological supervision and interpretation, including target zone angioplasty, when performed; including four or more visceral artery endoprostheses (superior mesenteric, celiac and/or renal artery[s]).	C	C	Finalize.
36475	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; first vein treated.	5.30	5.30	See II.J.5.a
36476	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, radiofrequency; second and subsequent veins treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure).	2.65	2.65	See II.J.5.a
36478	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; first vein treated.	5.30	5.30	See II.J.5.a.
36479	Endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, laser; second and subsequent veins treated in a single extremity, each through separate access sites (List separately in addition to code for primary procedure).	2.65	2.65	See II.J.5.a.
36818	Arteriovenous anastomosis, open; by upper arm cephalic vein transposition.	12.39	12.39	Finalize.
36819	Arteriovenous anastomosis, open; by upper arm basilic vein transposition	13.29	13.29	Finalize.
36820	Arteriovenous anastomosis, open; by forearm vein transposition	13.07	13.07	Finalize.
36821	Arteriovenous anastomosis, open; direct, any site (*e.g.,* Cimino type) (separate procedure).	11.90	11.90	Finalize.
36825	Creation of arteriovenous fistula by other than direct arteriovenous anastomosis (separate procedure); autogenous graft.	14.17	14.17	Finalize.
36830	Creation of arteriovenous fistula by other than direct arteriovenous anastomosis (separate procedure); nonautogenous graft (*e.g.,* biological collagen, thermoplastic graft).	12.03	12.03	Finalize.
36831	Thrombectomy, open, arteriovenous fistula without revision, autogenous or nonautogenous dialysis graft (separate procedure).	11.00	11.00	Finalize.
36832	Revision, open, arteriovenous fistula; without thrombectomy, autogenous or nonautogenous dialysis graft (separate procedure).	13.50	13.50	Finalize.
36833	Revision, open, arteriovenous fistula; with thrombectomy, autogenous or nonautogenous dialysis graft (separate procedure).	14.50	14.50	Finalize.
37218	Transcatheter placement of intravascular stent(s), intrathoracic common carotid artery or innominate artery, open or percutaneous antegrade approach, including angioplasty, when performed, and radiological supervision and interpretation.	15.00	15.00	Finalize.
43180	Esophagoscopy, rigid, transoral with diverticulectomy of hypopharynx or cervical esophagus (*e.g.,* Zenker's diverticulum), with cricopharyngeal myotomy, includes use of telescope or operating microscope and repair, when performed.	9.03	9.03	Finalize.
45399	Unlisted procedure, colon	I	C	Finalize.
47383	Ablation, 1 or more liver tumor(s), percutaneous, cryoablation	9.13	9.13	Finalize.
52441	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; single implant.	4.50	4.50	Finalize.
52442	Cystourethroscopy, with insertion of permanent adjustable transprostatic implant; each additional permanent adjustable transprostatic implant (List separately in addition to code for primary procedure).	1.20	1.20	Finalize.
55840	Prostatectomy, retropubic radical, with or without nerve sparing	21.36	21.36	Finalize.
55842	Prostatectomy, retropubic radical, with or without nerve sparing; with lymph node biopsy(s) (limited pelvic lymphadenectomy).	21.36	21.36	Finalize.
55845	Prostatectomy, retropubic radical, with or without nerve sparing; with bilateral pelvic lymphadenectomy, including external iliac, hypogastric, and obturator nodes.	25.18	25.18	Finalize.
58541	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less.	12.29	12.29	Finalize.
58542	Laparoscopy, surgical, supracervical hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s).	14.16	14.16	Finalize.
58543	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g.	14.39	14.39	Finalize.
58544	Laparoscopy, surgical, supracervical hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s).	15.60	15.60	Finalize.
58570	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less	13.36	13.36	Finalize.

TABLE 13—CY 2016 ACTIONS ON CODES WITH CY 2015 INTERIM FINAL RVUS—Continued

HCPCS code	Long descriptor	CY 2015 interim final work RVU	CY 2016 work RVU	CY 2016 action
58571	Laparoscopy, surgical, with total hysterectomy, for uterus 250 g or less; with removal of tube(s) and/or ovary(s).	15.00	15.00	Finalize.
58572	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g.	17.71	17.71	Finalize.
58573	Laparoscopy, surgical, with total hysterectomy, for uterus greater than 250 g; with removal of tube(s) and/or ovary(s).	20.79	20.79	Finalize.
62284	Injection procedure for myelography and/or computed tomography, lumbar (other than C1–C2 and posterior fossa).	1.54	1.54	Finalize.
62302	Myelography via lumbar injection, including radiological supervision and interpretation; cervical.	2.29	2.29	Finalize.
62303	Myelography via lumbar injection, including radiological supervision and interpretation; thoracic.	2.29	2.29	Finalize.
62304	Myelography via lumbar injection, including radiological supervision and interpretation; lumbosacral.	2.25	2.25	Finalize.
62305	Myelography via lumbar injection, including radiological supervision and interpretation; 2 or more regions (*e.g.,* lumbar/thoracic, cervical/thoracic, lumbar/cervical, lumbar/thoracic/cervical).	2.35	2.35	Finalize.
62310	Injection(s), of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, includes contrast for localization when performed, epidural or subarachnoid; cervical or thoracic.	1.91	1.91	Finalize.
62311	Injection(s), of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, including needle or catheter placement, includes contrast for localization when performed, epidural or subarachnoid; lumbar or sacral (caudal).	1.54	1.54	Finalize.
62318	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, includes contrast for localization when performed, epidural or subarachnoid; cervical or thoracic.	2.04	2.04	Finalize.
62319	Injection(s), including indwelling catheter placement, continuous infusion or intermittent bolus, of diagnostic or therapeutic substance(s) (including anesthetic, antispasmodic, opioid, steroid, other solution), not including neurolytic substances, includes contrast for localization when performed, epidural or subarachnoid; lumbar or sacral (caudal).	1.87	1.87	Finalize.
64486	Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) unilateral; by injection(s) (includes imaging guidance, when performed).	1.27	1.27	Finalize.
64487	Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) unilateral; by continuous infusion(s) (includes imaging guidance, when performed).	1.48	1.48	Finalize.
64488	Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) bilateral; by injections (includes imaging guidance, when performed).	1.60	1.60	Finalize.
64489	Transversus abdominis plane (TAP) block (abdominal plane block, rectus sheath block) bilateral; by continuous infusions (includes imaging guidance, when performed).	1.80	1.80	Finalize.
64561	Percutaneous implantation of neurostimulator electrode array; sacral nerve (transforaminal placement) including image guidance, if performed.	5.44	5.44	Finalize.
66179	Aqueous shunt to extraocular equatorial plate reservoir, external approach; without graft.	14.00	14.00	Finalize.
66180	Aqueous shunt to extraocular equatorial plate reservoir, external approach; with graft.	15.00	15.00	Finalize.
66184	Revision of aqueous shunt to extraocular equatorial plate reservoir; without graft.	9.58	9.58	Finalize.
66185	Revision of aqueous shunt to extraocular equatorial plate reservoir; with graft.	10.58	10.58	Finalize.
67036	Vitrectomy, mechanical, pars plana approach;	12.13	12.13	Finalize.
67039	Vitrectomy, mechanical, pars plana approach; with focal endolaser photocoagulation.	13.20	13.20	Finalize.
67040	Vitrectomy, mechanical, pars plana approach; with endolaser panretinal photocoagulation.	14.50	14.50	Finalize.
67041	Vitrectomy, mechanical, pars plana approach; with removal of preretinal cellular membrane (*e.g.,* macular pucker).	16.33	16.33	Finalize.

TABLE 13—CY 2016 ACTIONS ON CODES WITH CY 2015 INTERIM FINAL RVUS—Continued

HCPCS code	Long descriptor	CY 2015 interim final work RVU	CY 2016 work RVU	CY 2016 action
67042	Vitrectomy, mechanical, pars plana approach; with removal of internal limiting membrane of retina (*e.g.,* for repair of macular hole, diabetic macular edema), includes, if performed, intraocular tamponade (*i.e.,* air, gas or silicone oil).	16.33	16.33	Finalize.
67043	Vitrectomy, mechanical, pars plana approach; with removal of subretinal membrane (*e.g.,* choroidal neovascularization), includes, if performed, intraocular tamponade (*i.e.,* air, gas or silicone oil) and laser photocoagulation.	17.40	17.40	Finalize.
67255	Scleral reinforcement (separate procedure); with graft	8.38	8.38	Finalize.
70486	Computed tomography, maxillofacial area; without contrast material	0.85	0.85	See II.J.5.a.
70487	Computed tomography, maxillofacial area; with contrast material(s)	1.13	1.13	See II.J.5.a.
70488	Computed tomography, maxillofacial area; without contrast material, followed by contrast material(s) and further sections.	1.27	1.27	See II.J.5.a.
70496	Computed tomographic angiography, head, with contrast material(s), including noncontrast images, if performed, and image postprocessing.	1.75	1.75	Finalize.
70498	Computed tomographic angiography, neck, with contrast material(s), including noncontrast images, if performed, and image postprocessing.	1.75	1.75	Finalize.
71275	Computed tomographic angiography, chest (noncoronary), with contrast material(s), including noncontrast images, if performed, and image postprocessing.	1.82	1.82	Finalize.
72191	Computed tomographic angiography, pelvis, with contrast material(s), including noncontrast images, if performed, and image postprocessing.	1.81	1.81	Finalize.
72240	Myelography, cervical, radiological supervision and interpretation	0.91	0.91	Finalize.
72255	Myelography, thoracic, radiological supervision and interpretation	0.91	0.91	Finalize.
72265	Myelography, lumbosacral, radiological supervision and interpretation	0.83	0.83	Finalize.
72270	Myelography, 2 or more regions (*e.g.,* lumbar/thoracic, cervical/thoracic, lumbar/cervical, lumbar/thoracic/cervical), radiological supervision and interpretation.	1.33	1.33	Finalize.
74174	Computed tomographic angiography, abdomen and pelvis, with contrast material(s), including noncontrast images, if performed, and image postprocessing.	2.20	2.20	Finalize.
74175	Computed tomographic angiography, abdomen, with contrast material(s), including noncontrast images, if performed, and image postprocessing.	1.82	1.82	Finalize.
74230	Swallowing function, with cineradiography/videoradiography	0.53	0.53	Finalize.
76641	Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; complete.	0.73	0.73	Finalize.
76642	Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; limited.	0.68	0.68	Finalize.
76700	Ultrasound, abdominal, real time with image documentation; complete	0.81	0.81	Finalize.
76705	Ultrasound, abdominal, real time with image documentation; limited (*e.g.,* single organ, quadrant, follow-up).	0.59	0.59	Finalize.
76770	Ultrasound, retroperitoneal (*e.g.,* renal, aorta, nodes), real time with image documentation; complete.	0.74	0.74	Finalize.
76775	Ultrasound, retroperitoneal (*e.g.,* renal, aorta, nodes), real time with image documentation; limited.	0.58	0.58	Finalize.
76856	Ultrasound, pelvic (nonobstetric), real time with image documentation; complete.	0.69	0.69	Finalize.
76857	Ultrasound, pelvic (nonobstetric), real time with image documentation; limited or follow-up (*e.g.,* for follicles).	0.50	0.50	Finalize.
76930	Ultrasonic guidance for pericardiocentesis, imaging supervision and interpretation.	0.67	0.67	Finalize.
76932	Ultrasonic guidance for endomyocardial biopsy, imaging supervision and interpretation.	0.85	0.67	Finalize.
76942	Ultrasonic guidance for needle placement (*e.g.,* biopsy, aspiration, injection, localization device), imaging supervision and interpretation.	0.67	0.67	Finalize.
76948	Ultrasonic guidance for aspiration of ova, imaging supervision and interpretation.	0.38	0.38	Finalize.
77055	Mammography; unilateral	0.7	0.70	Finalize.
77056	Mammography; bilateral	0.87	0.87	Finalize.
77057	Screening mammography, bilateral (2-view film study of each breast)	0.7	0.70	Finalize.
77061	Digital breast tomosynthesis; unilateral	I	I	Finalize.
77062	Digital breast tomosynthesis; bilateral	I	I	Finalize.
77063	Screening digital breast tomosynthesis, bilateral (List separately in addition to code for primary procedure).	0.60	0.60	Finalize.
77080	Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; axial skeleton (*e.g.,* hips, pelvis, spine).	0.20	0.20	Finalize.
77085	Dual-energy X-ray absorptiometry (DXA), bone density study, 1 or more sites; axial skeleton (*e.g.,* hips, pelvis, spine), including vertebral fracture assessment.	0.30	0.30	Finalize.

TABLE 13—CY 2016 ACTIONS ON CODES WITH CY 2015 INTERIM FINAL RVUS—Continued

HCPCS code	Long descriptor	CY 2015 interim final work RVU	CY 2016 work RVU	CY 2016 action
77086	Vertebral fracture assessment via dual-energy X-ray absorptiometry (DXA).	0.17	0.17	Finalize.
77300	Basic radiation dosimetry calculation, central axis depth dose calculation, TDF, NSD, gap calculation, off axis factor, tissue inhomogeneity factors, calculation of non-ionizing radiation surface and depth dose, as required during course of treatment, only when prescribed by the treating physician.	0.62	0.62	See II.J.5.a.
77306	Teletherapy isodose plan; simple (1 or 2 unmodified ports directed to a single area of interest), includes basic dosimetry calculation(s).	1.40	1.40	See II.J.5.a.
77307	Teletherapy isodose plan; complex (multiple treatment areas, tangential ports, the use of wedges, blocking, rotational beam, or special beam considerations), includes basic dosimetry calculation(s).	2.90	2.90	See II.J.5.a.
77316	Brachytherapy isodose plan; simple (calculation[s] made from 1 to 4 sources, or remote afterloading brachytherapy, 1 channel), includes basic dosimetry calculation(s).	1.40	1.40	Finalize.
77317	Brachytherapy isodose plan; intermediate (calculation[s] made from 5 to 10 sources, or remote afterloading brachytherapy, 2–12 channels), includes basic dosimetry calculation(s).	1.83	1.83	Finalize.
77318	Brachytherapy isodose plan; complex (calculation[s] made from over 10 sources, or remote afterloading brachytherapy, over 12 channels), includes basic dosimetry calculation(s).	2.90	2.90	Finalize.
88341	Immunohistochemistry or immunocytochemistry, per specimen; each additional single antibody stain procedure (List separately in addition to code for primary procedure).	0.53	0.53	See II.I.5.d.
88342	Immunohistochemistry or immunocytochemistry, per specimen; initial single antibody stain procedure.	0.70	0.70	Finalize.
88344	Immunohistochemistry or immunocytochemistry, per specimen; each multiplex antibody stain procedure.	0.77	0.77	Finalize.
88348	Electron microscopy, diagnostic	1.51	1.51	Finalize.
88356	Morphometric analysis; nerve	2.80	2.80	Finalize.
88364	In situ hybridization (*e.g.,* FISH), per specimen; each additional single probe stain procedure (List separately in addition to code for primary procedure).	0.67	0.67	See II.I.5.d
88365	In situ hybridization (*e.g.,* FISH), per specimen; initial single probe stain procedure.	0.88	0.88	Finalize.
88366	In situ hybridization (*e.g.,* FISH), per specimen; each multiplex probe stain procedure.	1.24	1.24	Finalize.
88369	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), manual, per specimen; each additional single probe stain procedure (List separately in addition to code for primary procedure).	0.67	0.67	See II.I.5.d.
88373	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), using computer-assisted technology, per specimen; each additional single probe stain procedure (List separately in addition to code for primary procedure).	0.43	0.43	Finalize.
88374	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), using computer-assisted technology, per specimen; each multiplex probe stain procedure.	0.93	0.93	See II.I.5.d.
88377	Morphometric analysis, in situ hybridization (quantitative or semi-quantitative), manual, per specimen; each multiplex probe stain procedure.	1.40	1.40	Finalize.
88380	Microdissection (*i.e.,* sample preparation of microscopically identified target); laser capture.	1.14	1.14	See II.J.5.a.
88381	Microdissection (*i.e.,* sample preparation of microscopically identified target); manual.	0.53	0.53	See II.J.5.a.
91200	Liver elastography, mechanically induced shear wave (*e.g.,* vibration), without imaging, with interpretation and report.	0.30	0.27	See II.J.5.a.
92145	Corneal hysteresis determination, by air impulse stimulation, unilateral or bilateral, with interpretation and report.	0.17	0.17	Finalize.
92540	Basic vestibular evaluation, includes spontaneous nystagmus test with eccentric gaze fixation nystagmus, with recording, positional nystagmus test, minimum of 4 positions, with recording, optokinetic nystagmus test, bidirectional foveal and peripheral stimulation, with recording, and oscillating tracking test, with recording.	1.50	1.50	Finalize.
92541	Spontaneous nystagmus test, including gaze and fixation nystagmus, with recording.	0.40	0.40	Finalize.
92542	Positional nystagmus test, minimum of 4 positions, with recording	0.48	0.48	Finalize.
92543	Caloric vestibular test, each irrigation (binaural, bithermal stimulation constitutes 4 tests), with recording.	0.10	.....	Deleted.
92544	Optokinetic nystagmus test, bidirectional, foveal or peripheral stimulation, with recording.	0.27	0.27	Finalize.
92545	Oscillating tracking test, with recording	0.25	0.25	Finalize.

TABLE 13—CY 2016 ACTIONS ON CODES WITH CY 2015 INTERIM FINAL RVUS—Continued

HCPCS code	Long descriptor	CY 2015 interim final work RVU	CY 2016 work RVU	CY 2016 action
93260	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; implantable subcutaneous lead defibrillator system.	0.85	0.85	Finalize.
93261	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; implantable subcutaneous lead defibrillator system.	0.74	0.74	Finalize.
93282	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; single lead transvenous implantable defibrillator system.	0.85	0.85	Finalize.
93283	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; dual lead transvenous implantable defibrillator system.	1.15	1.15	Finalize.
93284	Programming device evaluation (in person) with iterative adjustment of the implantable device to test the function of the device and select optimal permanent programmed values with analysis, review and report by a physician or other qualified health care professional; multiple lead transvenous implantable defibrillator system.	1.25	1.25	Finalize.
93287	Peri-procedural device evaluation (in person) and programming of device system parameters before or after a surgery, procedure, or test with analysis, review and report by a physician or other qualified health care professional; single, dual, or multiple lead implantable defibrillator system.	0.45	0.45	Finalize.
93289	Interrogation device evaluation (in person) with analysis, review and report by a physician or other qualified health care professional, includes connection, recording and disconnection per patient encounter; single, dual, or multiple lead transvenous implantable defibrillator system, including analysis of heart rhythm derived data elements.	0.92	0.92	Finalize.
93312	Echocardiography, transesophageal, real-time with image documentation (2D) (with or without M-mode recording); including probe placement, image acquisition, interpretation and report.	2.55	2.55	Finalize.
93313	Echocardiography, transesophageal, real-time with image documentation (2D) (with or without M-mode recording); placement of transesophageal probe only.	0.51	0.51	Finalize.
93314	Echocardiography, transesophageal, real-time with image documentation (2D) (with or without M-mode recording); image acquisition, interpretation and report only.	2.10	2.10	Finalize.
93315	Transesophageal echocardiography for congenital cardiac anomalies; including probe placement, image acquisition, interpretation and report.	2.94	2.94	Finalize.
93316	Transesophageal echocardiography for congenital cardiac anomalies; placement of transesophageal probe only.	0.85	0.85	Finalize.
93317	Transesophageal echocardiography for congenital cardiac anomalies; image acquisition, interpretation and report only.	2.09	2.09	Finalize.
93318	Echocardiography, transesophageal (TEE) for monitoring purposes, including probe placement, real time 2-dimensional image acquisition and interpretation leading to ongoing (continuous) assessment of (dynamically changing) cardiac pumping function and to therapeutic measures on an immediate time basis.	2.40	2.40	Finalize.
93320	Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (List separately in addition to codes for echocardiographic imaging); complete.	0.38	0.38	Finalize.
93321	Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (List separately in addition to codes for echocardiographic imaging); follow-up or limited study (List separately in addition to codes for echocardiographic imaging).	0.15	0.15	Finalize.
93325	Doppler echocardiography color flow velocity mapping (List separately in addition to codes for echocardiography).	0.07	0.07	Finalize.

TABLE 13—CY 2016 ACTIONS ON CODES WITH CY 2015 INTERIM FINAL RVUS—Continued

HCPCS code	Long descriptor	CY 2015 interim final work RVU	CY 2016 work RVU	CY 2016 action
93355	Echocardiography, transesophageal (TEE) for guidance of a transcatheter intracardiac or great vessel(s) structural intervention(s) (*e.g.,* TAVR, transcatheter pulmonary valve replacement, mitral valve repair, paravalvular regurgitation repair, left atrial appendage occlusion/closure, ventricular septal defect closure) (peri-and intra-procedural), real-time image acquisition and documentation, guidance with quantitative measurements, probe manipulation, interpretation, and report, including diagnostic transesophageal echocardiography and, when performed, administration of ultrasound contrast, Doppler, color flow, and 3D.	4.66	4.66	Finalize.
93644	Electrophysiologic evaluation of subcutaneous implantable defibrillator (includes defibrillation threshold evaluation, induction of arrhythmia, evaluation of sensing for arrhythmia termination, and programming or reprogramming of sensing or therapeutic parameters).	3.29	3.29	Finalize.
93880	Duplex scan of extracranial arteries; complete bilateral study	0.80	0.80	Finalize.
93882	Duplex scan of extracranial arteries; unilateral or limited study	0.50	0.50	Finalize.
93886	Transcranial Doppler study of the intracranial arteries; complete study	0.91	0.91	Finalize.
93888	Transcranial Doppler study of the intracranial arteries; limited study	0.50	0.50	Finalize.
93895	Quantitative carotid intima media thickness and carotid atheroma evaluation, bilateral.	N	N	Finalize.
93925	Duplex scan of lower extremity arteries or arterial bypass grafts; complete bilateral study.	0.80	0.80	Finalize.
93926	Duplex scan of lower extremity arteries or arterial bypass grafts; unilateral or limited study.	0.50	0.50	Finalize.
93930	Duplex scan of upper extremity arteries or arterial bypass grafts; complete bilateral study.	0.80	0.80	Finalize.
93931	Duplex scan of upper extremity arteries or arterial bypass grafts; unilateral or limited study.	0.50	0.50	Finalize.
93970	Duplex scan of extremity veins including responses to compression and other maneuvers; complete bilateral study.	0.70	0.70	Finalize.
93971	Duplex scan of extremity veins including responses to compression and other maneuvers; unilateral or limited study.	0.45	0.45	Finalize.
93975	Duplex scan of arterial inflow and venous outflow of abdominal, pelvic, scrotal contents and/or retroperitoneal organs; complete study.	1.16	1.16	Finalize.
93976	Duplex scan of arterial inflow and venous outflow of abdominal, pelvic, scrotal contents and/or retroperitoneal organs; limited study.	0.80	0.80	Finalize.
93978	Duplex scan of aorta, inferior vena cava, iliac vasculature, or bypass grafts; complete study.	0.80	0.80	Finalize.
93979	Duplex scan of aorta, inferior vena cava, iliac vasculature, or bypass grafts; unilateral or limited study.	0.50	0.50	Finalize.
93990	Duplex scan of hemodialysis access (including arterial inflow, body of access and venous outflow).	0.50	0.50	Finalize.
95971	Electronic analysis of implanted neurostimulator pulse generator system (*e.g.,* 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 (*i.e.,* peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming.	0.78	0.78	Finalize.
95972	Electronic analysis of implanted neurostimulator pulse generator system (*e.g.,* 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 (*i.e.,* peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, up to 1 hour.	0.80	0.80	Finalize.
95973	Electronic analysis of implanted neurostimulator pulse generator system (*e.g.,* 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 (*i.e.,* 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).	0.49	.....	Deleted.
97605	Negative pressure wound therapy (*e.g.,* vacuum assisted drainage collection), utilizing durable medical equipment (DME), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters.	0.55	0.55	Finalize.

TABLE 13—CY 2016 ACTIONS ON CODES WITH CY 2015 INTERIM FINAL RVUS—Continued

HCPCS code	Long descriptor	CY 2015 interim final work RVU	CY 2016 work RVU	CY 2016 action
97606	Negative pressure wound therapy (*e.g.,* vacuum assisted drainage collection), utilizing durable medical equipment (DME), including topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters.	0.60	0.60	Finalize.
97607	Negative pressure wound therapy, (*e.g.,* vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters.	C	C	Finalize.
97608	Negative pressure wound therapy, (*e.g.,* vacuum assisted drainage collection), utilizing disposable, non-durable medical equipment including provision of exudate management collection system, topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area greater than 50 square centimeters.	C	C	Finalize.
97610	Low frequency, non-contact, non-thermal ultrasound, including topical application(s), when performed, wound assessment, and instruction(s) for ongoing care, per day.	0.35	0.35	Finalize.
99183	Physician or other qualified health care professional attendance and supervision of hyperbaric oxygen therapy, per session.	2.11	2.11	Finalize.
99184	Initiation of selective head or total body hypothermia in the critically ill neonate, includes appropriate patient selection by review of clinical, imaging and laboratory data, confirmation of esophageal temperature probe location, evaluation of amplitude EEG, supervision of controlled hypothermia, and assessment of patient tolerance of cooling.	4.50	4.50	Finalize.
99188	Application of topical fluoride varnish by a physician or other qualified health care professional.	N	N	Finalize.
99487	Complex chronic care management services, 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; establishment or substantial revision of a comprehensive care plan; moderate or high complexity medical decision making; 60 minutes of clinical staff time directed by a physician or other qualified health care professional, per calendar month.	B	B	Finalize.
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.	0.61	0.61	Finalize.
G0277	Hyperbaric oxygen under pressure, full body chamber, per 30 minute interval.	0.00	0.00	Finalize.
G0279	Diagnostic digital breast tomosynthesis, unilateral or bilateral (list separately in addition to G0204 or G0206).	0.60	0.60	Finalize.
G0389	Ultrasound b-scan and/or real time with image documentation; for abdominal aortic aneurysm (AAA) screening.	0.58	0.58	Finalize.
G0473	Face-to-face behavioral counseling for obesity, group (2–10), 30 minutes	0.23	0.23	Finalize.

a. Specific Issues for Codes With CY 2015 Interim Final Values

(1) Ablation Therapy (CPT Code 20983)

In CY 2015 we established the RUC-recommended work RVU for CPT code 20983 and made minor refinements to the RUC-recommended direct PE inputs.

Comment: A commenter stated that the total clinical labor times in the direct PE input database are inconsistent with the RUC-recommended values. The commenter mentioned that some of the service period activity time was assigned to the total post-service clinical labor time.

Response: We reviewed the direct PE input database and confirmed the time for clinical labor task ''Assist Physician'' was missing for labor type L046A. We will restore the missing labor time as we intended to establish as interim final the RUC recommendation for the clinical labor times without refinement.

(2) Automatic Fixation of Rib Fracture (CPT Codes 21811, 21812, and 21813)

For CY 2015, the CPT Editorial Panel deleted CPT code 21810 (Treatment of rib fracture requiring external fixation) and replaced it with CPT codes 21811, 21812, and 21813 to address internal fixation of rib fracture. As described in the CY 2015 PFS final rule with comment period, the RUC recommended that we value these procedures with 90-day global periods. We indicated that we believed it would be more appropriate to value these

procedures with 0-day global periods. We valued each of these services by subtracting the work RVU related to postoperative care from the total work RVU. We also refined the RUC-recommended time by subtracting the time associated with the postoperative visits, and removed direct PE inputs associated with the postoperative visits.

In the CY 2015 PFS final rule with comment period, we considered whether certain pre-service clinical labor tasks would typically be performed given that these procedures are frequently furnished on an emergency basis. We reviewed other emergency procedures valued under the PFS to determine whether pre-service clinical labor activities were typically included in the PE worksheets and found that the recommendations for these procedures were inconsistent. Therefore, in the CY 2015 PFS final rule with comment period, we did not remove the time allocated for certain clinical labor activities, but sought public comment on this issue.

Comment: One commenter expressed concerns with the methodology employed by CMS. The commenter stated that CMS staff had attended the RUC meeting where these codes were reviewed and were aware that a building block methodology (BBM) was not used to build the work RVUs for these codes. Therefore, the commenter suggested it was incorrect for CMS to use a reverse BBM to calculate a new value.

Response: We are committed to establishing the most accurate valuation possible for each procedure. In this case, we examined the results of the reverse BBM and determined that it was the most appropriate approach to value these services. Due to the emergency nature of these procedures, we believe that they are more accurately valued using a 0-day global period.

Comment: Another commenter reminded CMS that the specialty societies surveyed these three codes based on a 90-day global period and that CMS had ample opportunity to inform the RUC and the specialties of an impending change in the global assignment prior to the development of recommended RVUs.

Response: We understand that the specialties surveyed the codes under the assumption that they would be valued with a 90-day global period, prior to our determination that these services would be more accurately valued as 0-day globals due to their emergency nature. We believe that in the case of these emergent services, it may not be typical for the individual performing the initial procedure to be responsible for providing the follow-up care. Therefore, we believe that the 0-day global period to more accurately reflect the care furnished. This is precisely why it was necessary for us to account for the change in global period when establishing interim final work RVUs for the codes. To do so, we employed a reverse BBM to establish separate work RVUs for the individual procedure in each case. As we have previously stated, we believe that the best way to improve the valuation of codes that describe multiple services over long periods of time (for example, 90 days) is to develop discrete values for the component services. We agree that survey results are likely to be most useful when there is consistency between the global period as surveyed and the global period in the final valuation of the code. However, because we did not have such survey data in this case, we used another established methodology to develop a potential work RVUs. In this case, we believe that the reverse building block methodology establishes the most accurate value for this group of codes. Although the RUC recommends global periods for individual services and often consults with CMS staff regarding the typical global periods for such services, we believe that it is appropriate to establish global period for particular codes through rulemaking. If stakeholders are concerned about the final values for services surveyed based on a presumed global period that is not ultimately applied to the individual code, then we encourage stakeholders to consider nominating such codes as potentially misvalued through the public nomination process.

Comment: One commenter suggested that CMS did not provide reference codes with 0-day global periods to support the new interim final work RVUs. The commenter disagreed with the work RVUs established by CMS and suggested that all three of the codes in question were undervalued. The commenter provided information about other codes with 0-day global periods that had similar work time. The commenter urged CMS to reinstate the 90-day global period and accept the RUC recommendations for work RVUs, similar to other trauma codes.

Response: After reviewing the codes provided by the commenter, we believe that the values of other existing codes support our valuation of these procedures. For CPT code 21811, we note that CPT code 93650 (Intracardiac catheter ablation of atrioventricular node function) shares the same intraservice time of 120 minutes and has a higher total time (240 minutes compared to 220 minutes for CPT code 21811), but a lower work RVU of 10.49. We believe that the work RVU assigned to CPT code 21811 fits well within the work RVUs for the group of codes that have 0-day global periods and 120 intraservice minutes. For CPT code 21812, we note that 92997 (Percutaneous transluminal pulmonary artery balloon angioplasty), which has 5 additional minutes of intraservice time (155 minutes compared to 150 minutes for 21812) and a higher total time (275 minutes compared to 250 minutes for 21812), has a lower work RVU of 11.98. We believe that our valuation of CPT code 21812 maintains relativity within this group of 0-day global codes with times of approximately 150 intraservice minutes.

For CPT code 21813, we agree with the commenter that there is a lack of 0-day global codes with comparable intraservice times. We also agree with the commenter's suggestion that CPT codes 93654 and 93656 provide the best references available. These codes share an intraservice time of 240 minutes compared to the 210 minutes of intraservice time for CPT code 21813. However, we disagree with the commenter that CPT code 21813 is undervalued based on a comparison of these intraservice times. Applying the ratio between the 210 minutes for CPT code 21813 and the 240 minutes for the reference CPT code 93654 (0.875) to the work RVU of 20.00 for CPT code 93654, results in a work RVU of 17.50. This is similar to our valuation for CPT code 21813 of 17.61. We believe that this intraservice time ratio further supports our valuation of CPT code 21813, which maintains relativity with similar 0-day global codes. After consideration of comments received, we are finalizing the interim final work RVUs for CPT codes 21811, 21812, and 21813 for CY 2016.

(3) Percutaneous Vertebroplasty and Augmentation (CPT Codes 22510, 22511, 22512, 22513, 22514, and 22515)

In CY 2015, we established the RUC-recommended work RVUs as interim final for all of the codes in this family except CPT code 22511 because we did not agree with its RUC-recommended crosswalk. To value this code, we took the difference between the work RVUs for the predecessor codes for CPT codes 22510 and 22511, CPT codes 22520 (Percutaneous vertebroplasty (bone biopsy included when performed), one vertebral body, unilateral or bilateral injection; thoracic)) and 22521 (Percutaneous vertebroplasty (bone biopsy included when performed), one vertebral body, unilateral or bilateral injection; thoracic; lumbar)) and applied

that to the work RVU we established for CPT code 22510. We believed that increment established the appropriate rank order in the family, and thus, assigned an interim final work RVU of 7.58 for CPT code 22511.

Comment: A commenter disagreed with the methodology CMS used for valuing CPT code 22511 because they believed CMS' approach was arbitrary and invalidated the RUC process of using new survey data. The commenter urged CMS to accept the RUC-recommended work RVU of 8.05 for this code.

Another commenter requested that CMS reconsider the RVUs for these codes. The commenter believed that, due to the bundling of these imaging codes for CY 2015, additional PE costs were added to the service. The commenter expressed concerns that practitioners might find it infeasible to furnish these services in the non-facility setting if payment continues to be based on the interim final values we adopted for CY 2015.

Additionally, several commenters alerted CMS to missing clinical labor times for ''assist physician'' for all of the codes in this family. Some commenters also stated that clinical labor time was missing for the post-operative visit in CPT codes 22510, 22511, 22513, and 22514.

Response: Unlike other codes in this family for which the RUC-recommended work RVU was based on the 25th percentile in the survey, the RUC established its recommended work RVU for CPT code 22511 by crosswalking the service to CPT code 39400 (Mediastinoscopy, includes biopsy(ies), when performed), which has a work RVU of 8.05. Because the level of work performed by a practitioner in the two services differs, we continue to believe that this crosswalk is inaccurate. We maintain that a more accurate comparison is found in the difference between the work RVUs for the predecessor codes for CPT codes 22510 and 22511 and that applying this differential leads to appropriate valuation.

We agree with the commenters that there were inconsistencies in the clinical labor times for these codes as entered in our direct PE database. We direct the reader to section II.B. of this final rule with comment period for a discussion of these clinical labor input inconsistencies.

Therefore, we are finalizing our CY 2015 work valuation for CPT codes 22510, 22511, 22512, 22513, 22514, and 22515.

(4) Total Disc Arthroplasty (CPT code 22856)

In the CY 2015 PFS final rule with comment period, we maintained the CY 2014 work RVU for CPT code 22856, consistent with the RUC recommendation.

Comment: One commenter suggested that CPT code 22856 has been undervalued since 2009. The commenter believed CMS should value this service relative to several other codes that together comprise standard anterior cervical discectomy and fusion which the commenter believes is appropriately valued. The commenter stated that a higher valuation would be consistent with higher procedure operating room time included for CPT code 22856 in six clinical trials.

Response: We appreciate the submission of this additional information about the current practice of cervical disc replacement from the commenter. However, for the purpose of valuation, we typically compare a procedure against a broad range of other procedures across the PFS to help maintain relativity, rather than a single related procedure. In addition to intraservice operating time, other resource costs are included in the work RVU, such as the clinical intensity of the procedure and the time and intensity of the pre- and post-work, including post-operative visits.

After consideration of comments received, we are finalizing the CY 2015 interim final work RVU for CY 2016 without modification, consistent with the RUC recommendation.

(5) Sacroiliac Joint Fusion (CPT code 27279)

In the CY 2015 PFS final rule with comment period, we maintained the CY 2014 work RVU for CPT code 27279, consistent with the RUC recommendation.

Comment: Several commenters stated that the RUC survey data were not reliable because the reference service (CPT code 62287, Percutaneous discectomy) with a work RVU of 9.03 is not comparable. One of the commenters, a professional association, recommended a work RVU of 14.36 based upon its own survey or a work RVU of 13.18 based on a comparison with CPT code 63030 (Low back disk surgery). This commenter requested that CMS refer CPT code 27279 to the multispecialty refinement panel.

Response: CPT code 27279 was referred to the CY 2015 Multi-Specialty Refinement Panel per the commenter's request. The outcome of the refinement panel was a median of 9.03 work RVUs. After consideration of the comments and the results of the refinement panel, we are finalizing our interim final work RVU of 9.03 for CPT code 27279.

(6) Subcutaneous Implantable Defibrillator Procedures (CPT Codes 33270, 33271, 33272, 33273, 93260, 93261 and 93644)

For CY 2015, the CPT Editorial Panel added the word ''implantable'' to the descriptors for several codes in this family and created several new codes (CPT codes 33270, 33271, 33272, 33273, 93260, 93261, and 93644). We established as interim final the RUC-recommended work RVUs for all of the codes in this family except CPT code 93644. The RUC-recommended times for CPT code 93644 included an intraservice time of 20 minutes and a total time of 84 minutes. We disagreed with the RUC-recommended direct crosswalk for CPT code 93644 because the code that serves as the source for the crosswalk had greater intraservice time (29 minutes) and total time (115 minutes). We believed that a crosswalk to CPT code 32551 was more accurate since the intraservice time for CPT code 32551 was 20 minutes, total time was 83 minutes, and intensity was comparable. Therefore, we established a CY 2015 interim final work RVU of 3.29 for CPT code 93644.

Comment: Two commenters expressed disappointment that CMS did not accept the RUC recommendation for CPT code 93644. The commenters disagreed with the decision to crosswalk the work RVU for CPT code 93644 from CPT code 32551 because they believed that the services were not similar in nature. Commenters suggested that CMS accept the RUC recommendation with a crosswalk from CPT code 15002, due to a similar intraservice time. The commenters also requested that CPT code 93644 be referred to the multispecialty refinement panel.

Response: We continue to believe that crosswalking the value for CPT code 93644 from CPT code 32551 is the best way to value this service due to the codes' similar intraservice and total times and similar intensity. We believe that the difference in time values for the RUC-recommended crosswalk is too great to serve as a direct crosswalk for overall work. We did not receive any new clinical information needed for referral of this code to the multispecialty refinement panel. Therefore, we are finalizing our CY 2015 valuation.

(7) Fenestrated Endovascular Repair (FEVAR) Endograft Planning (CPT Codes 34839–34848)

For CY 2015, we examined several FEVAR codes. CPT code 34839 was created to report the planning that occurs prior to the work included in the global period for a FEVAR. We accepted the RUC recommendation for all of the codes in this family except CPT code 34839. We believed the planning that occurs prior to the work was included in the global period for FEVAR and should be bundled with the underlying service. We did not believe bundling was inappropriate in this case. Accordingly, we assigned a PFS procedure status indicator of B (Bundled Code) to CPT code 34839.

Comment: One commenter requested that CMS issue coding guidance regarding with which codes the FEVAR co-surgeon modifier can be used.

Response: We appreciate the commenter's feedback. We will take this comment into consideration in developing guidance for use of the co-surgeon modifier.

(8) Endovenous Ablation Therapy (CPT Codes 36475–36479)

For CY 2015, we examined several endovenous ablation therapy codes and used the RUC-recommended work RVUs to establish interim final work RVUs. We made minor refinements to the RUC recommended direct PE inputs to establish interim final direct PE inputs for this family of codes.

Comment: A commenter requested that CMS review the difference in PE inputs between CPT codes 36475 and 36478. The commenter stated that they believed CPT code 36478 was missing supplies which are commonly used in the procedure, and that this difference in reimbursement could only be explained by errors in the supply and staff inputs. The commenter also provided clinical information suggesting that the laser technique of endovenous ablation therapy described in CPT code 36478 is more effective than the radiofrequency treatment described in CPT code 36475.

Response: We thank the commenter for bringing this issue to our attention. We agree that there are errors in the direct PE database regarding these two codes. After consideration of comments received, we are making the following refinements. For CPT code 36475, we are adding one unit of supply item ''needle, spinal 18–26g'' (SC028) and one unit of supply item ''syringe 20 ml'' (SC053). For CPT code 36478, we are adding 5 minutes of clinical labor time of staff type L037D for ''Apply multi-layer comprehensive dressing'' and adding 3 minutes of clinical labor time of the same type for ''Check dressings & wounds.'' We are also removing 2 minutes of clinical labor time of staff type L054A for ''Patient clinical information and questionnaire reviewed by technologist'', as this time was inadvertently included in the direct PE database. This results in identical clinical labor inputs for the two procedures, as the commenter correctly pointed out should be the case.

With regards to the commenter's feedback regarding the supplies allocated to CPT codes 36475 and 36478, we reviewed the direct PE inputs as recommended by the RUC and agree that they represent the typical inputs used in furnishing these procedures.

Comment: One commenter disagreed with all of the PE refinements made in this family. The commenter stated that 30 minutes was typical recovery time for input code EF019 (stretcher chair) and that 32 minutes is the time the room is unavailable to other patients for input codes EL015 (room, ultrasound, general), EQ215 (radiofrequency generator (vascular)), and EQ160 (laser, endovascular ablation (ELVS)). The commenter also stated that additional images are inherent to the add-on codes which justify the extra minute in input code L054A (vascular technologist). Another commenter expressed support for CMS' acceptance of the RUC-recommended RVUs and times for these services.

Response: In establishing interim final times for the direct equipment inputs, we followed our standard methodologies that resulted in the allocated equipment times for EL015, EL215, and EQ160 for these codes in the direct PE input database. We believe that adherence to these standard methodologies maintains relativity within the development of PE RVUs and is likely to reflect the typical case. We disagree with commenters regarding the equipment times for EL015, El215, and EQ160. However, we agree additional images are inherent in the add-on codes, which supports the additional minute of clinical labor time. Therefore, we are finalizing the interim final values for these services, with the exception of the refinements to the clinical labor, supplies, and equipment described above.

(9) Cryoablation of Liver Tumor (CPT Code 47383)

For CY 2015, we proposed the RUC-recommended work RVU of 9.13 for CPT code 47383 and made several refinements to the recommended clinical labor and equipment times.

Comment: A commenter stated that the clinical labor time associated with the 99212 postoperative visit did not appear in the CMS direct PE public use files.

Response: We appreciate the assistance from the commenter in bringing this issue to our attention. We have corrected this error in the CMS direct PE public use files; we note that this issue was limited to the public use files and had no impact on the calculation of PE RVUs. For further information, please see the Identification of Database Errors in section II.H. of this final rule with comment period.

After consideration of comments received, we are finalizing the CY 2015 interim final work RVU and direct PE inputs as proposed for CPT code 47383.

(10) Transprostatic Implant Procedures (TIP) (CPT Codes 52441 and 52442)

In CY 2015, we established the RUC-recommended work RVUs and direct PE inputs as interim final for CPT codes 52441 and 52442.

Comment: One commenter agreed with the list and total cost of direct PE supplies established by CMS.

Response: We appreciate the commenter's supportive comments. We are finalizing our CY 2015 valuation for CPT codes 52441 and 52442.

(11) Laparoscopic Hysterectomy (CPT codes 58541, 58542, 58543, 58544, 58570, 58571, 58572, and 58573)

In the CY 2015 final rule with comment period, we established as interim final the RUC-recommended work RVUs and direct PE inputs for these codes.

Comment: Two commenters requested that these codes be sent to the multispecialty refinement panel prior to finalizing their work RVUs for CY 2016. Commenters stated that gynecologic oncologists were not offered the chance to participate in the RUC surveys for these procedures. As a result, the survey results did not reflect the typical patients that receive these procedures from practitioners of that specialty, who have complex medical needs with co-morbid conditions and complications. Commenters also indicated that the Food and Drug Administration (FDA) recently discouraged the use of morcellation during these procedures, which increases the amount of time it takes to perform the procedure and remove the fibroids prior to removing the uterus. The commenters stated that these changes need to be taken into account with new data prior to finalizing these work RVUs.

Response: We received and granted a request for multispecialty refinement panel review based on the presentation of new clinical information. However, the specialty groups making the original request later chose not to present these procedures at the 2015 Multi-Specialty Refinement Panel. After consideration of comments received and the lack of review by the multispecialty refinement panel, we are finalizing the CY 2015 interim final work RVUs for CPT codes 58541, 58542, 58543, 58544, 58570, 58571, 58572, and 58573 for CY 2016.

(12) Myelography (CPT Codes 62284, 62302, 62303, 62304, 62305, 72240, 72255, 72265, and 72270)

In the CY 2015 PFS final rule with comment period, we accepted the RUC-recommended work RVU for these nine codes on an interim final basis. We made refinements to the clinical labor and equipment time for the non-radiological codes in the family.

Comment: A commenter stated that the RUC recommended only a single staff type for the myelography codes, with clinical labor L041B for the radiological codes and L037D for the non-radiological ones. The commenter stated that they did not believe it would be typical to have two staff types involved in the procedure, and suggest allocating all minutes for the non-radiological codes to L037D.

Response: We agree with the commenter that assigning all of the clinical labor to a single staff type for each of the two types of procedure in the myelography family would be more typical for these services. Therefore we are changing the clinical labor type from L041B to L037D for the clinical labor activities ''Availability of prior images confirmed'', ''Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist'' and ''Assist physician in performing procedure'' for CPT codes 62302, 62303, 62304, and 62305. This ensures a single staff type for each of the nine codes in this family.

After consideration of comments received, we are finalizing these codes as proposed, with the change in clinical staff type detailed above.

(13) Maxillofacial Computed Tomography (CT) (CPT Codes 70486, 70487 and 70488)

In the CY 2015 PFS final rule with comment period, we used the RUC-recommended work RVU to establish an interim final work RVU of 0.85 for CPT code 70486 (Computed tomography, maxillofacial area; without contrast material). The RUC arrived at this value by crosswalking CPT code 70486 to CPT code 70460 (Computed tomography, head or brain; with contrast material(s)), which is the equivalent code in the head and brain CT family. To maintain rank order within and across CT families, we crosswalked the work RVU for CPT code 70487 (Computed tomography, maxillofacial area; with contrast material(s)) from CPT code 70460 (Computed tomography, head or brain; with contrast material(s)). We also crosswalked the work RVU for CPT code 70488 (Computed tomography, maxillofacial area; without contrast material, followed by contrast material(s) and further sections) from CPT code 70470 (Computed tomography, head or brain; without contrast material, followed by contrast material(s) and further sections). Therefore, we established interim final work RVUs of 1.13 for CPT code 70487 and 1.27 for CPT code 70488.

Comment: For CPT codes 70487 and 70488, commenters suggested that the CMS crosswalks did not accurately reflect the intensity of maxillofacial CT. Commenters suggested that CPT codes 70487 and 70488 require a thinner CT slice technique than the CMS crosswalks of CPT codes 70460 and 70470, and that the volume of images to be interpreted is greater. Commenters suggested that maxillofacial CTs were instrumental in imaging potentially dangerous conduits, which could be damaged due to maxillofacial disease.

Response: We continue to believe that since the lowest of the brain CT code family was an accurate crosswalk for CPT code 70486, the other two codes in the brain CT family are also accurate crosswalks for CPT codes 70487 and 70488. The procedures are similar in terms of both intraservice time and complexity of the anatomical region. While commenters requested that these codes be addressed by the multispecialty refinement panel, the request did not include information reflecting new clinical evidence, and therefore, did not meet the established criteria for review by the multispecialty refinement panel.

Comment: For CPT codes 70487 and 70488, commenters requested 3 minutes for the clinical labor task ''Provide pre-service education and obtain consent.''

Response: Upon review of the task ''provide pre-service education and obtain consent,'' we agree with commenters that 3 minutes is an accurate estimate for the amount of time required to discuss the risks involved in these procedures. Three minutes also maintains consistency within the code family. Therefore, we are including 3 minutes for ''provide pre-service education and obtain consent in the direct PE input database.

(14) Abdominal Ultrasound (CPT Codes 76700, 76705, 76770, 76775, 76856, and 76857)

For CY 2015, we used the RUC-recommended work RVUs and PE inputs to establish interim final values for six codes in the abdominal ultrasound family.

Comment: Commenters noted that CPT codes 76700 and 76705 were missing from the direct PE input database.

Response: We appreciate the commenters' attention to detail and we have included these codes in the updated direct PE input database.

(15) Breast Ultrasound (CPT Codes 76641 and 76642)

For CY 2015, the CPT Editorial Panel replaced CPT code 76645 (Ultrasound, breast(s) (unilateral or bilateral), real time with image documentation) with two codes: CPT codes 76641 (Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; complete) and 76642 (Ultrasound, breast, unilateral, real time with image documentation, including axilla when performed; limited). We used the RUC-recommended work RVUs of 0.73 and 0.68 to establish interim final work RVUs for CPT codes 76641 and 76642, respectively.

Comment: A few commenters encouraged CMS to refine the input for ultrasound room from 27 minutes to 29 minutes for CPT code 76641 and from 20 to 22 minutes for CPT code 76642 because ultrasound uses distinctive imaging equipment. All clinical labor tasks require usage of the machine, making the room unavailable during that time.

Response: The number of minutes assigned to the ultrasound room for both codes conforms to established times for highly technical equipment. We believe that adherence to these standard methodologies maintains relativity within the development of PE RVUs. Therefore, we are finalizing the interim final direct PE inputs for these services.

(16) CT Angiography (CTA) Head (CPT Codes 70496 and 70498)

In the CY 2015 PFS final rule with comment period, we used the RUC-recommended work and direct PE input recommendations without refinement to establish interim final values for these codes.

Comment: Some stakeholders stated that clinical staff time for confirming prior images and reviewing patient

clinical information was erroneously allocated to Rad Tech (L041B) instead of CT tech (L046A) and that CMS removed 2 minutes from clinical labor task ''technologist QC''. Commenters suggested that both actions were inconsistent with other codes in the CTA family.

Response: We reviewed the interim final direct PE inputs as well as the ''PE worksheet'' that accompanied the RUC recommendation. We noted that the values in ''CMS code'' and ''staff type'' columns were discrepant for the two clinical labor tasks noted by the commenters. While the CMS code indicated L041B, the Staff Type indicated CT Tech. We have therefore corrected the CMS code from L041B to L046A to correspond to the clinical staff type. We reviewed the direct PE database and confirmed that clinical labor task ''Technologist QC's images in PACS, checking for all images, reformats, and dose page'' is included for these codes. We are finalizing the interim final values for these services, with the additional correction of the staff type discrepancy.

(17) Breast Tomosynthesis (CPT Codes 77061, 77062, and 77063)

In the CY 2015 PFS final rule with comment period, we assigned a PFS indicator of ''I'' to CPT codes 77061 and 77062 on an interim basis while awaiting recommendations from the RUC for all mammography services. Since CPT code 77063 is an add-on code and did not have an equivalent CY 2014 code, we believed it was appropriate to value it on an interim final basis in advance of receiving the RUC recommendations for other mammography services. We assigned it a CY 2015 interim final work RVU of 0.60 as recommended by the RUC. We also removed the equipment time for the PACS Workstation proxy from all three codes, and removed the time for task ''Federally Mandated MQSA Activities Allocated To Each Mammogram'' from CPT code 77063.

Comment: A commenter indicated that the direct PE input files included a PACS Workstation proxy for CPT code 77063, but did not allocate clinical staff time to this proxy.

Response: We removed the 4 minutes of clinical labor associated with ''Federally Mandated MQSA Activities Allocated To Each Mammogram'' due to the fact that CPT code 77063 is an add-on code, and this task would already have been performed previously with another mammography service. We did not assign equipment time for the PACS Workstation as we do not believe that its use would be typical for this procedure.

After consideration of comments received, we are finalizing the PFS indicator ''I'' for CPT codes 77061 and 77062, the interim final work RVU of 0.60 for CPT code 77063, and the interim final direct PE inputs for all three codes.

(18) Dosimetry (CPT Codes 77300, 77306, and 77307)

To establish interim final RVUs for these codes, we used the RUC-recommend work and direct PE inputs for these codes with PE refinements, with the refinement of consideration of the ''record and verify system'' as an indirect PE.

Comment: A few commenters expressed support for CMS' adoption of the RUC-recommended work RVUs for CPT codes 77306 and 77307. Other commenters requested that CMS consider equipment item ED011 (record and verify) as a direct PE input because it is typically used during the procedures.

Response: We appreciate the commenters' feedback related to these services. We reviewed the ''record and verify'' equipment item and agree with commenters that ''record and verify'' should be included as a direct PE to maintain consistency with other services in the direct PE database, and have updated the direct PE input database accordingly.

(19) Brachytherapy Isodose Plan (CPT Codes 77316, 77317, and 77318)

For CY 2015, the CPT Editorial Panel replaced six CPT codes (77305, 77310, 77315, 77326, 77327, and 77328) with five new CPT codes to bundle basic dosimetry calculation(s) with teletherapy and brachytherapy isodose planning. We established interim final work RVUs based on the RUC-recommended work RVUs for CY 2015 for all of the codes in this family except CPT code 77316. Instead of using the RUC-recommended work RVU for CPT code 77316, a simple isodose planning code, we developed an interim final work RVU based on a direct crosswalk from the corresponding simple isodose planning code in the same family, CPT code 77306. Therefore, for CY 2015 we established an interim final work RVU of 1.40 for CPT code 77316. This approach is similar to the crosswalk the RUC used to develop the recommended work RVUs for CPT code 77318.

Comment: Commenters disagreed with CMS' refinements to CPT code 77316 and stated that although CPT code 77316 is the simple isodose planning code in the family, the CMS-recommended crosswalk to CPT code 77306 does not accurately capture the intensity of the procedure. Commenters suggested that CPT code 77316 is typically used for HDR brachytherapy with a single channel and more than four dwell positions. This requires more work than CPT code 77306, which is for external beam radiation planning. Commenters requested that CPT code 77316 be referred to the multispecialty refinement panel.

Response: Commenters did not provide new clinical information and, therefore we did not refer the codes to the multispecialty refinement panel. The RUC recommended a crosswalk for CPT code 77318 to CPT code 77307. We believe that if the work resources for the complex isodose planning codes are comparable between the two families, then the work resources between the simple isodose planning codes are also comparable. Therefore, we believe that the most accurate work RVU for CPT code 77316 is 1.40, based on a crosswalk to CPT code 77306.

Comment: Several commenters thanked CMS for adopting the RUC-recommended work RVUs for CPT codes 77317 and 77318.

Response: We appreciate the commenters' support. We are finalizing the CY 2015 interim final work RVUs as established.

(20) Electron Microscopy (CPT Code 88348)

We received PE-only recommendations for CPT code 88348 following the October 2013 RUC meeting. After reviewing these recommendations, we used the RUC recommendations without refinement to establish interim final values for CY 2015.

Comment: One commenter wrote to express their disagreement with the 79 percent reduction in the technical component of the procedure following the publication of the CY 2015 final rule. The commenter suggested that there was an error in evaluating the value and cost of this service, and provided additional information regarding the direct costs associated with providing electron microscopy to patients. The commenter stated that continued reduction in the value for CPT code 88348 will result in a reduction in the availability of tests which will provide impaired service to many patients with treatable conditions and salvageable kidney function.

Response: We concur with the commenter on the importance of providing patient access to quality testing. However, we do not believe that there was an error in evaluating the value and cost of this service. We agreed with the RUC recommendations for

direct PE inputs for CPT code 88348, and we continue to believe that these represent the most accurate values for this procedure.

(21) Microdissection (CPT Codes 88380 and 88381)

In reviewing the RUC recommendations for CPT code 88380, the work vignette indicated that the microdissection is performed by the pathologist. However, the PE worksheet also included several subtasks of ''Microdissect each stained slide sequentially while reviewing H and E stained slide'' that are performed by the cytotechnologist. Since we did not believe that both the pathologist and the cytotechnologist were completing these tasks, we did not allocate clinical labor time for the specific tasks we believe are completed by the pathologist. Table 31 of the CY 2015 final rule (FR 79 67697–67698) detailed our refinements to these clinical labor tasks. We accepted the RUC-recommended work RVU of 1.14 for CPT code 88380 and 0.53 for CPT code 88381 on an interim final basis for CY 2015.

Comment: A commenter urged CMS to accept and implement the practice expense inputs recommended by the RUC for CPT code 88380. For the clinical labor task ''Dispose of razor blade, Cap tube and vortex specimens'', the commenter stated that the recommended 3 minutes for blade disposal tube capping is part of the processing of the individual specimen. The commenter suggested that the word ''blade disposal'' may have been confusing since it is not a cleaning function. The commenter requested that CMS restore the RUC-recommended 3 minutes for this task.

Response: We do not believe that clinical labor time should be assigned for this task, as CPT code 88380 uses a laser to perform the same activity. We do not believe that the use of a razor blade, and associated clinical labor, would be typical for this procedure.

Comment: One commenter stated that the RUC recommended 18 minutes for the clinical labor task ''Turn on dissecting microscope, place slide on scope, remove razor blade from box. Microdissect tissue within etched area, while viewing slide under dissecting scope, place tissue into cap of collection tube with blade. Repeat this step for seven other slides.'' The commenter indicated that the cytotechnologist and pathologist are working together during this task, and the assistance of the cytotechnologist is necessary during these ancillary tasks for the efficiency of the dissection process. The work survey results indicated that some of the work time has shifted to the clinical labor time for this particular task.

Response: We continue to believe that the pathologist is the individual performing this clinical labor task, not the cytotechnologist.

Comment: One commenter disagreed with the CMS refinement to the equipment time for the Veritas microdissection instrument (EP087). The commenter stated that the equipment time associated with EP087 is the sum of time to prepare the instrument for use, plus the time the pathologist and cytotechnologist are using it, plus the time the room and equipment are cleaned. The commenter suggested that while microdissection is taking place, the equipment cannot be used for any other purpose. The commenter indicated that the sum of these time increments equals 34 minutes, not the 32 minutes as refined by CMS.

Response: We appreciate the commenter's assistance in providing clarification regarding the appropriate equipment time for EP087. After consideration of comments received, we agree that the Veritas microdissection instrument would typically be in use for 33 minutes of intraservice time, plus 3 minutes for laser preparation, plus one minute for room cleaning following equipment use. Therefore, we are refining the equipment time for EP087 to 37 minutes for CPT code 88380, to match the standard equipment time formula, and finalizing all other direct PE inputs as established as interim final.

(22) Electro-Oculography (EOG VNG) (CPT Code 92543)

We established a work RVU of 0.10 for CPT code 92543 as interim final for CY 2015. Several commenters disagreed with our interim final values. However, the CPT Editorial Panel deleted CPT code 92543 for CY 2016; we refer readers to section II.H. of this final rule with comment period, where we discuss CPT codes 9254A and 9254B, used to report related services.

(23) Doppler Echocardiography (CPT Codes 93320, 93321 and 93325)

As detailed in the CY 2015 PFS final rule with comment period, we maintained the CY 2014 work RVUs for CPT codes 93320, 93321 and 93325, based upon the RUC-recommended work RVUs. In establishing interim final direct PE inputs for CY 2015, we refined the RUC's recommendations for CPT codes 93320, 93321 and 93325 by removing the minutes associated with equipment item ED021 (computer, desktop, w/monitor) since a computer is included in the other equipment inputs associated with codes.

Comment: One commenter supported CMS' adopting the work RVUs and times recommended by the RUC for these services (CPT codes 93320, 93321, and 93325).

Response: We appreciate the commenters support. We are finalizing the CY 2015 interim final work RVUs as established.

Comment: One commenter stated that ED021 is not included in the room.

Response: We disagree that ''computer, desktop w/monitor'' (ED021) is not included in the equipment room ''room, vascular ultrasound.'' The PE reference materials submitted by the RUC indicate that ''ultrasound room, vascular'' includes a computer (Vascoguard II, main station with cart, keyboard, LCD monitor, deskjet printer, Doppler, and probe holder). Therefore, we are finalizing the direct PE inputs for CPT codes 93320, 93321, and 93225 as established as interim final.

(24) Interventional Transesophageal Echocardiography (TEE) (CPT Codes 93312, 93313, 93314, 93315, 93316, 93317, 93318 and 93355)

For CY 2015, we used the RUC-recommended work RVU of 2.40 to establish an interim final value for CPT code 93318 and 4.66 for CPT code 93355. Based on a crosswalk from CPT code 75573, we assigned CPT code 93312 a CY 2015 interim final work RVU of 2.55. We noted that based on the CPT descriptor for CPT code 93315, we believed that the appropriate work for this service was reflected in the combined work of CPT codes 93316 and 93317, resulting in a CY 2015 interim final work RVU of 2.94. For CPT codes 93313, 93314, 93316 and 93317, we assigned CY 2015 interim final work RVUs that corresponded to the 25th percentile survey result. Each of these codes had a significant reduction in intraservice time since the last valuation. We noted that we believe the 25th percentile survey values better describe the work and time involved in these procedures than the RUC recommendations, and that it helps maintain appropriate relativity in the family. Additionally, we refined the preservice and intraservice times for CPT codes 93314 and 93317 to 10 and 20 minutes, respectively, to maintain relativity among the interim final work RVUs and times.

Comment: Some commenters disagreed with CMS' decision to value the work RVU for CPT code 93312 by crosswalking it from CPT code 75573, rather than the RUC-recommended work

RVU based on a crosswalk from CPT code 43247 (Esophagogastroduodenoscopy).

Response: The RUC-recommended crosswalk code, CPT code 43247, is a 0-day global service, whereas CPT code 75573 has no global period. Since CPT code 75573 and CPT code 93312 do not have global periods, while 43247 has a global period, we do not believe that the latter code can serve as an appropriate crosswalk. Therefore, we are finalizing the CY 2015 work RVUs as established for CPT code 93312.

Comment: A few commenters disagreed with CMS' refinement of the work RVUs for CPT codes 93313 and 93314. The commenters stated that the work RVU that corresponds to the 25th percentile survey result fails to account for changes in technique, technology, and knowledge.

Response: After review of the comments, we continue to believe that the RUC-recommended work RVUs do not adequately reflect the significant reduction in intraservice time, and that our corresponding refinements to the work RVUs are appropriate. We do not believe that the work RVUs corresponding to the survey 25th percentile result fail to account for typical changes in technique, technology, and knowledge. Therefore, we are finalizing the CY 2015 work RVUs as established for CPT codes 93313 and 93314.

Comment: A few commenters disagreed with the time refinement made to CPT codes 93314 and 93317.

Response: To maintain consistency with the work RVUs, we continue to believe that these time refinements are appropriate. Therefore, we are finalizing the times for CPT codes 93314 and 93317 as established for CY 2015.

Comment: Some commenters disagreed with CMS' use of the BBM to determine a work RVU for CPT code 93315, suggesting that it did not incorporate updated service times and changes in technique, technology, and knowledge.

Response: After consideration of the comments received, we continue to believe that the appropriate work RVU for CPT code 93315 is reflected in the combined work of CPT codes 93316 and 93317, resulting in a CY 2015 interim final work RVU of 2.94. We are finalizing the interim final work RVUs for these codes as established.

Comment: A commenter requested that this family of codes be referred to the multispecialty refinement panel.

Response: The request for referral to the multispecialty refinement panel did not include new clinical information; therefore, the request did not meet the criteria for review by the multispecialty refinement panel.

Commen One commenter questioned why the TC codes within the congenital TEE family are contractor-priced.

Response: We did not receive recommendations for the direct PE inputs for CPT codes 93315, 93317, and 93318. Without such recommendations, we did not have sufficient information about the resource costs necessary to establish national pricing and we therefore assigned a contractor-priced status to the technical component of these codes. We are finalizing the contractor-priced status for the technical component of CPT codes 93315, 93317, and 93318.

Comment: One commenter supported CMS' proposal to adopt the RUC-recommended work RVU and times for CPT code 93355.

Response: We appreciate the commenter's feedback, and we are finalizing the CY 2015 work RVUs and direct PE inputs as established as interim final.

(25) Duplex Scans (CPT Codes 93880, 93882, 93886, 93888, 93926, 93975, 93976, 93977, 93978, and 93979)

For CY 2014, we maintained the CY 2013 RVUs for CPT codes 93880 and 93882. As we stated in the CY 2014 PFS final rule with comment period (78 FR 74342), we were concerned that the RUC-recommended work RVUs for CPT codes 93880 and 93882, as well as our final work RVUs for CPT codes 93925 (Duplex scan of lower extremity arteries or arterial bypass grafts; complete bilateral study) and 93926 (Duplex scan of lower extremity arteries or arterial bypass grafts; unilateral or limited study) did not maintain the appropriate relativity within the family. We referred the entire family to the RUC to assess relativity among the codes and to recommend appropriate work RVUs. We also requested that the RUC consider CPT codes 93886 (Transcranial Doppler study of the intracranial arteries; complete study) and 93888 (Transcranial Doppler study of the intracranial arteries; limited study) in conjunction with the duplex scan codes to assess the relativity between and among the codes. In the CY 2015 PFS final rule with comment period, we used the RUC-recommended work RVUs for CPT codes 93880, 93882, 93925, and 93926 while making several standard PE refinements consistent with standard inputs for digital imaging and our policies for not allocating quality assurance documentation to individual services as a direct expense.

Comment: Some commenters stated that quality assurance (QA) documentation is an integral part of the procedure, so it should be included as a direct PE input clinical labor task.

Response: We consider QA documentation to be an indirect PE since it is not generally allocated to a single patient during an individual procedure. Instead, we believe QA activities are undertaken through different means across a wide range of practices.

Comment: One commenter disagreed with the minutes assigned to the vascular ultrasound room (EL016) for CPT code 93880. The commenter disagreed with the CMS refinement from 68 minutes of equipment time to 51 minutes, and objected to the removal of equipment time for preservice tasks not typically associated with highly technical equipment. The commenter stated that there was no data to support the CMS rationale, and presented survey data suggesting that preservice activities are routinely carried out in the vascular ultrasound room.

Response: We continue to 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 and are typically available for other patients even when one member of the clinical staff may be occupied with a pre-service or post-service task related to the procedure. 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).

Comment: A few commenters stated that a desktop computer is a necessary PE input for these codes.

Response: We believe that computer processing functionality is inherent in the ultrasound system included in the general ultrasound room. We refer readers to Table 14 for the items and associated prices that constitute the ultrasound rooms.

TABLE 14—ITEMS THAT CONSTITUTE THE ULTRASOUND ROOMS

$369,945	General Ultrasound Room, General.

TABLE 14—ITEMS THAT CONSTITUTE THE ULTRASOUND ROOMS—Continued

$220,000 ...	GE Logic 9 ultrasound system (H4902SG).
$18,000	transducer, 3–8MHz matrix array convex (H40412LC).
$650	probe starter kit for H40412LD: bracket, needle guides, probe covers (E8385RF).
$18,000	transducer, 5–13MHz linear matrix array (H40412LD).
$650	probe starter kit for H40412LD: bracket, needle guides, probe covers (E8385RF).
$12,000	transducer, 4–10MH micro convex probe (H40412LE).
$11,000	transducer, 4–10MHz probe (H40412LG).
$10,000	transducer, 2–5MHz probe (H4901PE).
$12,500	software, B-flow (H4901BF).
$5,500	software, DICOM (H4901DM).
$8,000	software, LOGIQ View (h4901LW).
$4,900	VHS video recorder (Sony SVO–9500MD/2).
$6,500	digital printer (Sony UPD21).
$1,995	monochrome thermal printer (Sony UPD895).
$5,250	ultrasound table (E8375F).
$35,000	compound imaging.
$466,492 ...	Ultrasound Room, Vascular.
	General Ultrasound Room, General.
	Nicojet VasoGuard P84 (PPG & lower extremity):
	Nicolet Pioneer TC 8080 (transcranial).
	Atrium Medical Vaslab—software add-on for data collection, database maintenance, and accreditation processing.

In the CY 2014 PFS final rule with comment period (78 FR 74342), we requested that the RUC assess the relativity among the entire family of duplex scans codes and recommend appropriate work RVUs. We also requested that the RUC consider CPT codes 93886 (Transcranial Doppler study of the intracranial arteries; complete study) and 93888 (Transcranial Doppler study of the intracranial arteries; limited study) in conjunction with the duplex scan codes to assess the relativity between and among those codes. For CY 2015, we established the RUC-recommended work RVUs as interim final for all of the codes in the family except CPT codes 93886, 93888, 93926, 93975, 93976, 93977, 93978, and 93979. For several codes in this family with 10 minutes of intraservice time, the RUC recommended 0.50 work RVUs. CPT code 93926 (Duplex scan of lower extremity arteries or arterial bypass grafts; unilateral or limited study), CPT code 93979 (Duplex scan of aorta, inferior vena cava, iliac vasculature, or bypass grafts; unilateral or limited study,) and CPT code 93888 all have 10 minutes intraservice time and we assigned them an interim final work RVU of 0.50. For several codes in this family with 15 minutes of intraservice time, the RUC recommended work RVUs that corresponded to the 25th percentile survey result. We found this to appropriately reflect the work involved and applied the same logic to other codes with 15 minutes of intraservice time. We established the work RVUs for CPT codes 93975, 93976, and 93978 that corresponded to the 25th percentile survey result, which all have 15 minutes of intraservice time. Therefore, for CY 2015 we established the following interim final work RVUs: 1.16 for CPT code 93975; 0.80 for CPT code 93976; 0.80 for CPT code 93978; and 0.50 for CPT code 93979.

Comment: Several commenters disagreed with the allocation of 0.50 RVUs to codes with 10 minutes of intraservice time across the Doppler/duplex code family. The commenters suggested that 0.50 RVUs does not reflect the relationship between the codes based on their time, intensity, rank order, and complexity. Commenters stated that transcranial Doppler studies are more intense than Doppler studies of other body parts and thus should be valued with higher RVUs. Commenters requested that CPT codes 93886 and 93888 be referred to the multispecialty refinement panel.

Response: When valuing these codes, we used the RUC recommendation of 0.80 RVUs for CPT code 93880, which has an intraservice time of 15 minutes. Applying the work RVU-to-time ratio of CPT code 93880 to CPT code 93886, which has an intraservice time of 17 minutes, results in our interim final work RVU of 0.91 for CPT code 93886. For CPT code 93888, we noted that it had an identical time and similar intensity to code 93882; therefore, we found an RVU of 0.50 to be appropriate. The commenters did not include any new clinical information in their requests for referral of CPT codes 93886 and 93888. Therefore, the requests did not meet the criteria for referral to the multispecialty refinement panel.

Comment: Several commenters encouraged CMS to adopt the RUC recommendation for CPT code 93926, stating that, although CPT code 93926 has 10 minutes of intraservice time, the intensity is greater than 0.50 RVUs.

Response: We appreciate the commenters' feedback. However, we believe that 0.50 is the accurate work RVU for CPT code 93926 based on a crosswalk from CPT code 93880. We believe that because the intensity is similar and the overall time is the same, the overall work is comparable.

Comment: Several commenters pointed out that CPT code 93975 has 20 minutes of intraservice time, and should not have the same RVU as a code with 15 minutes of intraservice time. A few commenters suggested that CPT code 93976 involves arterial and venous blood flow and is therefore more intense than other procedures in the code family. Commenters requested that CPT codes 93975 and 93976 be referred to the multispecialty refinement panel.

Response: When valuing code 93965, we noted that we did not think the RVU that resulted in application of the intraservice ratio to 93880 accurately reflected the work involved in furnishing the procedure. Therefore, we used the work RVU that corresponded to the 25th percentile survey result to establish the RVU. For code 93976, we noted that the intraservice time is identical to CPT code 93880, which has a work RVU of 0.50. This value also corresponds to the 25th percentile survey result.

Comment: A commenter commended CMS for accepting the RUC-recommended work RVU for CPT code 93931.

Response: We appreciate the commenter's feedback and support.

After considering these comments, we are finalizing the CY 2015 interim final values as established.

(26) Carotid Intima-Media Thickness Ultrasound (CPT Code 93895)

For CY 2015, the CPT Editorial Panel created new CPT code 93895 to describe the work of using carotid ultrasound to measure atherosclerosis and quantify the intima-media thickness. After review of this code, we determined that

it was used only for screening, and therefore, we assigned a PFS procedure status indicator of N (Noncovered service) to CPT code 93895.

Comment: Two commenters were dissatisfied with our designation of this service as a noncovered screening tool. One commenter stated that ''other methods for atherosclerosis imaging are already approved for coverage under Medicare local coverage determination policies and are directly comparable to carotid atherosclerosis imaging in terms of their purpose and clinical application.'' Another commenter suggested that the test was ''designed to be used in patients with cardiovascular risk to enhance care and assist physicians in selection and intensity of risk reducing therapies.'' All commenters encouraged CMS to reconsider its decision to classify CPT code 93895 as a noncovered screening service.

Response: While we appreciate the commenter's feedback, we are unaware of other carotid atherosclerosis imaging services for which we provide payment when used for patients without signs or symptoms of disease. Information that we received from the RUC and specialty societies indicated that the typical patient would be one without signs or symptoms of carotid disease. Therefore, this test does not meet the statutory definition of a diagnostic test and as such, is not covered under Medicare.

(27) Negative Pressure Wound Therapy (CPT Codes 97605, 97606, 97607 and 97608)

Prior to CY 2013, CPT codes 97605 and 97606 were both used to report negative pressure wound therapy, which were typically reported in conjunction with durable medical equipment that was separately payable. In the CY 2013 final rule with comment period, we created two HCPCS codes to provide a payment mechanism for negative pressure wound therapy services furnished to beneficiaries using equipment that is not paid for as durable medical equipment: G0456 (Negative pressure wound therapy, (for example, vacuum assisted drainage collection) using a mechanically powered device, not durable medical equipment, including provision of cartridge and dressing(s), topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area less than or equal to 50 square centimeters) and G0457 (Negative pressure wound therapy, (for example, vacuum assisted drainage collection) using a mechanically-powered device, not durable medical equipment, including provision of cartridge and dressing(s), topical application(s), wound assessment, and instructions for ongoing care, per session; total wound(s) surface area greater than 50 sq. cm).

For CY 2015, the CPT Editorial Panel created CPT codes 97607 and 97608 to describe negative pressure wound therapy with the use of a disposable system. In addition, CPT codes 97605 and 97606 were revised to specify the use of durable medical equipment. Based upon the revised coding scheme for negative pressure wound therapy, we deleted the G-codes. We contractor-priced CPT codes 97607 and 97608 for CY 2015 and the CPT codes were designated ''Sometimes Therapy'' on our Therapy Code List, consistent with the G-codes.

Comment: One commenter was disappointed with CMS' decision to contractor price CPT Codes 97607 and 97608, since CMS originally created G-codes to provide a payment mechanism for negative pressure wound therapy services furnished to beneficiaries through means unrelated to the durable medical equipment benefit. They expressed concern that practitioners who utilize the new disposable device will be paid amounts derived from crosswalks from the DME-related codes (CPT codes 97605 and 97606), which include more work time and work.

Response: We agree that the codes are intended to provide a payment mechanism for negative pressure wound therapy services furnished to a beneficiary using equipment that is not paid for as durable medical equipment. However, we do not agree that contractor pricing the codes is unlikely to result in accurate payment amounts for the services. There are several obstacles to developing accurate payment rates for these services within the PE RVU methodology, including the indirect PE allocation for the typical practitioners who furnish these services and the diversity of the products used in furnishing these services. Since our methodology values services based on the typical case, and the cost structure differs among a variety of products, we believe that contractor pricing allows for more accurate payment than national prices that would be based on the cost structure of a single product. Thus, contractor pricing these codes allows for flexibility in the products used, pending additional information about what product is typically involved in furnishing these services.

Comment: One commenter expressed disappointment that CMS had adjusted the equipment and staff time downward for CPT codes 97605 and 97606. The commenter expressed that the timing of the publication of this rule does not allow adequate time to evaluate the impact these changes will have on operating expenses and noted that the complicated nature of the formula used to calculate PE RVUs limits their ability to predict the impact of these changes.

Response: The intraservice clinical labor time already included time for wound checking. As a result, the 5 minutes in the post-service period were refined to 2 minutes. Accordingly, equipment times were refined to conform to the changes in clinical labor time. After consideration of the comment, we are finalizing the direct PE inputs for CPT codes 97605 and 97606 as established. In response to the commenter's concerns regarding the timing of changes in values for particular PFS services, we note that beginning in rulemaking for CY 2017, we anticipate that most changes in payment based on review of individual codes will be proposed in the annual PFS proposed rule instead of established as interim final in the annual final rule. We also note that we display the resulting PE RVUs for each code in Addendum B for each proposed and final rule. This allows stakeholders to see the PE RVUs that result from any changes in input assumptions for particular codes.

(28) Hyperbaric Oxygen Therapy (HBOT) (CPT Code 99183 and HCPCS Code G0277)

For CY 2015, we received RUC recommendations for CPT code 99183 that included significant increases to the direct PE inputs, which assumed a treatment time of 120 minutes. Prior to CY 2015, CPT code 99183 was used to report both the professional attendance and supervision, and the costs associated with treatment delivery were included in nonfacility direct PE inputs for the code. We created HCPCS code G0277 to be used to report the treatment delivery separately, consistent with the OPPS coding mechanism, to allow the use of the same coding structure across settings. In establishing interim final direct PE inputs for HCPCS code G0277, we used the RUC-recommended direct PE inputs for CPT code 99183 and adjusted them to align with the 30-minute treatment interval. We observed that the quantity of oxygen increased significantly relative to the previous value. To better understand this change, we reviewed the instruction manual for the most commonly used HBOT chamber, which provided guidance regarding the quantity of oxygen used. Based on our review, we determined that 12,000, rather than 47,000, was the typical number of units. Therefore, in

aligning the direct PE inputs as described above, we first adjusted the units of oxygen to 12,000 for the recommended 120-minute time, and subsequently adjusted it to align with the 30 minute G-code.

Comment: Several commenters disagreed with the volume of oxygen consumed for a 120 minute treatment time cited in the final rule and some recommended adopting 42,000–47,000 liters or units for a typical 120-minute HBO2 profile. We also received a few additional comments on these services during the comment period for the proposed rule. The commenters reiterated that they support the change from C1300 to G0277 as the 30 minute interval for hyperbaric oxygen therapy; however, they suggested that the methodology used by the RUC more accurately reflects the amount of oxygen that is used in a hyperbaric oxygen treatment. They stated, ''the provision of a hyperbaric oxygen treatment requires a pressure of greater than 1.4 ATA and a therapeutic dose of as close to 100 percent oxygen as can be achieved in the monoplace environment. This level of oxygen delivery must be reached and maintained for the duration of the designated treatment time. Therefore, a treatment of 2.4 ATA for 120 minutes will require that the target chamber oxygen concentration must be achieved at the same time as the designated pressure.'' The commenter additionally requested that CMS not finalize the proposed CY 2016 reduction in PE RVUs.

Response: We thank the commenters for their feedback and have considered the materials submitted. We agree that a high purge flow rate is needed in order to reach maximum pressure/O2; however, we still have not seen data that demonstrates the need to continue a maximum flow rate throughout the entire session. The RUC forwarded an invoice for the Sechrist Model 3600E Hyperbaric Chamber for use in pricing the capital equipment for this service. According to the manufacturer's manual for this model, ''once the nitrogen has been purged from the chamber and the internal oxygen concentration has exceeded 95 percent, high flows are no longer needed to maintain the patient's saturation level.'' The manual also states that ''the plateau purge flow can be set to 80 lpm.'' We calculated that 13 minutes at 400 lpm plus 120 minutes at 80 lpm equals 14,800 liters of oxygen. Based on the current publicly available information in the manufacturer's manual, we believe that this represents the typical usage for a 120 minute treatment. This amount represents an increase from the interim final amount of 12,000. As we described in the CY 2015 final rule, we aligned this total oxygen requirement to the 30 minute G-code. Following that principle here, we are updating the direct PE inputs to 3,700 liters of oxygen for HCPCS code G0277. In response to the commenter's request regarding a reduction in the PE RVUs in the CY 2016 PFS proposed rule, any changes from the CY 2015 PE RVUs for HCPCS code G0277 to values displayed in association with the CY 2016 proposed rule resulted from overall changes in PE relativity and PFS budget neutrality and did not result from a change in the direct PE inputs.

9. CY 2016 Interim Final Codes

For recommendations regarding any new or revised codes received after the February 10, 2015 deadline, including updated recommendations for codes included in the CY 2016 proposed rule, we are establishing interim final values in this final rule with comment period, consistent with previous practice.

We note that in the CY 2016 PFS proposed rule, we inadvertently published work RVUs for several CPT codes in Addendum B that were not explicitly discussed in the text. Those CPT codes include 88341, 88364, and 88369; these codes had previously been proposed on an interim basis in the CY 2015 PFS final rule with comment period. While these codes were not discussed in the proposed rule because our files displayed incorrect work RVUs for these codes due to the data error, some commenters raised questions about these codes' displayed work RVUs. To allow public comment on the correct valuations, we are therefore establishing interim final work RVUs for these codes for CY 2016 and requesting comment on those interim final values in this final rule. We will respond to comments on these values in CY 2017 rulemaking.

TABLE 15—CY 2016 INTERIM FINAL WORK RVUS FOR NEW/REVISED OR POTENTIALLY MISVALUED CODES

HCPCS Code	Long descriptor	CY 2015 WRVU	RUC/HCPAC recommended work RVU	CMS 2016 work RVU	CMS time refinement
10035	Placement of soft tissue localization device(s) (e.g., clip, metallic pellet, wire/needle, radioactive seeds), percutaneous, including imaging guidance; first lesion.	NEW	1.70	1.70	No.
10036	Placement of soft tissue localization device(s) (e.g., clip, metallic pellet, wire/needle, radioactive seeds), percutaneous, including imaging guidance; each additional lesion.	NEW	0.85	0.85	No.
26356	Repair or advancement, flexor tendon, in zone 2 digital flexor tendon sheath (e.g., no man's land); primary, without free graft, each tendon.	10.62	10.03	9.56	No.
26357	Repair or advancement, flexor tendon, in zone 2 digital flexor tendon sheath (e.g., no man's land); secondary, without free graft, each tendon.	8.77	11.50	10.53	No.
26358	Repair or advancement, flexor tendon, in zone 2 digital flexor tendon sheath (e.g., no man's land); secondary, with free graft (includes obtaining graft), each tendon.	9.36	13.10	12.13	No.
41530	Submucosal ablation of the tongue base, radiofrequency, 1 or more sites, per session.	4.51	3.50	3.50	No.
43210	Esophagogastroduodenoscopy, flexible, transoral; with esophagogastric fundoplasty, partial or complete, includes duodenoscopy when performed.	NEW	9.00	7.75	Yes.
47531	Injection procedure for cholangiography, percutaneous, complete diagnostic procedure including imaging guidance (e.g., ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; existing access.	NEW	1.80	1.80	No.

TABLE 15—CY 2016 INTERIM FINAL WORK RVUS FOR NEW/REVISED OR POTENTIALLY MISVALUED CODES—Continued

HCPCS Code	Long descriptor	CY 2015 WRVU	RUC/HCPAC recommended work RVU	CMS 2016 work RVU	CMS time refinement
47532	Injection procedure for cholangiography, percutaneous, complete diagnostic procedure including imaging guidance (e.g., ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; new access (e.g., percutaneous transhepatic cholangiogram).	NEW	4.25	4.25	No.
47533	Placement of biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (e.g., ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; external.	NEW	6.00	6.00	No.
47534	Placement of biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (e.g., ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; internal-external.	NEW	8.03	8.03	No.
47535	Placement of biliary drainage catheter, percutaneous, including diagnostic cholangiography when performed, imaging guidance (e.g., ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; internal-external.	NEW	4.50	4.50	No.
47536	Exchange of biliary drainage catheter (e.g., external, internal-external, or conversion of internal-external to external only), percutaneous, including diagnostic cholangiography when performed, imaging guidance (e.g., fluoroscopy) and all associated radiological supervision and interpretation.	NEW	2.88	2.88	No.
47537	Removal of biliary drainage catheter, percutaneous, requiring fluoroscopic guidance (e.g., with concurrent indwelling biliary stents), including diagnostic cholangiography when performed, imaging guidance (e.g., fluoroscopy) and all associated radiological supervision and interpretation.	NEW	1.83	1.83	No.
47538	Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (e.g., fluoroscopy and/or ultrasound), balloon dilation, catheter exchange or removal when performed, and all associated radiological supervision and interpretation, each stent; existing access.	NEW	6.60	6.60	No.
47539	Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (e.g., fluoroscopy and/or ultrasound), balloon dilation, catheter exchange or removal when performed, and all associated radiological supervision and interpretation, each stent; new access, without placement of separate biliary drainage catheter.	NEW	9.00	9.00	No.
47540	Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (e.g., fluoroscopy and/or ultrasound), balloon dilation, catheter exchange or removal when performed, and all associated radiological supervision and interpretation, each stent; new access, with placement of separate biliary drainage catheter (e.g., external or internal-external).	NEW	12.00	10.75	No.
47541	Placement of access through the biliary tree and into small bowel to assist with an endoscopic biliary procedure (e.g., rendezvous procedure), percutaneous, including diagnostic cholangiography when performed, imaging guidance (e.g., ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation; new access.	NEW	5.61	5.61	No.
47542	Balloon dilation of biliary duct(s) or of ampulla (sphincteroplasty), percutaneous, including imaging guidance (e.g., fluoroscopy) and all associated radiological supervision and interpretation, each duct.	NEW	3.28	2.50	No.
47543	Endoluminal biopsy(ies) of biliary tree, percutaneous, any method(s) (e.g., brush, forceps and/or needle), including imaging guidance (e.g., fluoroscopy) and all associated radiological supervision and interpretation, single or multiple.	NEW	3.51	3.07	No.
47544	Removal of calculi/debris from biliary duct(s) and/or gallbladder, percutaneous, including destruction of calculi by any method (e.g., mechanical, electrohydraulic, lithotripsy) when performed, imaging guidance (e.g., fluoroscopy) and all associated radiological supervision and interpretation (List separately in addition to code for primary procedure).	NEW	4.74	4.29	No.
49185	Sclerotherapy of a fluid collection (e.g., lymphocele, cyst, or seroma), percutaneous, including contrast injection(s), sclerosant injection(s), diagnostic study, imaging guidance (e.g., ultrasound, fluoroscopy) and radiological supervision and interpretation when performed.	NEW	2.78	2.35	No.

TABLE 15—CY 2016 INTERIM FINAL WORK RVUS FOR NEW/REVISED OR POTENTIALLY MISVALUED CODES—Continued

HCPCS Code	Long descriptor	CY 2015 WRVU	RUC/HCPAC recommended work RVU	CMS 2016 work RVU	CMS time refinement
50606	Endoluminal biopsy of ureter and/or renal pelvis, non-endoscopic, including imaging guidance (e.g., ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation.	NEW	3.16	3.16	No.
50705	Ureteral embolization or occlusion, including imaging guidance (e.g., ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation.	NEW	4.03	4.03	No.
50706	Balloon dilation, ureteral stricture, including imaging guidance (e.g., ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation.	NEW	3.80	3.80	No.
55866	Laparoscopy, surgical prostatectomy, retropubic radical, including nerve sparing, includes robotic assistance, when performed.	32.06	26.80	21.36	No.
61645	Percutaneous arterial transluminal mechanical thrombectomy and/or infusion for thrombolysis, intracranial, any method, including diagnostic angiography, fluoroscopic guidance, catheter placement, and intraprocedural pharmacological thrombolytic injection(s).	NEW	17.00	15.00	Yes.
61650	Endovascular intracranial prolonged administration of pharmacologic agent(s) other than for thrombolysis, arterial, including catheter placement, diagnostic angiography, and imaging guidance; initial vascular territory.	NEW	12.00	10.00	Yes.
61651	Endovascular intracranial prolonged administration of pharmacologic agent(s) other than for thrombolysis, arterial, including catheter placement, diagnostic angiography, and imaging guidance; each additional vascular territory (List separately in addition to the primary code).	NEW	5.50	4.25	No.
64461	Paravertebral block (PVB) (paraspinous block), thoracic; single injection site (includes imaging guidance, when performed).	NEW	1.75	1.75	No.
64462	Paravertebral block (PVB) (paraspinous block), thoracic; second and any additional injection site(s), (includes imaging guidance, when performed).	NEW	1.10	1.10	No.
64463	Paravertebral block (PVB) (paraspinous block), thoracic; continuous infusion by catheter (includes imaging guidance, when performed).	NEW	1.90	1.81	No.
64553	Percutaneous implantation of neurostimulator electrode array; cranial nerve.	2.36	2.36	2.36	No.
64555	Percutaneous implantation of neurostimulator electrode array; peripheral nerve (excludes sacral nerve).	2.32	2.32	2.32	No.
64566	Posterior tibial neurostimulation, percutaneous needle electrode, single treatment, includes programming.	0.60	0.60	0.60	No.
65778	Placement of amniotic membrane on the ocular surface; without sutures.	1.19	1.00	1.00	No.
65779	Placement of amniotic membrane on the ocular surface; single layer, sutured.	3.92	2.50	2.50	Yes.
65780	Ocular surface reconstruction; amniotic membrane transplantation, multiple layers.	10.73	8.80	7.81	No.
65855	Trabeculoplasty by laser surgery	3.99	3.00	2.66	No.
66170	Fistulization of sclera for glaucoma; trabeculectomy ab externo in absence of previous surgery.	15.02	13.94	11.27	No.
66172	Fistulization of sclera for glaucoma; trabeculectomy ab externo with scarring from previous ocular surgery or trauma (includes injection of antifibrotic agents).	18.86	14.81	12.57	No.
67107	Repair of retinal detachment; scleral buckling (such as lamellar scleral dissection, imbrication or encircling procedure), including, when performed, implant, cryotherapy, photocoagulation, and drainage of subretinal fluid.	16.71	16.00	14.06	No.
67108	Repair of retinal detachment; with vitrectomy, any method, including, when performed, air or gas tamponade, focal endolaser photocoagulation, cryotherapy, drainage of subretinal fluid, scleral buckling, and/or removal of lens by same technique.	22.89	17.13	15.19	No.
67110	Repair of retinal detachment; by injection of air or other gas (e.g., pneumatic retinopexy).	10.25	10.25	8.31	No.
67113	Repair of complex retinal detachment (e.g., proliferative vitreoretinopathy, stage C–1 or greater, diabetic traction retinal detachment, retinopathy of prematurity, retinal tear of greater than 90 degrees), with vitrectomy and membrane peeling, including, when performed, air, gas, or silicone oil tamponade, cryotherapy, endolaser photocoagulation, drainage of subretinal fluid, scleral buckling, and/or removal of lens.	25.35	19.00	19.00	No.

TABLE 15—CY 2016 INTERIM FINAL WORK RVUS FOR NEW/REVISED OR POTENTIALLY MISVALUED CODES—Continued

HCPCS Code	Long descriptor	CY 2015 WRVU	RUC/HCPAC recommended work RVU	CMS 2016 work RVU	CMS time refinement
67227	Destruction of extensive or progressive retinopathy (e.g., diabetic retinopathy), cryotherapy, diathermy.	7.53	3.50	3.50	No.
67228	Treatment of extensive or progressive retinopathy (e.g., diabetic retinopathy), photocoagulation.	13.82	4.39	4.39	No.
72170	Radiologic examination, pelvis; 1 or 2 views	0.17	0.17	0.17	No.
73501	Radiologic examination, hip, unilateral, with pelvis when performed; 1 view.	NEW	0.18	0.18	No.
73502	Radiologic examination, hip, unilateral, with pelvis when performed; 2–3 views.	NEW	0.22	0.22	No.
73503	Radiologic examination, hip, unilateral, with pelvis when performed; minimum of 4 views.	NEW	0.27	0.27	No.
73521	Radiologic examination, hips, bilateral, with pelvis when performed; 2 views.	NEW	0.22	0.22	No.
73522	Radiologic examination, hips, bilateral, with pelvis when performed; 3–4 views.	NEW	0.29	0.29	No.
73523	Radiologic examination, hips, bilateral, with pelvis when performed; minimum of 5 views.	NEW	0.31	0.31	No.
73551	Radiologic examination, femur; 1 view	NEW	0.16	0.16	No.
73552	Radiologic examination, femur; minimum 2 views	NEW	0.18	0.18	No.
74712	Magnetic resonance (e.g., proton) imaging, fetal, including placental and maternal pelvic imaging when performed; single or first gestation.	NEW	3.00	3.00	No.
74713	Magnetic resonance (e.g., proton) imaging, fetal, including placental and maternal pelvic imaging when performed; each additional gestation.	NEW	1.85	1.78	No.
77778	Interstitial radiation source application, complex, includes supervision, handling, loading of radiation source, when performed.	11.32	8.78	8.00	No.
77790	Supervision, handling, loading of radiation	1.05	0.00	0.00	No.
78264	Gastric emptying imaging study (e.g., solid, liquid, or both)	0.80	0.80	0.74	No.
78265	Gastric emptying imaging study (e.g., solid, liquid, or both); with small bowel transit, up to 24 hours.	NEW	0.98	0.98	No.
78266	Gastric emptying imaging study (e.g., solid, liquid, or both); with small bowel and colon transit, multiple days.	NEW	1.08	1.08	No.
88104	Cytopathology, fluids, washings or brushings, except cervical or vaginal; smears with interpretation.	0.56	0.56	0.56	No.
88106	Cytopathology, fluids, washings or brushings, except cervical or vaginal; simple filter method with interpretation.	0.37	0.37	0.37	No.
88108	Cytopathology, concentration technique, smears and interpretation (e.g., Saccomanno technique).	0.44	0.44	0.44	No.
88112	Cytopathology, selective cellular enhancement technique with interpretation (e.g., liquid based slide preparation method), except cervical or vaginal.	0.56	0.56	0.56	No.
88160	Cytopathology, smears, any other source; screening and interpretation.	0.50	0.50	0.50	No.
88161	Cytopathology, smears, any other source; preparation, screening and interpretation.	0.50	0.50	0.50	No.
88162	Cytopathology, smears, any other source; extended study involving over 5 slides and/or multiple stains.	0.76	0.76	0.76	No.
91200	Liver elastography, mechanically induced shear wave (e.g., vibration), without imaging, with interpretation and report.	0.30	0.27	0.27	No.
93050	Arterial pressure waveform analysis for assessment of central arterial pressures, includes obtaining waveform(s), digitization and application of nonlinear mathematical transformations to determine central arterial pressures and augmentation index, with interpretation and report, upper extremity artery, noninvasive.	NEW	0.17	0.17	No.
95971	Electronic analysis of implanted neurostimulator pulse generator system (e.g., 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 (i.e., peripheral nerve, sacral nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming.	0.78	0.78	0.78	No.

TABLE 15—CY 2016 INTERIM FINAL WORK RVUS FOR NEW/REVISED OR POTENTIALLY MISVALUED CODES—Continued

HCPCS Code	Long descriptor	CY 2015 WRVU	RUC/HCPAC recommended work RVU	CMS 2016 work RVU	CMS time refinement
95972	Electronic analysis of implanted neurostimulator pulse generator system (e.g., 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 (i.e., peripheral nerve, sacral nerve, neuromuscular) (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming.	0.80	0.80	0.80	No.
G0416	Surgical pathology, gross and microscopic examinations, for prostate needle biopsy, any method.	3.09	3.09	3.09	No.

TABLE 16: CY 2016 Interim Final 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 recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
10035	Perq dev soft tiss 1st imag	ED050	PACS Workstation Proxy	NF		48	46	Refined equipment time to conform to established policies for PACS Workstation Proxy	$ (0.04)
		EQ168	light, exam	NF		26	43	Refined equipment time to conform to established policies for non-highly technical equipment	$ 0.07
		L051B	RN/Diagnostic Medical Sonographer	NF	Review/read X-ray, lab, and pathology reports	2	0	Clinical labor task redundant with clinical labor task Review examination with interpreting MD	$ (1.02)
10036	Perq dev soft tiss add imag	ED050	PACS Workstation Proxy	NF		26	25	Refined equipment time to conform to established policies for PACS Workstation Proxy	$ (0.02)
		EQ168	light, exam	NF		21	22	Refined equipment time to conform to	$ 0.00

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
								established policies for non-highly technical equipment	
		L051B	RN/Diagnostic Medical Sonographer	NF	Review/read X-ray, lab, and pathology reports	1	0	Clinical labor task redundant with clinical labor task Review examination with interpreting MD	$ (0.51)
41530	Tongue base vol reduction	EQ214	radiofrequency generator (NEURO)	NF		83	0	Equipment item replaced by another item (NEW)	$ (10.58)
		EQ374	radiofrequency generator (Gyrus ENT G3 workstation)	NF		0	83	Equipment item replaces another item (EQ374)	$ 3.29
47531	Injection for cholangiogram	ED050	PACS Workstation Proxy	NF		56	51	Refined equipment time to conform to established policies for PACS Workstation Proxy	$ (0.11)
		EF018	stretcher	NF		92	87	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ (0.03)
		EF027	table, instrument, mobile	NF		92	87	Refined equipment	$ (0.01)

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
								time to conform to established policies for equipment with 4x monitoring time	
		EL011	room, angiography	NF		32	29	Refined equipment time to conform to changes in clinical labor time	$ (15.76)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		92	87	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ (0.07)
		EQ032	IV infusion pump	NF		92	87	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ (0.03)
		EQ168	light, exam	NF		56	45	Refined equipment time to conform to established policies for non-highly technical equipment	$ (0.05)
		L037D	RN/LPN/MTA	NF	Assist physician in performing	20	0	Removed clinical labor associated with moderate sedation;	$ (7.40)

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
					procedure			moderate sedation not typical for this procedure	
		L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	$ (1.23)
		L051A	RN	NF	Sedate/Apply anesthesia	2	0	Removed clinical labor associated with moderate sedation; moderate sedation not typical for this procedure	$ (1.02)
47532	Injection for cholangiogram	ED050	PACS Workstation Proxy	NF		76	73	Refined equipment time to conform to established policies for PACS Workstation Proxy	$ (0.07)
		EF018	stretcher	NF		292	289	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ (0.02)
		EF027	table, instrument, mobile	NF		292	289	Refined equipment time to conform to established policies for equipment with	$ (0.00)

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
								4x monitoring time	
		EL011	room, angiography	NF		52	49	Refined equipment time to conform to changes in clinical labor time	$ (15.76)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		292	289	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ (0.04)
		EQ032	IV infusion pump	NF		292	289	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ (0.02)
		EQ168	light, exam	NF		76	67	Refined equipment time to conform to established policies for non-highly technical equipment	$ (0.04)
		EQ250	ultrasound unit, portable	NF		76	67	Refined equipment time to conform to established policies for non-highly technical equipment	$ (1.05)

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
		L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	$ (1.23)
		SA019	kit, iv starter	NF		1	0	Duplicative; supply is included in conscious sedation pack conscious sedation pack SA044	$ (1.60)
		SB028	gown, surgical, sterile	NF		2	1	Duplicative; supply is included in conscious sedation pack conscious sedation pack SA044	$ (4.67)
47533	Plmt biliary drainage cath	ED050	PACS Workstation Proxy	NF		96	93	Refined equipment time to conform to established policies for PACS Workstation Proxy	$ (0.07)
		EF018	stretcher	NF		312	309	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ (0.02)
		EF027	table, instrument, mobile	NF		312	309	Refined equipment time to conform to established policies	$ (0.00)

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
								for equipment with 4x monitoring time	
		EL011	room, angiography	NF		72	69	Refined equipment time to conform to changes in clinical labor time	$ (15.76)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		312	309	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ (0.04)
		EQ032	IV infusion pump	NF		312	309	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ (0.02)
		EQ168	light, exam	NF		96	87	Refined equipment time to conform to established policies for non-highly technical equipment	$ (0.04)
		EQ250	ultrasound unit, portable	NF		96	87	Refined equipment time to conform to established policies for non-highly	$ (1.05)

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
								technical equipment	
		L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	$ (1.23)
		SA019	kit, iv starter	NF		1	0	Duplicative; supply is included in conscious sedation pack conscious sedation pack SA044	$ (1.60)
		SB028	gown, surgical, sterile	NF		2	1	Duplicative; supply is included in conscious sedation pack conscious sedation pack SA044	$ (4.67)
47534	Plmt biliary drainage cath	ED050	PACS Workstation Proxy	NF		114	111	Refined equipment time to conform to established policies for PACS Workstation Proxy	$ (0.07)
		EF018	stretcher	NF		330	327	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ (0.02)
		EF027	table, instrument, mobile	NF		330	327	Refined equipment	$ (0.00)

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
								time to conform to established policies for equipment with 4x monitoring time	
		EL011	room, angiography	NF		90	87	Refined equipment time to conform to changes in clinical labor time	$ (15.76)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		330	327	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ (0.04)
		EQ032	IV infusion pump	NF		330	327	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ (0.02)
		EQ168	light, exam	NF		114	105	Refined equipment time to conform to established policies for non-highly technical equipment	$ (0.04)
		EQ250	ultrasound unit, portable	NF		114	105	Refined equipment time to conform to established policies	$ (1.05)

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
								for non-highly technical equipment	
		L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	$ (1.23)
		SA019	kit, iv starter	NF		1	0	Duplicative; supply is included in conscious sedation pack conscious sedation pack SA044	$ (1.60)
		SB028	gown, surgical, sterile	NF		2	1	Duplicative; supply is included in conscious sedation pack conscious sedation pack SA044	$ (4.67)
47535	Conversion ext bil drg cath	ED050	PACS Workstation Proxy	NF		81	78	Refined equipment time to conform to established policies for PACS Workstation Proxy	$ (0.07)
		EF018	stretcher	NF		297	294	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ (0.02)

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
		EF027	table, instrument, mobile	NF		297	294	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ (0.00)
		EL011	room, angiography	NF		57	54	Refined equipment time to conform to changes in clinical labor time	$ (15.76)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		297	294	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ (0.04)
		EQ032	IV infusion pump	NF		297	294	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ (0.02)
		EQ168	light, exam	NF		81	72	Refined equipment time to conform to established policies for non-highly technical equipment	$ (0.04)
		L041B	Radiologic Technologist	NF	Clean room/equipme	6	3	Refined time to standard for this	$ (1.23)

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
					nt by physician staff			clinical labor task	
		SA019	kit, iv starter	NF		1	0	Duplicative; supply is included in conscious sedation pack conscious sedation pack SA044	$ (1.60)
		SB028	gown, surgical, sterile	NF		2	1	Duplicative; supply is included in conscious sedation pack conscious sedation pack SA044	$ (4.67)
47536	Exchange biliary drg cath	ED050	PACS Workstation Proxy	NF		66	63	Refined equipment time to conform to established policies for PACS Workstation Proxy	$ (0.07)
		EF018	stretcher	NF		162	159	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ (0.02)
		EF027	table, instrument, mobile	NF		162	159	Refined equipment time to conform to established policies for equipment with	$ (0.00)

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
								4x monitoring time	
		EL011	room, angiography	NF		42	39	Refined equipment time to conform to changes in clinical labor time EL014	$ (15.76)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		162	159	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ (0.04)
		EQ032	IV infusion pump	NF		162	159	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ (0.02)
		EQ168	light, exam	NF		66	57	Refined equipment time to conform to established policies for non-highly technical equipment	$ (0.04)
		L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	$ (1.23)
		SA019	kit, iv starter	NF		1	0	Duplicative; supply is included in conscious	$ (1.60)

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
								sedation pack conscious sedation pack SA044	
		SB028	gown, surgical, sterile	NF		2	1	Duplicative; supply is included in conscious sedation pack conscious sedation pack SA044	$ (4.67)
47537	Removal biliary drg cath	ED050	PACS Workstation Proxy	NF		56	51	Refined equipment time to conform to established policies for PACS Workstation Proxy	$ (0.11)
		EF018	stretcher	NF		92	87	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ (0.03)
		EF027	table, instrument, mobile	NF		92	87	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ (0.01)
		EL011	room, angiography	NF		32	29	Refined equipment time to conform to changes in clinical	$ (15.76)

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
								labor time	
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		92	87	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ (0.07)
		EQ032	IV infusion pump	NF		92	87	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ (0.03)
		EQ168	light, exam	NF		56	45	Refined equipment time to conform to established policies for non-highly technical equipment	$ (0.05)
		L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	20	0	Removed clinical labor associated with moderate sedation; moderate sedation not typical for this procedure	$ (7.40)
		L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	$ (1.23)

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
		L051A	RN	NF	Sedate/Apply anesthesia	2	0	Removed clinical labor associated with moderate sedation; moderate sedation not typical for this procedure	$ (1.02)
47538	Perq plmt bile duct stent	ED050	PACS Workstation Proxy	NF		91	88	Refined equipment time to conform to established policies for PACS Workstation Proxy	$ (0.07)
		EF018	stretcher	NF		307	304	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ (0.02)
		EF027	table, instrument, mobile	NF		307	304	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ (0.00)
		EL011	room, angiography	NF		67	64	Refined equipment time to conform to changes in clinical labor time	$ (15.76)
		EQ011	ECG, 3-channel (with SpO2,	NF		307	304	Refined equipment	$ (0.04)

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
			NIBP, temp, resp)					time to conform to established policies for equipment with 4x monitoring time	
		EQ032	IV infusion pump	NF		307	304	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ (0.02)
		EQ168	light, exam	NF		91	82	Refined equipment time to conform to established policies for non-highly technical equipment	$ (0.04)
		L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	$ (1.23)
		SA019	kit, iv starter	NF		1	0	Duplicative; supply is included in conscious sedation pack conscious sedation pack (SA044)	$ (1.60)
		SB028	gown, surgical, sterile	NF		2	1	Duplicative; supply is included in conscious sedation pack conscious sedation	$ (4.67)

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
								pack (SA044)	
		SD150	catheter, balloon ureteral (Dowd)	NF		0	2	Supply item replaces another item; see preamble SD152	$ 130.00
		SD152	catheter, balloon, PTA	NF		2	0	Supply item replaced by another item; see preamble SD150	$ (487.00)
47539	Perq plmt bile duct stent	ED050	PACS Workstation Proxy	NF		116	113	Refined equipment time to conform to established policies for PACS Workstation Proxy	$ (0.07)
		EF018	stretcher	NF		332	329	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ (0.02)
		EF027	table, instrument, mobile	NF		332	329	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ (0.00)
		EL011	room, angiography	NF		92	89	Refined equipment time to conform to changes in clinical	$ (15.76)

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
								labor time	
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		332	329	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ (0.04)
		EQ032	IV infusion pump	NF		332	329	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ (0.02)
		EQ168	light, exam	NF		116	107	Refined equipment time to conform to established policies for non-highly technical equipment	$ (0.04)
		EQ250	ultrasound unit, portable	NF		116	107	Refined equipment time to conform to established policies for non-highly technical equipment	$ (1.05)
		L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	$ (1.23)
		SA019	kit, iv starter	NF		1	0	Duplicative; supply is	$ (1.60)

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
								included in conscious sedation pack SA044	
		SB028	gown, surgical, sterile	NF		2	1	Duplicative; supply is included in conscious sedation pack conscious sedation pack SA044	$ (4.67)
		SD150	catheter, balloon ureteral (Dowd)	NF		0	2	Supply item replaces another item; see preamble SD152	$ 130.00
		SD152	catheter, balloon, PTA	NF		2	0	Supply item replaced by another item; see preamble SD150	$ (487.00)
47540	Perq plmt bile duct stent	ED050	PACS Workstation Proxy	NF		126	123	Refined equipment time to conform to established policies for PACS Workstation Proxy	$ (0.07)
		EF018	stretcher	NF		342	339	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ (0.02)
		EF027	table, instrument, mobile	NF		342	339	Refined equipment time to conform to	$ (0.00)

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
								established policies for equipment with 4x monitoring time	
		EL011	room, angiography	NF		102	99	Refined equipment time to conform to changes in clinical labor time	$ (15.76)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		342	339	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ (0.04)
		EQ032	IV infusion pump	NF		342	339	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ (0.02)
		EQ168	light, exam	NF		126	117	Refined equipment time to conform to established policies for non-highly technical equipment	$ (0.04)
		EQ250	ultrasound unit, portable	NF		126	117	Refined equipment time to conform to established policies for non-highly	$ (1.05)

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
								technical equipment	
		L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	$ (1.23)
		SA019	kit, iv starter	NF		1	0	Duplicative; supply is included in conscious sedation pack conscious sedation pack SA044	$ (1.60)
		SB028	gown, surgical, sterile	NF		2	1	Duplicative; supply is included in conscious sedation pack conscious sedation pack SA044	$ (4.67)
		SD150	catheter, balloon ureteral (Dowd)	NF		0	2	Supply item replaces another item; see preamble SD152	$ 130.00
		SD152	catheter, balloon, PTA	NF		2	0	Supply item replaced by another item; see preamble SD150	$ (487.00)
47541	Plmt access bil tree sm bwl	ED050	PACS Workstation Proxy	NF		96	93	Refined equipment time to conform to established policies for PACS	$ (0.07)

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
								Workstation Proxy	
		EF018	stretcher	NF		312	309	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ (0.02)
		EF027	table, instrument, mobile	NF		312	309	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ (0.00)
		EL011	room, angiography	NF		72	69	Refined equipment time to conform to changes in clinical labor time	$ (15.76)
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		312	309	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ (0.04)
		EQ032	IV infusion pump	NF		312	309	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ (0.02)

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
		EQ168	light, exam	NF		96	87	Refined equipment time to conform to established policies for non-highly technical equipment	$ (0.04)
		EQ250	ultrasound unit, portable	NF		96	87	Refined equipment time to conform to established policies for non-highly technical equipment	$ (1.05)
		L041B	Radiologic Technologist	NF	Clean room/equipment by physician staff	6	3	Refined time to standard for this clinical labor task	$ (1.23)
		SA019	kit, iv starter	NF		1	0	Duplicative; supply is included in conscious sedation pack conscious sedation pack SA044	$ (1.60)
		SB028	gown, surgical, sterile	NF		2	1	Duplicative; supply is included in conscious sedation pack conscious sedation pack SA044	$ (4.67)
47542	Dilate biliary	SD150	catheter, balloon ureteral (Dowd)	NF		0	1	Supply item replaces another item; see	$ 65.00

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
	duct/ampulla							preamble SD152	
		SD152	catheter, balloon, PTA	NF		1	0	Supply item replaced by another item; see preamble SD150	$ (243.50)
47544	Removal duct glbldr calculi	SD150	catheter, balloon ureteral (Dowd)	NF		0	1	Supply item replaces another item; see preamble SD152	$ 65.00
		SD152	catheter, balloon, PTA	NF		1	0	Supply item replaced by another item; see preamble SD150	$ (243.50)
49185	Sclerotx fluid collection	EF018	stretcher	NF		60	76	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ 0.08
		EF027	table, instrument, mobile	NF		99	115	Refined equipment time to conform to established policies for equipment with 4x monitoring time	$ 0.02
		EQ168	light, exam	NF		39	115	Refined equipment time to conform to established policies for equipment with	$ 0.33

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
								4x monitoring time	
		L037D	RN/LPN/MTA	NF	Assist physician in performing procedure	30	0	Clinical labor task redundant with clinical labor task Assist physician in performing the procedure L041B	$ (11.10)
		SB024	gloves, sterile	NF		4	2	Aligned supply quantities with changes to number of clinical labor staff	$ (1.68)
50606	Endoluminal bx urtr rnl plvs	EF027	table, instrument, mobile	NF		46	45	Refined equipment time to conform to established policies for moderate sedation equipment	$ (0.00)
		EL011	room, angiography	NF		46	0	Equipment item replaced by another item EL014	$ (241.71)
		EL014	room, radiographic-fluoroscopic	NF		0	47	Equipment item replaces another item EL011	$ 65.48
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		46	45	Refined equipment time to conform to established policies	$ (0.01)

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
								for moderate sedation equipment	
		EQ032	IV infusion pump	NF		46	45	Refined equipment time to conform to established policies for moderate sedation equipment	$ (0.01)
		EQ168	light, exam	NF		46	49	Refined equipment time to conform to established policies for non-highly technical equipment	$ 0.01
50705	Ureteral embolizatio n/occl	EF027	table, instrument, mobile	NF		61	60	Refined equipment time to conform to established policies for moderate sedation equipment	$ (0.00)
		EL011	room, angiography	NF		61	0	Equipment item replaced by another item EL014	$ (320.54)
		EL014	room, radiographic-fluoroscopic	NF		0	62	Equipment item replaces another item EL011	$ 86.37
		EQ011	ECG, 3-channel (with SpO2, NIBP, temp, resp)	NF		61	60	Refined equipment time to conform to	$ (0.01)

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
								established policies for moderate sedation equipment	
		EQ032	IV infusion pump	NF		61	60	Refined equipment time to conform to established policies for moderate sedation equipment	$ (0.01)
		EQ168	light, exam	NF		61	64	Refined equipment time to conform to established policies for non-highly technical equipment	$ 0.01
50706	Balloon dilate urtrl strix	EF027	table, instrument, mobile	NF		61	60	Refined equipment time to conform to established policies for moderate sedation equipment	$ (0.00)
		EL011	room, angiography	NF		61	0	Equipment item replaced by another item EL014	$ (320.54)
		EL014	room, radiographic-fluoroscopic	NF		0	62	Equipment item replaces another item El011	$ 86.37
		EQ011	ECG, 3-channel (with SpO2,	NF		61	60	Refined equipment	$ (0.01)

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
			NIBP, temp, resp)					time to conform to established policies for moderate sedation equipment	
		EQ032	IV infusion pump	NF		61	60	Refined equipment time to conform to established policies for moderate sedation equipment	$ (0.01)
		EQ168	light, exam	NF		61	64	Refined equipment time to conform to established policies for non-highly technical equipment	$ 0.01
		SD019	catheter, balloon, ureteral-GI (strictures)	NF		0	1	Supply item replaces another item; see preamble SD152	$ 166.00
		SD152	catheter, balloon, PTA	NF		1	0	Supply item replaced by another item; see preamble SD019	$ (243.50)
65779	Cover eye w/membran e suture	EQ137	instrument pack, basic ($500-$1499)	NF		62	56	Refined equipment time to conform to established policies for surgical instrument packs	$ (0.01)

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
		L038A	COMT/COT/RN/CST	F	Dischrg mgmt same day (0.5 x 99238) (enter 6 min)	6	0	Aligned discharge day management clinical labor time with the discharge day management work time	$ (2.28)
66170	Glaucoma surgery	EL005	lane, exam (oph)	F		297	288	Refined equipment time to conform to office visit duration	$ (0.86)
		L038A	COMT/COT/RN/CST	F	99212 27 minutes	3	4	Refined clinical labor to align with number of post-operative visits	$ 10.26
		L038A	COMT/COT/RN/CST	F	99213 36 minutes	6	5	Refined clinical labor to align with number of post-operative visits	$ (13.68)
		SA050	pack, ophthalmology visit (no dilation)	F		3	4	Refined supply quantity to align with number of post-operative visits	$ 1.19
		SA082	pack, ophthalmology visit (w-dilation)	F		6	5	Refined supply quantity to align with number of post-operative visits	$ (2.00)

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
67110	Repair detached retina	EQ137	instrument pack, basic ($500-$1499)	NF		52	44	Refined equipment time to conform to established policies for surgical instrument packs	$ (0.02)
67113	Repair retinal detach cplx	SA082	pack, ophthalmology visit (w-dilation)	NF		6	0	This input is not applicable in the non-facility setting	$ (11.98)
67228	Treatment x10sv retinopathy	L038A	COMT/COT/RN/CST	F	Dischrg mgmt same day (0.5 x 99238) (enter 6 min)	6	0	Aligned discharge day management clinical labor time with the discharge day management work time	$ (2.28)
73523	X-ray exam hips bi 5/> views	ED050	PACS Workstation Proxy	NF		36	33	Refined equipment time to conform to changes in clinical labor time	$ (0.07)
		EL012	room, basic radiology	NF		30	27	Refined equipment time to conform to changes in clinical labor time	$ (1.45)
		L041B	Radiologic Technologist	NF	Acquire images	21	18	Refined clinical labor time to conform with identical labor activity in other	$ (1.23)

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
								codes in the family	
78264	Gastric emptying imag study	ED019	computer workstation, nuclear medicine analysis-viewing	NF		74	70	See preamble text Non-standard equipment time formula	$ (0.84)
		ED050	PACS Workstation Proxy	NF		82	98	Refined equipment time to conform to established policies for PACS Workstation Proxy	$ 0.35
		L049A	Nuclear Medicine Technologist	NF	Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist	4	2	Refined time to standard for this clinical labor task	$ (1.23)
78265	Gastric emptying imag study	ED019	computer workstation, nuclear medicine analysis-viewing	NF		88	84	See preamble text Non-standard equipment time formula	$ (0.84)
		ED050	PACS Workstation Proxy	NF		98	115	Refined equipment time to conform to	$ 0.37

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
								established policies for PACS Workstation Proxy	
		L049A	Nuclear Medicine Technologist	NF	Patient clinical information and questionnaire reviewed by technologist, order from physician confirmed and exam protocoled by radiologist	4	2	Refined time to standard for this clinical labor task	$ (1.23)
78266	Gastric emptying imag study	ED019	computer workstation, nuclear medicine analysis-viewing	NF		109	105	See preamble text Non-standard equipment time formula	$ (0.84)
		ED050	PACS Workstation Proxy	NF		119	130	Refined equipment time to conform to established policies for PACS Workstation Proxy	$ 0.24
		L049A	Nuclear Medicine Technologist	NF	Patient clinical information and questionnaire reviewed by	4	2	Refined time to standard for this clinical labor task	$ (1.23)

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
					technologist, order from physician confirmed and exam protocoled by radiologist				
88104	Cytopath fl nongyn smears	EP038	solvent recycling system	NF		2	0	See preamble text	$ (0.09)
		L033A	Lab Technician	NF	Recycle xylene from stainer	1	0	Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	$ (0.33)
		L035A	Lab Tech/Histotechnologist	NF	Order, restock, and distribute specimen containers and or slides with requisition forms.	0.5	0	Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	$ (0.18)
		L035A	Lab Tech/Histotechnologist	NF	Prepare specimen containers preload fixative label containers distribute requisition form(s) to	0	0.5	Refined clinical labor time to conform with identical labor activity in other codes in the family	$ 0.18

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
					physician				
88106	Cytopath fl nongyn filter	EP038	solvent recycling system	NF		2	0	See preamble text	$ (0.09)
		L033A	Lab Technician	NF	Recycle xylene from stainer	1	0	Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	$ (0.33)
		L035A	Lab Tech/Histotechnologist	NF	Order, restock, and distribute specimen containers and or slides with requisition forms.	0.5	0	Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	$ (0.18)
		L035A	Lab Tech/Histotechnologist	NF	Prepare specimen containers preload fixative label containers distribute requisition form(s) to physician	0	0.5	Refined clinical labor time to conform with identical labor activity in other codes in the family	$ 0.18
88108	Cytopath concentrate tech	EP038	solvent recycling system	NF		2	0	See preamble text	$ (0.09)
		L033A	Lab Technician	NF	Recycle xylene from stainer	1	0	Indirect Practice Expense input and/or not individually	$ (0.33)

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
								allocable to a particular patient for a particular service	
		L035A	Lab Tech/Histotechnologist	NF	Order, restock, and distribute specimen containers and or slides with requisition forms.	0.5	0	Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	$ (0.18)
		L035A	Lab Tech/Histotechnologist	NF	Prepare specimen containers preload fixative label containers distribute requisition form(s) to physician	0	0.5	Refined clinical labor time to conform with identical labor activity in other codes in the family	$ 0.18
		SB022	gloves, non-sterile	NF		0.2	2	See preamble text	$ 0.15
		SB027	gown, staff, impervious	NF		0.2	2	See preamble text	$ 2.13
		SM016	eye shield, splash protection	NF		0.2	1	See preamble text	$ 1.18
88112	Cytopath cell enhance tech	EP038	solvent recycling system	NF		2	0	See preamble text	$ (0.09)
		L033A	Lab Technician	NF	Recycle xylene from stainer	1	0	Indirect Practice Expense input and/or not individually	$ (0.33)

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
								allocable to a particular patient for a particular service	
		L035A	Lab Tech/Histotechnologist	NF	Order, restock, and distribute specimen containers and or slides with requisition forms.	0.5	0	Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	$ (0.18)
		L035A	Lab Tech/Histotechnologist	NF	Prepare specimen containers preload fixative label containers distribute requisition form(s) to physician	0	0.5	Refined clinical labor time to conform with identical labor activity in other codes in the family	$ 0.18
		SB022	gloves, non-sterile	NF		0.2	2	See preamble text	$ 0.15
		SB027	gown, staff, impervious	NF		0.2	2	See preamble text	$ 2.13
		SM016	eye shield, splash protection	NF		0.2	1	See preamble text	$ 1.18
88160	Cytopath smear other source	EP038	solvent recycling system	NF		2	0	See preamble text	$ (0.09)
		L033A	Lab Technician	NF	Recycle xylene from stainer	1	0	Indirect Practice Expense input and/or not individually	$ (0.33)

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
								allocable to a particular patient for a particular service	
		L035A	Lab Tech/Histotechnologist	NF	Order, restock, and distribute specimen containers and or slides with requisition forms.	0.5	0	Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	$ (0.18)
		L035A	Lab Tech/Histotechnologist	NF	Prepare specimen containers preload fixative label containers distribute requisition form(s) to physician	0	0.5	Refined clinical labor time to conform with identical labor activity in other codes in the family	$ 0.18
88161	Cytopath smear other source	EP038	solvent recycling system	NF		2	0	See preamble text	$ (0.09)
		L033A	Lab Technician	NF	Recycle xylene from stainer	1	0	Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	$ (0.33)
		L035A	Lab Tech/Histotechnologist	NF	Order, restock, and distribute	0.5	0	Indirect Practice	$ (0.18)

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
					specimen containers and or slides with requisition forms.			Expense input and/or not individually allocable to a particular patient for a particular service	
		L035A	Lab Tech/Histotechnologist	NF	Prepare specimen containers preload fixative label containers distribute requisition form(s) to physician	0	0.5	Refined clinical labor time to conform with identical labor activity in other codes in the family	$ 0.18
88162	Cytopath smear other source	EP038	solvent recycling system	NF		2	0	See preamble text	$ (0.09)
		L033A	Lab Technician	NF	Recycle xylene from stainer	1	0	Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	$ (0.33)
		L035A	Lab Tech/Histotechnologist	NF	Order, restock, and distribute specimen containers and or slides with requisition forms.	0.5	0	Indirect Practice Expense input and/or not individually allocable to a particular patient for a particular service	$ (0.18)

HCPCS code	HCPCS code description	Input Code	Input code description	NF/F	Labor activity (where applicable)	RUC recommend-ation or current value (min or qty)	CMS refine-ment (min or qty)	Comment	Direct costs change
		L035A	Lab Tech/Histotechnologist	NF	Prepare specimen containers preload fixative label containers distribute requisition form(s) to physician	0	0.5	Refined clinical labor time to conform with identical labor activity in other codes in the family	$ 0.18

TABLE 17—CY 2016 INTERIM FINAL CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITHOUT REFINEMENTS

HCPCS code	Description
26356 ..	Repair finger/hand tendon.
26357 ..	Repair finger/hand tendon.
26358 ..	Repair/graft hand tendon.
43210 ..	Egd esophagogastrc fndoplsty.
47543 ..	Endoluminal bx biliary tree.
55866 ..	Laparo radical prostatectomy.
64461 ..	Pvb thoracic single inj site.
64462 ..	Pvb thoracic 2nd+ inj site.
64463 ..	Pvb thoracic cont infusion.
64566 ..	Neuroeltrd stim post tibial.
65778 ..	Cover eye w/membrane.
65780 ..	Ocular reconst transplant.

TABLE 17—CY 2016 INTERIM FINAL CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITHOUT REFINEMENTS—Continued

HCPCS code	Description
65855 ..	Trabeculoplasty laser surg.
66172 ..	Incision of eye.
67107 ..	Repair detached retina.
67108 ..	Repair detached retina.
67227 ..	Dstrj extensive retinopathy.
72170 ..	X-ray exam of pelvis.
73501 ..	X-ray exam hip uni 1 view.
73502 ..	X-ray exam hip uni 2–3 views.
73503 ..	X-ray exam hip uni 4/> views.
73521 ..	X-ray exam hips bi 2 views.
73522 ..	X-ray exam hips bi 3–4 views.
73551 ..	X-ray exam of femur 1.

TABLE 17—CY 2016 INTERIM FINAL CODES WITH DIRECT PE INPUT RECOMMENDATIONS ACCEPTED WITHOUT REFINEMENTS—Continued

HCPCS code	Description
73552 ..	X-ray exam of femur 2.
74712 ..	Mri fetal sngl/1st gestation.
74713 ..	Mri fetal ea addl gestation.
77778 ..	Apply interstit radiat compl.
77790 ..	Radiation handling.
88104 ..	Cytopath fl nongyn smears.
91200 ..	Liver elastography.
93050 ..	Art pressure waveform analys.
95971 ..	Analyze neurostim simple.
95972 ..	Analyze neurostim complex.
G0416	Prostate biopsy, any mthd.

TABLE 18—INVOICES RECEIVED FOR NEW DIRECT PE INPUTS FOR CY 2016 INTERIM FINAL CODES

CPT/HCPCS codes	Item name	CMS code	Average price	Number of invoices	Estimated non-facility allowed services for HCPCS codes using this item
41530, 43229, 43270	radiofrequency generator (Gyrus ENT G3 workstation).	EQ374	$10,000.00	1	2,932
47534, 47535, 47536, 47538, 47539, 47540.	internal/external biliary catheter	SD312	162.80	1	220
47538, 47539, 47540	Viabil covered biliary stent	SD313	2,721.00	2	26
47543	Radial Jaw	SD314	94.20	1	0
47543	stone basket	SD315	417.00	1	0
64463	Catheter securement device	SD316	.....	0	514
76377	computer workstation, 3D reconstruction CT–MR ...	ED014	45,926.00	1	67,296
77778	Applicator (TPV–200)/Kit	EQ373	9,770.00	1	517
77778	reentrant well ionization chamber	EP117	5,180.00	2	517
77778, 77790	L-block (needle loading shield)	EP118	1,195.00	1	1,848
78264, 78265, 78266	Bread	SK121	0.16	1	9,735
78264, 78265, 78266	Egg Whites	SK122	0.16	1	9,735
78264, 78265, 78266	Jelly	SK123	0.06	1	9,735
78264, 78265, 78266	paper plate	SK124	0.17	1	9,735
93050	Central Blood Pressure Monitoring Equipment (XCEL PWA & PWV System).	EP119	14,700.00	2	25,000

TABLE 19—INVOICES RECEIVED FOR EXISTING DIRECT PE INPUTS

CPT/HCPCS codes	Item name	CMS code	Current price	Updated price	% Change	Estimated non-facility allowed services for HCPCS codes using this item
10035, 10036, 19081, 19082, 19083, 19084, 19085, 19086, 19285, 19286, 19287, 19288.	clip, tissue marker	SD037	$75.00	$98.20	31	58,640
20982, 32998, 50592, 64600, 64605, 64610, 64633, 64634, 64635, 64636.	radiofrequency generator (NEURO).	EQ214	$ 10,000.00	$32,900.00	229	262,846
65778	human amniotic membrane allograft mounted on a non-absorbable self-retaining ring.	SD248	$895.00	$949.00	6	8,807
65779	human amniotic membrane allograft.	SD247	$595.00	$670.00	13	104
88106	Millipore filter	SL502	$4.15	$0.75	−82	1,204

TABLE 19—INVOICES RECEIVED FOR EXISTING DIRECT PE INPUTS—Continued

CPT/HCPCS codes	Item name	CMS code	Current price	Updated price	% Change	Estimated non-facility allowed services for HCPCS codes using this item
95018	benzylpenicilloyl polylysine (*e.g.*, PrePen) 0.25ml uou.	SH103	$83.00	$86.00	4	60,683

(1) Repair Flexor Tendon (CPT Codes 26356, 26357, and 26358)

The RUC recommended a work RVU of 10.03 for CPT code 26356. Although the RUC-recommended work RVU represents a reduction from the current work RVU of 10.62, we believe that the decrease in resource costs as reflected in the survey data (specifically in the intraservice time, the total time, and the change in the office visits) are not adequately reflected in the recommended work RVU. The intraservice time decreased from 90 minutes to 60 minutes (33 percent) while the RUC-recommended work RVU decreased from 10.62 to 10.03, a reduction of less than 6 percent. The total time and the number of office visits were also reduced by about 25 percent in each case, which is significantly greater than the 6 percent decrease in the recommended work RVU. We examined CPT code 25607 (Open treatment of distal radial extra-articular fracture), which has an intraservice time of 60 minutes and a total time of 275 minutes, which closely approximates the 60 minutes and 277 minutes reflected in the survey results for CPT code 26356. We also believe that these procedures have similar intensity based on their clinical profiles. We are therefore establishing an interim final work RVU of 9.56 for CPT code 26356 after considering both its similarity in time to CPT code 25607 and the reduction in time relative to the current times included for this procedure.

The RUC recommended a work RVU of 11.50 for CPT code 26357. We refined the RUC-recommended work RVU, employing a similar methodology to the one we used in valuing CPT code 26356. While we agree that the value of this code should increase from its current work RVU of 8.77, we believe that the RUC-recommended work RVU of 11.50 does not accurately reflect the change in time for this code. The RUC-recommended work RVU is an increase of 31 percent from the current work RVU of the code, while the total time increases from 256 minutes to 302 minutes, an increase of only 18 percent. The intraservice time for CPT code 26357 decreases from 89 minutes to 85 minutes, which does not suggest that a significant increase to the work RVU is accurate. Therefore, we considered CPT code 27654, (Repair, secondary, Achilles tendon, with or without graft) which has a similar intraservice time of 90 minutes, a total time of 283 minutes, a similar intensity, and a work RVU of 10.53. We are establishing an interim final work RVU of 10.53 for CPT code 26357 based on this direct crosswalk from CPT code 27654, as we believe this work RVU better reflects the changes in time for this procedure.

The RUC recommended a work RVU of 13.10 for CPT code 26358. We do not believe that this value accurately reflects the change in the intraservice time and the total time for this code. The RUC-recommended work RVU is an increase of 40 percent over the current work RVU of 9.36, while the total time only increases from 286 minutes to 327 minutes, an increase of 14 percent, and the intraservice time only increases from 108 minutes to 110 minutes, an increase of 2 percent. We do not believe that the RUC-recommended work RVU of 13.10, which corresponds to the survey median result, accurately reflects the increase in time. In the interest of preserving relativity among the codes in this family, we are maintaining the RUC-recommended increment of 1.6 work RVUs between CPT codes 26257 and 26358. Therefore, we are establishing an interim final work RVU of 12.13 for CPT code 26358, based on an increase of 1.6 work RVUs relative to CPT code 26357.

(2) Submucosal Ablation of Tongue Base (CPT Code 41530)

In the proposed rule, we proposed CPT code 41530 as potentially misvalued based on a public nomination. The nominator stated that CPT code 41530 is misvalued because there have been changes in the direct PE inputs used in furnishing the service. In the CY 2015 PFS Final Rule (79 FR 67575), we noted that the RUC submitted PE recommendations and stated that, under our usual process, we value work and PE at the same time and would expect to receive RUC recommendations for both before we revalued this service. Subsequently, the RUC submitted recommendations for both. The RUC recommended a work RVU of 3.50 for CPT code 41530, which we are establishing as the interim final work RVU for the code. To address the concerns raised by CMS in the CY 2015 PFS Final Rule, the PE Subcommittee reviewed minor revisions submitted by the specialty society. The RUC determined that this service should not be performed in the office setting and recommended removing the nonfacility direct PE inputs from the direct PE input database. However, 2014 Medicare claims data indicate that this service is furnished in the office setting 95 percent of the time, and that this service is frequently furnished multiple times to a beneficiary. Due to this discrepancy, we are seeking comment about the typical site of service and whether changes to the coding are needed to clarify this issue. For CY 2016, we have established interim final nonfacility direct PE inputs based on the current direct PE inputs for the code.

(3) Esophagogastric Fundoplasty Trans-Oral Approach (CPT Code 43210)

The CPT Editorial Panel established CPT code 43210 to describe trans-oral esophagogastric fundoplasty. The RUC recommended a work RVU of 9.00 for CPT code 43210. We were unable to identify CPT codes with an intraservice time of 60 minutes that have an RVU of 9.00 or greater. We were also unable to identify esophagogastroduodenoscopy (EGD) codes with an RVU of 9.00 or greater. We compared this code to CPT code 43240 (Drainage of cyst of the esophagus, stomach, and/or upper small bowel using an endoscope), which has similar total work time and a work RVU of 7.25. We believe a work RVU of 7.75, which corresponds to the 25th percentile survey result, more accurately reflects the resources used in furnishing the service. Therefore, for CY 2016 we are establishing an interim final work RVU of 7.75 for CPT code

43210. Additionally, in accordance with our established policy, as described in the CY 2012 PFS Final Rule (76 FR 73119), we removed the subsequent observation visit (99224) included in the RUC recommended value for this code and adjusted the total work time accordingly, by including the intraservice time of the inpatient hospital visit in the immediate post-service time of the code.

(4) Percutaneous Biliary Procedures (CPT Codes 47531, 47532, 47533, 47534, 47535, 47536, 47537, 47538, 47539, 47540, 47541, 47542, 47543, and 47544)

Several percutaneous biliary catheter and related image guidance procedures were identified through a misvalued code screen of codes reported together more than 75 percent of the time. For CY 2016, the CPT Editorial Panel deleted six existing biliary catheter codes (47500, 47505, 47510, 47511, 47525, and 47530) and five related image-guidance codes (74305, 74320, 74327, 75980, and 75982) and created 14 new codes, CPT codes 47531 through 47544, to describe percutaneous biliary procedures and to bundle inherent imaging services. We are establishing the RUC recommended work RVUs as interim final for CY 2016 for all of the percutaneous biliary procedures with the exception of CPT codes 47540, 47542, 47543, and 47544.

The RUC recommended a work RVU of 12.00 for CPT code 47540 (Placement of stent(s) into a bile duct, percutaneous, including diagnostic cholangiography, imaging guidance (*e.g.*, fluoroscopy and/or ultrasound), balloon dilation, catheter exchange or removal when performed, and all associated radiological supervision and interpretation, each stent; new access, with placement of separate biliary drainage catheter (*e.g.*, external or internal-external)) corresponding to the survey median result. We believe that a work RVU of 10.75, which corresponds to the 25th percentile survey result, more accurately reflects the work associated with this service. The RUC used magnitude estimation to value CPT code 47540, considering reference codes CPT code 37226 (Revascularization, endovascular, open or percutaneous, femoral, popliteal artery(s), unilateral; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed) and CPT code 37228 (Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal angioplasty). These codes have work RVUs of 10.49 and 11.00 RVUs respectively; both less than the RUC-recommended work RVU of 12.00 for CPT code 47540. In reviewing CPT codes with 90 minutes of intraservice times and a 0-day global period, we found that the majority of codes had a work RVU of less than 12.00. As such, we believe that a work RVU of 10.75 better aligns this service with other 0 day global codes with similar intraservice times and maintains appropriate relativity among the codes in this family. We are establishing a CY 2016 interim final work RVU of 10.75 for CPT code 47540.

The RUC recommended a work RVU of 3.28 for 47542. We believe that a work RVU of 2.50 more accurately reflects the work associated with this service. In valuing CPT code 47542, the RUC used a direct crosswalk from CPT code 37185 (Primary percutaneous transluminal mechanical thrombectomy, noncoronary, arterial or arterial bypass graft, including fluoroscopic guidance and intraprocedural pharmacological thrombolytic injection(s); second and all subsequent vessel(s) within the same vascular family), which has an intraservice time of 40 minutes. We believe that a more appropriate direct crosswalk is CPT code 15116 (Epidermal autograft, face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, or multiple digits) because it shares an intraservice time of 35 minutes. Therefore, we are establishing an interim final work RVU of 2.50 for CPT code 47542 for CY 2016.

The RUC recommended work RVUs of 3.51 and 4.74 for CPT codes 47543 and 47544, respectively. We do not believe the RUC-recommended work RVUs accurately reflect the work involved in furnishing these procedures. To value the work described in these procedures, we used the intraservice time ratio to identify values. We used CPT code 47542 as the base code, and calculated an intraservice time ratio by dividing the intraservice time of CPT code 47543 (43 minutes) by the intraservice time of CPT code 47542 (35 minutes); we then applied that ratio (1.228) to the interim final work RVU of 2.50 for CPT code 47542. This resulted in a work RVU of 3.07 for CPT code 47543. We used the same intraservice time ratio approach to calculate the interim final work RVU for CPT code 47544. We divided the intraservice time for CPT code 47544 (60 minutes) by the intraservice time for CPT code 47542 (35 minutes), and then applied that ratio (1.714) to the interim final work RVU of 2.50 for CPT code 47542, which results in a work RVU of 4.29. We are establishing an interim final work RVU of 3.07 for CPT code 47543 and 4.29 for CPT code 47544 for CY 2016.

We also refined a series of RUC-recommended direct PE inputs. We are replacing supply item ''catheter, balloon, PTA'' (SD152) with supply item ''catheter, balloon ureteral (Dowd)'' (SD150) on an interim final basis. We believe that the use of this balloon catheter, which is specifically designed for catheter and image guidance procedures, would be more typical than the use of a PTA balloon catheter.

We are also refining the RUC-recommended malpractice crosswalks for most of the codes in this family to align with the specialty mix that furnishes these procedures; we believe that these better reflect the malpractice risk associated with these procedures. We are establishing as interim final the malpractice crosswalks listed in Table 20.

TABLE 20—MP CROSSWALKS FOR BILIARY AND CATHETER PROCEDURES

HCPCS code	RUC recommended MP crosswalk	CMS interim final MP crosswalk
47531	49450	49450
47532	49407	49407
47533	37191	47510
47534	36247	47511
47535	36247	47505
47536	49452	49452
47537	49451	47505
47538	37191	47556
47539	37226	47556
47540	37226	47556

TABLE 20—MP CROSSWALKS FOR BILIARY AND CATHETER PROCEDURES—Continued

HCPCS code	RUC recommended MP crosswalk	CMS interim final MP crosswalk
47541	36247	47500
47542	37222	47550
47543	22515	47550
47544	37235	47630

(5) Percutaneous Image Guided Sclerotherapy (CPT Code 49185)

The CPT Editorial Panel created CPT code 49185 (Sclerotherapy of a fluid collection (eg, lymphocele, cyst, or seroma), percutaneous, including contrast injection(s), sclerosant injection(s)) to describe percutaneous image-guided sclerotherapy of fluid collections. These services were previously reported using CPT code 20500 (Injection of sinus tract; therapeutic (separate procedure)). To develop recommended work RVUs for CPT code 49185, the RUC used a direct crosswalk from reference code 31622 (Bronchoscopy, rigid or flexible, including fluoroscopic guidance, when performed; diagnostic, with cell washing, when performed), which has an intraservice time of 30 minutes and work RVU of 2.78. Although CPT code 31622 is clinically similar to CPT code 49185, we do not believe CPT code 31622 has a similar intensity to CPT code 49185. To establish the CY 2016 interim final work RVU for CPT code 49185, we instead used a direct crosswalk from CPT code 62305 (injection, radiologic supervision and interpretation), which shares an intraservice time of 30 minutes and is clinically similar, as it also includes an injection, radiologic supervision, and interpretation. We are establishing an interim final work RVU of 2.35 for CPT code 49185.

The RUC recommended including 300 ml of supply item ''sclerosing solution injection'' (SHO62) for CPT code 49185, which is priced at $2.29 per millimeter. The predecessor code included supply item ''obupivacaine (0.25% inj (Marcaine)'' (SH021)), which is priced at 25.4 cents per millimeter. We are concerned that supply item SH062 may not be used in the typical case for this procedure. We note that other CPT codes that include supply item SH062 include between 1 and 10 ml. We request that stakeholders review this supply item and provide invoices to improve the accuracy of pricing. We are also requesting information regarding the price of supply item SH062 given the significant increase in volume used in this procedure relative to other procedures.

(6) Genitourinary Catheter Procedures (CPT Codes 50606, 50705, and 50706)

We are establishing as interim final the RUC-recommended work RVUs for all three codes.

For CPT code 50706, we are replacing the RUC-recommended supply item ''catheter, balloon, PTA'' (SD152) with a ''catheter, balloon, ureteral-GI (strictures)'' (SD019) in the nonfacility setting. We believe that the latter balloon catheter, which is specifically designed for ureteral procedures, would be more typically used for these procedures than a PTA balloon catheter. We welcome further comment regarding the appropriate catheter supply for CPT code 50706, including any objective data regarding which supply item is more typically used for these procedures.

The RUC recommended the inclusion of ''room, angiography'' (EL011) for this family of codes. As discussed in section II.H.d.8. of this final rule with comment period, we do not believe that an angiography room would be used in the typical case for these procedures, and are therefore replacing the recommended equipment item ''room, angiography'' with equipment item ''room, radiographic-fluoroscopic'' (EL014) for all three codes on an interim final basis. Since the predecessor procedure codes generally did not include an angiography room and we do not have a reason to believe that the procedure would have shifted to an angiography room in the course of this coding change, we do not believe that the use of an angiography room would be typical for these procedures.

We are refining the RUC-recommended MP crosswalks for the codes in this family, as we do not believe that the source codes, which are cardiovascular services, are representative of the specialty mix that would typically furnish the genitourinary catheter procedures. Instead, we are establishing interim final MP crosswalks from codes with a specialty mix similar to the expected mix of those furnishing the services described by the new codes. We are therefore establishing the following MP crosswalks as interim final for 2016: CPT code 50606 from 50955, CPT code 50705 from 50393, and CPT code 50706 from 50395.

(7) Laparoscopic Radical Prostatectomy (CPT Code 55866)

For CPT code 55866, the RUC recommended a work RVU of 26.80. This is significantly higher than the work RVU for CPT code 55840 (Prostatectomy, retropubic radical, with or without nerve sparing), the key reference code selected by the specialty society's survey participants. This reference code shares an intraservice time of 180 minutes as well as similar total time (442 minutes for CPT code 55866, relative to 448 minutes for CPT code 55840). We believe that these codes are medically similar and would require similar work resources, and CPT code 55840 was recently reviewed in CY 2014. However, CPT code 55840 has a work RVU of 21.36 while the RUC-recommended work RVU for CPT code 55866 is 26.80. We do not believe that difference in intensity between CPT code 55840 and CPT code 55866 is significant enough to warrant the difference of 5.50 work RVUs.

In addition to CPT code 55840, we also examined CPT code 55845 as another medically similar and recently RUC-reviewed procedure. CPT code 55845 is an open procedure that involves a lymphadenectomy, while CPT code 55866 is a laparoscopic procedure without a lymphadenectomy. In the CY 2014 PFS Final Rule with Comment Period, CMS requested review of CPT codes 55845 and 55866 as potentially misvalued because the work RVU for the laparoscopic procedure (55866) was higher than for the open procedure (55845). In general, we do not believe that a laparoscopic procedure would require greater resources than the open procedure. However, the RUC-recommended work RVU for CPT code 55866 is 26.80, which is still higher than the work RVU of 25.18 for CPT code 55845. We do not believe that the rank order of these work RVUs accurately reflects the relative resources

typically required to furnish these procedures, and believe that the work RVU for CPT code 55866 should be lower than that of CPT code 55845. Therefore, we are establishing an interim final work RVU of 21.36 for CPT code 55866 based on a crosswalk from CPT code 55840.We believe that this is an appropriate valuation based on the procedure time and the resources typically used to furnish the procedure.

(8) Intracranial Endovascular Intervention (CPT Codes 61645, 61650 and 61651)

The CPT Editorial Panel created three new codes to describe percutaneous intracranial endovascular intervention procedures and to bundle inherent imaging services. These services were previously reported using CPT codes 61640–61642 (Balloon dilatation of intracranial vasospasm). In establishing interim final values for these services, we are refining the RUC-recommended work RVUs for all of the codes in this family. The RUC recommended a work RVU of 17.00 for CPT code 61645 (Percutaneous arterial transluminal mechanical thrombectomy and/or infusion for thrombolysis, intracranial), referencing CPT code 37231 (Revascularization, endovascular, open or percutaneous, tibial, peroneal artery, unilateral, initial vessel; with transluminal stent placement(s) and atherectomy, includes angioplasty within the same vessel, when performed) and CPT code 37182 (Insertion of transvenous intrahepatic portosystemic shunt(s) (TIPS)). We believe that CPT code 37231 is an appropriate direct crosswalk because the overall work is similar to that of CPT code 61645. Therefore, we are establishing an interim final work RVU of 15.00 for CPT code 61645. Additionally, in reviewing the work time for CPT code 61645, we noted that it includes postservice work time associated with postoperative visit CPT code 99233 (level 3 subsequent hospital care, per day). As we stated in the CY 2010 PFS proposed rule (74 FR 33557) and affirmed in the CY 2011 PFS proposed rule (75 FR 40072), we believe that for the typical patient, these services would be considered hospital outpatient services, not inpatient services. We believe that we should treat the valuation of the work time in the same manner as discussed previously, that is, by valuing the intraservice time of the hospital observation care service in the immediate post service time of the 23-hour stay code being valued. Therefore, we refined the work time for CPT code 61645 by removing the 55 minutes of work time associated with CPT code 99233 (subsequent hospital care) and instead included the 30 minutes of intraservice time from CPT code 99233 in the immediate postservice time of the procedure. This reduces the total work time from 266 minutes to 241 minutes and increases the immediate post service time from 53 minutes to 83 minutes.

The RUC recommended a work RVU of 12.00 for CPT code 61650 (Endovascular intracranial prolonged administration of pharmacologic agent(s) other than for thrombolysis, arterial, including catheter placement, diagnostic angiography, and imaging guidance; initial vascular territory). We believe the RUC-recommended work RVU overestimates the work involved in furnishing this procedure. To establish an interim final work RVU for CPT code 61650, we are using a direct crosswalk from CPT code 37221 (Revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed), which shares an intraservice time of 90 minutes with similar intensity. Therefore, we are establishing an interim final work RVU of 10.00 for CPT code 61650.

For CY 2016, we are also establishing interim final work time by removing the 55 minutes total time associated with CPT code 99233 (subsequent hospital care) as recommended by the RUC and instead allocating the intraservice time of 30 minutes to the immediate postservice time of the procedure. This reduces the total time from 231 minutes to 206 minutes and the immediate post service time from 45 minutes to 75 minutes.

The RUC recommended a work RVU of 5.50 for CPT code 61651 (Endovascular intracranial prolonged administration of pharmacologic agent(s) other than for thrombolysis, arterial, including catheter placement, diagnostic angiography, and imaging guidance; each additional vascular territory (List separately in addition to the primary code)). We believe that a direct crosswalk from CPT code 37223 (Revascularization, endovascular, open or percutaneous, iliac artery, each additional ipsilateral iliac vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed (List separately in addition to code for primary procedure)), more accurately reflects the work described by CPT code 61651. We believe that CPT code 37223 is an appropriate crosswalk because it shares intraservice time, has similar intensity, and is clinically similar to CPT code 61651. Therefore, we are establishing an interim final work RVU of 4.25 for CPT code 61651.

We have also refined the RUC-recommended malpractice crosswalks for this family of codes to align with the specialty mix that furnish the services in this family. We are establishing the following interim final malpractice crosswalks in place of the RUC-recommended malpractice crosswalks: CPT code 37218 to CPT code 61645; and CPT code 37202 to CPT codes 61650 and 61651.

(9) Paravertebral Block Injection (CPT Codes 64461, 64462, and 64463)

In CY 2015, the CPT Editorial Panel created three new codes to describe paravertebral block injections at single or multiple levels, as well as for continuous infusion for the administration of local anesthetic for post-operative pain control and thoracic and abdominal wall analgesia. We are establishing as interim final the RUC-recommended work RVUs for CPT codes 64461 and 64462. For CPT code 64463 (Paravertebral block (PVB) (paraspinous block), thoracic continuous infusion by catheter (includes imaging guidance, when performed) the RUC recommended a work RVU of 1.90, which corresponds to the 25th percentile survey result. After considering similar injection codes with identical intra-service time and longer total times, we believe the RUC recommendation for CPT code 64463 overestimates the work involved in furnishing the service. We believe a direct crosswalk from three other injection codes which all have a work RVU of 1.81 (CPT codes 64461, 64446, and 64449) more accurately reflects the work involved in furnishing this service. Therefore, for CY 2016, we are establishing an interim final work RVU of 1.81 for CPT code 64463.

(10) Ocular Surface Membrane Placement (CPT Codes 65778 and 65779)

These services were identified through the New Technology/New Services List in February 2010. For CY 2015, the RUC's Relativity Assessment Workgroup noted there may have been diffusion in technology for these services and requested that the specialty society survey these codes for work and direct PE inputs. While we are establishing the RUC-recommended work RVUs for CPT code 65778 and 65779 as interim final, we removed the work time associated with the half-day discharge management from CPT code 65779.

(11) Ocular Reconstruction Transplant (CPT Code 65780)

The RUC identified 65780 as potentially misvalued through a misvalued code screen of 90-day global services (based on 2012 Medicare utilization data) reported at least 1,000 times per year that included more than 6 office visits. The RUC recommended a direct work RVU crosswalk from CPT code 27829 (Open treatment of distal tibiofibular joint (syndesmosis) disruption, includes internal fixation, when performed). After examining comparable codes, we believe the RUC-recommended work RVU of 8.80 for CPT code 65780 overstates the work involved in the procedures given the reduction in intraservice and total times. We believe that the ratio of the total times (230/316) applied to the work RVU (10.73) more accurately reflects the work involved in this procedure. Therefore, we are establishing an interim final work RVU of 7.81 to CPT code 65780.

(12) Trabeculoplasty by Laser Surgery (CPT Code 65855)

The RUC identified CPT code 65855 (Trabeculoplasty by laser surgery, 1 or more sessions (defined treatment series)) as potentially misvalued through the review of 10-day global services with more than 1.5 postoperative visits. The RUC noted that the code was changed from a 90-day to a 10-day global period when it was last valued in 2000. However, the descriptor was not updated to reflect that change. CPT code 65855 describes multiple laser applications to the trabecular meshwork through a contact lens to reduce intraocular pressure. The current practice is to perform only one treatment session of the laser for glaucoma during a 10-day period and then wait for the effect on the intraocular pressure. The descriptor for CPT code 65855 has been revised and removes the language ''1 or more sessions'' to clarify this change in practice.

The RUC recommended a work RVU of 3.00. While the RUC-recommended value represents a reduction from the CY 2015 work RVU of 3.99, we believe that significant reductions in the intraservice time, the total time, and the change in the office visits represent a more significant change in the work resources involved in furnishing the typical service. The intraservice and total times were decreased by approximately 33 percent while the elimination of two post-operative visits (CPT code 99212) alone would reduce the overall work RVU by at least 24 percent under the reverse BBM. However, the recommended work RVU only represents a 25 percent reduction relative to the previous value. To develop an interim final work RVU for this service, we calculated an intraservice time ratio between the CY 2015 intraservice time, 15 minutes, and the RUC-recommended intraservice time, 10 minutes, and applied this ratio to the current work RVU of 3.99 to arrive at a work RVU of 2.66 for CPT code 65855. Therefore, for CY 2016, we are establishing an interim final work RVU of 2.66 for CPT code 65855.

(13) Glaucoma Surgery (CPT Codes 66170 and 66172)

The RUC identified CPT codes 66170 and 66172 as potentially misvalued through a 90-day global post-operative visits screen (services reported at least 1,000 times per year that included more than 6 office visits). We believe the RUC-recommended work RVU of 13.94 for CPT code 66170 (fistulization of sclera for glaucoma; trabeculectomy ab externo in absence of previous surgery) does not accurately account for the reductions in time. Specifically, the survey results indicated reductions of 25 percent in intraservice time and 28 percent in total time. These reductions suggest that the RUC-recommended work RVU for CPT code 66170 overstates the work involved in furnishing the service, since the recommended value only represents a reduction of approximately seven percent. We believe that applying the intraservice time ratio, as described above, to the current work RVU results in a more appropriate work RVU. Therefore, for CY 2016, we are establishing an interim final work RVU of 11.27 for CPT code 66170.

For CPT code 66172 (fistulization of sclera for glaucoma; trabeculectomy ab externo with scarring from previous ocular surgery or trauma (includes injection of antifibrotic agents)), the RUC recommended a work RVU of 14.81. After comparing the RUC-recommended work RVUs for this code to the work RVUs of similar codes (for example, CPT code 44900 (Incision and drainage of appendiceal abscess, open) and CPT code 59100 (Hysterotomy, abdominal (eg, for hydatidiform mole, abortion)), we believe the RUC-recommended work RVU of 14.81 overstates the work involved in this procedure. For the same reasons and following the same valuation methodology utilized above, we applied the intraservice time ratio between the CY 2015 intraservice time and the survey intraservice time, 60/90, to the CY 2015 work RVU of 18.86. This results in a work RVU of 12.57 for CPT code 66172. Therefore, for CY 2016, we are establishing an interim final work RVU of 12.57 for CPT code 66172.

(14) Retinal Detachment Repair (CPT Codes 67107, 67108, 67110, and 67113)

CPT codes 67107, 67108, 67110 and 67113 were identified as potentially misvalued through the 90-day global post-operative visit screen (either directly or indirectly as being part of the same family). The RUC recommended a work RVU of 16.00 for CPT code 67107, which corresponds to the 25th percentile survey result. While the RUC recommendation represents a 5 percent reduction from the current work RVU of 16.71, we believe the RUC recommendation still overvalues the service given the 15 percent reduction in intraservice time and 25 percent reduction in total time. Using the methodology previously described, we used the intraservice time ratio to arrive at an interim final work RVU of 14.06. We believe this value more accurately reflects the work involved in this service and is comparable to other codes that have the same global period and similar intraservice time and total time. For CY 2016, we are establishing an interim final work RVU of 14.06 for CPT code 67107.

For CPT code 67108, the RUC recommended a work RVU of 17.13 based on the 25th percentile survey result, which reflects a 25 percent reduction from the current work RVU. The survey results reflect a 53 percent reduction in intraservice time and a 42 percent reduction in total time. We believe the RUC-recommended work RVU overstates the work, given the significant reductions in intraservice time and total time and does not maintain relativity among the codes in this family. To determine the appropriate value for this code and maintain relativity within the family, we preserved the 1.13 increment recommended by the RUC, between this code and CPT code 67107, and applied that increment to the interim final work RVU of 14.06 for CPT code 67107. Therefore, we are establishing an interim final work RVU of 15.19 for CPT code 67108.

For CPT code 67110, the RUC recommended maintaining the current work RVU of 10.25. To maintain appropriate relativity with the work RVUs established for the other services within this family, we are using the RUC-recommended -5.75 RVU differential between CPT code 67107 and CPT code 67110 to establish the CY 2016 interim final work RVU of 8.31 for CPT code 67110.

(15) Fetal MRI (CPT Codes 74712 and 74713)

For CY 2016, the CPT Editorial Panel established two new codes to describe fetal MRI services, which were previously billed using CPT codes 72195 (Magnetic resonance (eg, proton) imaging, pelvis; without contrast material(s)), 72196 (with contrast material(s)) and 72197 (without contrast material(s), followed by contrast material(s) and further sequences). For CY 2016, we are establishing as interim final the RUC-recommended work RVU of 3.00 for 74712. The RUC recommended a work RVU of 1.85 for add-on code 74713, with an intra-service time of 35 minutes. Based on the ratio of work to time for these codes, we believe that the add-on code should approximate the relationship between work and time in the base code; therefore, we are establishing as interim final a work RVU of 1.78 for CPT code 74713, which corresponds to the 25th percentile survey result.

(16) Interstitial Radiation Source Codes (CPT Codes 77778 and 77790)

The RUC identified CPT code 77778 (interstitial radiation source application, complex, includes supervision, handling, loading of radiation source, when performed) and CPT code 77790 (supervision, handling, loading of radiation source) through a misvalued code screen of codes reported together more than 75 percent of the time. After reviewing the entire code family (CPT codes 77776, 77777, 77778, and 77790), the CPT Editorial Panel deleted the interstitial radiation source codes (CPT codes 77776 and 77777) and revised CPT code 77778 to incorporate the supervision and handling of brachytherapy sources previously reported with CPT code 77790. The RUC recommended that CPT code 77790 be valued without work, and recommended a work RVU of 8.78 for CPT code 77778. We are establishing an interim final value for CPT code 77790 without a work RVU, consistent with the RUC's recommendation.

The specialty society's survey indicated that the total service time for CPT code 77778 was 220 minutes and the median work RVU was 8.78; however, the RUC recommended a total work time of 145 minutes. In reviewing that recommendation, we cannot reconcile how the RUC determined that the same survey results that overestimated the time by over 50 percent at the same time accurately estimated the work, given that time is a component of overall work. We believe that the 25th percentile survey result is more likely to represent the typical overall work in a survey in which time is overestimated. Therefore, we are establishing an interim final work RVU of 8.00 for CPT code 77778 based on the 25th percentile survey. However, we are also seeking comment regarding the accuracy of the survey results given the significant disparity between the survey results and the considered judgment of the RUC regarding the amount of overall time required to furnish this service.

(17) Colon Transit Imaging (CPT Codes 78264, 78265, and 78266)

For CY 2016, the CPT Editorial Panel revised CPT code 78264 (gastric emptying study) to describe gastric emptying procedure, and also created two new add-on codes, CPT code 78265 (gastric emptying imaging study (eg, liquid, solid, or both); with small bowel transit up to 24 hours) and CPT code 78266 (gastric emptying study (eg, liquid, solid, or both with small bowel and colon transit for multiple days)). The RUC recommendation indicates that the base CPT code 78264 was previously used to report three distinct procedural variations. The new codes were created to describe the services in the procedures.

We are establishing as interim final the RUC-recommended work RVUs for CPT codes 78265 and 78266. However, we believe the RUC-recommended work RVU of 0.80 overstates the work involved in CPT code 78264. We note that CPT code 78264 has a higher recommended work RVU and a shorter intraservice time relative to the other codes in the family. Additionally, the CY 2016 RUC survey result showed a two minute decrease, from 12 to 10 minutes, in the intraservice time for CPT code 78264. We considered reference CPT code 78226 (Hepatobiliary system imaging, including gallbladder when present), as it shares the same intraservice time of 10 minutes and has similar intensity, and we are using a direct crosswalk from the work RVU of 0.74. We are establishing an interim final work RVU of 0.74 for CPT code 78264.

We received invoices for several new supply and equipment items for colon transit imaging services, as listed in Table 21. We have accepted the invoices for these items and added them to the direct PE input database. However, we are concerned that these invoice prices may not be reflective of the typical costs associated with the submitted supply items. We request that stakeholders review these prices and provide invoices or other information to improve the accuracy of pricing for these and other items in the direct PE database. Additionally, as discussed in section II.A of the proposed rule, 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.

(18) Liver Elastography (CPT Code 91200)

For CY 2015, we used the RUC recommendation of 0.30 RVUs and direct PE inputs without refinement to establish interim final values for CPT code 91200. For CY 2016, we received an updated RUC recommendation of 0.27 RVUs; we have established the RUC-recommended work RVU and direct PE inputs as interim final.

Comment: One commenter stated a concern about the assumption that CMS used regarding the proportion of the total Medicare utilization furnished in nonfacility and facility settings. The commenter suggested that the assumption CMS used had a significant negative impact on the PE RVUs so drastic as to not allow for the procedure to be furnished in nonfacility settings.

Another commenter requested reconsideration for the nonfacility payment rates stating the PE RVUs for the comparison codes CPT code 76700 (Ultrasound, abdominal, real time with image documentation; complete) and CPT code 76102 (Radiologic examination, complex motion (ie, hypercycloidal) body section (eg, mastoid polytomography), other than with urography; bilateral) are significantly higher than CPT code 91200. The commenter also stated the nonfacility payment was lower than the OPPS rate while the equipment costs are the same.

Response: We note that the proportion of services in the non-facility setting versus the facility setting in our utilization has no direct impact on the development of PE RVUs for each setting. We also note that the comparison codes, CPT code 76700 and CPT code 76102 have higher work RVUs; 0.81 for 76700 and 0.58 for 76102; since work is a portion of the indirect PE allocator, the comparison codes would be expected to have higher PE RVUs. Also, the capital equipment included as a direct PE input for CPT code 76700 is more expensive and is used for twice as long. While we agree with commenters that 76102 includes similarly priced equipment to 91200, we note that this equipment is used for more than 6 times as long (104 minutes vs. 16 minutes), and the clinical labor staff time is also 6 times as long. These differences in direct PE inputs and work result in a PE RVUs for the comparison

codes suggested by the commenter that are far higher than the PE RVU for 91200.

With respect to the commenter's statement about the comparison of the PFS payment amount to the OPPS payment amount, we note that OPPS payments for individual services are grouped into rates that reflect the cost of a range of services. We also note that for services newly priced under the OPPS, the APC assignment is based on that of the predecessor codes and clinical similarity to other services. As such, the payment rates for newly priced services may not be reflective of the rates that will be assigned once claims data for these services becomes available.

As stated above, we are establishing an interim final work RVU and direct PE inputs; we will accept comments during the comment period for this final rule with comment period.

(19) Electronic Analysis of Implanted Neurostimulator (CPT Codes 95971 and 95972)

For CY 2015, the RUC reviewed CPT codes 95971 and 95972 because they were identified by the High Volume Growth Services Screen which identifies services in which Medicare utilization increased by at least 100 percent from 2006 to 2011 screen. In the CY 2015 final rule with comment period, we stated that the lack of survey data for CPT code 95973, along with the confusing descriptor language and intraservice time for CPT code 95972, suggested the need for these services to be described through revised codes. However, to facilitate more accurate payment for these services pending such revisions, we adopted the RUC-recommended intraservice time of 20 minutes and work RVU of 0.78 for CPT code 95971. For CPT code 95972, we refined the RUC-recommended work RVU of 0.90 to establish an interim final value of 0.80 and adopted the RUC-recommended intraservice time of 23 minutes.

Comment: A commenter was disappointed that CMS did not accept the RUC recommendation for CPT code 95972. The commenter stated support for the RUC's determination of the work of CPT code 95972, based on its similarity to CPT code 62370. The commenter also stated that the CMS valuation for these services was arbitrary because CMS did not fully detail its methodology. The commenter recommended that CMS adopt the RUC recommendation for CPT code 95972 and continue to use the work RVU value of 0.92 for 95973 until the RUC is able to conduct a survey of 95973 and provide an updated recommendation of the work RVU value for this code.

Response: We appreciate the commenter's feedback and will consider it in finalizing values for these codes. We note that in the CY 2015 final rule with comment period (79 FR 67670), we described our use of the instraservice time ratio methodology to develop the work RVU for 95972. Additionally, we note that for CY 2016 the RUC recommended work RVU is the same as the work RVU CMS established in the CY 2015 final rule with comment period.

For CY 2016, the CPT Editorial Panel deleted CPT code 95973 and modified the descriptor for CPT code 95972. The RUC again reviewed CPT codes 95971 and 95972 and recommended no change to the work RVU of 0.78 with an intraservice time of 20 minutes for CPT code 95971. Because the survey for CPT code 95972 had used the older descriptor, the RUC recommended that the code be resurveyed with the correct descriptor and that the current RVU of 0.80 with an intraservice time of 23 minutes be maintained until the new survey is complete. We agree with the RUC that we should use these values for these codes on an interim final basis pending new recommendations from the RUC for the CY 2017 rule based on a new survey for CPT code 95972. We look forward to receiving recommendations from the AMA RUC, and intend to consider both codes using the most recent survey data available.

(20) Prostate Biopsy, Any Method (HCPCS Code G0416)

For CY 2014, we finalized interim final work RVUs and direct PE inputs for the surgical pathology services described by CPT codes 88300–88309 (Surgical Pathology, Levels I through VI). In conjunction with the revaluation of these procedures, we modified the code descriptors of G0416 through G0419 so that they described any method of prostate needle biopsy services, rather than only saturation biopsies. To simplify the coding, for CY 2014, we revised the descriptor for G0416 on an interim final basis to reflect all prostate biopsies, regardless of the number of specimens taken or the method used, and we deleted the remaining G-codes. We also maintained the existing RVUs for G0416, pending additional information, including recommendations from the RUC, about the typical resource costs associated with prostate biopsies. For CY 2016, we received and will be establishing as interim final, the RUC's recommended direct PE inputs to use in valuing G0416. However, we also received comments suggesting that the typical number of blocks used in these services can be significantly lower than what is assumed in the RUC recommendations. Given our consideration of those comments and our anticipation of a RUC-recommended work RVU for CY 2017 rulemaking, we emphasize that we are seeking evidence of the typical batch and block size used in furnishing this service.

We also note that the RUC recommended that, for purposes of calculating overall PFS budget neutrality, we assume that more practitioners will report these services accurately in the future than did so in prior years. For purposes of calculating budget neutrality, we generally assume that the Medicare utilization data reflect the accurate reporting of PFS services in compliance with Medicare payment rules. Therefore, we did not incorporate an anticipated shift toward compliant coding as recommended by the RUC. The utilization crosswalk used in setting rates for CY 2016 is available on the CMS Web site under downloads for the CY 2016 PFS Final Rule at *http://www.cms.gov/physicianfeesched/PFSFederalRegulationNotices.html/*.

TABLE 21—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
41530, 43229, 43270	radiofrequency generator (Gyrus ENT G3 workstation).	EQ374	$ 10,000.00	1	2,932

TABLE 21—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
47534, 47535, 47536, 47538, 47539, 47540.	internal/external biliary catheter	SD312	162.80	1	220
47538, 47539, 47540	Viabil covered biliary stent	SD313	2,721.00	2	26
47543	Radial Jaw	SD314	94.20	1	0
47543	stone basket	SD315	417.00	1	0
64463	Catheter securement device	SD316		0	514
76377	computer workstation, 3D reconstruction CT–MR	ED014	45,926.00	1	67,296
77778	Applicator (TPV–200)/Kit	EQ373	9,770.00	1	517
77778	reentrant well ionization chamber	EP117	5,180.00	2	517
77778, 77790	L-block (needle loading shield)	EP118	1,195.00	1	1,848
78264, 78265, 78266	Bread	SK121	0.16	1	9,735
78264, 78265, 78266	Egg Whites	SK122	0.16	1	9,735
78264, 78265, 78266	Jelly	SK123	0.06	1	9,735
78264, 78265, 78266	paper plate	SK124	0.17	1	9,735
93050	Central Blood Pressure Monitoring Equipment (XCEL PWA & PWV System).	EP119	14,700.00	2	25,000

I. 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 other 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 a telehealth 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 MACs 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 facility fee under the PFS 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 area (MSA).

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 *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html*.

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. 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 telehealth services, see the CMS Web site at *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html*.

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 *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html*.

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 for 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 found that the following services were sufficiently similar to psychiatric diagnostic procedures or office/outpatient visits currently on the telehealth list to qualify on a category 1 basis. Therefore, we proposed 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 30 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 could be furnished when a patient is located at a telehealth 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 to provide 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 did not propose to add the following procedures for the reasons noted:

• All E/M 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, based on the category 2 criteria at the time of that request. 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 new request for CY 2016, 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 telemedicine significantly reduced mortality rates or hospital length of stay, we do not believe that the submitted evidence demonstrates a clinical benefit to patients. Therefore, we did not propose 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 did not propose to add these nonpayable 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 service 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 did not propose 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 did not propose to add these services to the list of Medicare telehealth services for CY 2016.

In summary, we proposed 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 90963 through 90966. 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 30 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, CNS, NP, or PA.

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) of the Act, which includes a certified registered nurse anesthetist (CRNA) as defined in section 1861(bb)(2) of the Act.

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 proposed 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.

The following is a summary of the comments we received on proposals related to telehealth services.

Comment: All commenters supported one or more of our proposals to add prolonged service inpatient procedures (CPT codes 99356 and 99357) and ESRD-related services for home dialysis procedures (CPT codes 90963, 90964, 90965 and 90966) to the list of Medicare telehealth services for CY 2016.

Response: We appreciate the commenters' support for the proposed additions to the list of Medicare telehealth services. After consideration of the public comments received, we are finalizing our CY 2016 proposal to add these services to the list of telehealth services for CY 2016 on a category 1 basis.

Comment: Concerning our proposal to add prolonged services in the inpatient or observation setting (CPT codes 99356 and 99357) to the telehealth list, a few commenters questioned the need for CMS to establish a limit on the frequency with which these services can be provided, since there is no such limit when they are provided in-person. The commenter suggested that the criteria should be whether the services are reasonable and necessary, safe and effective, medically appropriate, and provided in accordance with accepted standards of medical practice. The commenter concluded that care provided via telemedicine should be paid as other physician services and that the technology used to deliver the services should not be the primary consideration.

Response: In the PFS final rule for CY 2011 (75 FR 73317), we concluded that subsequent hospital care visits by a patient's admitting practitioner may sufficiently resemble follow-up inpatient consultation services to add these subsequent hospital care services on a category 1 basis for the telehealth list. Although we still believed the potential acuity of hospital inpatients is greater than those patients likely to receive currently approved Medicare telehealth services, we also believed that it would be appropriate to permit some subsequent hospital care services to be furnished through telehealth to ensure that hospitalized patients have frequent encounters with their admitting practitioner. However, we also believed that the majority of these visits should be in-person to facilitate the comprehensive, coordinated, and personal care that medically volatile, acutely ill patients require on an ongoing basis.

Therefore, we added subsequent hospital care services, specifically CPT codes 99231, 99232, and 99233, to the list of telehealth services on a category 1 basis in CY 2011, but with some limitations on the frequency with which these services may be furnished through telehealth. Because of our concerns regarding the potential acuity of hospital inpatients, we limited the provision of subsequent hospital care services through telehealth to once every 3 days. We were confident that admitting practitioners would continue to make appropriate in-person visits to all patients who need such care during their hospitalization.

Likewise, for CY 2011, we concluded that subsequent nursing facility visits by a patient's admitting practitioner sufficiently resemble follow-up inpatient consultation services to consider them on a category 1 basis for the telehealth list. We concluded that it would be appropriate to permit some subsequent nursing facility care services to be furnished through telehealth to ensure that complex nursing facility patients have frequent encounters with their admitting practitioner, although we continued to believe that the federally mandated visits should be in-person to facilitate the comprehensive, coordinated, and personal care that these complex patients require on an ongoing basis.

Therefore, we added subsequent nursing facility care services, specifically CPT codes 99307, 99308, 99309, and 99310, to the list of Medicare telehealth services on a

category 1 basis in CY 2011, with some limitations on furnishing these services through telehealth. Because of our concerns regarding the potential acuity and complexity of SNF inpatients, we limited the provision of subsequent nursing facility care services furnished through telehealth to once every 30 days.

We believe the concerns that we addressed in the cases discussed in this section continues to hold for CPT codes 99356 and 99357, and that frequency limits are appropriate to ensure that patients continue to receive appropriate and high-quality care.

We note that section 1834(m) of the Act requires Medicare to make the same payment for services furnished via telehealth as is made for face-to-face services. In addition, it provides for payment of an originating site facility fee. However, the statute does not require that all conditions for payment for telehealth services be the same as for the services when furnished without the use of an interactive telecommunications system. We continue to believe the established frequency limits are appropriate and will leave them in place for these services.

Comment: Some commenters supported and others disagreed with our decision not to add critical care services (CPT codes 99291 and 99292) to the list of telehealth services. One commenter questioned why intensive care unit (ICU) telemedicine (TM) must demonstrate significantly reduced mortality rates or hospital length of stay for Medicare coverage. The commenter further noted that CMS covers new codes and procedures routinely without any evidence that they significantly reduce mortality rates or hospital length of stay. The commenter suggested that the criteria should be whether the proposed telehealth services are reasonable and necessary, safe and effective, medically appropriate, and provided in accordance with accepted standards of medical practice. The commenter believes CMS is applying a comparative effectiveness standard to coverage of telehealth services that it does not apply elsewhere in its coverage and payment for physician services, resulting in a double standard for coverage.

Another commenter questioned our statement that there is ''no evidence that the implementation of ICU TM significantly reduce[s] mortality rates or hospital length of stay,'' noting that these are not category 2 criteria and that telemedicine for critical care services clearly meets the following three criteria for adding services on a category 2 basis:

- 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.

The commenter maintained that telemedicine is safe and feasible for all patients. The commenter further maintained that advances in today's technology enable health care providers to deliver a focused, critical intervention no matter where the patient may be situated and/or what services are delivered.

Another commenter questioned the relevance of the ''JAMA Internal Medicine Study'' we cited because it involved VA hospitals whose patients do not represent the Medicare patient population. Finally, a commenter indicated that adding these services to the telehealth list would support the clinical stabilization of such patients awaiting critical care and/or surgical intervention or transport, in which a specialist may not be available to support the immediate clinical needs of the patient.

Response: We disagree that we have applied a comparative effectiveness standard to the coverage of telehealth. As noted, in reviewing requests to add services on a category 2 basis, we look for evidence indicating that the use of a telecommunications system in furnishing the candidate telehealth service produces clinical benefit to the patient. In this circumstance of ICU critical care, we did not review the evidence to determine if the evidence demonstrated that the benefit of in-person ICU critical care was greater than in a telemedicine setting. We limited our review to the evidence of benefit of telemedicine in ICU critical care.

As noted in the proposed rule (80 FR 41783), we reviewed the information provided by the ATA. We also reviewed 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* that addressed potential clinical benefits of these kinds of services furnished via telehealth. The two studies had contradictory conclusions. In any evidentiary review, valid conclusions must be made based upon the totality of the available evidence. One must look at the quality of the study, the study hypothesis, appropriate study design, appropriate inclusion/exclusion factors, appropriate statistical analyses, and many other factors to adequately address the validity of the data. These factors are then used to draw conclusions about the totality of the evidence. In doing so for this service, we concluded that the totality of the evidence did not demonstrate a benefit for ICU telemedicine. This conclusion does not mean that a benefit does not exist. This conclusion only states that the totality of the evidence is not sufficient to reach a conclusion that a benefit exists. Although our proposal not to add these codes to the telehealth list did not specifically address whether or not the critical care service is accurately described by the requested codes when furnished via telehealth, we also reconsidered that portion of the category 2 criteria when we reconsidered our assessment in the context of the comments on the proposed rule. Based on our review of the code descriptors and CPT prefatory language, we do not believe that the services described by the critical care codes accurately describe the full range of services required by patients in need of that level of care. Instead, we believe that the kinds of services furnished to these patients via telehealth are more accurately described by the inpatient/emergency department telehealth consultation codes, which are already on the list of Medicare telehealth services. Specifically, we believe that the kinds of telehealth services commenters describe as effective in the clinical stabilization of patients awaiting critical care and/or surgical intervention or transport, and in which a specialist may not be available to support the immediate clinical needs of the patient, are more accurately described and paid through the telehealth g-codes than through the critical care E/M CPT codes that describe in-person services.

In Response to commenters who suggested that we are applying a ''double standard'' for coverage of telehealth services, we note that section 1834(m)(4)(F) of the Act initially provided a payment mechanism for services furnished via telehealth for professional consultations, office visits, and office psychiatry services. The statute further required the Secretary to establish a process for annual additions or deletions to the telehealth list to be paid under particular circumstances. The statute does not suggest that any service that potentially could be furnished via telehealth should be included. Rather, the statute specifies a consideration process by CMS before making changes to the list of Medicare telehealth services. Since establishing the process in 2002, we have added codes to the telehealth list on a regular

basis and we will continue to do so, as appropriate, using the established process.

Comment: A few commenters objected to our decision not to add online E/M service, chronic care management services, and medication therapy management services to the telehealth services list.

Response: As noted, online E/M service (CPT code 99444) is currently noncovered; there would be no Medicare payment if this service was furnished without the use of a telecommunications system. Chronic care management services (CPT code 99490) can be furnished without the beneficiary's face-to-face presence and using any number of non-face-to-face means of communication. Therefore, it is unnecessary to add this service to the list of Medicare telehealth services. The chronic care management service can inherently be furnished using a wide range of remote communication technologies. Medication therapy management services (CPT codes 99605–99607) are noncovered services for which no payment may be made under the PFS. Therefore, we did not propose to add these services to the list of Medicare telehealth services for CY 2016.

Comment: Concerning our decision to add ESRD services (CPT codes 90963 through 90764) which includes counseling of parents, a commenter requested adding counseling of caregiver and family as all patients may not have parents as their only caregiver.

Response: Although the CPT code descriptor specifies only parents, we believe that legal guardians would be recognized in lieu of parents.

Comment: Commenters requested that:

- A patient's home, a dialysis facility, and an assisted living facility serve as originating sites for telehealth services.
- Originating site restrictions to rural areas be eliminated.
- Home health providers, registered nurses (RNs), Certified Pediatric Nurse Practitioners (CPNPs) and Certified Family Nurse Practitioners (CFNPs) be included in the list of eligible providers telehealth.
- The ability of NPs and PAs in a retail clinic setting to furnish telehealth services be clarified and that payment be commensurate with furnishing an in-person service.

Response: Section 1834(m)(4)(C) of the Act does not include a patient's home, a dialysis facility, or an assisted living facility as an originating site. Additionally, an originating site must be in a rural HPSA; in a county that is not in an MSA; or a participant in a federal telemedicine demonstration project approved as of December 31, 2000.

Section 1834(m)(4)(E) of the Act defines a practitioner for telehealth services per section 1842(b)(18)(C), which does not include home health providers or RNs. CPNPs or CFNPS are authorized to furnish telehealth services if they meet the conditions for NPs in section 1861(a)(a)(5) of the Act. NPs and PAs can furnish telehealth service as distant site practitioners. There are no specific criteria for a distant site. Therefore, there are no telehealth rules that would prohibit eligible distant site practitioners from furnishing telehealth services from a retail clinic, assuming the telehealth individual (beneficiary) is located at a telehealth originating site. Section 1834(m)(2)(A) of the Act provides that payment for a service furnished via telehealth equals the payment that would be made for an in-person service. Because these requirements are specified in the statute, we do not have discretion to revise the telehealth rules as desired by the commenters.

Comment: Many commenters supported, and one commenter opposed, our proposal to revise § 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. One commenter expressed concern that CRNAs furnish only services they are qualified to furnish.

Response: We appreciate the commenters' support for the proposal to revise the regulation. We note that section 1834(m)(4)(E) of the Act defines a practitioner for telehealth services per section 1842((b)(18)(C) of the Act, which includes CRNAs. We also note that CRNAs can only furnish services they are legally authorized to perform in the state in which the services are performed. After consideration of the public comments received, we are finalizing our proposal to revise § 410.78(b)(2) to include a CRNA.

We wish to inform stakeholders of the following initiatives to promote telehealth:

The CMS Innovation Center is responsible for developing and testing new payment and service delivery models to lower costs and improve quality for Medicare, Medicaid, and CHIP beneficiaries. As part of that authority, the CMS Innovation Center can consider potential new payment and service delivery models to test changes to Medicare's telehealth payment policies. For example, the Next Generation Accountable Care Organization (ACO) Model is an Innovation Center initiative for ACOs that are experienced in coordinating care for populations of patients. It will allow these provider groups to assume higher levels of financial risk and reward than are available under the current Pioneer ACO Model and Medicare Shared Savings Program (Shared Savings Program). The goal of the Model is to test whether strong financial incentives for ACOs, coupled with tools to support better patient engagement and care management, can improve health outcomes and lower expenditures for Medicare fee-for-service (FFS) beneficiaries. Central to the Next Generation ACO Model are several benefit enhancement tools to help ACOs improve engagement with beneficiaries. ACOs participating in this Model have the opportunity to provide aligned beneficiaries with access to home visits and telehealth services that exceed what is currently covered under the Medicare program, and CMS will make reward payments to aligned beneficiaries who receive a high percentage of their care from the ACO and from certain providers and suppliers that have agreed to participate in the ACO's network as ACO Participants or Preferred Providers under this Model.

The Fed-Tel Committee is comprised of employees from various federal agencies whose purpose is to facilitate telehealth education and information sharing, as well as coordinate funding opportunity announcements and other programmatic materials.

We reminded 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 *https://www.cms.gov/Medicare/Medicare-General-Information/Telehealth/index.html.*

5. Telehealth Originating Site Facility Fee Payment Amount Update

Section 1834(m)(2)(B) of the Act establishes the Medicare telehealth originating site facility fee for telehealth services furnished from October 1, 2001 through December 31 2002, at $20.00. For telehealth services furnished on or after January 1 of each subsequent

calendar year, the telehealth originating site facility fee is increased by the percentage increase in the MEI as defined in section 1842(i)(3) of the Act. The MEI increase for 2016 is 1.1 percent. Therefore, for CY 2016, the payment amount for HCPCS code Q3014 (Telehealth originating site facility fee) is 80 percent of the lesser of the actual charge or $25.10. The Medicare telehealth originating site facility fee and the MEI increase by the applicable time period is shown in Table 22.

TABLE 22—THE MEDICARE TELEHEALTH ORIGINATING SITE FACILITY FEE AND MEI INCREASE BY THE APPLICABLE TIME PERIOD

Time period	MEI increase	Facility fee
10/01/2001–12/31/2002	N/A	$20.00
01/01/2003–12/31/2003	3	20.60
01/01/2004–12/31/2004	2.9	21.20
01/01/2005–12/31/2005	3.0	21.86
01/01/2006–12/31/2006	2.8	22.47
01/01/2007–12/31/2007	2.1	22.94
01/01/2008–12/31/2008	1.8	23.35
01/01/2009–12/31/2009	1.6	23.72
01/01/2010–12/31/2010	1.2	24.00
01/01/2011–12/31/2011	0.4	24.10
01/01/2012–12/31/2012	0.6	24.24
01/01/2013–12/31/2013	0.8	24.43
01/01/2014–12/31/2014	0.8	24.63
01/01/2015–12/31/2015	0.8	24.83
01/01/2016–12/31/2016	1.1	25.10

J. 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, the regulation at § 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 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 supervision (as specified under § 410.26(a)(2) and § 410.26(b)(5)) 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) (PAs' services), § 410.75(d) (NPs' services), § 410.76(d) (CNSs' services), and § 410.77(c) (certified nurse-midwives' services). 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, when referring in this discussion 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 final rule with comment period, 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)) with the exception that allows care management services and transitional care management services (other than the required face-to-face visit) to be furnished under the general supervision of the physician (or other practitioner).)

We proposed 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 (66 FR 55267), in response to a comment seeking clarification regarding what physician billing number should be used on the claim form for an incident to service, 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. Additionally, in Transmittal 148, which was published on April 23, 2004, effective May 24, 2004, we specifically instructed practitioners as to how claim forms should be completed to account for the fact that the supervising physician or other practitioner is responsible for the incident to service. 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 proposed to amend § 410.26(b)(5), consistent with previous preamble discussion and subregulatory guidance, 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 proposed to remove the last sentence from § 410.26(b)(5), which specified 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. We proposed 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 (OIG) 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 being inadvertently deemed non-compliant. Therefore, while we believe that the initial responsibility of compliance rests with the practitioner, we invited comments through this final rule with comment period about possible approaches we could take to improve our ability to ensure that incident to services are provided to beneficiaries by qualified individuals in a manner consistent with Medicare statute and regulations. We invited commenters to consider the options we considered, 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 considered these comments in the course of finalizing proposals for CY 2016, and will continue to consider these comments should 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.

The following is a summary of the comments we received regarding our proposals on ''incident to'' services.

Comment: Many commenters sought clarification on whether CMS's proposal requires that a physician or other practitioner who furnishes the initial care and/or orders or refers incident to services must also be the same

individual who also directly supervises and bills Medicare for incident to services. These commenters urged CMS to clarify that the proposed change would not require that the physician or other practitioner who orders, refers, develops a treatment plan, or initiates treatment must also directly supervise all incident to services.

Response: We understand these comments, and in making our proposal, we intended to amend the current incident to regulations to state explicitly that only the physician or other practitioner who directly supervises the auxiliary personnel who provide the incident to services may bill Medicare for the incident to services. The proposed policy was not intended to require that the supervising physician or other practitioner must be the same individual as the physician or other practitioner who orders or refers the beneficiary for the services, or who initiates treatment. Rather, we intended to clarify that under circumstances where the supervising practitioner is not the same as the referring, ordering, or treating practitioner, only the supervising practitioner may bill Medicare for the incident to service. As stated in the CY 2002 PFS final rule at 66 FR 55267 in response to a comment seeking clarification regarding what physician billing number should be used on the claim form for an incident to service, we stated that 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. When the billing number of the physician or other practitioner is reported on the claim form, the physician or practitioner is stating that he or she directly performed the service, or supervised the auxiliary personnel performing the service consistent with the required level of supervision. Accordingly, we believe that an explicit statement in the regulations text further strengthens our intent that only the physician or other practitioner directly supervising the incident to services may bill Medicare for the incident to services.

Comment: While some commenters supported our proposal to amend regulatory text regarding incident to services, the majority of commenters opposed our proposal to remove the last sentence from § 410.26(b)(5) to clarify our proposal to require that the billing physician or other practitioner for incident to services must have directly supervised the auxiliary personnel who provided incident to services. This sentence in the current incident to regulations 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. Most of these commenters believe that the removal of this sentence represents a change in longstanding policy regarding how incident to services are furnished and billed, especially by group practices and multispecialty clinics, rather than a clarification about who the program requires to bill for incident to services. Other commenters stated that we should maintain the final sentence of § 410.26(b)(5), in current regulations because they believe the policy, as expressed in the sentence allows for situations where incident to services may be furnished during an extended course of care under the supervision of a different physician or other practitioner than the one that is ordering, referring, diagnosing, or initially treating the patient. Still other commenters suggested that our proposal to remove the sentence will severely impact patient care in terms of access, creating delays in care and in some cases restricting care for patients—particularly those in rural areas and low-income populations, when the same physician or other practitioner who orders services and/or initiates care is not also available and present to directly supervise the incident to services. Additionally, many of these commenters urged us to restore the sentence that we proposed to remove, or to not finalize the proposal, because they believe it would be overly burdensome to group practices and multispecialty clinics to impose the proposed billing and supervision requirements. These commenters indicated that, for these types of practices or for anything other than a solo practice, our proposal creates a financial burden, requires extensive restructuring, and imposes operational and staff coverage difficulties particularly in locum tenens situations, scheduling vacations and, in situations where the same physician or other practitioner does not practice daily at the same location.

Response: We appreciate the concerns of commenters who urged us not to delete the final sentence in regulation at § 410.26(b)(5). Since we believe the incident to services provided by auxiliary personnel are based on the professional services of the directly supervising physician or other practitioner (who has a personal role in, and responsibility for, furnishing services for which they are billing and receiving payment), we thought our regulations would be made clearer by removing the final sentence of the regulation at § 410.26(b)(5). We have considered the extensive and insightful comments expressing concern about how the removal of the subject sentence might be construed to be a change in policy that would require that the physician (or other practitioner) supervising the auxiliary personnel must be the same physician (or other practitioner) who is treating the patient more generally. We also considered the comments from stakeholders who suggested the change in the regulatory language would adversely impact the physician community, particularly group practices and multispecialty clinics. Given the concerns that have been expressed, we are not finalizing our proposal to delete the final sentence of the regulatory language. Instead, we will revise this sentence to reflect our policy that the physician (or other practitioner) supervising the auxiliary personnel need not be the same physician (or other practitioner) treating the patient more broadly. In addition to this revised sentence, we will add clarifying regulation text specifying that only the physician or other practitioner under whose supervision the incident to service(s) are being provided is permitted to bill the Medicare program for the incident to services.

Comment: One commenter disagreed with our proposal to specify that only the directly supervising physician or other practitioner is permitted to bill for incident to services. The commenter advised that, in single specialty groups, to require that incident to services must be billed by the directly supervising physician or other practitioner who is present at the time the incident to services are furnished, rather than the ordering physician or other practitioner who is also present, creates an unnecessary tracking, accounting, and scheduling burden on the practice. The commenter suggested that in situations where the ordering physician or other practitioner and the directly supervising physician or other practitioner are in the same single specialty group, and both are present at the time that auxiliary personnel are providing incident to services, either the ordering or supervising physician or other practitioner should be permitted to bill for the incident to services.

Response: Although the physician or practitioner who orders or refers a beneficiary for a service has a connection to the services, we believe the physician or other practitioner directly supervising the incident to service assumes responsibility and accountability for the care of the patient that is provided by auxiliary personnel.

Hence, we maintain that it is appropriate to limit billing for incident to services to the physician or practitioner who supervises the provision of those services. Although we understand that individual practitioners or practices may need to improve the tracking and accounting regarding the supervision and billing of incident to services, we do not agree with the commenter that such tracking or accounting is unnecessary. Instead, we believe that such tracking and accounting is necessary to ensure that practitioners bill appropriately for services furnished incident to their professional services.

Comment: Some commenters supported our proposal to amend the current regulations to state explicitly that only the directly supervising physician or other practitioner can bill the program for incident to services, and to remove the sentence under current regulations indicating that the physician or other practitioner directly supervising the auxiliary personnel need not be the same physician or other practitioner upon whose professional service the incident to service is based. These commenters interpreted our proposal to promote clear direction on the appropriate billing practices for incident to services in that the proposals are transparent and impose accountability. Additionally, one of these commenters characterized our proposals as clarifications that will allow small primary care practices to continue providing high quality and coordinated care.

Response: We appreciate these comments, which indicate that the commenters understood the intent of our proposals and did not interpret them as requiring changes in the way incident to services are furnished and billed.

Comment: Most commenters that addressed our proposal regarding auxiliary personnel who have been excluded or revoked from the Medicare program supported our approach. The commenters stated that since excluded or revoked individuals are already prohibited from furnishing incident to services to Medicare patients, our proposal will 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 program requirements. The commenters believe that our proposed prohibition will improve the quality of incident to services overall because it offers an additional safeguard against the possibility of auxiliary personnel who have been excluded or revoked from the Medicare program continuing to provide services to beneficiaries by obscuring them as incident to the services of another practitioner. However, one commenter opposed the proposal because the commenter believed that it would prevent marriage and family therapists from providing incident to services as auxiliary personnel since the commenter believed these therapists are excluded from the Medicare program.

Response: We appreciate the support for our proposal and are finalizing our proposal. We clarify that the term ''excluded'' in this context does not refer to the kinds of practitioners who do not have a benefit, and are not permitted to bill independently for their services under Medicare law.

Comment: In addition to the comments discussed above that are specifically related to our proposals, we received several comments in response to our solicitation of comments regarding future potential compliance and oversight considerations for incident to services. We also received several comments on the incident to benefit that are outside the scope of our specific proposal or solicitation. These comments addressed issues such as: Developing a list of CPT codes to distinguish therapeutic services that can be billed on an incident to basis from diagnostic tests that cannot be billed incident to; an explicit determination about whether CPT codes representing services that contain both a technical component and a professional component can be billed incident to; or whether CPT codes representing services with only a technical component can be billed incident to; and how transition care management and chronic care management services are affected by incident to requirements.

Response: We thank commenters for their feedback. We will consider these comments in the context of developing future improvements to guidance regarding incident to services.

After considering the comments that we received on incident to services under our proposed rule, we are finalizing the changes to our regulation at § 410.26(a)(1) without modification, and we are finalizing the proposed change to the regulation at § 410.26(b)(5) with a clarifying modification. Specifically, we are amending the definition of the term, ''auxiliary personnel'' at § 410.26(a)(1) that are permitted to provide ''incident to'' services to exclude individuals who have been excluded from the Medicare program or have had their Medicare enrollment revoked. Additionally, we are amending § 410.26(b)(5) by revising the final sentence to make clear that the physician (or other practitioner) directly supervising the auxiliary personnel need not be the same physician (or other practitioner) that is treating the patient more broadly, and adding a sentence to specify that only the physician (or other practitioner) that supervises the auxiliary personnel that provide incident to services may bill Medicare Part B for those incident to services.

K . Portable X-Ray: Billing of the Transportation Fee

Part B's payment to portable X-ray suppliers includes 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 during the course of the visit, the portable X-ray transportation fee is prorated to reflect this. We have received feedback that some portable X-ray suppliers have been operating under the assumption that when multiple patients receive portable X-ray services in this manner, the transportation fee would only be prorated among a subset of those 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 determine the transportation fee attributable to Medicare Part B by allocating it among all patients who receive portable X-ray services in a single trip. Medicare Part B should not pay for more than its share of the transportation costs for portable X-ray services.

For CY 2016, we proposed 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 also proposed to clarify that this subregulatory guidance means that, when more than one patient is X-rayed at the same location, the transportation payment under the PFS for the Part B

patient(s) is to be prorated by allocating the trip 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 during a single trip to a skilled nursing facility (SNF), we believe that the transportation fee should be allocated among all patients receiving services during the trip, irrespective of whether the patient is in a Part A stay, a Part B patient, or not a Medicare beneficiary at all. Thus, for a Medicare Part B patient, the prorated transportation fee made under Part B would appropriately reflect the share of the trip that is actually attributable to that patient. The following is a summary of the comments we received on our proposal to clarify the subregulatory guidelines to determine Medicare Part B's portion of the portable X-ray services' transportation fee.

Comment: Some commenters supported our proposal to clarify the current subregulatory guidance for the portable X-ray transportation fee. The commenters believe that this proposal will ensure consistent treatment of the payment for transportation among the different MACs and will eliminate the overpayment of portable X-ray transportation services. Other commenters supported our proposal, but advised CMS not to implement the proposal without also including a transportation fee proration policy for payers under Medicare Part A, Medicare Advantage, and Medicaid to pay an amount for transportation that is equal to the proportion of their covered patients receiving an X-ray on that trip to the facility. If CMS implements the proration of the transportation fee for Medicare Part B only, the commenters stated that the result will be reduced payment to the portable X-ray transportation suppliers.

Response: We appreciate the commenters' support for our proposal. With regard to the commenters that asked CMS to consider requiring Medicare Part A and non-Medicare payers to pay a prorated transportation fee amount for their covered patients receiving portable X-ray services during the same trip, we note that such requirements generally are beyond the scope of this rule. However, with regard to payment under Medicare Part A, as we noted in the SNF prospective payment system (PPS) final rule for CY 2016 (80 FR 46408, August 4, 2015), under the SNF PPS, a SNF's global per diem payment for its resident's covered Part A stay specifically includes the portable X-ray's transportation and setup. Further guidance on arrangements between SNFs and their suppliers is contained in CY 2016 SNF prospective payment system (PPS) final rule with comment period, which is available online at *http://www.gpo.gov/fdsys/pkg/FR-2015-08-04/pdf/2015-18950.pdf.*

Comment: Another commenter disagreed with the proposal and indicated that the proration among Part B patients may discourage community-based services if portable X-ray suppliers reduce their services in light of the potential reduction in the payment they previously received for the transportation fee. The commenter is concerned that if portable X-ray suppliers do not provide X-ray services in SNFs or other places where Medicare Part B beneficiaries reside, that the beneficiaries would be required to receive X-ray services in a hospital or other facility. The commenter suggested CMS consider the negative impact of the proposal in the context of the improved care and lowered cost of services in the community as compared to facility-based care. The commenter also expressed concern about how this would affect non-Medicare patients since third party payers often end up paying more to offset reduced Medicare payments levels.

Response: We appreciate the commenter's feedback, and understand the concerns raised regarding the implications of our proposal. We agree that Medicare payment for services should encourage access to care for Medicare beneficiaries. However, we do not believe that the consistent application of payment policies that permit Medicare Part B to make payment only for costs attributable to services furnished to Medicare Part B patients is likely to discourage community-based care such as portable X-ray services provided to individuals residing in a SNF.

After consideration of the comments we received, we are finalizing our proposed change to the subregulatory guidance in the Medicare Claims Processing Manual (Pub. 100–4, Chapter 13, Section 90.3) to clarify the portable X-ray transportation fee proration policy, effective January 1, 2016. We believe the revision to the Manual provides consistent direction to all MACs in the payment of portable X-ray transportation for Medicare Part B claims. In addition, we believe the revision strengthens program integrity under Medicare Part B because Medicare will no longer pay for more than its share of the portable X-ray transportation costs.

We received several comments that are not within the scope of our proposal to clarify the subregulatory guidance in § 90.3 of the Medicare Claims Processing Manual, which pertains to portable X-ray transportation fee proration policy. The topics addressed by commenters included recommendations that CMS:

- Update regulations which govern conditions for coverage of portable x-ray services.
- Consider allowing certain services to be performed in a mobile setting.
- Clarify and/or change the consolidated billing payment policy of diagnostic tests including portable X-ray.
- Use multiple transportation codes that describe costs attributable to different imaging modalities.

Response: We appreciate these comments, but they are beyond the scope of this rule. However, we will review all recommendations provided and consider them in the development of future policy.

L. 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 § 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)) 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. Although we modified the definition of colorectal cancer screening services in § 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 proposed a technical correction to amend § 410.160(b)(8) to expressly recognize anesthesia services. Specifically, we proposed 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.

Comment: A few commenters thanked us for modifying the definition of colorectal cancer screening services to include anesthesia care and for making the conforming change to regulations, noting that this will help to increase access to screening colonoscopies. The commenters also stated that the coinsurance should be waived in instances where the screening becomes diagnostic, but noted that they understand that CMS may not have the statutory authority to make this change. Commenters also stated that if CMS were to receive such authority, they hope CMS would make the associated regulatory change as quickly as possible so that beneficiaries would be further encouraged to seek the screening.

One commenter urged CMS to identify a way a way under the existing authority to redefine colorectal cancer screening to include colonoscopy with removal of polyp or abnormal growth during the screening encounter. The commenter stated that nearly half of all patients who undergo screening colonoscopy have a polyp or other tissue removed, and believed that the current policy is unfair and disproportionately affects lower income beneficiaries. The commenter also stated that there are various types of colorectal cancer screenings, including fecal occult blood test, double contrast barium enema, and CT colonography, and urged CMS to cover these other screening tests without cost-sharing obligations for the beneficiary.

Response: We thank the commenters for their feedback and will consider the issues that are within our authority for future rulemaking. After consideration of these comments, we are finalizing our proposed technical correction to amend § 410.160(b)(8).

M. Therapy Caps

1. Outpatient Therapy Caps for CY 2016

Section 1833(g) of the Act requires application of annual per beneficiary limitations on the amount of expenses that can be considered as incurred expenses for outpatient therapy services under Medicare Part B, commonly referred to as ''therapy caps.'' There is one therapy cap for outpatient occupational therapy (OT) services and another separate therapy cap for physical therapy (PT) and speech-language pathology (SLP) services combined.

The therapy caps apply to outpatient therapy services furnished in all settings, including the previously exempted hospital setting (effective October 1, 2012) and critical access hospitals (CAHs) (effective January 1, 2014).

The therapy cap amounts under section 1833(g) of the Act are updated each year based on the Medicare Economic Index (MEI). Specifically, the annual caps are calculated by updating the previous year's cap by the MEI for the upcoming calendar year and rounding to the nearest $10.00. Increasing the CY 2015 therapy cap of $1,940 by the CY 2016 MEI of 1.1 percent and rounding to the nearest $10.00 results in a CY 2016 therapy cap amount of $1,960.

An exceptions process for the therapy caps has been in effect since January 1, 2006. Originally required by section 5107 of the Deficit Reduction Act of 2005 (DRA), which amended section 1833(g)(5) of the Act, the exceptions process for the therapy caps has been extended multiple times through subsequent legislation as described in the CY 2015 PFS final rule with comment period (79 FR 67730) and most recently extended by the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 114–10). The Agency's current authority to provide an exceptions process for therapy caps expires on December 31, 2017.

CMS tracks each beneficiary's incurred expenses annually and counts them towards the therapy caps by applying the PFS rate for each service less any applicable multiple procedure payment reduction (MPPR) amount. As required by section 1833(g)(6)(B), added by section 603(b) of the American Taxpayer Relief Act of 2012 (ATRA) (Pub. L. 112–240) and extended by subsequent legislation, the PFS-rate accrual process is applied to outpatient therapy services furnished by CAHs even though they are paid on a cost basis. After expenses incurred for the beneficiary's outpatient therapy services for the year have exceeded one or both of the therapy caps, therapy suppliers and providers use the KX modifier on claims for subsequent services to request an exception to the therapy caps. By use of the KX modifier, the therapist is attesting that the services above the therapy caps are reasonable and necessary and that there is documentation of medical necessity for the services in the beneficiary's medical record. Claims for outpatient therapy services over the caps without the KX modifier are denied.

Since October 1, 2012, under section 1833(g)(5)(C) of the Act, we have been required to apply a manual medical review process to therapy claims when a beneficiary's incurred expenses for outpatient therapy services exceed a threshold amount of $3,700. There are two separate thresholds of $3,700, just as there are two separate therapy caps, one for OT services and one for PT and SLP services combined; and incurred expenses are counted towards the thresholds in the same manner as the caps. Now, under section 1833(g)(5) of the Act as amended by section 202(b) of the MACRA, claims exceeding the therapy thresholds are no longer automatically subject to a manual medical review process as they were before. Rather, CMS is permitted to do a more targeted medical review on these claims using factors specified in section 1833(g)(5)(E)(ii) of the Act as amended by section 202(b) of the MACRA, including targeting those therapy providers with a high claims denial rate for therapy services or with aberrant billing practices compared to their peers. The statutorily-required manual medical review process required under section 1833(g)(5)(C) of the Act expires at the same time as the exceptions process for therapy caps on December 31, 2017.

For information on the manual medical review process, go to *https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/Medical-Review/TherapyCap.html.*

2. Applying Therapy Caps to Maryland Hospitals

Since October 1, 2012, the therapy caps and related provisions have applied to the outpatient therapy services furnished by hospitals as recognized under section 1833(a)(8)(B) of the Act. Before then, outpatient therapy services furnished by hospitals had been exempted from the statutory therapy caps. Since 1999, hospitals have been paid for the outpatient therapy services they furnish at PFS rates—the applicable fee schedule established under section 1834(k)(3) of the Act.

Beginning October 1, 2012, CMS has been required to apply the therapy caps and related provisions to outpatient therapy services under section 1833(g) of the Act furnished in hospitals. As with other statutory provisions on therapy caps, this provision has been extended several times by additional legislation. Most recently, section 202(a) of the MACRA extended this broadened application of the therapy caps to include outpatient therapy services furnished by hospitals through December 31, 2017.

When we first implemented the statutory provision that extended application of the therapy caps to outpatient therapy services furnished by hospitals, we did not apply the therapy caps to most hospitals in Maryland. Originally, this omission was linked to our longstanding waiver policy under section 1814(b) of the Act, which allowed Maryland to set the payment rates for hospital services, including those for the outpatient therapy services they furnish. Since 2014, most hospitals in Maryland are paid at rates determined under the Maryland All-Payer Model, which is being tested under the authority of section 1115A of the Act.

To correct this oversight, we recently issued instructions through Change Request 9223 (available online at *https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R3367CP.pdf*) to our Maryland MAC to revise our systems to ensure the application of the therapy caps and related provisions to the outpatient therapy services provided in all Maryland hospitals. These instructions included the direction to use the rates established under the Maryland All-Payer Model rather than the PFS rates to accrue towards the per-beneficiary therapy caps and thresholds. We believe using the Maryland All-Payer Model rates rather than the PFS rates is consistent with the statute at sections 1833(g)(1) and (3) of the Act that requires us to count the actual expenses incurred in any calendar year towards the beneficiary's therapy caps. These instructions will become effective January 1, 2016.

III. Other Provisions of the Final Rule With Comment Period

A. 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 proposed 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) and the CY 2015 PFS final rule with comment period (79 FR 67743)).

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. We received several comments regarding this proposal. The following is a summary of the comments we received and our response.

Comment: Several commenters supported the implementation of the extension of the ambulance payment add-ons. These commenters also agreed that these provisions are self-implementing. One commenter encouraged CMS to seek to make these add-on payments permanent.

Response: We appreciate the commenters' support of these provisions, but we do not have the authority to make these provisions permanent.

After consideration of the public comments received, we are finalizing our proposal to revise § 414.610(c)(1)(ii) to conform the regulations to this statutory requirement.

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 in this section (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 proposed 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) and the CY 2015 PFS final rule with comment period (79 FR 67743 through 67744)).

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. We received several comments regarding this proposal. The following is a summary of the comments we received and our response.

Comment: Several commenters supported the continued implementation of the percent increase in the base rate of the fee schedule for transports in areas defined as super rural. These commenters also agreed with CMS that these provisions are self-implementing. One commenter encouraged CMS to seek to make these add-on payments permanent.

Response: We appreciate the commenters' support of these provisions, but we do not have the authority to make these provisions permanent.

After consideration of the public comments received, we are finalizing our proposal to revise § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement.

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 from stakeholders expressing concerns about the implementation of the new geographic area delineations finalized in that rule (as corrected). In response to these concerns, in the CY 2016 PFS proposed rule (80 FR 41788 through 41792), we clarified our implementation of the revised OMB delineations and the updated RUCA codes in CY 2015, and reproposed the implementation of the revised OMB delineations and updated RUCA codes for CY 2016 and subsequent calendar years. We requested public comment on our proposals, which comments are further discussed in section III A.3.b. of this final rule with comment period.

b. Provisions of the Final Rule With Comment Period

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 in the June 28, 2010 **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 in the CY 2016 PFS proposed rule (80 FR 41788), 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/LTCH PPS 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, we believe that it was 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, in the CY 2016 PFS proposed rule (80 FR 41788), we proposed 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 stated in the CY 2016 PFS proposed rule (80 FR 41788) that 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 invited 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), the CY 2015 PFS final rule with comment period (79 FR 67745 through 67746) and the CY 2016 PFS proposed rule (80 FR 41788 through 41789). As stated previously, on February 28, 2013, OMB issued OMB Bulletin No. 13–01, which established revised delineations for MSAs, 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* and at *http://www.census.gov/programs-surveys/acs/guidance/training-presentations/acs-basics.html*. We stated in the CY 2016 PFS proposed rule (80 FR 41789) that we believe the most recent RUCA codes provide more accurate and up-to-date information regarding the rurality of census tracts throughout the country. Accordingly, we proposed 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. We stated that 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) and in the CY 2016 PFS proposed rule (80 FR 41789), 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 proposed 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), the CY 2015 PFS final rule with comment period (79 FR 67745), and the CY 2016 PFS proposed rule (80 FR 41789), 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 proposed for CY 2016 and subsequent CYs, to designate as rural areas those census tracts that fall at or above RUCA level 4.0. We stated that 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 did not propose in the CY 2016 PFS proposed rule (80 FR 41789) to 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 stated in the CY 2016 PFS proposed rule (80 FR 41789) that it is not feasible to implement this guideline due to the complexities of identifying these areas at the ZIP code level. We stated that 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 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 stated that we believe payment for all ambulance transportation services at the ZIP code level provides for a more consistent and administratively feasible payment system. For example, 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 if we were to pay based on ZIP codes for some areas and counties or census tracts for other areas. Therefore, we stated in the proposed rule (80 FR 41789) that, 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 invited public comments on our proposals, as discussed in in the CY 2016 PFS proposed rule, to continue to use the revised OMB delineations and updated RUCA codes under the ambulance fee schedule for CY 2016 and subsequent CYs.

As we stated in the CY 2015 PFS final rule with comment period (79 FR 67746) and the CY 2016 PFS proposed rule (80 FR 41789 through 41790), 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 final rule with comment period, we are revising § 414.610(c)(5)(ii) to conform the regulations to this statutory requirement. As we stated in the CY 2015 PFS final rule with comment period (79 FR 67746) and the CY 2016 PFS proposed rule (80 FR 41790), 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 final rule with comment period, we are revising § 414.610(c)(1)(ii) to conform the

regulations to this statutory requirement.

Similar to our discussion in the CY 2015 PFS final rule with comment period (79 FR 67746) and the CY 2016 PFS proposed rule (80 FR 41790), 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 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 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 in this section, we proposed 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. To determine which ZIP codes are included in each such rural census tract, we proposed 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 stated that 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 August 2015 USPS ZIP code file that we are using in this final rule with comment period to assess the impacts of the revised geographic delineations, there are a total of 42,927 ZIP codes in the U.S. Table 23 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 August 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), and the CY 2016 PFS proposed rule (80 FR 41790 through 41791), as reflected in Table 23, 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 of all zip codes in the state. 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 of all zip codes in the state). As discussed in this section, these findings are illustrated in Table 23.

TABLE 23—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	2,723	85	3.12	43	1.58	2,595	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	1,513	69	4.56	9	0.59	1,435	94.84
FM	4	0	0.00	0	0.00	4	100.00
GA	1,032	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	1,080	20	1.85	3	0.28	1,057	97.87
ID	335	0	0.00	0	0.00	335	100.00
IL	1,629	68	4.17	7	0.43	1,554	95.40

TABLE 23—ZIP CODE ANALYSIS BASED ON OMB'S REVISED DELINEATIONS AND UPDATED RUCA CODES—Continued

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
IN	1,000	33	3.30	20	2.00	947	94.70
KY	1,030	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	1,185	22	1.86	21	1.77	1,142	96.37
MN	1,043	31	2.97	7	0.67	1,005	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	1,102	87	7.89	10	0.91	1,005	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	2,246	84	3.74	42	1.87	2,120	94.39
OH	1,487	23	1.55	54	3.63	1,410	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	2,244	129	5.75	38	1.69	2,077	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	2,726	64	2.35	32	1.17	2,630	96.48
UT	360	2	0.56	0	0.00	358	99.44
VA	1,277	98	7.67	19	1.49	1,160	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	42,927	1,600	3.73	451	1.05	40,876	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 these changes, in addition to Table 23, 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*, Downloads, CY 2016 Final Rule; 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.

We stated in the CY 2015 PFS final rule with comment period (79 FR 67750) and in the CY 2016 PFS proposed rule (80 FR 41792) that 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 stated in the CY 2016 PFS proposed rule (80 FR 41792) that we continue to believe 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 stated that 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 stated in the proposed rule that 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 did not propose a delay in implementation or a transition period for the revised OMB delineations and updated RUCA codes for CY 2016 and subsequent CYs.

We invited 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 invited public comments on any alternative methods for implementing the revised OMB delineations and the updated RUCA codes.

We received several comments from ambulance providers and suppliers and associations representing ambulance providers and suppliers on our proposals to continue implementation of the revised OMB delineations and the most recent modifications of the RUCA codes as discussed above for CY 2016 and subsequent CYs. The following is a summary of those comments along with our responses.

Comment: A commenter supported our proposal to continue implementation of the new OMB delineations for CY 2016 and subsequent CYs to more accurately identify urban and rural areas for ambulance fee schedule payment purposes.

Response: We appreciate the commenter's support of our proposal.

Comment: Several commenters agreed with CMS that it is appropriate to adjust the geographic area designations periodically so that the ambulance fee schedule reflects population shifts. These commenters remain concerned, however, because they contend that the modifications finalized last year have led to some rural ZIP codes being designated as urban. Several commenters urged CMS to refine the modified geographic area designations to restore rural status to those ZIP codes the commenters contended were improperly classified as urban last year. Specifically, commenters urged CMS to adopt HRSA's rural designations of 132 census tracts with RUCA codes of 2 and 3 that are at least 400 square miles in area with a population density of no more than 35 people per square mile. According to the commenters, the discrepancy between CMS and HRSA in the application of RUCA codes appears to result from the fact that HRSA designates rural areas for its programs by focusing on the Census tract, while CMS focuses on a U.S. Department of Agriculture (USDA) ZIP code list. The commenters stated that it is important for these 132 Census tract areas to be taken into account for making geographic designations. The commenters suggested that CMS adopt a methodology to adjust the RUCA code status for the 132 census tracts recognized by HRSA as rural to RUCA code status 4 before cross walking the ZIP codes. According to the commenters, when the analysis is re-run, the resulting ZIP codes would be appropriately designated as rural. The commenters stated that by recognizing the 132 census tracts as rural, CMS's policy would align with HRSA's policy and address the concerns raised by ambulance providers and suppliers. According to the commenters, this approach would avoid the concerns that CMS has raised about splitting ZIP codes.

Response: We appreciate the commenters' support for adjusting the geographic area designations periodically to reflect population shifts. As discussed in this section and in the CY 2016 PFS proposed rule (80 FR 41788 through 41792), we believe that the most current OMB delineations, coupled with the updated RUCA codes, more accurately reflect the 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 enhances the accuracy of ambulance fee schedule payments. Further, as discussed previously, we believe that our methodology of designating rural geographic areas by using OMB's delineations, and by using RUCA codes of 4 and above to identify rural census tracts within MSAs, is appropriate for ambulance fee schedule payment purposes.

We have concerns with the methodology proposed by the commenters to identify as rural certain census tracts with RUCA codes of 2 and 3. The 132 census tracts recognized as rural by HRSA have RUCA code designations of 2 or 3, indicating that the census tracts are predominantly urban. To assign these entire census tracts a RUCA code of 4 before cross walking the ZIP codes could result in inappropriate classifications of urban areas as rural. Payment under the ambulance fee schedule is based on ZIP codes (§ 414.610(e)). We would require a list of ZIP codes assigned to the 132 census tracts with RUCA codes of 2 and 3 that are at least 400 square miles in area with a population density of no more than 35 people per square mile to appropriately identify these areas as rural. As we previously discussed, we do not have sufficient information available to identify the ZIP codes that fall in these specific census tracts. We do not believe it would be prudent at this time to implement the commenters' suggested methodology absent the data and methodology to precisely identify the ZIP codes for the census tracts with RUCA codes of 2 and 3 that are at least 400 square miles in area with a population density of no more than 35 people per square mile. We will consider further evaluating for CY 2017 these additional census tracts that HRSA has designated as rural and the feasibility of identifying the ZIP codes that are assigned to those areas.

Comment: Several commenters requested that CMS issue an Advanced Notice of Proposed Rulemaking (ANPRM) prior to the CY 2017 rulemaking cycle to seek input from all interested stakeholders about whether a new urban-rural data set should be used or other policy modifications should be adopted to apply the RUCA designations. According to the commenters, the data to determine the levels for RUCAs are no longer collected through the long-form census, which had a high response rate. The commenters contend that the RUCA data are now based on a response rate in the single digits which is not high enough to accurately identify urban-rural areas when it comes to access to vital ambulance services. The commenters stated that an ANPRM would allow CMS to hear from all interested parties at an early stage in the process and provide CMS with the information it needs to fully evaluate the current policy and to identify options for addressing the issues that have been raised by commenters with

RUCA being used as the data set for identifying rural census tracts within urban areas.

Response: The updated RUCA code definitions are based on data from the 2010 decennial census and the 2006–2010 American Community Survey (ACS). According to the United States Census Bureau's Web site, *http://www.census.gov/programs-surveys/acs/guidance/training-presentations/acs-basics.html*, ACS is a nationwide survey that provides characteristics of the population and housing throughout the country, similar to the long-form questionnaire used in Census 2000. The ACS produces estimates of these characteristics for small areas and small population groups throughout the country.

According to the Census Bureau's Web site, the content collected by the ACS can be grouped into four main types of characteristics—social, economic, demographic, and housing. For example, economic characteristics include such topics as health insurance coverage, income, benefits, employment status, occupation, industry, commuting to work, and place of work. This is the same information that was collected by the 2010 Census.

The ACS is a continuous survey, in which, each month, a sample of housing unit addresses receives a questionnaire. For the ACS, the Census Bureau selects a random sample of addresses where workers reside to be included in the survey, and the sample is designed to ensure good geographic coverage. About 3.5 million addresses are surveyed each year. The ACS collects data from the 50 states, the District of Columbia, and Puerto Rico. The survey had the following response rates at the state level for 2006–2010: 91.1 percent to 99.0 percent in 2006, 91.7 percent to 99.3 percent in 2007, 91.4 percent to 99.4 percent in 2008, 94.9 percent to 99.4 percent in 2009, and 95.3 percent to 99.0 percent in 2010. The ACS collects survey information continuously and then aggregates the results over a specific period of time—1 year, 3 years, or 5 years. The ACS period estimates describe the average characteristics of the population or housing over a specified period of time. For smaller geographic areas, such as the census tracts, 5 year estimates are used. As mentioned in this section, the most recent update of the RUCA codes was developed using data collected from the 2006, 2007, 2008, 2009, and 2010 ACS. According to the Census Bureau, the estimates that they published based on the ACS had a 90 percent confidence interval.

According to the USDA's Web site, *http://www.ers.usda.gov/data-products/rural-urban-commuting-area-codes.aspx*, the RUCA codes were based on a special tabulation for the Department of Transportation, Census Transportation Planning Products, Part 3, Worker Home-to-Work Flow Tables (*http://www.fhwa.dot.gov/planning/census_issues/ctpp/data_products/2006-2010_table_list/sheet04.cfm*). According to the USDA, as with all survey data, ACS estimates are not exact because they are based on a sample. Nevertheless, we believe that the ACS provides the most recent comprehensive source of data on the population and is robust enough for use for purposes of determining the rural status of census tracts throughout the country.

We do not believe it is necessary to issue an ANPRM prior to the CY 2017 rulemaking cycle. In the CY 2016 PFS proposed rule and in past rules, we have discussed the implementation of the OMB delineations and the RUCA codes for purposes of payment under the ambulance fee schedule, and we believe that the public has had ample opportunity to provide comments and suggestions about other methodologies for designating geographic areas or other policy modifications that should be adopted to apply the RUCA code designations. We note that the public did not provide any suggestions for any alternative data sources for designating rural geographic areas.

We note that we utilize the ACS data in other Medicare payment systems as well. In the FY 2016 IPPS/LTCH PPS final rule (80 FR 49501), we finalized our proposal that the out-migration adjustments be based on commuting data compiled by the Census Bureau that were derived from a custom tabulation of the ACS, an official Census Bureau survey, utilizing 2008 through 2012 (5-Year) Microdata. (See also the FY 2016 IPPS/LTCH PPS proposed rule (80 FR 24471)). Furthermore, the physician fee schedule uses the 2008–2010 ACS data for calculating the office rent component of the PE of the geographic practice cost index (78 FR 74390).

After consideration of the public comments received and for the reasons discussed in this section and in the CY 2016 PFS proposed rule, we are finalizing without modification our proposal 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 in this section, for CY 2016 and subsequent CYs for purposes of payment under the ambulance fee schedule. As we proposed, using the updated RUCA code definitions, we will continue to designate any census tracts falling at or above RUCA code 4.0 as rural areas. In addition, as discussed in this section, none of the current super rural areas will lose their super rural status upon implementation of the revised OMB delineations and the updated RUCA codes.

4. Proposed Changes to the Ambulance Staffing Requirements

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, and, additionally, that 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.

As we stated in the CY 2016 PFS proposed rule (80 FR 41792), 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. In the CY 2016 PFS proposed rule, we stated that 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, in the CY 2016 PFS proposed rule (80 FR 41792), we proposed 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 proposed 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) (80 FR 41793). We stated that these 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 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, we stated in the proposed rule that we believe these proposals would enhance the quality and safety of ambulance services provided to Medicare beneficiaries.

In addition, we proposed 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 (80 FR 41793). 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 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 proposed 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 (80 FR 41793). This sentence 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 proposed 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 invited public comments on our proposals to revise the ambulance vehicle staffing requirements in § 410.41(b) and the definition of Basic Life Support (BLS) in § 414.605, as discussed in this section. We also stated that, if we finalized these proposals, we would revise our manual provisions addressing ambulance vehicle staffing as appropriate, consistent with our finalized policy.

We received approximately 21 comments from ambulance providers and suppliers and associations representing such entities. The following is a summary of the comments we received along with our responses.

Comment: Several commenters supported the proposed changes to the ambulance staffing requirements. Commenters also requested that CMS support efforts to designate ambulance services as providers under the Medicare program (rather than having some designated as suppliers).

Response: We appreciate the commenters' support of our proposals. Comments requesting us to support efforts to designate ambulance services as providers are outside the scope of this final rule with comment period.

Comment: One commenter requested additional clarification on whether the proposed revision would require both ambulance medical technicians to be certified by the state as EMTs. This same commenter requested clarification on whether both technicians would need to be legally authorized to operate lifesaving and life-sustaining equipment on board the vehicle.

Two commenters opposed the proposed changes to the ambulance staffing requirements, expressing concern that the proposed changes would require both crew members to be certified as EMTs, a change they believed would negatively impact ambulance services in rural communities. One of these commenters stated that such a change would (1) not increase the level of care provided to the patient being transported, and (2) make it more difficult for volunteer Emergency Medical Services (EMS) providers to be properly reimbursed for their work. The commenters also stated that this requirement would limit access in rural communities, and that it would be difficult for volunteer EMS staff to meet such requirements.

Response: We believe that these commenters misinterpreted our proposal. We did not propose to require that both ambulance crew members be certified as EMTs or that both ambulance crew members be legally authorized to operate all lifesaving and life-sustaining equipment on board the vehicle. The only change we proposed to our current policy was to require both ambulance vehicle staff to meet the requirements of state and local laws where the services are being furnished. Thus, our proposed policy would require that both ambulance vehicle staff be certified as EMTs only when this is required by the state or local laws where the services are being furnished. As we stated in the CY 2016 PFS proposed rule (80 FR 41942), because we expect that ambulance providers and suppliers already comply with their state and local laws, we expect that this requirement would have a minimal

impact on ambulance providers and suppliers.

Comment: Several commenters supported the proposed revision to the definition of Basic Life Support (BLS) in § 414.605 to delete the last sentence, which sets forth examples of certain state law provisions.

Response: We appreciate the commenters' support for our proposed revision to the definition of Basic Life Support (BLS) in § 414.605.

After consideration of the public comments received, and for the reasons discussed in this section, we are finalizing without modification our proposals to revise (1) § 410.41(b) and the definition of Basic Life Support (BLS) in § 414.605, as discussed in this section, to require that all Medicare-covered ambulance transports be staffed by at least two people who meet both the requirements of state and local laws where the services are being furnished, and the current Medicare requirements, (2) § 410.41(b) and the definition of Basic Life Support (BLS) in § 414.605 to clarify that for BLS vehicles, one of the staff members must be certified at a minimum as an EMT-Basic, and (3) the definition of Basic Life Support (BLS) in § 414.605 to delete the last sentence, which sets forth examples of certain state law provisions. We will also revise our manual provisions addressing ambulance vehicle staffing, as appropriate, to be consistent with these finalized policies.

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) model 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. Although 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 generally not included in the RHC or FQHC payment. We proposed 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 final rule, ''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. Payment Methodology and Billing for CCM Services in RHCs and FQHCs

a. Payment Methodology and Billing Requirements

The requirements we proposed 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 24. We proposed to establish payment, beginning on January 1, 2016, for RHCs and FQHCs that furnish a minimum of 20 minutes of qualifying CCM services during a calendar month to patients with multiple (two or more) chronic conditions that would be expected to last at least 12 months or until the death of the patient, and that would 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 would 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 sub-regulatory guidance.

We proposed that a RHC or FQHC could bill for CCM services furnished by, or incident to, the services of a RHC or FQHC physician, NP, PA, or certified nurse midwife (CNM) for a RHC or FQHC patient once per month, and that only one CCM payment per beneficiary per month could be paid. If another practice furnishes CCM services to a beneficiary, the RHC or FQHC could not bill for CCM services for the same beneficiary for the same service period. We also proposed that TCM and any other program that provided 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. We proposed CCM payment for RHCs and FQHCs because we believe that the non-face-to-face time required to coordinate care is 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 components of CCM services.

We proposed 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 was $42.91 per beneficiary per calendar month.) This rate would not be subject to a geographic adjustment. 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 proposed 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 to RHC claims as applicable. 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.

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 did not propose 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 did not propose 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 did not propose 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 through the cost report. We did not propose 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. Requirements for CCM Payment in RHCs and FQHCs

a. Beneficiary Eligibility for CCM Services

Consistent with beneficiary eligibility requirements under the PFS, we proposed that RHCs and FQHCs receive payment for furnishing CCM services to patients with multiple chronic conditions that are expected to last at least 12 months or until the death of the patient, as determined by the RHC or FQHC practitioner, and that place the patient at significant risk of death, acute exacerbation/decompensation, or functional decline. We encouraged RHCs and FQHCs to focus on patients with high acuity and high risk when furnishing CCM services to eligible patients, including those who would be returning to a community setting following discharge from a hospital or SNF.

b. 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 were being furnished under the RHC AIR or FQHC PPS payment system.

Consistent with beneficiary notification and consent requirements under the PFS, we proposed 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 calendar month, 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. Scope of CCM Services in RHCs and FQHCs

We proposed 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.

• The electronic care plan 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 to review the care plan criterion for health information technology (IT) finalized in the 2015 Edition of Health Information Technology Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications final rule (80 FR 62648), which aims to enable users of certified health IT to create and receive care plan information in accordance with the C–CDA Release 2.1 standard.

• 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. Such 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. 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 proposed 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 24—SUMMARY OF 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 visit.	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 appointments.	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 medications.	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 invited 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. The following is a summary of the comments we received and our responses.

Most of the comments we received were very supportive of our proposal to establish payment for CCM services in RHCs and FQHCs. Several commenters agreed that allowing separate payment for CCM services in RHCs and FQHCs will better reflect the additional resources necessary for the unique services that are required to furnish CCM services to the populations served by RHCs and FQHCs. Many commenters appreciated that the proposed methodology would enable RHCs and FQHCs to be paid for these services even if there was no billable visit. A few commenters had concerns regarding health information technology requirements or beneficiary copayment requirements. One commenter had concerns about potential duplication in payment and increased Medicare spending. Several commenters requested clarification on specific aspects of the program. A few commenters asked questions that were beyond the scope of the proposal.

Comment: One commenter noted that in a few instances, our proposal alternately used ''a CCM 30-day period'' and ''only one CCM payment can be paid per beneficiary per month.'' The commenter stated that under the Medicare PFS and the definition of CPT code 99490, CCM services are based on a calendar month, not a 30-day period.

Response: The commenter is correct that the CCM period is based on a calendar month, not a 30-day period.

Comment: A few commenters were concerned that charging a beneficiary coinsurance for non-face-to-face services will be confusing to the beneficiary and create a barrier to receiving care. One commenter recommended that we waive coinsurance for CCM services, and another recommended that we waive the applicable coinsurance and deductible through CMMI's waiver authority.

Response: We do not have the statutory authority to waive coinsurance for CCM services, and CMMI waiver authority is only applicable to CMMI demonstration programs. Although there may be potential for confusion on the part of the beneficiary who receives a bill for services that were conducted on their behalf but not furnished directly to them, this should be fully explained to the beneficiary during the consent process and in subsequent patient interactions as necessary. We suggest that when practitioners explain the benefits of receiving CCM, they include the possibility that it may help the beneficiary to avoid the need for more costly face-to-face visits that would entail greater cost sharing.

Comment: A commenter was concerned that many beneficiaries and their caregivers will not fully understand the beneficiary consent for CCM services requirements, including what they are being asked to accept or decline, or why they are being asked to approve in writing the provision of certain services and not others. The commenter recommended that CMS take steps to ensure that beneficiaries will have a proper understanding of CCM and its value, as well as their right to decline enrollment in CCM, and that family caregivers be included in these conversations, whenever possible.

Response: We agree with the commenter regarding the importance of the beneficiary's understanding of CCM services and their right to accept or decline this service. Beneficiary education on CCM services, including information on the value of this service and the beneficiary's right to accept or decline it, is a required component of CCM services and must be provided to beneficiaries as part of the consent process. We also agree that these discussions should include the caregiver, when applicable.

Comment: A commenter urged CMS to ensure that communication methods are conducted in a culturally and linguistically appropriate manner. The commenter suggested that notices and agreements regarding CCM services should be written in plain language and in their patients' preferred languages, and be accessible to those with visual, hearing, cognitive, and communication impairments.

Response: RHCs and FQHCs serve diverse populations, and we thank the commenter for this important reminder that written and oral communication materials should be accessible and understandable to the patient population being served.

Comment: Some commenters expressed concerns with the proposed technological requirements for CCM services. They noted that interoperability and electronic exchange of medical information is costly and there are technological barriers that may prevent the seamless transmission and recording of patient information. One commenter stated that since RHCs and FQHCs were not eligible for Meaningful Use incentives, they may not have the health information technology in place to support some of the requirements, and that those RHCs and FQHCs that cannot meet the health information technology requirements will be excluded from payment for CCM services. Other commenters were concerned that some patients served by RHCs and FQHCs may not have the resources to receive secure messages via the Internet. These commenters recommended that the electronic health record requirements, and the electronic exchange of information and interoperability with other providers, be encouraged but not required for CCM payment.

Response: We appreciate the concern regarding the cost and challenges inherent in adopting new technological requirements and understand that not all RHCs or FQHCs may be able to meet the technological requirements at this time. RHCs and FQHCs that do not have an EHR system in place, or are not able to meet the CCM interoperability requirements, will not be able to furnish and bill for CCM services. However, based on recent surveys, we believe that many, if not most, RHCs and FQHCs have the capability to meet the technological requirements now or in the near future. For example, a recent survey showed that nearly 72 percent of RHCs have an operational EHR system, with 63 percent indicating use by 90 percent or more of their staff. The same study showed that slightly over 17 percent of RHCs without an EHR plan to implement one within 6 months, and 27 percent plan to do so within 7 to 12 months.[1] A 2014 study showed that 93 percent of FQHCs have an EHR system, and that 76 percent reported meeting the criteria to qualify for meaningful use incentive payments.[2] We would also note that eligible professionals working in RHCs and FQHCs are eligible to receive payment under the EHR Incentive Programs.

We are aware that not all patients, particularly those served by RHCs and FQHCs, may be able to receive secure messages via the Internet, and they are not required to do so. However, to furnish and bill for CCM services, RHCs and FQHCs must have the capability to communicate with the beneficiary and any caregiver, not only through telephone access, but also through the use of secure messaging, Internet, or other asynchronous non face-to-face consultation methods. Beneficiaries are not required to have this capability to receive CCM services.

Comment: One commenter disagreed with the proposed requirement that an electronic care plan be made available 24 hours a day, 7 days a week, and believes that this unrealistically fails to account for ''system maintenance, down-time, change in EHR vendor, or the event of technological glitches and cyber-attacks''. The commenter recommended that at a minimum, CMS should provide for exceptions in the event of any of these circumstances.

Response: RHCs and FQHCs that choose to furnish and bill CCM services must have a system that supports 24 hours a day, 7 days a week, access to the electronic care plan. We understand that there may be times when the system is not operable, but we expect that this will not be a frequent occurrence.

Comment: A commenter stated that they were worried that adding very prescriptive technological requirements may stifle innovation and prevent the use of technology that is more appropriate and tailored for chronically ill patients. The commenter recommended that any technological requirements for CCM services should be broadly drafted to allow for future changes and advancements over time.

[1] Adoption and Use of Electronic Health Recoreds by Rural Health Clinics Results of a National Survey; Maine Rural Health Research Center, Research and Policy Brief, September 2015.

[2] The Adoption and Use of Health Information Technology by Community Health Centers, 2009–2013; The Commonwealth Fund; Issue Brief; May 2014.

Response: We appreciate the commenter's concerns about the need to avoid stifling innovation. In including these technology requirements, we are seeking to ensure that all RHCs and FQHCs furnishing CCM services have the technological capabilities that are needed to deliver high-quality services while allowing the flexibility needed to adopt appropriate technology solutions. By proposing the adoption of a minimal set of certified health IT capabilities, and allowing flexibility around more advanced capabilities such as shared care planning, we believe that these goals will be met.

Comment: A commenter stated that physicians have significant problems and usability concerns with the clinical care summaries, and recommended that these summaries not be required for CCM services.

Response: We respectfully disagree with this commenter's recommendation that clinical care summaries not be required for CCM services. We believe that the transmission of clinical care summaries is an important component of supporting effective care transitions and should be available electronically to effectively furnish CCM services.

Comment: A commenter stated that the proposed care plan for CCM services in RHCs and FQHCs, which includes the patient's medical, functional, and psychosocial needs and has system-based approaches for receipt of services, provides a comprehensive definition of care management that should be used in other CPT codes to assure consistency across programs and settings.

Response: We appreciate the comment, but the description of ''care management'' utilized in other CPT codes is outside the scope of this rule.

Comment: A commenter requested that CMS provide an optional patient-centered plan of care document template that can be used as an example to create a comprehensive care plan that is compliant with CCM requirements. Another commenter asked for clarification on the documentation requirements for billing CCM services, and another stated that physicians are likely to need assistance from CMS in providing educational materials for their patients regarding CCM. A commenter urged CMS to expand the use of CCM codes to all Medicare beneficiaries.

Response: While we have not provided a template for RHCs and FQHCs to use in developing care plans, we would refer these commenters to the CMS Web site at *https://www.cms.gov/Outreach-and-Education/Outreach/NPC/National-Provider-Calls-and-Events-Items/2015-02-18-Chronic-Care-Management-new.html* for general information on CCM, including educational materials.

Comment: A commenter requested that auxiliary personnel, including pharmacists, be allowed to provide CCM services in RHCs and FQHCs, including furnishing the AWV. Another commenter asked for clarification of what positions qualify as auxiliary staff.

Response: The CMS Benefit Policy Manual, Chapter 9, describes auxiliary personnel in RHCs and FQHCs as a nurse, medical assistant, or anyone acting under the supervision of the physician. Auxiliary personnel are not RHC or FQHC practitioners and cannot bill for a visit in a RHC or FQHC. However, the time spent by auxiliary personnel in furnishing CCM services could be counted towards meeting the 20 minute minimum requirement for billing a CCM visit.

Comment: A commenter urged CMS to recognize occupational therapy practitioners as RHC and FQHC practitioners, and to include occupational therapy in all CMS's efforts to ensure beneficiary care is appropriately provided and managed. The commenter states that this would assist in promoting patient self-management, reduce caregiver burden, decrease hospitalizations, increase effective resource utilization, and contribute to improved beneficiary and population health.

Response: We agree that occupational therapists can be a valuable and important part of the health care team and can contribute to improved outcomes and reduced costs. The full list of statutorily-defined RHC and FQHC practitioners is set out at section 1861(aa)(2) of the Act, and includes physicians, NPs, PAs, CNMs, CPs, or CSWs. Other qualified practitioners, such as occupational therapists, may furnish services incident to a RHC or FQHC practitioner's services. For additional information on the provision of occupational therapy in RHCs and FQHCs, see the CMS Benefit Policy Manual, Chapter 13, on the CMS Web site at *https://www.cms.gov/Center/Provider-Type/Rural-Health-Clinics-Center.html,* or *https://www.cms.gov/Center/Provider-Type/Federally-Qualified-Health-Centers-FQHC-Center.html.*

Comment: A commenter questioned what specific tasks can be counted toward the 20 minute CCM requirement.

Response: The tasks comprising CCM services are described in the scope of service requirements in section III.B. of this final rule with comment period.

Comment: A commenter urged CMS to emphasize and reiterate the scope of services that are expected, including 24–7 access to care management, continuity with a designated provider, and creation of a patient-centered care plan document.

Response: The scope of services that are required for CCM payment, including 24–7 access to care management, continuity of care with a designated provider, and creation of a patient-centered care plan document, are all required components of CCM services.

Comment: A commenter asked what would be considered the date of service for CCM if multiple days per month are used to get to the 20-minute mark.

Response: The service period for billing CCM services is one calendar month, and we expect the RHC or FQHC to continue furnishing services during a given month as applicable even after the 20-minute time threshold to bill the service is met. The RHC or FQHC could bill for the CCM service after completion of at least 20 minutes of qualifying CCM services during the service period, or any time after that until the end of the month. Additional billing information will be provided in subregulatory guidance.

Comment: A commenter was concerned that CMS's proposed reimbursement level for CCM services in RHCs and FQHCs is low, and asked that we re-evaluate the time and effort needed for the appropriate provision of these important services.

Response: We proposed 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. Since the commenter did not provide any rationale or additional data supporting an increase in the payment rate for RHCs or FQHCs, we cannot address this comment.

Comment: A commenter was concerned that separate payment for CCM services in RHCs and FQHCs may lead to duplicative payments because the FQHC PPS payment reflects the costs for all services associated with a comprehensive primary care visit, even if not all the services occur on the same day. The commenter also suggested that separate payment for CCM services could lead to duplicative payment for FQHCs that receive a Public Health Service grant because the grant already requires the provision of health services that are available and accessible promptly and in a manner which will assure continuity of service to the residents of the center's catchment area.

Response: We would like to alleviate any concerns that separate payment for CCM services is a duplication of RHC

and FQHC payment. Although the FQHC PPS payment, and the RHC AIR, do reflect the costs for all services associated with a comprehensive primary care visit, even if not all the services occur on the same day, it does not generally include the costs of the services required for CCM payment. For example, FQHCs are required to provide case management that includes an assessment of factors affecting health (for example, medical, social, housing, or educational), counseling and referrals to address identified needs and periodic follow-up of services. They are not required to create a structured recording of demographics, problems, medications, medication allergies, and structured clinical summary records using CCM certified technology, or to share the care plan as appropriate with other practitioners and providers. FQHCs are required to have an on-call provider for after-hours care, but they are not required to have the 24/7 case management services that the CCM billing code requires. RHCs do not have these requirements for primary care visits.

In general, although a few of the services required for CCM payment may be provided by some RHCs and FQHCs on occasion, the systematic provision of care management, the level and intensity of care coordination, and the interoperability of care plans with external providers is not typically found in RHCs or FQHCs.

Comment: A commenter noted that the increase Medicare expenditures for CCM services in RHCs and FQHCs would not trigger a budget-neutrality adjustment, even though the estimated increase in spending is material.

Response: The commenter is correct that payment for RHC and FQHC services is not subject to budget neutrality. We believe that the additional cost for furnishing CCM services in RHCs and FQHCs is an investment in comprehensive and coordinated care that is likely to be offset by reduced hospitalizations and readmissions. We would also note that, based on the current utilization under the PFS, we have revised our original estimate to reflect the expected phased in rate of CCM utilization.

Comment: A commenter stated that FQHCs should not be required to exclude any activities related to CCM from their Medicare cost reports.

Response: Any cost incurred as a result of the provision of CCM services (as defined in the task list in section III.B.) is an allowable cost and should be included in the Medicare cost report.

Comment: A commenter requested that CMS clarify in the final rule that Medicare Advantage (MA) enrollees are entitled to the same CCM services as non-MA enrollees, and that MA-contracted FQHCs are entitled to the same payment for CCM services as FQHCs providing qualifying CCM services to non-MA enrollees.

Response: In addition to Medicare Part A and Part B services, MA organizations (MAOs) are required to furnish care coordination services that are substantially similar to the Original Medicare CCM services. They have flexibility in terms of how to furnish care coordination services to ensure ongoing continuity of care and care management for all enrollees. MA regulations at § 422.256(a)(2)(ii) expressly preclude CMS from interfering in payment rates agreed to by an MA plan and its contracted providers. Whether or not a MAO pays its providers for furnishing care coordination services through use of the CPT code or some other mechanism can vary depending on the contract agreement in place. Thus, the amount the MA plan will pay the contracted FQHC depends on the terms of the contract. We note that MA PPO enrollees have the option to obtain covered services from non-contracted providers. Thus, if a PPO enrollee chooses an out-of-network provider to furnish chronic care management services and all criteria for billing the CCM code is met, the MAO must pay for those services consistent with Original Medicare payment rules. In this scenario, enrollees are responsible for any plan established out-of-network cost sharing. Additionally, although not coordinated care plans, Medicare PACE Organizations, MA private fee-for-service plans and MA Medicare Savings Account plans are required to cover Medicare Part A and Part B services, which include coverage of the CCM services consistent with Medicare coverage and payment rules.

Comment: A commenter stated that RHCs and FQHCs cannot bill for an IPPE or AWV visit in addition to the AIR and that RHCs and FQHCs are doing this work at their own expense and without compensation. The commenters stated that CMS has proposed the ability for RHCs to bill for CCM in addition to the AIR in the CY 2016 PFS, and asked that this RHCs and FQHCs also be allowed to bill separately for the IPPE and AWV.

Response: It is unclear why the commenter stated that the IPPE and AWV are uncompensated, since these services are billable visits. Although we do not agree that RHCs and FQHCs are furnishing IPPEs and AWVs at their own expense and without compensation, payment for IPPEs and AWVs in RHCs and FQHCs is outside of the scope of this proposal.

Comment: A commenter expressed concern that the unique RHC and FQHC billing structures may preclude them from receiving payment for newly developed care coordination payment codes, and suggested that RHCs and FQHCs be guaranteed care coordination payments. The commenter stated that including RHCs and FQHCs in ensuring better care coordination is vital, and suggested that CMS make payments for care coordination services available to RHCs and FQHCs through ''crosswalk'' procedures or similar technical allowances,

Response: We agree that care coordination in RHCs and FQHCs is extremely important, and would note that the payment methodology proposed for RHCs and FQHCs is due to the non-face-to-face nature of this benefit. As the commenter did not provide any specific suggestions on ''crosswalk procedures or similar technical allowances,'' we cannot address this comment.

Comment: A commenter requested that PAs in RHCs be allowed to bill for laboratory, X-rays, and other services using a methodology similar to what was proposed for CCM services.

Response: This comment is outside the scope of this rule.

Comment: A few commenters requested that an exception to the direct supervision requirements be made for CCM and TCM services that are furnished incident to physician services in RHCs and FQHCs. The commenters suggested that the regulatory language be amended to be consistent with the provisions in § 410.26(b)(5), which state that CCM and TCM services (other than the required face-to-face visit) can be furnished under general supervision of the physician (or other practitioner) when they are provided by clinical staff incident to the services of a physician (or other practitioner). 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.

Response: We believe that due to their different model of care and payment structure, requiring direct supervision for ''incident to'' services is appropriate for RHCs and FQHCs at this time. However, we will consider this for future rulemaking if RHCs and FQHCs find that requiring direct supervision presents a barrier to furnishing CCM services.

Comment: A commenter stated that the limitation of one CCM payment per month per beneficiary does not support

the scope of services that beneficiaries often need.

Response: We are not sure if this commenter is suggesting that CCM payments be made more frequently to the same RHC or FQHC (or other practitioner), or if more than one entity (for example, RHC, FQHC, a physician's office, etc.) should be able to bill for CCM services within the month. For either of these situations, we respectfully disagree with this commenter. We believe that a minimum of 20 minutes of CCM services over a one-month period is required to achieve the benefits of CCM services, and that there should be a single and consistent point of contact for these services.

Comment: A commenter recommended the creation of a modifier for services furnished by a specialist to establish a link between a primary care referral and the specialist for CCM.

Response: Since services furnished directly by a primary care practitioner or a specialist are separately billable services, we believe this commenter may be suggesting a way to document referrals to specialist services that result from CCM services. We thank the commenter for the suggestion but do not believe this would be necessary or beneficial.

As a result of the comments, we are finalizing these provisions as proposed, except to change ''30-day period'' to ''calendar month'' wherever it was used in the proposed rule.

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 report 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, RHCs have been required to report HCPCS coding for these preventive services, for which coinsurance and deductible are waived. 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. 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(1)(a) 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 proposed 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 proposed that RHCs exempt from electronic reporting under section 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 proposed 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 also proposed 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 proposed 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 invited 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.

The following is a summary of the comments we received and our responses.

Comment: We received a few comments on our proposal and all were supportive of requiring RHCs to report HCPCS for all services furnished. Most commenters agreed with our assertions that the data could potentially inform future policy decisions by providing useful information on individual patient attributes and the types of services/procedures furnished by RHCs. One commenter supported this proposal because currently all other providers such as hospitals, physicians, and FQHCs report HCPCS on claims to Medicare. Another commenter expressed interest in reporting HCPCS to enable participation in PQRS and other quality reporting programs. A commenter stated that HCPCS could be determined from the services recorded in the electronic medical record system and office systems that generate claim forms could be modified easily to bill all services furnished. A commenter believed that the majority of RHCs would experience minimal burden fulfilling this requirement. Although all commenters supported the requirement, a few commenters raised concerns about operational challenges of the requirement. One commenter stated, ''The operational challenge for providers will be capturing the appropriate charge for 'all' services provided.'' Another commenter was concerned about whether CMS and the MACs would be ready by January 1, 2016 to process RHC claims under the proposed requirement.

Response: We appreciate the support for our proposal to require RHCs to report HCPCS on RHC claims for Medicare services. We want to clarify that the reporting of HCPCS does not necessarily convey eligibility to participate in PQRS and other value-based payments since these programs have additional eligibility requirements that RHCs may be unable to meet. We do not believe there will be an operational challenge for providers to capture the charge for all services provided. There is no change to the methodology for reporting charges under this requirement. We acknowledge the commenter's concerns about the system's readiness to process claims under the requirement and we have been working with the MACs to implement the required updates. We are finalizing the reporting requirement as proposed with an effective date of April 1, 2016 to allow the MACs additional time to implement the necessary claims processing systems changes completely.

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, Pub. 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, Pub. 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)), Pub. L. 83–568 (42 U.S.C. 2001(a)), and the IHCIA, 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 CY 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. Commenters 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.

However, the Medicare Conditions of Participation (CoPs) for Medicare-participating hospitals at § 482.12 require administrative and clinical integration between a hospital and its provider-based clinics, departments, and locations. 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, it became apparent that a different structure was 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. We believed that the FQHC program may provide an alternative structure that met the needs of these tribal clinics and the populations they served, while also ensuring the IHS hospitals were not at risk of being cited for non-compliance with the requirements in their CoPs.

c. Federally Qualified Health Centers (FQHCs)

FQHCs were established in 1990 by section 4161 of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101–508, enacted on November 5, 1990) (OBRA 90), 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'' for FQHCs. 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), as added by the Affordable Care Act, requires that Medicare payment for FQHC services under section 1834(o) of the Act 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 statute, as amended by 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 CY 2016 by the 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 under 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. Payment Methodology and Requirements

We proposed that IHS and tribal facilities and organizations that met the conditions of § 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 referred 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 proposed 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 proposed that these grandfathered tribal FQHCs would be paid based on the IHS payment rates and not the FQHC PPS payment rates, we also proposed 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 proposed not to apply the MEI or a FQHC market basket adjustment that is applied annually to the FQHC PPS base rate. We proposed 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. 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 final rule with comment period. Therefore, we proposed 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 was 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 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 proposed 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.

We invited public comments on all aspects of our proposal to allow IHS and tribal facilities and organizations that met the conditions of § 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, to become certified as grandfathered tribal FQHCs.

We received comments on this proposal from the Alaska Native Health Board, Alaska Native Tribal Health Consortium, Citizen Potawatomi Nation, Southern Ute Indian Tribe, Southcentral Foundation, and the Tribal Technical Advisory Group (TTAG). All the commenters were strongly opposed to the proposal and requested that it be either withdrawn or revised.

The following is a summary of the comments we received and our responses.

Comment: Commenters questioned the necessity of changing the payment system for grandfathered tribal outpatient clinics that are no longer provider-based to a hospital, and cited our history of interpreting and applying the provider-based regulations in a manner which granted provider-based status to these clinics even though they do not meet the provider-based requirements.

Response: In the proposed rule, we stated several reasons for proposing that these grandfathered tribal outpatient clinics transition to grandfathered tribal FQHC status. First, a grandfathered tribal outpatient clinic billing under an IHS hospital's CCN, without any administrative or clinical relationship with the IHS hospital, violates our hospital CoPs, which as noted, requires a hospital to function as one integrated entity, no matter how many off campus locations it may have. This would include having one governing body, one organized medical staff, one organized nursing department, one quality assessment and improvement program, and so forth. Non-compliance with any CoP requirement is cited as non-compliance for the entire hospital (§ 482.12). Serious noncompliance in any part of the hospital puts the entire hospital at risk for termination of its Medicare agreement, which would impact not just the hospital, but also the community it serves.

Second, a hospital may be legally liable for actions that occur by any part of their organization, which would include a clinic that is billing for Medicare services under the hospital's CCN, even if the hospital exercises no control over the clinic. We believe this puts a hospital in the untenable position of being legally responsible for actions over which it has no control.

Finally, under the current practice, grandfathered tribal outpatient clinics receive Medicare payment for services to Medicare beneficiaries and are subject to the hospital's CoPs. The Medicare CoPs are sets of requirements for acceptable quality in the operation of health care entities that must be met in order to bill Medicare, and an entity cannot participate in Medicare unless it meets every Condition. Because the facility would no longer be associated with a hospital, we believe that the FQHC CoPs would be an appropriate standard that all of these clinics would be able to meet.

For these reasons, we believe it is prudent for grandfathered tribal outpatient clinics to be directly responsible for their operations and held to Medicare CoPs that are reasonable and achievable, and that the option to become grandfathered tribal FQHCs will achieve these goals.

Comment: Commenters stated that provider-based status is already guaranteed under existing law and does not jeopardize the Medicare certification of IHS hospitals.

Response: As discussed in the previous response, a hospital that is not in compliance with its Medicare hospital CoPs is at risk for termination of its Medicare certification. The CoPs at § 482.12 and § 485.627, as applicable, require that each hospital have a governing body legally responsible for its operations, and do not provide an exception where a tribal clinic is billing as an outpatient department of the hospital but otherwise has no clinical or administrative relationship with that hospital. As we discussed in the proposed rule, a letter was issued to Trailblazer Health Enterprises, LLC, on August 11, 2003, 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. This letter has been interpreted by some as the basis for allowing tribal clinics that no longer meet the provider-based requirements to maintain their provider-based status and continue to be paid as an outpatient department of a hospital. We would note that although this letter acknowledged the continued provider-based status of some tribal clinics, no statute guarantees provider-based status to outpatient departments of hospitals that have changed their status such that they are no longer integrated with the hospital under whose Medicare CCN they are billing.

Comment: Commenters stated although they believe no clarification is needed, CMS could amend the regulations to state that (1) IHS and tribal facilities qualify for grandfathered provider-based status solely by virtue of satisfying § 413.65(m) and that (2) changes in the IHS or tribal status of a hospital or facility's operation will not lead to the loss of provider-based status, or jeopardize the associated hospital's Medicare certification, if the resulting configuration would have qualified as a grandfathered provider-based tribal facility as of April 7, 2000. Alternately, CMS could reaffirm its longstanding reading of the regulations as stated in the preamble to the CY 2000 PFS final rule.

Response: We appreciate the suggestion, but neither of these approaches would relieve the hospital from liability for CoP violations found in a grandfathered tribal provider-based clinic using the hospital's CCN, or, in the alternative, address the lack of applicable CoPs for tribal clinics claiming to operate as outpatient departments of a hospital with which they do not otherwise have an administrative or clinical relationship.

Comment: Commenters requested that CMS withdraw the proposed rule, or make the grandfathered tribal FQHC status optional for eligible tribal facilities and allow them time to compare the alternatives and make an informed choice.

Response: We stated in the proposal that IHS and tribal facilities and organizations that met the conditions of § 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. Although we would encourage all facilities that qualify for this status to become certified as grandfathered tribal FQHCs as soon as possible, they are not required to do so. We do, note, however, that CMS has an obligation to enforce compliance with the hospital CoPs at § 482.12. Thus, if CMS were to survey a hospital, and find Medicare being billed for hospital outpatient services by a provider-based department that was not in compliance with the hospital CoPs, the hospital would have to submit an acceptable plan of correction consistent with provisions of § 488.28 and demonstrate compliance via an on-site survey or risk termination of its Medicare certification. Such an action could potentially lead to an interruption in Medicare Part B payments for the tribal facility. It is for this reason that we would encourage all facilities that meet the requirements to be grandfathered tribal FQHCs to transition to this status at the soonest possible time.

Comment: Commenters stated that the proposed change would disrupt operations at the affected tribal facilities and potentially disqualify them from receiving any Medicare payments between the time they lose their grandfathered provider-based status and the time they qualify for the grandfathered tribal FQHC certification. Commenters stated that CMS has not indicated when a currently grandfathered tribal provider-based

clinic will be deemed to lose that status, or how they should bill and be paid during the interim period between submitting the Form 855A and ultimately receiving their first payment as a grandfathered tribal FQHC.

Response: We recognize that any change, especially one as significant as a change in a payment system, can be disruptive. We have taken numerous steps to assure that there would be no gap in Medicare payments between the time that one of these clinics ceases billing as a grandfathered tribal outpatient clinic and begins billing as a grandfathered tribal FQHC. We contacted the tribal clinics that would be eligible for grandfathered tribal FQHC certification and held several training calls to explain the proposed changes. We pledged to work closely with the tribes and affected clinics throughout the process to assure that the transition proceeds as smoothly as possible. We also note that other clinics have gone through similar transitions in payment systems, and we expect that this one would also be implemented with minimum disruption.

Comment: Commenters expressed concern regarding tribal preparedness to transition to a new payment system and the lack of technical assistance to date. The commenters noted that tribal facilities are unfamiliar with the FQHC rules and are apprehensive about what this change will entail in terms of reimbursement rates and covered services, as well as the legal and technical costs associated with the transition. Commenters stated that the lack of technical assistance will discourage tribes from transitioning to grandfathered tribal FQHC status. The commenters requested that CMS provide extensive and ongoing technical assistance to facilitate this transition, including practical training for tribal billing offices and financial officers and associated legal analysis for tribal attorneys and technical advisors. Commenters also requested a ''reasonable transition period'' and a ''generous grace period'' for any facility that must change to grandfathered tribal FQHC status, and suggested that these clinics be allowed twelve months before they are required to submit an application to become a grandfathered tribal FQHC.

Response: We understand the apprehension associated with changes that may impact the financial operations of a clinic. Following the issuance of the CY 2016 PFS proposed rule, we held several public calls to further explain the grandfathered tribal FQHC proposal. An ''All Tribes Call'' was held on July 29, 2015, to review the proposed rule, including eligibility, certification and billing requirements, and transitioning to the new system for grandfathered tribal FQHCs. This was followed by an August 12, 2015, call with the Northeast Tribal Health Consortium, and an August 26, 2015, call with the Osage Nation, and a call on September 30 with the Southern Ute and Alaska tribes. Members of and advisors to the TTAG also participated on all of these calls. A slide presentation was provided to outline key components of the proposed rule and we were available to answer any questions. During these calls, we reaffirmed our commitment to assisting these clinics in the transition and providing technical assistance as appropriate and necessary.

We also held calls with the CMS Regional Office Survey and Certification staff in the regions that have clinics eligible for this transition, and with the MAC responsible for the processing of claims and payment to these clinics, to ensure that they are aware of the proposal and are prepared to assist clinics as necessary in the transition. Subregulatory guidance on payment policies and claims processing will be available following publication of the final rule with comment period.

We intend to continue to provide technical assistance to affected clinics to facilitate the transition to grandfathered tribal FQHC, but we cannot provide training for financial officers or legal analysis.

Comment: Commenters were concerned that once a clinic self-attests or is informed by CMS that it no longer satisfies grandfathered provider-based tribal clinic status, it would not be able to bill Medicare at all until the clinic receives its Medicare CCN as new grandfathered tribal FQHC. Commenters also requested assurance that Medicare payments made to a grandfathered provider-based tribal clinic for services it provides between the date CMS determines it has lost provider-based status, and the date it begins billing as a grandfathered tribal FQHC, will not be treated as overpayments.

Response: We will assist eligible tribal outpatient departments with the transition to status as grandfathered tribal FQHCs so that there will be no overlap or gap in Medicare certification or payment. Further instructions on billing and claims processing will be provided in subregulatory guidance.

Comment: Commenters stated that the proposed change would dramatically lower their reimbursement rates.

Response: We respectfully disagree with this comment. We proposed to set the grandfathered tribal FQHC PPS rate at the same rate that the clinics are currently billing as grandfathered tribal outpatient clinics, subject to the FQHC PPS statutory requirement of paying 80 percent of the lesser of actual charges or the PPS rate. We note that this rate is significantly higher than the FQHC PPS rate and higher than payments made under the PFS. Although we have designed the proposal such that it continues to pay the same rate per encounter, we also note that services covered under the FQHC benefit differ from those covered under the hospital outpatient benefit, so an exact comparison is not possible. For example, the IHS hospital outpatient department's AIR includes technical services such as lab and X-rays. Under the FQHC PPS, these services are separately billable by the facility. The FQHC's per-diem payment includes practitioner services, and these services are separately billable under the IHS hospital outpatient department's AIR. The final payment under both systems is a result of the clinic's charges and the mix of services that are furnished by the particular clinic. Both IHS hospital outpatient departments and grandfathered tribal FQHCs are paid a single per diem visit for Medicare beneficiaries.

Comment: Commenters stated that grandfathered tribal FQHCs would see a reduction in their Medicare reimbursement because they would be paid ''the lesser of'' their charges or the grandfathered tribal FQHC PPS rate, and because the FQHC PPS rates include the professional services for which provider-based tribal facilities receive separate reimbursement in addition to their Medicare outpatient per-visit payment. Commenters stated that the grandfathered tribal FQHC will only be paid at the IHS hospital outpatient department's AIR if the G-code-based charges are higher than the AIR, and that this will result in a cap on their payment instead of a floor or a guarantee, as it is under the provider-based payment methodology. The commenters also stated that the proposed payment methodology will result in lost revenue for facilities assumed by tribes under the ISDEAA and would hamper the financial feasibility of tribes assuming the responsibility to carry out IHS programs. The commenters believe that this would contradict congressional intent to encourage self-determination and self-governance by tribes through the exercise of their rights under the ISDEAA.

Response: Grandfathered tribal FQHCs, like all FQHCs, would be paid the lesser of their charges or the grandfathered tribal FQHC PPS rate.

This is in accordance with section 1833(a)(1)(Z) of the Affordable Care Act, which requires 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.

As noted in the previous response, the services included in the FQHC benefit are different than the services included in the IHS hospital outpatient department AIR, and a direct comparison in Medicare payments cannot be made without factoring in the clinic's charges and the mix of services that are furnished. We have no reason to believe that there will be a significant increase or decrease in Medicare payments to those clinics that become grandfathered tribal FQHCs.

We fully support the rights of tribes to take over IHS facilities under the ISDEAA, and believe that the proposed payment system will enable tribes to continue to exercise self-determination and self-governance of their health care services. These clinics currently have the option of billing for Medicare services as a standard FQHC which has a 2015 PPS payment rate of $158.85, or billing for Medicare services separately under the PFS. We believe the proposed grandfathered tribal FQHC PPS rate, with an adjusted 2015 PPS rate of $307, will enable these clinics to provide Medicare services and bill at approximately the same rate.

Comment: Commenters stated that the proposed G code system is vague, and that little guidance has been provided as to how tribal health programs should go about determining the charge levels for their G codes. The commenters cited a July 29, 2015 ''All Tribes Call'' where CMS explained that charges must be ''reasonable'' and ''uniform for all patients, regardless of insurance status.'' The commenters stated that what constitutes a ''reasonable medical charge'' is highly context-specific, and usually includes some combination of analyzing the relevant market for hospital services, the usual and customary rate the hospital charges, the hospital's internal cost structure, the nature of the services provided, the average payment the provider would have accepted as full payment from third-parties, and the price an average patient would agree to pay for the service at issue. Commenters stated that it would be difficult for tribal facilities to know whether or not they are devising charge rates that would withstand judicial scrutiny if challenged as unreasonable, that tribes will have to devote additional time, resources, and legal analysis to devising G codes, and the G codes will likely vary from tribe to tribe for providing identical services to the same patient population. Commenters requested consultation to develop uniform standards as to what constitutes reasonable charges for the purposes of grandfathered tribal FQHC payments. The commenters also noted their preference to eliminate the charge-based ''lesser of'' G-code standard and instead authorize grandfathered tribal FQHCs to be paid as if they were provider-based outpatient hospital departments.

Response: Eliminating the charge-based ''lesser of'' G-code standard and instead authorizing grandfathered tribal FQHCs to bill as if they were provider-based hospital outpatient departments is not legally permissible. As previously noted, section 1833(a)(1)(Z) of the Affordable Care Act requires 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.

As discussed in the proposed rule, there are five FQHC G codes (G0466–FQHC visit, new patient; G0467–FQHC visit, established patient; G0468–FQHC visit, IPPE or AWV; G0469–FQHC visit, mental health, new patient, and G0470–FQHC visit, mental health, established patient). Each grandfathered tribal FQHC would determine which services to include in each G code, based on the services typically furnished per diem by that grandfathered tribal FQHC to their Medicare patients. Once the typical bundle of services in each G code is established, the grandfathered tribal FQHC would total their normal charges for those services. The sum of the charges for the services included in the bundle of services is the G code amount. Since grandfathered tribal outpatient clinics already have established charges for their services, it should not be difficult for them to establish their G codes.

Consistent with longstanding policy, the use of these payment codes does not dictate to providers how to set their charges. A grandfathered tribal FQHC would set the charge for a specific payment code pursuant to its own determination of what would be appropriate for the services normally provided and the population served at that grandfathered tribal FQHC, based on the description of services associated with the G code. The charge for a specific payment code would reflect the sum of regular rates charged to both beneficiaries and other paying patients for a typical bundle of services that would be furnished per diem to a Medicare beneficiary.

In setting its charges, a grandfathered tribal FQHC would have to comply with established cost reporting rules in § 413.53 which specify that charges must reflect the regular rates for various services that are charged to both beneficiaries and other paying patients who receive the services. Each grandfathered tribal FQHC would establish charges for Medicare visits that reflect the sum of regular rates charged to both beneficiaries and other paying patients for a typical bundle of services that the FQHC would furnish per diem to a Medicare beneficiary. We note that establishing Medicare per diem rates that are substantially in excess of the usual rates charged to other paying patients for a similar bundle of services could be subject to section 1128(b)(6) of the Act, as codified at 42 CFR 1001.701.

Comment: Commenters objected to withdrawing grandfathered provider-based status for certain tribal facilities and replacing it with a new status that is untested and poorly understood and may not fit their administrative and clinical operations.

Response: FQHCs began transitioning from an AIR payment system to the FQHC PPS on October 1, 2014. The system was thoroughly tested prior to implementation, and FQHCs have been submitting claims and receiving payment under this system without disruption. The proposed grandfathered tribal FQHC payment is an adjustment under the FQHC PPS to maintain the same payment rate that these clinics previously billed Medicare. Therefore, we do not agree that the system is untested or poorly understood, although we understand that it would be new for those clinics that choose to transition to become grandfathered tribal FQHCs. We created this option because we believe that the FQHC model most closely aligns with the operations of tribal outpatient clinics, and being included in this benefit category would enable these tribal clinics to continue their services and meet the Medicare CoPs.

Comment: Commenters requested that CMS extend grandfathered provider-based status to certain tribal facilities in Oklahoma, and perhaps other locations, which were denied that status because of errors committed by federal agencies.

Response: This comment is beyond the scope of this rule.

Comment: Commenters stated that the proposed rule is unclear whether Alaska clinics that become grandfathered tribal FQHCs would be paid at the $564 Alaska Medicare outpatient rate, or at the $307 rate that applies in the lower 48 states, and stated that if the proposal is finalized, Alaska facilities should be paid at the higher Medicare outpatient

hospital rate that reflects their higher cost of services.

Response: At this time, it is our understanding that there are no IHS or tribal facilities in Alaska that are eligible to become grandfathered tribal FQHCs. However, it is our intention that the reference to the payment rate in § 405.2462(d)(4) would include the rates specific to facilities in Alaska pursuant to the IHS reimbursement rates. In the event that any Alaska facilities are eligible and convert to a grandfathered tribal FQHC, the specific rates for facilities in Alaska would apply.

Comment: Some commenters were concerned that CMS might propose further reimbursement reductions for these clinics because the proposed rule states that CMS ''will monitor future costs and claims data of these tribal clinics and reconsider options as appropriate.''

Response: We have a responsibility to assure that Medicare Trust funds are utilized in accordance with Congressional intent and make adjustments to payments as necessary. Any changes to the payment methodology would be made through notice and rulemaking and with appropriate tribal consultation.

Comment: A commenter was concerned that the proposed regulation may impose more stringent physician supervision requirements than those that apply to provider-based clinics under the Medicare Part A and B rules and that it may be difficult or impossible for some affected clinics to meet these more stringent requirements, particularly those in remote locations where there are few or no physicians and services are provided primarily by mid-level practitioners or through the use of telemedicine. The commenter requested that grandfathered tribal FQHCs be exempt from physician supervision and other clinical requirements that are more stringent than those that apply to grandfathered provider-based programs.

Response: Grandfathered tribal outpatient clinics that choose to transition to become a grandfathered tribal FQHC will be required to be in compliance with the Medicare CoPs and other Medicare FQHC requirements and policies, unless such provisions are in conflict with applicable Federal law. Medicare requires most hospital outpatient services to be furnished under direct supervision as a condition of payment, including services furnished in a location that is a provider-based department of the hospital. FQHC practitioners practice under general supervision requirements and in accordance with state licensure requirements. However, state-specific licensure requirements are exempted for IHS and tribal programs under section 25 U.S.C. 1647a of the IHCIA. General supervision means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the furnishing of the service. We also note that the FQHC conditions for coverage generally impose significantly fewer regulatory burdens on facilities than the hospital CoPs that would otherwise apply.

Further instructions on Medicare CoPs for participation for grandfathered tribal outpatient clinics will be provided in subregulatory guidance.

Comment: A commenter requested confirmation that the governing board exception for tribes under section 330 of the PHS Act (42 U.S.C. 254b) would apply to grandfathered tribal FQHCs.

Response: We believe that the commenter is referring to section 330(k)(3)(H) of the PHS Act, and specifically to the exception to the requirements in section 330(k)(3)(H)(i)–(iii) of the PHS Act for entities operated by an Indian tribe or tribal or Indian organization under the ISDEAA or an urban Indian organization under the IHCIA. A grandfathered tribal FQHC that is operated by one of the aforementioned entities would not be required to meet the governing board requirements in section 330(k)(3)(H) of the PHS Act. The governing board exemption would not apply to an IHS clinic operating as a FQHC look-alike that meets the requirements for a grandfathered tribal FQHC.

Comment: Commenters expressed disappointment with the extent and quality of tribal consultation that has occurred and believe that CMS should have consulted with the TTAG prior to issuing the proposed rule. The commenters referenced a letter sent to CMS on July 9, 2015, in response to a request for more information regarding the grandfathered provider-based status of tribal clinics and why their associated hospitals maintain Medicare certification absent administrative or clinical integration. Commenters stated that they expected CMS to study the letter and give it due consideration before issuing a proposed rule, but CMS released the proposed rule without prior tribal consultation or consideration of the TTAG's analysis, despite their request for further discussion prior to any action.

Response: On February 18, 2015, CMS representatives met with the TTAG to discuss the concerns regarding outpatient tribal clinics billing Medicare as provider-based clinics to IHS hospitals. In response to comments made during the discussion, we requested that the TTAG send additional information that explains the TTAG's understanding of the provider-based rules and how they apply to these clinics.

We appreciate the detailed and thoughtful information that was provided by the TTAG in their July 9, 2015 letter. We regret that the letter was not provided in time to be addressed in the CY 2016 PFS proposed rule that was issued on July 8, 2015.

Comment: Commenters stated that CMS should have consulted with the TTAG and tribes nationwide prior to issuing the proposed rule. Commenters requested that CMS withdraw the proposal and engage in further tribal consultation before releasing a proposal. The commenters requested that CMS consult with the TTAG and other tribal stakeholders in the future before issuing proposed changes to regulations that affect tribes.

Response: We have a long history of tribal consultation on issues pertaining to tribes, and the discussions that have occurred have had a significant and beneficial influence on our policies. We believe that the tribal consultation that occurred prior to the publication of the proposed rule was both adequate and informative. We are subject to the provisions of the Administrative Procedure Act (APA) (5 U.S.C.), and external discussions on the development of proposed rules are limited during the regulatory process. We met with the TTAG before developing the proposed rule, and have had several national calls (as noted above) since the proposed rule became public. We look forward to continuing our dialogue with the TTAG and the tribes regarding this and any other Medicare issue that affects tribes.

Comment: Commenters requested the formation of a Tribal-CMS provider-based status workgroup prior to CMS issuing a final rule, as well as nationwide tribal consultation concerning CMS's interpretation of the proposed rule and applicable requirements. The commenters stated that consultation must go beyond providing comments on a proposed rule.

Response: Formation of a Tribal-CMS workgroup is not in the purview of this final rule. We suggest that the commenters make this request through the CMS Division of Tribal Affairs. As noted above, the process for regulatory notice and comment is in accordance with the APA.

Comment: Commenters requested that the proposed revisions at § 405.2462(d)(1)(ii) that defines a

grandfathered tribal FQHC be revised to ensure that grandfathered provider-based tribal facilities qualify for the new tribal FQHC status so long as they fulfilled the applicable grandfathering requirements as of the relevant date.

They also suggested that because eligibility for becoming a grandfathered tribal FQHC applies to clinics that had provider-based status on or before April 7, 2000, tribal clinics that were provider-based before but not on April 7, 2000, should be eligible for grandfathered tribal FQHC status.

Response: The proposed rule stated that grandfathered tribal FQHC status would not apply to a currently certified tribal FQHC, a tribal clinic that was not provider-based on or before April 7, 2000, or an IHS-operated clinic that is no longer provider-based to a tribally operated hospital, and that 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. We believe the eligibility criteria are clear and no revisions are needed.

As a result of the comments, we are finalizing this rule as proposed.

E. Part B Drugs

1. Payment for Biosimilar Biological Products Under Section 1847A of the Act

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, also 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: (1) The ASP as determined using the methodology described under section 1847A(b)(6) of the Act 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 (2) 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 section 3139 of the Affordable Care Act regarding payment for biosimilars under the ASP system 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 the CY 2011 PFS final rule with comment period (75 FR 73393 and 73394) in the November 29, 2010 **Federal Register**. 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 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 monitor the implementation of the FDA biosimilar approval process and the emerging biosimilar marketplace. As biosimilars now begin 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 proposed to amend § 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 consistent with section 1847A(b)(8) of the Act), which directs the Secretary to use the weighted average payment methodology that is applied to drugs. We also proposed to amend § 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 PFS final rule with comment period. We welcomed comments about these proposals.

We also took 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 (BLA) will be grouped into the same payment calculation for determining the single ASP payment limit. 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 for a biosimilar biological product is determined using the methodology in section 1847A(b)(6) of the Act 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 described 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 also clarified 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 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.

The following is a summary of the comments we received regarding our proposals and related discussion in the proposed rule. In general, a number of commenters opposed a single payment amount for all biosimilars that rely on a common reference product. Commenters included individuals, pharmaceutical manufacturers, patient advocate groups, providers, and members of the House of Representatives. Most of these commenters stated that the CMS proposal will create access issues, and that grouping payment for biosimilar biological products is inconsistent with the statute. Other concerns included a belief that as a result of the proposal, prescribers' choices will be limited, that tracking or pharmacovigilance activities will be impaired, and that innovation and product development will be harmed, leading to increased costs for biosimilar products. Many of these commenters suggested that CMS determine a payment amount for each biosimilar. However, several commenters also supported CMS's proposal to amend the regulation text effective January 1, 2016. Commenters who supported the proposal also suggested that CMS remain mindful of its policy as the biosimilar marketplace evolves. However, several commenters asked that policy decisions be delayed while issues such as naming conventions and interchangeability standards are finalized by the FDA.

We would also like to remind readers about the scope of CMS's proposals. The proposals and additional discussion encompass payment policy under Medicare Part B; they do not encompass claims processing instructions, coverage policies, clinical decision making and the clinical use of biosimilars, FDA policies, or payments made by other payers. However, some of these issues overlap with payment policy and we have mentioned them as they pertain to payment policy or specific comments in the more detailed comment responses below.

Comment: Some commenters stated that the proposed rule did not include sufficient explanation of the reasoning behind the proposed change to the regulation text.

Response: Our proposal would amend § 414.904(j) to be consistent with a biosimilar payment approach that groups biosimilars with a common reference product. We believe that the proposed change to § 414.904(j) would more accurately reflect our interpretation of section 1847A(b)(8)(A) of the Act, which states that the payment for a biosimilar biological product is determined using the methodology in section 1847A(b)(6) of the Act applied to a biosimilar biological product for all NDCs assigned to such product in the same manner as such paragraph is applied to the multiple source drugs described in such paragraph.

Our rationale for this clarification arises from our understanding of both the abbreviated approval pathway for biosimilars and the amendments to section 1847A of the Act to address payment for biosimilars. As further explained below, we believe the approach we are finalizing in this rule is consistent with our statutory authority.

The Affordable Care Act contains two provisions for biosimilars: one setting forth a Medicare Part B payment methodology (section 3139); and one setting forth an approval pathway (section 7002). Our proposal addressed Part B payment policy, and therefore, focused on section 3139, but section 7002 is also relevant.

Section 3139 of the Affordable Care Act amends section 1847A of the Act to define the term ''biosimilar biological product'' to mean ''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 7002 of the Affordable Care Act defines the terms biosimilar and biosimilarity for purposes of section 351 of the PHSA to mean (A) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and (B) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.

This statutory definition establishes that biosimilar products and their corresponding reference products share a number of significant similarities. That is, the biosimilar biological product and reference product must rely on data from a single biologics license application (BLA)—the BLA of the reference product; they share high degree of similarity in the active component; and have no clinically meaningful differences in safety, purity, and potency. While we have not stated, nor are we suggesting now, that these similarities must (or even should) drive clinical decision making for an individual patient, they persuade us that our proposed payment policy approach is reasonable.

Because of the degree of similarity that biosimilars share with their reference products, we believe it is appropriate to price biosimilar products in groups in a manner similar to how we price multiple source or generic drugs. In other words, it is reasonable to look to our payment policy for multiple source drugs to guide our policy on payment for biosimilars because multiple source drugs are biosimilars' closest analogues compared to the other categories of drugs and biologicals for which we make payment under section 1847A of the Act, such as single source drugs. Of course, we acknowledge the comparison between biosimilars and multiple source drugs is not a perfect one because of the distinct approval processes, statutory definitions, and potentially, the differences in molecular complexity between drugs and biologicals. From the perspective of part B drug payment policy, however, we believe that, the abbreviated pathway for biosimilar approval and the abbreviated pathway for generic drug approval have relevant parallels—such as the approval of a predecessor product (a reference product for biosimilars; an innovator product for drugs) and the comparison of a product that is being approved through an abbreviated pathway to the predecessor. Further, we believe that biosimilar products and multiple source drugs will have similar marketplace attributes. Although lack of statutory authority prevents us from pricing a biosimilar reference product with biosimilar products, like multiple source drugs, we see biosimilars competing for market share with each other, as well as competing with the reference or innovator product.

Finally, how the payment provision in section 3139 of the Affordable Care Act addresses interchangeability also supports the position that biosimilars

can be treated like multiple source drugs. Under section 1847A of the Act, the potential for interchangeability does not factor into how payment is determined for a biosimilar. Neither the definitions in section 1847A, nor the requirements for how payment amounts are calculated treat biosimilars that are interchangeable (and could be potentially be substituted much like generic drugs) differently from other biosimilars. This suggests that Congress contemplated that we should group all biosimilars with a common reference product (in a manner that is similar to multiple source drugs).

Thus, in light of our belief that biosimilars with a common reference product are—for payment policy purposes—analogous to multiple source drugs, we believe that our biosimilars payment policy should mirror payment policy for multiple source drugs to the extent possible. We further believe, as described below, that the statute supports such an approach. We would like to make clear that although our payment policy approach for biosimilars is analogous to our payment policy for multiple source drugs as described in this response, we take no position on whether a biosimilar is completely or partially analogous to its biologic reference product as a clinical matter.

Comment: Many commenters believe that the proposal is inconsistent with the statute and with the regulation text at § 414.904(j). Most commenters who provided specific concerns believe that that the use of the singular form of ''product'' when used to describe payment for biosimilars in section 1847A of the Act requires that CMS determine separate ASP-based payment amounts for each manufacturer's biosimilar product. Commenters who provided specific concerns quoted some or all of section 1847A(b)(8) of the Act to support their argument that the statute requires that there be a single billing code and payment rate for each biosimilar product. The commenters focused use of the singular form of ''product,'' and said they believe it is a clear indication that the statute requires separate payment for each individual biosimilar product.

Response: We disagree with the commenters and believe that the proposed biosimilar payment approach is consistent with section 1847A of the Act.

We do not believe the use of the singular is dispositive of the issue. The statute directs CMS to apply the payment approach for a given biosimilar biological product in the same manner as such paragraph is applied to drugs described in such paragraph. ''Such paragraph'' is paragraph (b)(6) of section 1847A of the Act. Section 1847A(b)(6)(A) of the Act states that it applies to all drug products included within the same multiple source drug billing and payment code before setting forth the methodology for determining a volume weighted average sales price for multiple source drugs. The statute also specifies the use of this methodology for determining the average sales prices for single source drugs (under section 1847A(b)(4) of the Act) and biosimilars (under section 1847A(b)(8) of the Act). However, sections 1847A(b)(4) and 1847A(b)(8) of the Act differ in one significant respect; namely, that only section 1847A(b)(8) of the Act includes language that directs the payment determination in paragraph (b)(6) to be carried out in the same manner as paragraph (b)(6) is applied to drugs that are described in paragraph (b)(6). Because all drugs and biologicals paid for under section 1847A of the Act have their ASP-based payment allowances calculated using the methodology set forth in section 1847A(b)(6) of the Act, to give meaning to the phrase that directs that the payment determination be made in the same manner as paragraph (b)(6) is applied to drugs described in paragraph (b)(6), we concluded that the statute authorizes us to develop coding and pricing for biosimilars in the same manner as for multiple source drugs. Our conclusion is based on the language in section 1847A(b)(6)(A) of the Act, which clearly refers to drug products that are within the same multiple source drug billing code. The paragraph also states that the amount specified (or determined by this approach) is the amount determined using the mathematical calculation in section 1847A(b)(6) of the Act that is applied to all drugs and biologicals paid for under section 1847A of the Act.

We further note that the commenters have emphasized use of the singular form ''biosimilar product'' to support their statutory interpretation. However, we do not believe whether ''product'' is used in the singular or plural is the critical point for determining coding and pricing of biosimilars. Rather, we believe the critical point is that Congress is directing us to use the methodology specified in section 1847A(b)(6) of the Act for all drug products that are included with the same multiple source drug billing and payment code to determine coding and pricing for biosimilars.

We believe it is reasonable to interpret the phrase that directs the pricing to be carried out in the same manner as such paragraph (that is, paragraph (b)(6)) is applied to drugs described in paragraph (b)(6), to mean that we have the discretion to calculate an ASP-based payment methodology for grouped biosimilars in the same way that we have discretion to calculate an ASP-based payment methodology for grouped multiple source drugs. CMS's historical practices have been to develop coding and pricing for programmatic purposes. This approach is consistent with the provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), which required CMS to adopt standards for coding systems that are used for reporting health care transactions, and in October of 2003, the Secretary of HHS delegated authority under the HIPAA legislation to CMS to maintain and distribute HCPCS Level II Codes (the alphanumeric codes that are typically used in part B drug claims) (Source: *https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/HCPCSLevelIICodingProcedures7-2011.pdf*. We believe it is reasonable to believe that Congress is aware of this longstanding policy and that the policy would apply for the pricing and payment of biosimilars. Indeed, had Congress intended a specific and different result than the one we proposed, it could have required a separate payment allowance for each biosimilar biological product. Section 3139 of the Affordable Care Act could have explicitly stated that payment for a biosimilar biological product be determined as provided in section 1847A(b)(4) of the Act. We note that Congress did not specify in the statute how CMS must assign biosimilars to a HCPCS billing and payment code other than direct us to section 1847A(b)(6) of the Act and do so in the same manner as we do for all drug products included with the same multiple source drug billing and payment code.

For these reasons, we disagree with commenters that a proposal to group biosimilar products together for Part B payment purposes and the associated coding approach are inconsistent with the statute. While other interpretations of the statute may be possible, we believe our interpretation is consistent with the statute. We also note that the proposed revised regulation text would not preclude CMS from separating some, or all, of a group of biosimilars for payment (and the creation of one or more separate HCPCS codes) should a program need to do so arise.

Comment: One commenter stated that if Congress had intended that the multiple source drug approach could be used to pay for biosimilars, it would have so specified. This commenter further stated that the detailed direction

in the statute that describes the payment for multiple source drugs, including the use of Therapeutic Equivalency ratings, suggests that Congress would have included the same amount of detail for biosimilars had Congress intended for payment to be grouped.

Response: We disagree with this comment. Therapeutic equivalency ratings for drugs have been published by the FDA in the ''Orange Book'' since 1980 (source: *http://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm*). The Medicare Modernization Act, which authorized the use of the ASP payment methodology and defined multiple source drugs for purposes of the ASP payment methodology, was enacted in 2003. We believe that the level of detail in statutory provisions for the payment of multiple source drugs reflects 23 years of experience that Congress could draw on as it carefully crafted a payment approach. Also, the ''Orange Book'' limits its scope to approved drug products; we would not expect ratings for biological products to be included in this publication.

In contrast, the Affordable Care Act was enacted in 2010, when there was no interchangeability or equivalency pathway available for biosimilar biological products. The ''Purple Book'', a list of biosimilar and interchangeable biological products licensed by FDA, was published in 2014. However, no interchangeable products are currently on the market, nor are any expected to enter the marketplace in the next year, and interchangeability standards have not yet been finalized.

We attribute this contrast to the fact that there is insufficient experience or information at this time to create an approach for biosimilars that is as specific as that which exists for multiple source drugs, and therefore, do not believe that the lack of specificity upon which the commenter relies is indicative of Congressional intent to limit CMS's ability to group biosimilars together for coding and payment purposes.

Comment: Several commenters also cited Senate Committee language that they believe indicates clear Congressional intent to pay for biosimilars separately. (See Senate Committee Report 111–089, pages 225–226 located at *http://www.gpo.gov/fdsys/pkg/CRPT-111srpt89/pdf/CRPT-111srpt89.pdf*.) Commenters focused on the final paragraph of the Committee language as the basis for their opinion about Congressional intent. Specifically, commenters noted that the committee report states that the Committee Bill would allow a Part B biosimilar product approved by the Food and Drug Administration and assigned a separate billing code to be reimbursed at the ASP of the biosimilar plus 6 percent of the ASP of the reference product. A biosimilar biological product would mean a 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 the Public Health Service Act. The term reference biological product means the licensed biological product that is referred to in the application for the biosimilar product.

Commenters contended that this report's reference to assigning a separate billing code for a biosimilar biological product shows that Congress intended that CMS make separate payment for each biosimilar biological product.

Response: We disagree with these comments for two reasons. First, we believe that the statements commenters characterize as inconsistent with our interpretation of the statute are actually consistent with our interpretation. Second, although commenters focused on one statement in particular, a review of the entire relevant section of the report further indicates our interpretation seems to be consistent with the committee's views.

As noted above, commenters believe that the report indicates that Congress intended biosimilar biological products each to have their own ASP-based payment allowance. However, a closer look at the relevant language indicates that instead, Congress was acknowledging CMS's current coding discretion: ''The Committee Bill would allow a Part B biosimilar product approved by the Food and Drug Administration and assigned a separate billing code to be reimbursed at the ASP of the biosimilar plus 6 percent of the ASP of the reference product'' (emphasis added). This statement's use of the phrase ''would allow'' (as opposed to ''would require'') indicates that CMS has discretion, rather than the obligation, to price biosimilars separately. Moreover, the statement appears to acknowledge that such separate payment would occur only when the biosimilar is assigned its own billing and payment code.

Similarly, the rest of this section of the report supports the notion that biosimilars are analogous to multiple source drugs. The report indicates the committee's view that the approval pathway to be enacted for biosimilars would be comparable to the approval process for generic drugs, stating:

> [t]he new [abbreviated biological] regulatory pathway *would be analogous* to the FDA's existing authority for approving generic chemical drugs under the Drug Price Competition and Patent Term Restoration Act of 1984 (P.L. 98–417). Often referred to as the Hatch-Waxman Act, this law allows the generic company to establish that its drug product is chemically the same as the already approved innovator drug, and thereby its application for FDA approval relies on FDA's previous finding of safety and effectiveness for the approved drug.

For these reasons, we believe that contrary to commenters' assertions, our proposed approach to coding and payment for biosimilar biological products is consistent with the Senate Committee report.

Comment: One commenter also suggested that the proposal would be contrary to a 2009 court decision (*Hays v. Sebelius*) which does not allow Medicare drug payments to be based on the least costly item in a group.

Response: We do not believe that the proposed approach is inconsistent with the *Hays v Sebelius* ruling on least costly alternatives. In that case, the Court ruled that the Secretary could not rely on section 1862(a)(1)(A) of the Act to pay for one drug product in a given HCPCS code using the lower price for a drug product in a different HCPCS code because it was the ''least costly alternative.'' Instead, the court ruled that the Secretary must either cover or deny payment altogether if the service or item is not reasonable and necessary. As we have explained earlier, we believe that the statutory authority to group biosimilars for payment exists in section 1847A of the Act. Payment for groups of biosimilars will be made under the statutory provision that requires the determination of a weighted average price. Since the approach is consistent with statutory authority for grouping biosimilars and the use of a weighted average calculation (not a partial payment), we believe that our approach is consistent with *Hays v. Sebelius*.

Comment: Several commenters stated that the proposed Part B payment policy is not consistent with Medicare Part D and particularly Medicaid requirements. Some commenters also stated that the inconsistencies would impact rebate calculations.

Response: Medicare Part B groups and pays for drugs and biologicals differently from Medicare Part D and Medicaid. Drug payment under these programs is authorized by three different parts of the statute, and although they share some similarities, for the most part these payment approaches do not overlap. The different statutory and operational

requirements of each program can lead to differences between how drugs and biologicals are treated under each program. The biosimilar payment policies we are finalizing in this rule relate only to the Part B payment requirements described in section 1847A of the Act.

Comment: Some commenters stated that blending of biosimilar product payment amounts is an indication that CMS believes that biosimilars are generic drugs. Commenters expressed concerns about a range of issues related to this position. These concerns focused on provider impact, including negative effects on prescribers' choice, medical record keeping and billing. Some commenters also mentioned that effects on prescribers' choice would include a greater emphasis on cost rather than clinical considerations. Other commenters expressed concerns that brands of biosimilars that may be approved for fewer than all indications approved for the reference product would lead to confusion about the identity of which product was administered to the patient, and make adherence to billing and coverage requirements difficult.

Response: We appreciate that there are differences between multiple source small molecule drugs and biosimilar biological products. The proposals and related discussion in the proposed rule relate only to payment and coding for biosimilar biological products. Thus, although our payment policy for biosimilars is analogous to our payment policy for multiple source drugs, we take no position on whether a biosimilar is completely or partially analogous to its biologic reference product as a clinical matter.

Issues such as the clinical use of drugs and medical recordkeeping are outside the scope of this rule.

We are aware of situations where products with different indications share a HCPCS code; [3] however, we are not aware of significant instances of provider confusion resulting from these groupings and therefore, we do not believe that this concern should drive the current policy approach for biosimilars.

Comment: Many commenters discussed how CMS could approach interchangeability between biosimilar products. Positions varied; for example, some commenters suggested grouping interchangeable biosimilars together, others suggested paying interchangeable biosimilars separately. Some commenters also asked that CMS consider blending the biosimilar payment calculation so that the reference product is included in the ASP calculation.

Response: CMS' proposals and related discussion about how biosimilar product ASPs would be grouped did not encompass clinical interchangeability, substitution of biosimilar products or clinical decision making when prescribing these products. While section 7002 of the Affordable Care Act (the Biologics Price Competition and Innovation Act of 2009) outlines specific criteria for a determination of interchangeability, at this point, there are no interchangeable biosimilars products on the market. Thus, we are not addressing whether a product's interchangeability status should be the basis for a different approach to Part B payment in this rule at this time. To the contrary, our proposed approach, which we are finalizing in this rule, would preserve our discretion to group interchangeable biosimilars together for payment purposes in the same manner we will code and pay for biosimilars that do not have a designation of interchangeability under section 7002 of the Affordable Care Act. However, given that no interchangeable biosimilars are currently available, we will consider whether further refinements to our biosimilar payment policy may be necessary as the market develops in the future.

In response to comments recommending that CMS include the reference product in the ASP payment calculation for biosimilars, we note that such an approach is not consistent with section 1847A of the Act.

Comment: Some commenters stated that the payment policy approach may encourage inappropriate interchange between biosimilar products.

Response: We disagree with this comment. We understand that groups of biosimilar products may not have all of the same indications as the reference product in common, all the same indications as other biosimilars within that group, or may have other clinical differences such as fewer than all routes of administration as the reference product. We are not aware of situations where providers have assumed that biological products grouped together for payment purposes are clinically equivalent, or that confusion regarding coverage, billing, coding, or medical records has been a problem.

Comment: A number of commenters also expressed concern about how grouping biosimilar products for payment purposes when they have a common reference product would affect the marketplace. Commenters stated that CMS's proposal would discourage product development and innovation and would affect this new segment for the drug and biological marketplace in a negative manner. Commenters also cited the high risk for biosimilar product manufacturers because of factors such as high product development costs and long product development timelines for biosimilars (compared to small molecule drugs), and suggested that grouping biosimilar products into a single payment code could lead to a competitive environment that decreases profit margin, forcing manufacturers to leave the marketplace, resulting in less competition, access problems for patients and higher prices. Some of this information appears to have been extrapolated from experience with (small molecule) Part B drugs. However, several commenters who discussed potential differences between biosimilars and drugs suggested that assessing the proposed policy's impact as the market develops and actual experience with this new category of products is gained is a reasonable approach. One commenter believed that the size of the biosimilar marketplace and the regulatory environment created less risk for biosimilar manufacturers than for reference product manufacturers and that CMS's proposed approach would be an incentive for price competition. One commenter suggested that separate pricing of biosimilars was comparable to price protection and that separate pricing is not supported by actual facts. Another commenter stated that separate pricing would reduce competition and would result in a market where biosimilars were sold as branded drugs with small discounts.

Response: We do not agree that our approach to Medicare Part B payment policy will stifle or damage the marketplace. Biological products are heavily utilized in Part B and account for a significant share of spending compared to drugs. According to a GAO report dated October 12, 2012 (GAO–13–46R High Expenditure Part B Drugs, *http://www.gao.gov/products/GAO-13-46R*, pages 6 and 7), Medicare and its beneficiaries spent $19.5 billion on Part

[3] For examples: J3489 zoledronic acid injection includes Reclast® (indicated for osteoporosis and Paget's disease of the bone), Zometa® (indicated for hypercalcemia of malignancy, and the treatment of multiple myeloma and bone metastases of solid tumors) and generic versions of both zoledronic acid products; J0153 adenosine injection includes Adenocard® (indicated for the treatment of certain types of supraventricular tachycardia), Adenoscan® (indicated as an adjunct to thallium stress tests for patients who cannot exercise adequately) and generic versions of both adenosine products. Also, certain lyophilized versions of intravenous immunoglobulins (IVIG) have been paid using the HCPCS code J1566 (and its predecessor codes); at this time, the biological products in this HCPCS code do not have the same indications.

B drugs and biologicals in 2010. The 10 most expensive products accounted for about $9.1 billion of that amount and 8 of 10 of the highest expenditure Part B drugs were biologicals. Given the robust marketplace for biologicals, we do not believe that a payment policy that encourages greater competition will drive manufacturers out of the market. To the contrary, we believe there is a strong need for lower cost alternatives to high cost biologicals, and the statute provides an incentive for the development of the biosimilars market by providing for reimbursement that includes a 6 percent add-on of the more expensive reference product's ASP. Competition fosters innovations that redefine markets. Overall, the availability of generic drugs, in competition with each other and with branded products, has improved price and availability of drugs. Competition among biosimilars can do the same for Medicare beneficiaries—improving the quality, price, and access. We agree that it is desirable to have fair reimbursement in a healthy marketplace that encourages product development, and we agree with commenters who support future refinements to policy as needed based on actual experience with this new segment of the market.

Comment: Several commenters suggested that CMS consider delaying action on the proposals to allow for FDA policies on issues like naming and interchangeability standards to be developed, and to allow the marketplace to develop.

Response: We disagree with this comment. Issues such as the naming convention and specific interchangeability standards are complicated, may require some time to finalize, and are not directly relevant to Medicare Part B payment policy. Rather, we believe it is important to implement a payment policy for biosimilars now, before the second biosimilar for any reference product becomes available, in order to provide certainty for providers and suppliers who will be billing Medicare for these products in the near term.

Comment: Several commenters stated that the proposed approach is consistent with savings for the beneficiary and sustainability of the Medicare program.

Response: We thank the commenters for their support.

Comment: Commenters stated that the proposed approach would negatively impact tracking and safety monitoring because products could not be distinguished on claims. Commenters stated that separate codes are necessary to track the safety of biosimilars and to conduct effective pharmacovigilance efforts, and a few commenters also expressed concerns that clinical outcomes studies would be difficult to conduct. These commenters expressed concern that obtaining data about potential differences in safety and efficacy would be difficult if Medicare paid for all biosimilars that are related to a common reference product the same amount and used a single HCPCS billing code to indicate that a biosimilar product was administered. However, several commenters suggested other possible mechanisms for using claims data to track biosimilar products, including the use of modifiers.

Response: Pharmacovigilance and the postmarketing assessment of the safety and efficacy of drugs and biologicals are frequently conducted by the FDA. Coding determinations, including the assignment of HCPCS codes, are a part of Medicare payment policy. The FDA's determinations are outside the scope of this rule. However, we agree that it is desirable to have the ability to track biosimilars. We also agree with commenters who suggested that alternative means of tracking biosimilar are possible. We will provide guidance on mechanisms for tracking drug use through information on claims in the near future. Specifically, we are developing an approach for using manufacturer-specific modifiers on claims to assist with pharmacovigilance.

Final Decision: After considering the comments, we are finalizing our proposal 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 finalizing the proposal's effective date: January 1, 2016.

Comment: Several commenters also acknowledged or agreed with the use of WAC-based pricing during the initial period of sales while an ASP is not available. One commenter understood CMS' discussion to mean that a greater reliance on invoice pricing would result.

Response: We are not changing how pricing determinations by contractors (MACs) are made in situations where national pricing data is not available. We appreciate the comments on our discussion about how biosimilar products will be paid before an ASP is available.

In addition to the comments on biosimilars discussed, we received comments about specific issues pertaining to HCPCS coding and descriptor development such as the use of J codes and Q codes, claims submission and medical record keeping (including the use of NDCs on Medicare Part B claims), notification of substitution to providers and pharmacy dispensing and substitution activities, coverage policies for biosimilars, effects on other payers, Therapeutic Equivalency determinations based on either the Orange Book or interchangeability determinations based on the Purple Book, and the FDA approval process for biosimilars. Comments on these issues are outside the scope of this rule. Therefore, these comments are not addressed in this final rule with comment period.

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 discussed the IGI changes to the MFP proxy series in the CY 2016 PFS proposed rule (80 FR 41802) and in this final rule with comment period, 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 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 services. 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 are integrated into broader care management and continuous quality improvement (QI) programs. Successful QI programs in turn have provider-led multidisciplinary teams that 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.[4]

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. A second 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

[4] Timbie J, Hussey P, Burgette L, *et al*. Medicare Imaging Demonstration Final Evaluation: Report to Congress. 2014 The Rand Corporation.

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 a number of sets of AUC developed by different provider-led entities, and an array of CDS mechanisms, from which providers may choose.

3. Statutory Authority

Section 218(b) of the PAMA amended Title XVIII of the Act by adding a new section 1834(q) 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 the proposed rule, we primarily addressed 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, 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) of the PAMA requires consultation with physicians, practitioners, and other stakeholders, and notice and comment rulemaking. We believe the PFS calendar year rulemaking process is the most appropriate and administratively feasible implementation vehicle. Given the timing of the PFS rulemaking process, 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 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 proposed 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 also proposed to define the term, ''provider-led entity,'' which is included in section 1834(q)(1)(B) of the Act so that the public had 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 (PLE) 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 the CY 2016 PFS 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 did not include proposals to implement section 1834(q)(3) of the Act in the CY 2016 PFS proposed rule. We needed 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 intend 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. If we were to follow a similar process for CDS as we have for specifying AUC, the initial list of CDS mechanisms would be available in the summer of 2017. 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 PFS, hospital outpatient prospective payment system, and the ambulatory surgical center payment system.

We did not include proposals to implement section 1834(q)(4) of the Act in the CY 2016 PFS 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. Therefore, we do not intend to require that ordering professionals meet this requirement by January 1, 2017.

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 did not include proposals to implement these sections in the CY 2016 PFS proposed rule, we proposed to identify outlier ordering professionals from within priority clinical areas. Prior clinical areas will be identified through subsequent rulemaking.

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 (as some eligible PLEs have large libraries 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 the CY 2017 PFS rulemaking process, with the benefit of public comments, we will begin to identify 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 proposed to amend our regulations to add a new § 414.94, ''Appropriate Use Criteria for Certain Imaging Services.''

a. Definitions

In § 414.94(b), we proposed 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 we provide a description of the terms we proposed to codify to facilitate understanding and encourage public comment on the 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 furnished) and a furnishing professional (the physician or practitioner that actually performs the imaging service and provides the interpretation of the imaging study) involved in imaging services. In some cases the ordering professional and the furnishing professional are the same.

This AUC program only applies in applicable settings as defined in section 1834(q)(1)(D) of the Act. An applicable setting would include a physician's office, a hospital outpatient department (including an emergency department), an ambulatory surgical center, and any provider-led outpatient setting determined appropriate by the Secretary. The inpatient hospital setting, for example, is not an applicable setting. Further, the program only applies to applicable imaging services as defined in section 1834(q)(1)(C) of the Act. 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 proposed to clarify the definition for appropriate use criteria, which is defined in section 1834(q)(2)(B) of the Act to include only criteria developed or endorsed by national professional medical specialty societies or other PLEs, 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 proposed 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 proposed to define new terms in § 414.94(b). A PLE 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 or modified by a qualified PLE, or when a qualified PLE endorses AUC developed by another qualified PLE. A PLE is not considered qualified until CMS makes a determination via the qualification process finalized in this CY 2016 PFS final rule with comment period. We introduced priority clinical areas to inform ordering professionals and furnishing professionals of the clinical topics alone, clinical topics and imaging modalities combined or imaging modalities alone 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 definitions in § 414.94 are important in understanding implementation of the program. Only AUC developed, modified or endorsed by organizations meeting the definition of PLE would be considered specified applicable AUC. As required by the statute, specified applicable AUC 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 proposed 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 proposed to include regulations to implement the first component of the Medicare AUC program—specification of applicable AUC. We first proposed a process by which PLEs (including national professional medical specialty societies) become qualified by Medicare to develop or endorse AUC. The cornerstone of this process is for PLEs to demonstrate that they engage in a rigorous evidence-based process for developing, modifying, or endorsing AUC. It is through this demonstration that we proposed to meet the requirements of section 1834(q)(2)(B) of the Act to take into account certain considerations for specifying 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 of an AUC. Rather, we proposed to establish a qualification process and requirements for qualified PLEs to ensure that the AUC development or endorsement processes used by a PLE result in high quality, evidence-based AUC in accordance with section 1834(q)(2)(B). Therefore, we proposed that AUC developed, modified, or endorsed by qualified PLEs will constitute the specified applicable AUC that ordering professionals would be required to consult when ordering applicable imaging services.

To become and remain a qualified PLE, we proposed to require a PLE 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 PLE 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 proposed that the PLE'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 PLE in the development of AUC. We proposed that the PLE must have a publicly transparent process for identifying and disclosing potential conflicts of interest of members on the multidisciplinary AUC development team. The PLE 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. In addition, the information must be made available to the public, if requested, in a timely manner.

For individual criteria to be available for practitioners to review prior to incorporation into a CDS mechanism, we proposed that the PLE 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 recognized 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 proposed 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 PLEs 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 proposed that a PLE'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 AUC program, local adaptation of AUC will 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 PLEs can get local feedback at the outset and build alternative options into the design of their AUC. Third, local PLEs 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 proposed that PLEs must apply to CMS to become qualified. We proposed that entities that believed they met 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 PLE. Applications will be accepted each year but must be received by January 1. A list of all applicants that we determine to be qualified PLEs will be posted to our Web site by the following June 30 at which time all AUC developed or endorsed by that PLE will be considered to be specified AUC. We proposed all qualified PLEs 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 provide information about the CDS mechanism consultation to the furnishing professional, 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 proposed 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 proposed 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 proposed 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 PLE qualification process that should ensure evidence-based AUC development, we remain concerned that non-evidence-based criteria may be developed or

endorsed by qualified PLEs. Therefore, we proposed 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 proposed 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 proposed 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 PLE 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 PLE 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 proposed 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 proposed definitions of terms necessary to implement the AUC program. We were particularly seeking comment on the proposed definition of PLE as these are the organizations that have the opportunity to become qualified to develop, modify, or endorse specified AUC. We also proposed an AUC development process which allows some flexibility for PLEs but sets standards including an evidence-based development process and transparency. In addition, we proposed the concept and definition of priority clinical areas and how they may contribute to the identification of outlier ordering professionals. Lastly, we proposed to develop a process by which non-evidence-based AUC will be identified and discussed in the public domain. We invited the public to submit comments on these proposals.

The following is a summary of the comments we received regarding our proposals.

Comment: There was disagreement among commenters regarding the proposed definition of PLE. Numerous commenters supported finalization of the proposed definition for PLE. One commenter noted that national professional medical specialty societies were specified in PAMA as an example of a PLE and therefore the definition should encompass such societies. Another commenter requested the agency provide a definition of national professional medical specialty societies. Some commenters requested the definition ensure that provider groups, physicians, and alliances of provider organizations are included. Some commenters requested that the definition of PLE be expanded to include radiology benefit management (RBM) or similar companies, health plans and manufacturers. These commenters stated that providers, physicians and other practitioners are integrally involved if not in control of their AUC development processes. They stated that by including these entities in the definition of PLE, there would be more AUC available in the market (which they believe would yield healthy competition). They also indicated that these entities can move more quickly to update AUCs. Commenters in support of RBMs stated that national professional medical specialty societies had potential conflicts of interest when developing AUC for use by their own medical specialty as some specialties are paid by performing imaging services. Commenters in support of national professional medical specialty societies state that RBMs had potential conflicts of interest and were incentivized to control costs. Commenters also expressed conflicting opinions regarding the intent of the term ''provider-led entities'' as used in section 218(b) of the PAMA.

Response: We agree with the commenter that national professional medical societies were identified in the statute as an example of the entities that should fall within the definition of PLE. The proposed definition of PLE explicitly included national professional medical specialty societies, as well as organizations comprised primarily of providers and actively engaged in the practice and delivery of health care. The way that national professional medical societies and other similar organizations are structured, many would not have been considered ''actively engaged in the practice and delivery of healthcare'' under the proposed definition. This is because national professional medical specialty societies and other similar entities do not, as an organization, deliver care to patients. Therefore, we are modifying the proposed definition of PLE to finalize a definition that focuses on the practitioners and providers that comprise an organization and not on whether the organization, as an entity, delivers care. This approach subsumes national professional medical specialty societies whose members are actively engaged in delivering care in the community and eliminates the need to establish a separate definition for national professional medical specialty societies as they are now an example of a PLE. This will also include alliances and collaboratives of hospitals and hospital system.

Some commenters suggested that physicians and other practitioners are involved in the AUC development process and, therefore, should be considered PLEs. However, we believe the AUC development process typically would be embedded within a larger organization, and the organization as a whole may not be primarily comprised of practitioners. We continue to believe that the statute is intended to focus on the structure of the entire organization, and to require that it be ''provider-led.'' We believe that the PLE definition must apply to the organization as a whole, as processes that are embedded within the organization are not the same as a separately identifiable entity. We do not believe the modified definition of PLE that we are finalizing will limit the AUC market or the participation of third parties (such as RBMs) in the AUC development process. There may be opportunity for third parties to collaborate with PLEs to develop AUC.

Comment: Some commenters expressed concerns that the process to become a qualified PLE is more restrictive than section 218(b) of the PAMA requires and could prohibit some organizations with evidence-based AUC from participating in the program, which could limit physician and practitioner choice for AUC consultation.

Response: Section 1834(q)(2)(A) of the Act, as added by section 218(b) of the PAMA, requires that we specify AUC for applicable imaging services only from among AUC developed or endorsed by

national professional medical specialty societies or other PLEs. Section 1834(q)(2)(B) of the Act requires that, in specifying these AUC, we must take into account whether the AUC have stakeholder consensus, are scientifically valid and evidence-based, and are based on published studies that are reviewable by stakeholders. We believe the process we proposed to identify qualified PLEs is essential to ensuring that we take into account the factors described in the statute.

Comment: Regarding our proposal to require that, in order to be considered a qualified PLE, the PLE's AUC development process be led by a multidisciplinary team with specific characteristics, some commenters requested that the multidisciplinary team should include more than the minimum three members we had proposed, with some commenters suggesting upwards of 15 members. Other commenters suggested the requirements for the team should not restrict the participation of any qualified participants; in other words, expertise should not be dictated entirely by CMS and teams should have the option to add whomever they determine appropriate. Still other commenters suggested that CMS should require representation on the multidisciplinary team from primary care, industry, patient advocates and insurers and experts on the imaging study and clinical topic.

Response: We agree that the multidisciplinary team would benefit from additional representation and, more specifically, from representation by primary care practitioners, because a large proportion of imaging orders will be made by primary care practitioners. In response to these comments, we are modifying our proposal to instead require that the multidisciplinary team must have at least seven members including a primary care practitioner. We are also modifying the requirements to clearly state that the required expertise in the clinical topic and imaging service related to the AUC that are being developed must be provided by practicing physicians. These modifications to the multidisciplinary team requirements align with many of the commenters' support for more representation from practitioners in the field.

We agree with the commenters' suggestions that the team should be required to include more members, and that the types of experts required on the team should also be expanded. In addition to primary care, we are also modifying our proposal to require that experts in clinical trial design and statistical analysis be required members of the team. While we do not agree that involvement from industry or patient advocates should be required on the team, we do believe that teams could benefit from dialogue with such stakeholders. In response to the commenters that expressed concern about CMS restricting team participation, we encourage teams to be inclusive and seek members with any other relevant expertise.

Comment: Some commenters expressed concerns regarding the burden associated with the evidence review process we proposed to require for qualified PLEs in the AUC development process. Commenters indicated that the evidence review process that we proposed to require would be expensive, as commissioned systematic reviews are costly, and the process would require a significant amount of time which would be burdensome especially for smaller organizations. Some commenters suggested replacing ''systematic'' with ''thorough'' in describing the evidence review process to avoid unintentionally requiring a commissioned systematic review, and to account for specific methods included in systematic reviews that may not be applicable to all advanced diagnostic imaging studies. One commenter recommended that the cost of systematic reviews and the costs associated with AUC development should be at least partially mitigated by government organizations like CMS, and tax incentives or grant money should be available to medical specialty societies to help offset the costs.

Response: While we understand the commenters' concerns about the cost and time necessary to comply with the proposed evidence review requirement for developing AUC, we believe that this is a fundamental to ensuring that AUC are evidence-based to the extent feasible as required by section 1834(q)(1)(B) of the Act. We also believe the proposed evidence review process is essential to ensuring that the AUC that are developed can serve their purpose, as indicated in section 1834(q)(1)(B) of the Act, to assist ordering professionals in making the most appropriate treatment decision for specific clinical conditions for individual patients. However, we believe some commenters might have misinterpreted the reference in the proposed rule to a ''systematic'' review. To clarify, we did not intend to require that the evidence review process must be accomplished by commissioning external systematic evidence reviews or technology assessments. We expect PLEs to undertake evidence reviews of sufficient depth and quality to ensure that all relevant evidence-based publications on trials, studies and consensus statements are identified, considered and evaluated; and that such reviews are reproducible. In response to the commenter that requested financial support in the development of AUC, we note that section 218(b) of the PAMA included no provisions authorizing funding tax incentives, grants, or other financial assistance to PLEs developing AUC.

Comment: Commenters requested clarification on the requirements for modifying and endorsing AUC. Some commenters suggested that qualified PLEs that modify or endorse AUC should be required to go through the same process required for initial AUC development while other commenters recommended different requirements for modification or endorsement of AUC. Other commenters stated that modification of AUC should not be permitted, and that evidence-based AUC should not be changed to fit local scenarios.

Response: We believe the same process and requirements should apply to the AUC development process for all qualified PLEs, and that modification of AUC should be accomplished using the same process and requirements that apply to the development of AUC. This will ensure that there is documented evidence for the modification. In the proposed rule, we did not intend to differentiate between the process and requirements for AUC development, modification, and endorsement by qualified PLEs. We are clarifying in this rule that this is because a PLE must be qualified to endorse another qualified PLE's AUC. Both entities would have followed the process to become qualified and both entities would be listed on the CMS Web site as such. Endorsement is not intended to be duplicative. In other words it is not necessary for the endorsing qualified PLE to duplicate the extensive evidence review process performed by the qualified PLE that developed the AUC set or individual criterion.

Regarding local adaption, we believe it is important to fit AUC to local circumstances, while also ensuring application of a rigorous process in doing so. However, only AUC modified by qualified PLEs can become specified applicable AUC.

Comment: Some commenters recommended that CMS identify specific evidence grading methodologies that AUC developers are required to use, for example the GRADE, AHRQ and USPSTF grading systems.

Response: We believe that evidence grading is an essential component of the

AUC development process and that AUC developers should have flexibility when working within the requirements we have set forth. In addition, one grading system may be more appropriate for AUC development for a certain clinical condition while another grading system may be best for another condition. Therefore, we will not require the use of specific grading mechanisms.

Comment: Some commenters requested clarification regarding the meaning of ''autonomous governance'' specific to the multidisciplinary team.

Response: In proposing that, in order to be a qualified PLE, the PLE's AUC development process must be led by at least one multidisciplinary team with autonomous governance, we intended to highlight the need for the multidisciplinary team to be independent in its work from influence and oversight by components of the PLE not involved or associated with the multidisciplinary team.

Comment: Some commenters requested the inclusion of a requirement for public comment and/or stakeholder feedback on AUC developed, modified or endorsed by qualified PLEs.

Response: We recognize that some AUC development processes could invite public comment. While we believe this would be appropriate, we do not believe we should establish this as a requirement for the development of AUC by a qualified PLE. We do however believe that public transparency of the resulting AUC and the corresponding evidence base is critical to this program. In order to be a qualified PLE, the PLE must post AUC on their Web site in the public domain that allows all developed AUC to be reviewed by all stakeholders.

Comment: Some commenters requested further clarification regarding the requirement for AUC to be reviewed and updated. Many had concerns that some PLEs would not update AUC on a frequent enough basis to capture changes in the medical literature. One commenter agreed with requiring regular reviews and updating, and another commenter suggested that review be continuous and should occur on a cycle shorter than 1 year.

Response: We agree that AUC should be reviewed and updated frequently and have included a requirement for qualified PLEs to go through this process at least annually. We believe that qualified PLEs that produce quality AUC should have a process in place to evaluate the state of the medical literature on an annual basis. These annual reviews will not always result in changes to the AUC, rather, it will ensure that the AUC reflect the current body of evidence.

Comment: Some commenters recommended including processes approved by the National Guidelines Clearinghouse (NGC) as examples of a rigorous evidence-based process, and that we grant provisional approval as qualified to PLEs that have met the NGC inclusion criteria and whose AUC are posted to the NGC.

Response: While the NGC serves as an important repository for clinical practice guidelines, we believe that the CMS application process for qualified PLE status is not overly burdensome as a stand-alone process. We believe our application process is appropriate to assure key aspects of AUC development. We also recognize that PLEs that have their AUC posted to the NGC may find that they are at an advantage in the application process to become a qualified PLE because they have already prepared a package with some similar information.

Comment: One commenter stressed the importance of allowing expert opinion in the AUC development process, especially when relevant studies are limited or lacking in available literature. The commenter also noted the importance of transparency and disclosure of conflict of interest for experts.

Response: The process of AUC development allows for the opportunity for expert opinion, especially as we expect the multidisciplinary team to be populated with such experts. In addition, in the literature review we would expect published consensus papers and similar documents to be identified and be part of the evidentiary review. AUC developers may choose to put their draft AUC into the public domain for comment and receive expert opinion in that manner.

Comment: One commenter recommended that CMS should initiate the AUC development process and use public comment, qualified PLEs and multidisciplinary committees to develop AUC.

Response: Section 1834(q)(7) of the Act clarifies that section 1834(q) of the Act does not authorize the Secretary to develop or initiate the development of clinical practice guidelines or AUC. Additionally, under section 1834(q)(1)(B) of the Act, AUC are defined as criteria only developed or endorsed by national professional medical specialty societies or other PLEs. As such, we do not believe it would be appropriate for us to develop or initiate the development of AUC for purposes of the program under section 1834(q) of the Act.

Comment: One commenter recommended that CMS create a concise list of AUC development requirements or create a template for entities to use for their application and post the list or template to the CMS Web site.

Response: At least for the first round of applications for qualified PLEs, we will not be making available templates or applications. CMS might consider developing such templates or applications in the future if we find it would be useful, efficient or necessary.

Comment: Some commenters expressed their confusion with the AUC terminology used in the proposed rule. One commenter recommended, for the sake of clarity, using the terms ''AUC'', ''AUC set'' and ''required AUC'' in the final rule and to revise the definition of AUC accordingly.

Response: We understand that there might have been some confusion, and we have revised the terminology used in this final rule with comment period to provide greater clarity. In general, when we refer to AUC we mean a set or library of AUC, and when we use the term ''individual criterion'' we are referring to a single appropriate use criterion.

Comment: Some commenters opposed our proposal to specify applicable AUC by first identifying qualified PLEs, and recommended instead that we specify a small group of AUC in order to meet the timeline specified under section 218(b) of the PAMA, and then expanding the list of AUC over time. Other commenters requested that we adopt a phased approach with a focus on AUC for a limited number of clinical conditions that would be used first in larger hospitals and health systems with gradual expansion to smaller practices.

Response: We believe some of these concerns will be addressed by clarifying our expected timeline which allows additional time for all impacted providers and practitioners to prepare for the AUC consultation program specified under section 1834(q) of the Act. There will be a delay in not only specifying applicable AUC and identifying qualifying CDS mechanisms, but these delays will necessarily result in a delay of the date when ordering practitioners will be expected to report on the Medicare claim form information on their consultation with CDS mechanisms.

Specified AUC must first exist prior to being loaded into CDS mechanisms, and qualified CDS mechanisms must exist prior to consultation by ordering professionals.

We fully anticipate that we will be able to finalize rules and requirements around the CDS mechanism and approve mechanisms through

rulemaking in 2017. This timeline will significantly impact when we would expect practitioners to begin using those CDS mechanisms to consult AUC and report on those consultations. We do not anticipate that the consultation and reporting requirements will be in place by the January 1, 2017 deadline established in section 218(b) of the PAMA. Again, we are not in a position to predict the exact timing of this deliverable; however, we do not anticipate that it will take place, conservatively, until CDS mechanisms are established through rulemaking. We do not agree that the requirement to consult with specified AUC should be limited to certain topics or program areas as we believe such consultation will help to improve appropriate utilization across-the-board. We believe that section 218(b) of the PAMA can be rolled out in a stepwise manner to allow adequate time for all providers and practitioners to prepare.

Comment: Some commenters recommended that priority clinical areas be established prior to AUC development and physicians and other practitioners be required to consult AUC only within these areas. Commenters stated priority clinical areas should focus on areas with AUC for which there are consistently available appropriateness ratings and improved practices resulting from AUC consultation. Other commenters recommended placing limitations on specified AUC, for example limiting the number specified for each clinical condition and limiting specified AUC to those developed by national professional associations.

Response: We do not agree that we should limit the areas in which AUC may be specified. We believe it is more advantageous to specify libraries of AUC because this program is intended to assist ordering professionals in making the most appropriate treatment decisions for a specific clinical condition for an individual with reference to ordering practices for all advanced diagnostic imaging services. However, we believe that the identification of priority clinical areas will allow for physicians and other practitioners to focus their efforts on clinical areas for which there is strong evidence and which may have high impact on patients and society. Our goal is to tie outlier calculations to these high impact clinical areas.

Comment: One commenter requested that we include a process by which AUC developed by national professional medical specialty societies that do not seek to be qualified PLEs can be considered specified applicable AUC and, thereby, incorporated into CDS mechanisms (for example, PLEs with small, specific AUC libraries).

Response: We do not believe it would be appropriate either to allow AUC to be specified that do not meet the development criteria we have established, or to presume that AUC developed by a national professional medical specialty society would meet the requirements of this rule or to develop a separate process for specifying individual appropriate use criterion other than through the PLE qualification process. The requirements for the AUC developed process logically apply whether the PLE is producing only a few subspecialty criteria or hundreds of criteria to covering a large portion of all advanced diagnostic imaging services.

Comment: Some commenters suggested that CMS ensure that PLEs provide all specified AUC to any developers of CDS mechanisms and do so in a similar manner in order to allow ordering professionals to choose any AUC and any CDS mechanism, and to promote innovation. Other commenters recommended requiring standardization of AUC for the purposes of CDS mechanism integration.

Response: While we are not able to respond fully to these comments in this rule, we believe comments regarding standardization of AUC and CDS mechanisms for purposes of interoperability are very important, and we intend to further consider these comments and address this issue through rulemaking next year.

Comment: One commenter requested that CMS ensure that AUC developers do not use the process to restrict the scope of practice and limit a CRNA's ability to provide comprehensive pain management care.

Response: We are not aware of AUC developed with the goal of limiting the scope of practice for any practitioners. However, should this become a concern, especially to the extent that the limitations might not be evidence-based, then we would take measures to review these AUC, possibly including a review by the MEDCAC of their evidentiary basis.

Comment: One commenter recommended that qualified PLEs that develop AUC for a priority clinical area should be required to produce AUC that reasonably encompass the entire scope of that priority clinical area, so as to ensure that ordering professionals cannot use only a very small number of criteria with the goal of participating in the program as little as possible.

Response: We agree that for a qualified PLE to identify their AUC as addressing a priority clinical area, the AUC must address the area comprehensively; and we are revising our regulations to include language that addresses this concern.

Comment: Some commenters requested clarification about the AUC consultation process. For example, commenters questioned whether ordering professionals are expected to consult all AUC developed by qualified PLEs or just the AUC incorporated into the CDS mechanism they use. Some commenters supported the former approach. Other commenters recommended that ordering professionals would only be required to consult and report on AUC included in priority clinical areas.

Response: Additional details regarding how this new program will be operationalized and what will appear on the Medicare claim form will be forthcoming in future rulemaking. However, section 218(b) of the PAMA does not expressly limit consultation to only a subset (priority clinical area) of AUC; rather, it is clear that AUC must be consulted for all advanced imaging services. Section 218(b) of the PAMA also recognizes the possibility that ordering practitioners could consult CDS and find no corresponding AUC. We anticipate that more details regarding consultation with CDS mechanisms and claims-based reporting will be released through rulemaking in CY 2017.

Comment: Some commenters expressed concern regarding conflicting AUC and conflicts between AUC and other policies (such as national coverage determinations). Some commenters requested clarification as to a reconciliation process for conflicting AUC and other commenters suggested that specialty societies work together to publish information regarding conflicting AUC.

Response: While we believe that qualified PLEs will be using an evidence-based AUC development process that will reduce the likelihood and frequency of conflicting AUC, we agree that conflicting AUC may be of concern. Conflicting AUC are now highlighted in our rule as an example of situations in which it might be appropriate for CMS and the MEDCAC to review the evidence base. Dramatically conflicting AUC may be a signal that one of them is not evidence-based. The MEDCAC could review the underlying evidence and the committee could discuss whether that evidence supports the conclusions of the AUC thereby exposing any non-evidence-based AUC.

Comment: Some commenters recommended including a mechanism to suspend or remove qualification for PLEs before the periodic requalification process in the event that the PLE has non-evidence-based AUC and does not take steps to remediate or remove those criteria. Concerns from commenters included that a qualified PLE might fail to follow the process, but continue to have their AUC specified and used by ordering practitioners. Further, there was concern by commenters that non-evidence-based AUC would continue to be used by ordering practitioners for an extended period of time since requalification only occurs every 5 years.

Response: We agree with this comment and have added language to enable us to take steps to remove the qualified status of qualified PLEs that have non-evidence-based AUC within their AUC libraries and do not take prompt measures to resolve or remove the criteria. In addition to this scenario of non-evidence-based AUC, it is important that we have the ability to remove the qualified status from a PLE that fails to meet any of the other requirements set forth in our regulations under § 414.94(c) relating to AUC development processes and transparency.

Comment: One commenter suggested that CMS accept applications to become a qualified PLE until March of 2016 rather than requiring them to be submitted by January 1, 2016. Other commenters request a further extension of the deadline, or postponement altogether of the PLE application process.

Response: We are finalizing the proposed deadline of January 1, 2016 for PLEs to apply to become qualified PLEs because we believe it is important that we avoid further delay of AUC specification and program implementation. We note that PLEs will have an annual opportunity to apply to become qualified.

Comment: Some commenters disagreed with our proposal to require qualified PLEs to reapply for qualification every 6 years, and were instead in favor of a shorter time frame for review.

Response: We carefully reviewed the timeline for reapplication and have determined that an application submitted by January of the 5th year of approval will receive a determination prior to the start of the qualified PLE's 6th year. Therefore, the cycle of approval for qualified PLEs is every 5 years. This is different than what was proposed as we had originally proposed a cycle that was every 6 years. As finalized, a PLE that becomes qualified for the first 5-year cycle beginning July 2016 would be required to submit an application for requalification by January 2021. A determination would be made by June 2021 and, if approved, the second 5-year cycle would begin in July 2021. For example:

Year 1 = July 2016 to June 2017
Year 2 = July 2017 to June 2018
Year 3 = July 2018 to June 2019
Year 4 = July 2019 to June 2020
Year 5 = July 2020 to June 2021
(reapplication is due by January 1, 2021)

We believe the reapplication timeline is appropriate and allows for PLEs, CDS mechanism developers and ordering practitioners to enter into longer term agreements without the constant concern that the PLE will lose its qualified status. We will assess whether a qualified PLE consistently has developed evidence-based AUC and met our other requirements at the time of requalification. We note, however, that if it appears that qualified PLEs are not maintaining compliance with our requirements for AUC development, we could reevaluate the requalification timeline in future rulemaking.

Comment: One commenter recommended listing all qualified PLEs on the CMS Web site.

Response: We agree with this comment and will list all qualified PLEs on the CMS Web site.

Comment: One commenter recommended a limit to the number of PLEs that can be qualified.

Response: We do not, at this time, believe it is necessary to limit the number of PLEs that can be qualified. If a PLE becomes qualified and is developing evidence-based AUC we believe they should have the opportunity for their AUC to become specified.

Comment: We received numerous comments regarding how to identify priority clinical areas. Some commenters recommended that CMS initially focus on a small number of high volume services. One commenter recommended limiting the priority clinical areas to only those with a strong evidence base rather than areas reliant on consensus opinions. Another commenter recommended including areas where a large gap exists between currently available AUC and studies that are ordered in the Medicare program (for example muscular-skeletal conditions, abdominal conditions). One commenter recommended that the priority clinical areas should clearly define cohorts of patients with common disease processes or symptom complexes. One commenter recommended that qualified PLEs identify the priority clinical areas or that CMS should accept proposals from qualified PLEs when identifying these areas. One commenter suggested that CMS consider imaging studies that have had high utilization rates over the past 10 years, conditions for which AUC have been most recently adopted where significant inappropriate use may still exist, and simple, common conditions.

Response: We appreciate these recommendations and believe that the proposals that we are finalizing will allow for consideration of varying elements in identifying priority clinical areas. We expect to propose the first priority clinical areas in next year's PFS rule based on stakeholder consultation, and hope to receive further, more specific public comments at that time.

Comment: Some commenters suggested that CMS identify a substantial number of priority clinical areas to ensure enough data are available to calculate outlier ordering professionals with statistical significance. One commenter recommended that, for the purpose of outlier identification, these areas should include those where there is wide clinical variance in appropriate ordering patterns.

Response: We appreciate these suggestions and will consider them when identifying proposed priority clinical areas.

Comment: Many comments strongly supported the proposed transparency requirements for qualified PLEs. Commenters supported the public posting of AUC, references to the information considered in developing AUC and AUC development, and the review and updating processes to qualified PLE Web sites. One commenter recommended posting all AUC development information to a Web site hosted by CMS. Another commenter requested clarification about acceptance of alternate means of making the information public (for example, hard copies upon request, electronically upon request, but not posted in full to the Web site).

Response: We agree that the transparency requirements are important and essential to this program. Public posting of the AUC and other required information to each PLE's Web site is required; and it will not suffice to make the information available in other, less accessible and transparent ways. It is our goal that the information be easily accessible and reviewable by all stakeholders. We do not anticipate posting this information on a CMS Web site as each qualified PLE retains

responsibility for public posting of the required information.

Comment: Most commenters supported our proposed policies on transparency and conflicts of interest for multidisciplinary team members. Some commenters recommended further strengthening these requirements to incorporate references to AUC-related activities or relationships specific to commercial, non-commercial, intellectual, institutional, patient/public arenas. Other commenters recommended requiring the exclusion of team members with any significant conflicts of interest. Some commenters recommended that we impose transparency requirements for individuals and organizations at the commercial level specific to CDS mechanism sales/marketing, licensing relationships and advisory board memberships. One commenter requested clarification regarding conflict of interest requirements for entities that endorse AUC.

Response: We agree that transparency and disclosure of conflicts of interest is essential for multidisciplinary team members, and we are clarifying in this final rule with comment period that these requirements apply to the team and to any other party involved in developing AUC including the qualified PLE itself. We disagree with the commenter's suggestion to categorically exclude through our regulations team members for whom there is a conflict of interest as those individuals may also have the greatest knowledge base for particular issues. Some conflicts may be unavoidable, and we believe transparency and disclosure will go far toward promoting objectivity. We believe that qualified PLEs should use their judgment to establish thresholds where certain conflicts would result in recusal or removal of an individual from the multidisciplinary team. We are aware that there are a number of existing templates, thresholds, and mechanisms that might reasonably apply to address conflicts of interest. We might address this issue further, and standardization of the treatment of conflicts could evolve through our annual rulemaking process. At this time we believe it is appropriate for conflicts to be disclosed and for the PLE to have a reasonable process in place to identify and address them. The final rule with comment period also provides for the information to be documented and available to the public upon request for a period of 5 years.

Comment: One commenter requested that transparency requirements specific to AUC and AUC development processes be balanced with ''intellectual property protection for evidence-based content produced by commercial entities . . .'' which could involve a process by which interested parties request access to criteria while intellectual property is protected. One commenter stated that CMS should not require public release of evidence-based content published under copyright protection.

Response: We support and have received strong support for the required public disclosure of these processes and resulting content. Transparency is essential to ensure all patients and stakeholders can review and understand how and why AUC are developed, and to which types of patients they do and do not apply. Making this information public is particularly important for ordering professionals when they are selecting the qualified PLEs and CDS mechanisms that best address their practice needs. CDS mechanism developers and qualified PLEs may need to enter into agreements for AUC to be loaded into the mechanisms and used by ordering professionals.

Comment: One commenter recommended that we adopt a requirement for AUC developers to disclose any participating medical specialty societies that do not endorse the AUC being developed and the rationale for their not endorsing.

Response: PLEs may choose to list which medical specialties societies agree with their AUC and which ones do not. However, we do not believe it would be appropriate for us to require this disclosure or explanation. By having AUC in the public domain, any organization may respond to the AUC and state their agreement or disagreement in any format they determine is appropriate.

Comment: Many commenters expressed significant concerns regarding the implementation timeline set forth in section 218(b) of the PAMA. Commenters questioned whether it is feasible or reasonable to meet the January 1, 2017 deadline to require consultation by ordering professionals with CDS mechanisms given that we do not anticipate finalizing requirements for CDS mechanisms until rulemaking for the CY 2017 PFS and CDS mechanism developers and ordering professionals will need 12–18 months to incorporate the requirements into clinical practice.

Response: We understand these concerns and agree that the timeline set forth in section 218(b) of the PAMA is difficult to meet. As such, we will delay implementation of certain AUC program components including the requirement for consultation with CDS mechanisms. Consultation with a CDS mechanism will not be required on January 1, 2017 because we do not expect to have approved CDS mechanisms by that date. Although we will develop our plans through further rulemaking, at this time, we do not expect to have approved CDS mechanisms until approximately summer of 2017. In that event, consultations with CDS mechanisms could not take place on January 1, 2017.

Comment: Some commenters supported maintaining the timeline set forth in the PAMA for AUC program implementation. One commenter stated that their organization was able to comply with the timeline. Some commenters also recommended using subregulatory guidance and requests for information (RFIs) outside of rulemaking to meet the timeline set forth in the PAMA.

Response: We appreciate the willingness and enthusiasm of these stakeholders in moving quickly forward in AUC program implementation; however, we believe that it is important to take a stepwise approach to implementation and to establish the components of this program as proposed through notice and comment rulemaking. This approach will ensure that we fully comply with requirements set forth in PAMA for stakeholder consultation, and that we develop a sound implementation plan. We will continue to engage with stakeholders to inform development of future AUC program components and we will consider using an RFI to help inform the next rulemaking cycle.

Comment: Many commenters encouraged CMS to engage in continued stakeholder interactions and dialogue for all aspects of the AUC program. Commenters particularly advocated for continued stakeholder involvement as we develop CDS mechanism requirements during the CY 2017 rulemaking cycle. Some commenters recommended more engagement with professional societies representing ordering physicians and one commenter suggested representation of ordering and primary care physicians if a MEDCAC is convened.

Response: We will continue to have an open-door policy and engage all stakeholders to develop and refine the AUC program. Not only is stakeholder consultation a requirement of PAMA, but we have found these interactions to be highly informative and critical in building this program.

Comment: Many commenters offered suggestions regarding the CDS component of the AUC program. Commenters identified specific areas of importance for CMS to focus on such as

interoperability of CDS mechanisms and electronic health records (EHRs) and the relationship between AUC developers and CDS mechanisms. Commenters also cautioned against a roll out of this component that would not allow sufficient time for CDS mechanisms to comply with the requirements yet to be established in rulemaking or the incorporation of AUC consultation through approved CDS mechanisms into clinical practice. Commenters further requested that CMS address the CDS mechanisms as soon as possible, potentially via avenues outside of the rulemaking process, to account for the short implementation timeline specified in section 218(b) of the PAMA. Commenters provided important and thoughtful recommendations and feedback regarding the CDS component of this program.

Response: We understand the interest in, and concerns expressed about the need for more information and details regarding the CDS mechanism requirements and incorporation into clinical practice; however, as discussed in our proposal, we anticipate that details regarding CDS mechanisms will be the focus of rulemaking during 2016 for the CY 2017 PFS. We appreciate these comments and will use them to inform development of future proposals. We will also continue to consult and interact with stakeholders. We note again that we do not expect that the AUC consultation through approved CDS mechanisms could be required on January 1, 2017.

Comment: Some commenters expressed concern regarding the burden placed on furnishing professionals in reporting on ordering professionals' compliance with AUC consultation. One commenter recommended that the furnishing professional should only be required to report on the claim whether or not the ordering professional consulted AUC.

Response: Under section 1834(q)(4)(B) of the Act, the furnishing professional is required by statute to include information on the claim (for an applicable imaging service furnished in an applicable setting and paid under an applicable payment system) that identifies what qualified CDS mechanism was consulted by the ordering professional, whether the service ordered would or would not adhere to that AUC, or was not applicable to the service, and the NPI of the ordering professional.

Comment: Some commenters requested clarification about allowing variations in AUC based on local populations and circumstances and cautioned that allowing exceptions to specified AUC could work against the goal of the AUC program. Many commenters supported flexibility in allowing variations based on local populations and circumstances, but some commenters suggested that processes for variations should still meet the AUC program requirements and should be rare.

Response: We believe that allowing for variations in AUC based on local circumstances is important to ensure that AUC consultation can be incorporated into clinical practice throughout the country. We agree that local variations should still meet the program requirements to ensure that the evidence to support modification is evaluated and graded and only performed by qualified PLEs.

Comment: Some commenters noted that section 218(b) of the PAMA allows for an exception to the requirement to consult AUC in the case of certain emergency services, but our proposal states that AUC applies to various settings including the Emergency Department. Commenters stated that this ambiguity could cause a delay in the delivery of emergency services to patients and requested clarification on the application of the AUC program in emergency departments and exceptions for certain emergency services.

Response: We understand the confusion and will take these comments into account as we further develop our policies on exceptions in the case of certain emergency services. We anticipate addressing this issue in rulemaking for the CY 2017 PFS.

Comment: One commenter requested clarification on whether mobile, free-standing high tech radiology units are subject to this program.

Response: Whether the equipment is mobile or fixed, the requirement to consult AUC is based on whether the service at issue is an applicable imaging service ordered by an ordering professional that would be furnished in an applicable setting and paid for under an applicable payment system. Applicable imaging services include, in general, advanced diagnostic imaging services for which AUC are publicly available without charge. Applicable settings include a physician's office, hospital outpatient department (including an emergency department), an ambulatory surgical center, and any other provider-led outpatient setting determined appropriate by the Secretary. Applicable payment systems include the PFS, the hospital outpatient prospective payment system, and the ambulatory surgical center payment system. Although we anticipate developing further details regarding these specifications through future rulemaking, we believe the statutory specifications are fairly clear as to the services for which ordering professionals will be required to consult, and report on their consultation of, AUC. We believe the commenter can make a good preliminary assessment as to whether its services fall within these specifications.

Comment: One commenter stated that the proposed AUC program will have unintended consequences on ordering professionals and creates a burden for these practices without the promise of improved care. This commenter stated that some professional societies were not consulted in development of section 218(b) of the PAMA.

Response: AUC consultation by all advanced diagnostic imaging ordering professionals is a requirement under section 218(b) of the PAMA. We are developing this program with extensive stakeholder consultation and input to ensure that the program is implemented in a manner that does not create excessive burden for ordering professionals; yet we recognize that there unavoidably will be some underlying burden for ordering professionals in consulting AUC and reporting on that consultation.

Comment: Some commenters recommended that physicians and hospitals already involved in payment reform models be exempt from reporting requirements for ordering professionals under this program.

Response: Section 218(b) of the PAMA does not include a provision for exceptions for participants in payment reform models. We will consider whether there is authority within the context of such models to consider developing exceptions for model participants.

Comment: Some commenters requested clarification regarding the use of non-evidence-based AUC, particularly when evidence-based AUC are available. Commenters suggested that non-evidence-based AUC may be more prevalent in the everyday practice of medicine.

Response: Section 218(b) of the PAMA requires that, to the extent feasible, AUC must be evidence-based; and we are including that requirement in the AUC development process. However, the process allows for the spectrum of the hierarchy of evidence to be used as part of the systematic review. AUC based on lower levels of evidence will be apparent as each appropriate use criterion posted to the PLE Web site would include the level of evidence for each of the decision node.

Comment: Some commenters expressed support for our proposal to identify non-evidence-based AUC through annual rulemaking and encourage public and stakeholder input in the process. One commenter suggested requiring all non-evidence-based AUC to be reviewed by the MEDCAC. One commenter recommended that CMS define and implement an additional auditing process that could be used to identify abuses and systematic failures.

Response: We are finalizing this proposal with additional language stating that conflicting AUC will be incorporated into the process for addressing non-evidence-based AUC. The MEDCAC may be convened to review these AUC. If a non-evidence-based appropriate use criterion is identified by the MEDCAC and the qualified PLE fails to revise the criterion to reflect the evidence then we may take action regarding the qualified PLE's status. In other words, we may determine that qualification should be reconsidered outside the 5 year reapplication process. We have not created additional auditing processes beyond those that we already possess. We could consider this in future rulemaking if the agency and MEDCAC become overwhelmed by the volume of non-evidence-based AUC.

Comment: One commenter requested incorporation of a process for hardship exemptions to consider factors that might prevent or delay institutions from meeting the requirements of the AUC program.

Response: We will address the significant hardship exemption (section 1834(q)(4)(C)(iii) of the Act) in future rulemaking, and anticipate doing so in rulemaking for the CY 2017 PFS.

Comment: Some commenters recommended that ordering professionals who follow AUC that are developed by internationally-accepted methodologies should not have to complete prior authorizations related to that treatment. One commenter cautioned against including new care improvements in the identification of outliers as clinical practice will continue to change. One commenter requested that the CMS definition for outliers and mechanisms used to identify and penalize outliers must have the necessary flexibility to account for differences in volume of advanced imaging studies due to the composition of a physician's practice.

Response: We will address outlier identification and the prior authorization component of this program in future rulemaking.

Comment: Many commenters expressed concerns about the absence of claims processing instructions and reporting requirements for AUC consultation in our proposal, and the short time frame between publication of the CY 2017 PFS and the PAMA deadline for consultation with CDS mechanisms. Some of these commenters included suggestions for these instructions and reporting requirements.

Response: As discussed in the proposal, we anticipate addressing claims reporting requirements during the CY 2017 PFS rulemaking process. The deadline for consulting CDS mechanisms and reporting such consultations on Medicare claims will be delayed for a year consistent with our proposals in the proposed rule.

Comment: Some commenters believed that our proposal addressed problems encountered in the MID. One commenter specifically noted that the proposal accomplished this by: (a) Expanding on the AUC definition to identify AUC as link between presenting clinical conditions and appropriate imaging services, not just based on imaging service; (b) correctly stressing the importance of integration of the CDS into clinical workflow; and (c) recognizing the importance of flexibility in implementing best practices given local circumstances. Other commenters stated that the proposal ignored some recommendations from the MID, specifically the recommendation to include guidelines from entities other than national specialty societies as the MID noted that societies ''have a vested interest in advising that imaging be ordered.''

Response: We have attempted to balance the findings of the MID with the statutory requirements by specifying libraries of AUC as opposed to individual criteria, and we hope that our transparency and conflict of interest requirements will address concerns that commenters had regarding conflict of interest of AUC developers. We also believe that lessons learned in the MID will benefit CDS mechanism development, and we encourage additional comments in that regard in the future.

Comment: One commenter requested confirmation that the AUC program will only be applicable to Medicare FFS, and not Medicare Advantage.

Response: This program is applicable only to services for which payment is made under the PFS, the hospital outpatient prospective payment system, and the ambulatory surgical center payment system.

Comment: One commenter suggested that AUC should fit under the Merit-Based Incentive Payment System and should not be a stand-alone program.

Response: We do not believe, at this time, that it would be feasible for this program to be incorporated under other quality or value-based programs. However, we could explore whether there are opportunities for consolidation in the future.

In response to comments, we are making some changes to our proposals as well as finalizing most aspects of the policies as they were proposed in the CY 2016 PFS proposed rule.

We are finalizing the majority of definitions as they were proposed. However, based on public comments, we are changing the definitions of AUC, PLE and priority clinical area.

We proposed to define AUC as criteria only developed or endorsed by national professional medical specialty societies or other provider-led entities, to assist ordering 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 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). We are revising the last two sentences of the definition in response to public comments that expressed confusion regarding the AUC terminology used in our proposal. We have also revised related language throughout the final regulation accordingly.

We proposed to define PLE as 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. We are revising the definition of PLE to refer to organizations comprised primarily of providers or practitioners who, either within the organization or outside of the organization, predominantly provide direct patient care. The definition of PLE will retain the direct reference to national professional medical specialty societies, and other organizations like them are now subsumed within the definition.

This definition of PLE will include health care collaboratives and other similar organizations such as the National Comprehensive Cancer Network and the High Value Healthcare Collaborative. While this is not a dramatic change from the proposed rule, the focus is now on the role of the members that comprise the organization and not the function of the organization

itself. This definition aligns with the statute in that national professional medical specialty societies are given as an example of a PLE. Under the proposed definition, these societies were expressly specified as PLEs. It is not the function of the society to deliver care but rather their members are actively engaged in practicing medicine in the field. This final definition appropriately encompasses these organizations and others that are comprised of providers or practitioners who care for patients.

We are also modifying our proposed definition of priority clinical area. We proposed to define priority clinical area as 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. We are changing the language to better describe the breadth of clinical areas that may be the focus of priority clinical areas. The finalized definition better reflects that priority clinical areas may identify clinical conditions, diseases or symptom complexes and their associated advanced diagnostic imaging services. This definition will allow the priority clinical areas to better align with the variety of clinical situations for which a patient may present to the ordering practitioner.

In response to the comments we received regarding the role of endorsement of AUC, we are adding a new § 414.94(d) to the regulations. This new section clearly describes the role of endorsement. We note that only a qualified PLE may provide endorsement of AUC. Further, qualified PLEs may only endorse the AUC of other qualified PLEs. Independently, each organization must have been qualified, and therefore, we do not envision participation by CMS in the endorsement relationship. The primary function of endorsement is for qualified PLEs to combine their AUC to create a larger, more clinically encompassing library. For example, one qualified PLE may focus on developing AUC related to neuroimaging, another may focus on developing AUC related to abdominal imaging. The endorsement relationship gives recognition to this type of collaboration.

While we are finalizing the requirements for developing or modifying AUC as proposed (with the exception of grammatical, non-substantive changes for regulatory consistency) in § 414.94(c)(1), we provide clarification in this final rule with comment period around what is expected regarding a systematic literature review as public commenters did not indicate a consistent understanding of this concept. To clarify, the evidence review requirement does not mean that PLEs must commission external systematic evidence reviews or technology assessments. We expect many organizations will undertake their own systematic evidence review to ensure all relevant evidence-based information is considered and evaluated. The literature review must be systematic, reproducible and encompass all relevant literature related to the specific imaging study. Ideally, the review would include evidence on analytical validity, clinical validity, and clinical utility of the specific imaging study. In addition, the PLE must assess the evidence using a formal, published, and widely recognized methodology for grading evidence. We do not require that a particular methodology be used as there may be certain methodologies better suited to some evidentiary assessments than others.

For consistency with regulatory structure, we have revised the proposed language throughout § 414.94(c) to more clearly represent the responsibility of the PLEs seeking qualification in demonstrating adherence to AUC development requirements under this section.

Based on public comments, we are changing the requirements for the multidisciplinary team that must be used in the AUC development process. We proposed 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. While we proposed to require a smaller team, we are finalizing § 414.94(c)(1)(ii) to state that a qualified PLE must utilize at least one multidisciplinary team with autonomous governance, decision making and accountability for developing or modifying AUC. At a minimum the team must be comprised of seven members including at least one practicing physician with expertise in the clinical topic related to the appropriate use criterion being developed or modified, at least one practicing physician with expertise in the imaging studies related to the appropriate use criterion, at least one primary care physician or practitioner (as defined in sections 1833(u)(6), 1833(x)(2)(A)(i)(I), and 1833(x)(2)(A)(i)(II) of the Act), one expert in statistical analysis and one expert in clinical trial design. A given team member may be the team's expert in more than one domain. A team comprised in this manner and at this size better encompasses the expertise and the dedication needed to develop quality AUC. We encourage such teams to be larger where appropriate, and to include experts in medical informatics and quality improvement. These experts should contribute substantial work to the development of the criteria, not simply review the team's work. Teams may also consider involving other stakeholders.

Based on public comments in support of frequent review of AUC, we are adding language to § 414(c)(1)(vii) to require at least annual review by qualified PLEs of their AUC.

In addition, since new § 414.94(d) has been added to clarify the role of qualified PLE endorsement, the term endorsement has been removed from § 414(c)(1)(ii) as it relates to the multidisciplinary team. Since only qualified PLEs can provide endorsement, these qualified PLEs have already demonstrated they meet the requirements of § 414.94(c)(1)(ii).

We have added language to the conflict of interest disclosure requirement in § 414.94(c)(1)(iii) to make clear that the conflict of interest processes and disclosures would apply not only to members of the multidisciplinary team but also the PLE and any entity that participated in the development of AUC.

In addition, and in response to comments, we have included that the conflict of interest process put in place by the PLE must also include processes to recuse or exclude members of the multidisciplinary team where appropriate. This language was not included in the proposed language of § 414.94(c)(1)(iii). We are finalizing conflict of interest language in § 414.94(c)(1)(iii) and § 414.94(c)(1)(iii)(A) and § 414.94(c)(1)(iii)(B).

We are finalizing language to clarify that CMS will perform a review of each PLE's application for qualification. We have added ''for review'' to § 414.94(c)(2)(i) to make it clear that PLEs must submit an application to CMS for review that documents adherence to each of the AUC development requirements outlined in paragraph (c)(1) of this section.

We proposed the requalification timeline in § 414.94(c)(2)(v). We revised the language and finalized two sections to clarify the requirements related to qualified PLE reapplication.

In the proposed rule we stated that PLEs, on their Web site, must identify when they have AUC that address a priority clinical area. Section 414.94(c)(1)(iv) included that, if relevant to a CMS identified priority clinical area, such a statement must be included. We have expanded this requirement and created § 414.94(c)(1)(v) to include this requirement. This ensures that the AUC are broad enough in scope that an ordering professional could use those AUC to satisfy the priority clinical area.

Section 414.94(f)(3) has been added to clearly specify that CMS will consider information related to a PLE's failure to correct non-evidence-based AUC to determine whether CMS should terminate the PLE's qualified status, and that the information would be used during the PLE's re-qualification review.

To broaden the scope of which potentially non-evidence-based AUC may be reviewed by the MEDCAC, we have revised the language so as not to be limited to reviewing AUC that correspond to priority clinical areas. We proposed § 414.94(e)(1) to state that 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. We have added language to § 414.94(f)(1) that gives priority to AUC that correspond to priority clinical areas but does not limit review to such. In this section, we have also identified that conflicting AUC may receive priority in MEDCAC review.

We thank the public for their comments and believe the changes based on these comments have improved the requirements and process that we will follow to specify AUC under this program for advanced diagnostic imaging services. Following the publication of this final rule with comment period, we will post information on our Web site for this program accessible at *www.cms.gov/Medicare/Quality-Initiatives/Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program*.

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.

We received several comments about the enhancements made to the Physician Compare Web site and the data currently on the Web site.

Comment: Several commenters noted the improvements made to the Physician Compare Web site, as well as appreciation for the transparency and easy-to-use, comprehensive information available on the site to aid consumers in making informed health care decisions. Some commenters suggested CMS make continued improvements to the Intelligent Search functionality particularly around finding professionals other than physicians and including additional specialty labels for Advanced Practice Registered Nurses (APRNs) and allied health professionals. One commenter encouraged CMS to continue its discussions on how to make the Web site fully accessible and useable by persons with a wide range of disabilities, including vision, sight, and cognitive challenges.

Some commenters provided suggestions for additional information to publicly report on Physician Compare, including whether a health care professional offers patients online access to their health information, specialist-specific training and certification data, and other qualifications, such as the Certified Medical Director designation and the Certificate of Added Qualifications in Geriatric Medicine, testimony of enhanced comprehensive care services, expanded access or non-traditional hours, and care management and coordination information. One commenter urged CMS to include information about accessibility.

Response: We are committed to continuing to improve the site and its functionality to ensure it is a useful resource for Medicare consumers, including information that can help these consumers make informed health care decisions. We appreciate the recommendations for specific information to consider for inclusion on the Web site and the recommendations regarding usability. CMS works to ensure the Web site is accessible to all users and we will continue to ensure Physician Compare meets accessibility standards. Also, we will be sure to consider the specific recommendations received for possible information to add for future inclusion, if appropriate. We are continually working to improve and enhance the Intelligent Search functionality, and we will continue to do so. Currently, APRNs are searchable on the Web site through this functionality, but we will continue to work with stakeholders to further improve upon this option.

Comment: Some commenters expressed concerns with the accuracy of demographic data including addresses, education, and hospital affiliation. Several commenters urged CMS to continue to work to correct any demographic data errors prior to expanding public reporting on the Web site. Other commenters requested we implement a streamlined process by which professionals can confirm or correct their information in a timely manner. Some commenters urged CMS to ensure that updates made in PECOS are reflected on Physician Compare within 30 days. One commenter suggested a new mechanism for real-time address updates on the Web site and several other commenters suggested a process that allows stakeholders to review and correct information on the site.

Response: We appreciate the commenters' feedback regarding concerns over the accuracy of the demographic information currently available on Physician Compare. We are committed to including accurate and up-to-date information on Physician Compare and continue to work to make improvements to the information presented.

The underlying database for Physician Compare is generated from PECOS, as well as fee-for-service (FFS) claims, and therefore, it is critical that physicians, other health care professionals, and group practices ensure that their information is up-to-date and as complete as possible in the national PECOS database. Currently, the most immediate way to address inaccurate PECOS data on Physician Compare is by updating information via Internet-based PECOS at *https://pecos.cms.hhs.gov/pecos/login.do*. Please note that the specialties as reported on Physician Compare are those specialties reported to Medicare when a physician or other health care professional enrolls in Medicare and are limited to the specialties noted on the 855i Enrollment Form. Also, all addresses listed on Physician Compare must be entered in and verified in PECOS. There is a lag between when an edit is made in PECOS and when that edit is processed by the MAC and available in the PECOS data pulled for Physician Compare. This is time necessary for data verification. Unfortunately, this means there is a delay. We are continually working to find ways to minimize this delay, and, in the past year we reduced the data refresh cycle from monthly to bi-weekly to further improve data timeliness.

To update information not found in PECOS, such as hospital affiliation, professionals should contact the Physician Compare support team directly at *PhysicianCompare@Westat.com*. Information regarding how to keep your information current is also on the Physician Compare Initiative page on *CMS.gov (//westat.com/dfs/PHYSCOMPARE/Proposed Rule and Public Comment/2016 PFS Rule/Final Rule/CMS.gov)*.

We appreciate the suggestions for alternative ways to update demographic data. However, PECOS is the sole verified source of Medicare information, and thus, some information must come to Physician Compare through PECOS. We are aware of PECOS' limitations and recognize that PECOS' primary purpose is not to provide up-to-the-minute information for a consumer Web site. For these reasons, we completely overhauled the underlying database and began using Medicare claims data to verify the information in PECOS in 2013. Because of this, the data are significantly better today than they were prior to the 2013 redesign and we will continue to work to find ways to further improve the data and the process of receiving and updating the data. We strongly encourage all professionals and group practices listed on the site to regularly check their data and to contact the support team with any questions or concerns. Together, we can continue to make the Web site better.

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 received comments regarding this previously finalized policy related to quality program participation.

Comment: A commenter urged CMS to reconsider publicly reporting participation in the Medicare EHR Incentive Program due to ongoing issues related to the program. Some commenters suggested adding indicators for individual health care professionals or group practices who participate in a QCDR, participate in a quality improvement registry for other services, or participate in other voluntary quality improvement initiatives. One commenter requested that quality program participation be reported at an aggregated level rather than by each program. Another commenter noted that consumers are not familiar with quality initiatives, so an indicator should be tested with consumers.

Response: We appreciate the commenters' feedback, and we will take the suggestions provided regarding indicators into consideration for possible future enhancements. However, since participation in the EHR Incentive Program is currently included on Physician Compare, as previously finalized, and consumers find this information interesting and helpful, we are going to continue including an indicator for participation in the EHR Incentive Program on the Web site. Quality initiatives include a variety of programs with distinct goals. Therefore, we will continue to include an indicator for each program. We also understand that explanatory language helps inform health care consumers as they use the Web site. We currently test all information included on the Web site with consumers to ensure they understand the information provided. We recently focused testing on the quality initiative indicators. Plain language updates are forthcoming as a result of this testing. We will continue to work to ensure that the language included on Physician Compare helps users understand these quality initiatives and use the information provided appropriately and accurately.

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.

Comment: We received one comment commending CMS for including Diabetes quality measures.

Response: We appreciate the commenter's support, and will continue to publicly report relevant quality measures that meet the public reporting standards.

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 pubic reporting.

Measures must be based on reliable and valid data elements to be useful to consumers. Therefore, for all measures available for public reporting, including both group and individual EP level measures—regardless of reporting mechanism, only those 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 and that prove to resonate with consumers 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 received several comments regarding the public reporting standards we have established for Physician Compare. The following is a summary of the comments received about the public reporting standards.

Comment: Many commenters supported only publishing on Physician Compare those measures that meet the public reporting standards. Several commenters urged CMS to carefully assess if all measure data are sufficiently reliable and valid for public reporting before posting the data. One commenter requested CMS to publish the results of validity and reliability studies, as well as the methodology for choosing measures prior to posting on Physician Compare. Several commenters are concerned that measures related to patient behavior, preferences, or abilities do not provide a statistically valid portrayal of a physician's performance and should not be published unless the data is appropriately risk adjusted. Several other commenters also strongly urge CMS to move forward with expanding its risk adjustment methodology to account for these patient behavior, preferences, or abilities that may influence quality and performance measurement. Many commenters supported not publicly reporting first year measures. Several commenters requested flexibility, noting that some measures may be appropriate for public reporting immediately while others may need additional time to mature. A few commenters recommended a three-year delay in public reporting of all new measures to enable professionals to accurately report the measures and to account for measure testing and validity.

Response: We appreciate the commenters' feedback, and understand the various concerns raised. As required under section 10331(b) of the Affordable Care Act, in developing and implementing the plan to include

performance data on Physician Compare, we must include, to the extent practicable, processes to ensure that the data posted on the Web site are statistically valid, reliable, and accurate, including risk adjustment mechanisms used by the Secretary. We understand that this information is complex, and are committed to providing data on Physician Compare that are useful to beneficiaries in assisting them in making informed health care decisions, while being accurate, valid, reliable, and complete. We will closely evaluate all quality measures under consideration for public reporting on the Web site to ensure they are meeting these standards. We will also only post data that meet this standard of reliability regardless of threshold, and regardless of measure type. Should we find a measure meeting the minimum threshold to be invalid or unreliable for any reason, the measure will not be reported. We will also not publicly report first year measures to allow health care professionals to learn from the first year of reporting and to account for measure testing and validity. After a measure's first year in use, we will evaluate the measure to see if and when the measure is suitable for pubic reporting. We also continue to encourage measure developers to build in risk adjustment at this level. We will continue to analyze the measures available for public reporting to ensure that risk adjustment concerns are taken into consideration. This is true for all measures, clinical quality, and patient experience. Again, all measures must meet the public reporting standards established for Physician Compare to be included on the Web site.

As mentioned above, in previous rulemaking, we have outlined some of the types of reliability studies that are conducted for measures (79 FR 67764 through 79 FR 67765). Additional information is also shared annually via our Technical Expert Panel (TEP) summaries which can be found on the Physician Compare Initiative page on www.CMS.gov. We will evaluate the feasibility of the request to share additional information.

Comment: Several commenters supported a minimum sample size of 20 patients. However, the majority of commenters find a patient threshold of 20 to be too low to be statistically valid, which may result in inaccurate quality scores based on one outlier, and some commenters recommended increasing the threshold to 30 patients. Commenters recommended CMS use a higher threshold to ensure validity. Several commenters also urged CMS to provide an opportunity for the public to review reliability and validity tests.

Response: We appreciate the commenters' feedback regarding the 20 patient minimum sample size; however, it is important to note that all measures considered for public reporting are subject to additional validity and reliability tests prior to being publicly reported even if the minimum sample threshold is met. Therefore, we believe this threshold of 20 patients is sufficient. In addition, it is a large enough sample to protect patient privacy for reporting on the Web site, and it is the threshold previously finalized for both the physician value-based payment modifier (VM) for most measures and the PQRS criteria for reporting measure groups (77 FR 69166). As mentioned, we will evaluate the feasibility of sharing additional information about the testing done. 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.[5]

Comment: Some commenters expressed concern with the comparability of measures reported through different reporting mechanisms and support an indicator specifying the differences.

Response: Though we understand concerns regarding including measures collected via different mechanisms, analyses are conducted to ensure that the consistencies and inconsistencies across reporting mechanisms are understood. Only those measures that are proven to be comparable and most suitable for public reporting will be included on Physician Compare and made publicly available. Comparability is one of the public reporting standards established for Physician Compare that must be met. Therefore, we will continue to report data from the available reporting mechanisms and make public a notation of which reporting mechanism was used.

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 will 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 the data are collected, it is possible that clinical guidelines may have changed 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.

Comment: Commenters encouraged continued involvement of measure developers and stakeholders in the public reporting development process. Several commenters appreciated the continued collaboration with specialty societies via town hall meetings and other mechanisms. Several commenters advocated for more transparency by providing the opportunity for the public to comment on the deliberations of the Physician Compare TEP, regular engagement with interested stakeholders, and increased communication about the measure consideration process including methods and consumer interpretation of performance. Some commenters appreciated that CMS will continue to reach out to stakeholders in the professional community to ensure that the measures under consideration for public reporting remain clinically relevant and accurate.

Response: As noted, section 10331(d) of the Affordable Care Act requires that the Secretary take into consideration input provided by multi-stakeholder groups, consistent with sections 1890(b)(7) and 1890A of the Act, as added by section 3014 of the Act, in selecting quality measures for use on Physician Compare. We are also dedicated to providing opportunities for stakeholders to provide input. We will continue to identify the best ways to accomplish this so that all stakeholders have a voice and we are able to meet the statutory and regulatory mandates and deadlines. We will review all recommendations provided for future consideration, and we strongly

[5] 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.

encourage all stakeholders to regularly visit the Physician Compare Initiative (*https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/physician-compare-initiative/*) page for information about the latest opportunities to engage with the Physician Compare team. Stakeholders are also encouraged to reach out with any questions and comments at any time via email at *PhysicianCompare@Westat.com.*

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.

Comment: Most commenters supported consumer testing to ensure only meaningful measures are included on the Web site. One commenter urged CMS to consult a broader array of stakeholders during concept testing, including individuals with disabilities. Some commenters requested that CMS share with professional associations or measure developers any information obtained through consumer concept testing. A few commenters asked for more details on concept testing plans, while another recommended CMS use concept testing to evaluate the information currently on the Physician Compare site. One commenter would like CMS to assess the extent to which Physician Compare is effectively fulfilling the Web site's goals.

Response: We will continue to conduct consumer testing in terms of both usability testing—to ensure the site is easy to navigate and functioning appropriately—and concept testing—to ensure users understand the information included on the Web site and that information included resonates with health care consumers and allows the Web site to accomplish the goals as stated. We are continually working to test the information planned for public reporting with consumers and we regularly test the information currently on the Web site with site users. Once a set of measures is finalized as available for public reporting, we begin planning concept testing of the measures. Therefore, the measures finalized in this rule will be tested prior to publicly reporting in late 2017. We also continually work to ensure that valid, reliable, and meaningful information is included on the Web site. We will also continue to work to ensure that all stakeholders, including consumers and health care professionals, are included in the testing and review process as appropriate and feasible. We will review recommendations shared regarding sharing testing results for future consideration. It is important to note that many stakeholders are already involved in the dissemination of testing findings, and we are continually working to ensure the best audience for that information.

Comment: We received several comments that supported including all valid and reliable measures in the downloadable database while including only a select group of measures on the Web site. Some commenters urged CMS not to include data in a downloadable raw data file if it has already been deemed unsuitable for profile pages. There was concern that these data may be misused or misinterpreted by consumers, researchers, and the public.

Response: We will continue to include all measures that meet all stated public reporting standards that include that all measures included on Physician Compare must be statistically valid, accurate, reliable, and comparable in the downloadable file in order to further transparency. However, we will continue to limit the measures available on Physician Compare profile pages to those measures that meet these public reporting standards and are also of the greatest value to consumers. As noted above, consumer testing helps determine which information resonates with health care consumers. This will ensure that the measures presented on Physician Compare help consumers make informed health care decisions without overwhelming them with too much information. However, it is very possible that there are strong measures that provide valuable clinical information that may be difficult for consumers to understand. We believe these are the types of measures that are more appropriately accessed in the downloadable database, rather than the profile pages. Again, only those measures that meet the public reporting standards established for Physician Compare will be included in either the downloadable database or the profile pages.

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. Although the 30-day preview has been previously finalized and we were not seeking comment on this, several comments were received. The following is a summary of the comments received on the 30-day preview period.

Comment: We received several comments in support of the 30-day preview period prior to publicly reporting quality data. Many commenters urged CMS to allow physicians and group practices the opportunity to correct and/or appeal any errors found in the performance information before it is posted on the site. Other commenters stated that a 30-day preview period was insufficient and requested that CMS extend the period to 45, 60, or 90 days. Several commenters stated the preview period should match the Informal Review timeline of 60 days. One commenter requested that if there is a pending PQRS Informal Review request, then public reporting should be delayed until there is a final resolution. Several commenters recommended that if an EP or group practice files an appeal and flags their demographic data or quality information as problematic, CMS should postpone posting their information until the issues are resolved. Some commenters sought clarification on how CMS plans to notify EPs of the preview period and requested more detail about the process in the event an error is found during the preview period.

Response: As noted in this rule, the details of the 30-day preview period are communicated each year via various mechanisms, such as listserv announcements, Webinars, and other education and outreach opportunities, and information is always available on the Physician Compare Initiative page (*https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/physician-compare-initiative/*). There is currently no appeals process for data made public on Physician Compare. If a group practice or individual EP has any concerns regarding the data viewed during preview, they are provided with multiple options to reach out to the Physician Compare support team to report their concern and have the issue investigated. Any issue raised would be addressed prior to publicly reporting of the data. In addition, the PQRS and VM programs offer an annual Informal

Review Period following the release of the Quality and Resource Use Reports (QRURs). We are currently working with the PQRS and VM programs to ensure that if there are data concerns raised during the Informal Review period, those concerns are taken into consideration around public reporting. Regarding concerns around demographic data, these data are driven primarily by the Provider Enrollment Chain and Ownership System (PECOS). There is detailed information available on the Physician Compare Initiative page about how to address any concerns with the demographic data available on Physician Compare. We strongly encourage all individual EPs and group practices to regularly review their data on Physician Compare and ensure their PECOS records are up to date. If there are any concerns, please contact the Physician Compare support team at *PhysicianCompare@Westat.com.*

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 at *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 are made available to ACOs for review at least 30 days prior to the start of public reporting on Physician Compare. The quality reports 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. In the CY 2014 PFS final rule with comment period, we finalized a decision that 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 were available for public reporting in CY 2015 (78 FR 74450). We also finalized a plan to make available for public reporting performance on certain measures that group practices reported 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. After review and analysis of these data, it was determined that neither 2014 EHR or registry data would be publicly reported in CY 2015. The 2014 EHR data will not be publicly reported on Physician Compare because CMS was unable to determine the accuracy of these data, and 2014 registry data will not be publicly reported because these data do not meet the public reporting standards. However, we will continue to analyze EHR and registry data for future inclusion on the Web site in 2016 and beyond.

We received comments specifically about EHR measures.

Comment: Commenters were opposed to publicly reporting EHR measures citing the CY 2014 data inaccuracies, specifically given the number of errors in the eCQM submission data. Some commenters stated it was too soon to publicly report data from eCQMs without additional work to verify the validity and accuracy of the measure results. One commenter encouraged CMS to develop information to help the public to better understand these data.

Response: We decided not to publicly report 2014 EHR data because we were unable to determine the accuracy of these data. Only comparable, valid, reliable, and accurate data will be included on Physician Compare. In addition, all measures slated for public reporting will be consumer tested to ensure they are accurately understood prior to public reporting. If concerns surface from this testing, we will evaluate the best course forward to ensure only those measures that meet the public reporting standards established for Physician Compare are included on the site.

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).

In late CY 2015, certain 2014 individual PQRS measure data reported by individual EPs are also available for public reporting. Specifically, we finalized to make 20 individual measures collected through a registry, EHR, or claims available for public reporting (78 FR 74453 through 74454). These are measures that are in line with those measures reported by groups via the Web Interface. As noted above, however, both the 2014 EHR and registry data are not being publicly reported for either group practices or individual EPs who reported these data.

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 were finalized as available for public reporting in CY 2015 (78 FR 74454). Again, these data are ultimately not going to be publicly reported in late 2015 because they are collected only via registry.

We continue to expand public reporting on Physician Compare by making an even broader set of quality measures available for public reporting 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 finalized to make twelve 2015 CAHPS for PQRS summary survey measures available for public reporting 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 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 finalized to make all 2015 PQRS measures for individual EPs collected through a registry, EHR, or claims available for public reporting in CY 2016 on Physician Compare (79 FR 67773).

Furthermore, in support of the HHS-wide Million Hearts initiative, four 2015 PQRS measures reported by individual EPs in support of Million Hearts will be available for public reporting in CY 2016.

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 that 2015 Qualified Clinical Data Registry (QCDR) PQRS and non-PQRS measure data collected at the individual EP level are available for public reporting in late CY 2016. The QCDR is required to declare during their self-nomination if it plans to post data on its own Web site and allow Physician Compare to link to it or if it 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 25 for a summary of our previously finalized policies for public reporting data on Physician Compare.

TABLE 25—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	14 measures reported via the WI for group practices of 2 or more EPs reporting under PQRS with a minimum sample size of 20 patients.
2014	Expected to be late 2015	WI, Survey Vendor	All Web Interface measures reported by Shared Savings Program ACOs, and CAHPS for ACO measures.
2014	Expected to be late 2015	WI, Certified Survey Vendor	8 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	Claims	A sub-set of 6 PQRS measures submitted by individual EPs that align with those available for group reporting via the WI and that are collected through claims with a minimum sample size of 20 patients.
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.

TABLE 25—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	Registry, EHR, or Claims	All PQRS measures for individual EPs collected through a registry, EHR, or claims.
2015	Expected to be late 2016	QCDR	All individual EP QCDR measures, including PQRS and non-PQRS measures.

3. Final 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 public reporting 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 proposed (80 FR 41811–41814) 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. We received several comments on the phased approach to public reporting. A summary of the comments received follows.

Comment: While many commenters supported continuing the phased approach to public reporting of quality data, several commenters noted concern with what they perceive is an aggressive timeline for publicly reporting physician performance data. Commenters supported a more gradual approach to public reporting to allow time to evaluate the public response to data prior to widespread implementation, ensure accuracy, and permit data to be presented in a format that is easy to understand, meaningful, and actionable for both patients and physicians. Some commenters opposed the extensive expansion until existing Web site problems are addressed. Several commenters suggested focusing on educating and implementing the Merit-based Incentive Payment System (MIPS) program before expanding public reporting.

Response: We believe that public reporting of quality data has been a measured, phased approach which started with publicly reporting just five 2012 PQRS GPRO measures collected via the Web Interface for 66 group practices and 141 ACOs (76 FR 73417) and continued with a similarly limited set of 2013 PQRS GPRO Web Interface measures (77 FR 69166). We started to build on this plan with the CY 2014 PFS final rule with comment period (78 FR 74446). In that rulemaking, we adopted additional PQRS measures available for public reporting, including a subset of individual EP PQRS measures. Therefore, the proposals put forth this year are just the next step in the process to realize the goals of Physician Compare. We are confident that taking this phased approach has afforded us the opportunity to prepare for this significant expansion.

Throughout this process, we have been engaging with consumers and stakeholders and regularly testing the site and the information to be included to ensure it is accurately presented and understood. We are also continually working to improve the Web site and the administrative and demographic information included. We continue to encourage physicians, other health care professionals, and group practices to ensure their information is updated in PECOS so that we can ensure the most accurate information is available on Physician Compare. We also encourage individuals and groups to reach out to the Physician Compare support team at *PhysicianCompare@Westat.com* for any questions or concerns regarding the information included on the Web site.

We are committed to public reporting to provide consumers with information to help them make informed health care decisions. Even though we will be moving to MIPS as required by the Medicare Access and CHIP Reauthorization Act (MACRA), we are committed to continue providing this useful information to consumers and to continue to be transparent so that health care professionals can evaluate their own performance and the performance of their peers. As we move towards implementation of the new MIPS program, we will continue to engage and educate our stakeholders.

a. Value Modifier

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).[6] We proposed (80 FR 41811) 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 physician value-based payment modifier (VM). This VM indicator can help consumers identify higher quality care provided at a lower cost. 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. 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-friendly, easy-to-understand format. We proposed 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. We solicited comments on this proposal.

The following is a summary of the comments we received on our proposal to include a green check mark indicator of the names of those individual EPs and group practices who receive the VM upward adjustment on profile pages on Physician Compare.

Comment: We received both positive and negative comments on this proposal. Supporters noted that the addition of VM data supports transparency, encourages improvement, and provides important information to the public. One commenter suggested adding additional VM performance information to the Web site. Several commenters urged CMS to include educational information about the VM for consumers or an explanation for physicians who are not eligible for the VM. Another commenter urged CMS to clarify which performance year data will be published on Physician Compare to ensure the information is accurately

[6] *http://www.hhs.gov/strategic-plan/goal1.html.*

understood. One commenter suggested collaborating with consumer advocacy groups to educate consumers about VM data if the visual indicator is included.

However, several commenters had significant concerns that the VM is not well-understood by the public, may be misinterpreted, or does not provide value to consumers. Many commenters were also opposed to this proposal due to concerns with the VM calculation methodology and the resulting proportion of health care professionals that will receive ''average'' scores for the cost and/or quality composite. One commenter recommended that EPs who participate in programs that exempt them from VM should receive a checkmark because without this indicator, they would appear lower quality. Several commenters opposed these data being added on the profile page, but supported inclusion in a downloadable database. Some commenters also noted that the VM program will sunset after 2018, and suggested waiting to publicly report cost data until the MIPS is implemented. One commenter suggested an indicator for participating in a QCDR is a better indicator of physician quality and overall value than the VM.

Response: We appreciate the commenters' feedback, and we appreciate the concerns raised. We do believe that in time, information such as this can provide consumers with valuable information to help them make informed health care decisions and help CMS advance our overall quality strategy. We agree that this or similar information needs to be presented on profile pages in a way that will ensure it is accurately understood and interpreted and is seen as valuable information from the consumer perspective. We also appreciate that because the VM adjustment will end after CY 2018, it may be confusing to consumers to add a new indicator for only a short period of time followed by potentially another indicator related to the MIPS in later years. As a result, we are not finalizing this proposal, and therefore, will not be including a visual indicator of the VM upward adjustment on profile pages at this time. Regarding the recommendation to add an indicator for participation in a QCDR, that is not something currently being considered as we appreciate this is not a concept consumers are familiar with. However, we will take it into consideration for potential future evaluation.

b. Million Hearts

In support of the HHS-wide Million Hearts initiative, we included 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 proposed (80 FR 41811) 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 that was proposed (and is being finalized in this final rule) under PQRS. 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 solicited comments on this proposal.

The following is a summary of the comments we received on our proposal to include an indicator on profile pages for EPs who satisfactorily report the Cardiovascular Prevention measures group in support of Million Hearts.

Comment: Commenters supported including an indicator on profile pages for individual EPs who satisfactorily report the new PQRS Cardiovascular Prevention measures group in support of Million Hearts. One commenter suggested adding context and information about the program to help consumers better understand the information. One commenter recommended that the final rule reference the Million Hearts measures by the PQRS number rather than the short name. Another commenter suggested recognizing EPs that report other cardiovascular PQRS measures in addition to those who report the specific measure group.

Response: We are committed to supporting the Million Hearts initiative and we believe that recognizing EPs who report this measures group is aligned with promoting the Million Heats initiative. We appreciate that some commenters would like additional measures to be considered in support of the initiative, and we will review this suggestion for potential future rulemaking. We are also working on a Web site update that will provide more plain language descriptions and context of all quality programs represented on the site to ensure consumers have the context and understanding commenters noted is important. We are also consumer testing this information on an ongoing basis to ensure consumers are getting the most out of this information. As a result, we are finalizing this proposal to include a visual indicator on EP profile pages in support of the Million Hearts initiative as it is deemed valuable by consumers and including this information may incentivize health care professionals to focus on the Million Hearts measures.

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 policy to make available for public reporting on Physician Compare all PQRS GPRO measures collected in 2015 via the Web Interface, registry, or EHR. In the proposed rule, we proposed (80 FR 41811) 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 would be represented on the Web site. We solicited comments on this proposal.

The following is a summary of the comments we received on our proposal to make PQRS GPRO measures across all reporting mechanisms for groups of 2 or more EPs and Shared Savings Program ACO measures available for public reporting.

Comment: We received both positive and negative comments regarding our group practice proposal. Commenters in support noted that publicly reporting quality measures is helpful to consumers and supports transparency. In general, commenters were more supportive of publicly reporting group level measures over individual EP level measures. Some commenters, however, opposed the continued public reporting of PQRS data generally, noting concerns

such as the accuracy of current data reported via an EHR, the potential for consumer misinterpretation, and the limited measures available for some specialists to report. One commenter suggested CMS focus on preparing for MIPS rather than continuing with the current public reporting plan.

Response: We are committed to public reporting to provide consumers with information to help them make informed health care decisions. We are also working to fulfill the public reporting requirements of the Affordable Care Act. Even though we will be moving to MIPS as a result of the MACRA, we are committed to continuing our phased approach to public reporting and providing this useful information to consumers consistently year to year, as possible. We are also committed to supporting transparency so that health care professionals can evaluate their own performance and the performance of their peers. We understand that there are concerns with the available data. As noted above, all data must meet the public reporting standards outlined in this rule and in previous rulemaking in order to be publicly reported. For instance, because the accuracy of the 2014 data reported via an EHR could not be determined, these data will not be publicly reported. Data that do prove to be valid, reliable, accurate, comparable, and that resonate with consumers, however, will be publicly reported.

Regarding concerns about potential consumer misinterpretation of the data, we do conduct regular consumer testing to address this issue. In general, consumers find this information interesting and beneficial in their decision making process. If a measure is not accurately interpreted or well understood, or if consumers do not find it to be valuable, that measure is not considered for public reporting on Physician Compare profile pages. We do appreciate that PQRS does not contain a similar number of measures for all possible specialties; we are working on strategies to help fill this gap. One strategy is looking toward QCDRs, which are better able to address the needs of specific specialties with relevant measures.

After considering the issues raised by commenters and for the reasons we articulated, we are finalizing our proposal to continue to make all PQRS group practice level and ACO Shared Savings Program measures available for public reporting annually, including making the 2016 PQRS group practice and ACO data available for public reporting on Physician Compare in late 2017.

d. Individual EP PQRS Reporting

Consumer testing indicates that consumers are looking for measures regarding individual doctors and other health care professionals above all other data. As a result, we decided to make individual EP level measure data available for public reporting on Physician Compare starting with a subset of 2014 PQRS measures (78 FR 74451). We expanded this plan by making all 2015 individual EP level PQRS measures collected through a registry, EHR, or claims available for public reporting (79 FR 67773). Through 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 proposed 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 would be included on Physician Compare in 2017). For individual EP measures, the measure performance rate would be represented on the Web site. We solicited comments on this proposal.

The following is a summary of the comments we received on our proposal to make all individual EP level PQRS measures available for public reporting on Physician Compare.

Comment: As with the group practice level PQRS measures, we received both positive and negative comments regarding this proposal. Commenters in support again noted that quality measures are helpful to consumers and support transparency. Several commenters that supported publicly reporting group level measures did not support reporting individual EP level measures noting that individual level reporting may be subject to more data accuracy issues and suffer from small sample sizes. Another commenter asked for clarification about which performance score is publicly reported if an EP reports PQRS data through multiple reporting mechanisms.

Response: We appreciate the commenters' feedback on individual EP PQRS measures. Again, as is the case with all measures under consideration for inclusion on Physician Compare, the public reporting standards established for Physician Compare must be met for the measure to be publicly reported. As a result, if analyses show that the data are not accurate, valid, reliable, comparable, or do not resonate with consumers, they will not be publicly reported on Physician Compare profile pages. Regarding concerns around small sample sizes, only those measures that are reported for the accepted sample size of 20 patients and that meet all stated public reporting standards will be publicly reported. We understand that it may be harder to meet this minimum sample size at the individual EP level. However, that will simply mean the measure is not listed on the individual EP's profile page and no performance rate is reported. PQRS does encourage EPs to report via a single reporting mechanism. If data from multiple reporting mechanisms are deemed eligible for public reporting and an individual EP reports through more than one of the available mechanisms, we will look at the reporting mechanism that is used to determine PQRS satisfactory reporting and work to use the performance rate consistent with that mechanism.

As a result of the comments received and the importance of individual EP level quality measure data to consumers, we are finalizing our proposal to continue to make all PQRS individual EP level PQRS measures available for public reporting annually, including making the 2016 PQRS individual EP level data available for public reporting on Physician Compare in late 2017.

e. Individual EP and Group Practice QCDR Measure Reporting

As previously stated, 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 when deciding who they should 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 proposed 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 (80 FR

41812). In addition, we proposed 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 (80 FR 41812). Previously, the PQRS program only included QCDR data at the individual EP level. In section III.I.2.a. of this final rule with comment period, we are finalizing, under the PQRS, a decision to expand QCDR reporting 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 proposed 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 would be represented on the Web site. We solicited comments on these proposals.

The following is a summary of the comments we received on our proposal to make both group practice and individual EP level QCDR data available for public reporting on Physician Compare.

Comment: Many commenters support publicly reporting QCDR measures for group practices, as well as individual EPs, noting that it promotes flexibility in reporting, provides additional information to consumers, and addresses sample size concerns. One commenter requested that CMS explore ways for quality reporting to be publicly available at the level of the entire care team. Another commenter expressed concern that attributing group practice data to an individual physician does not provide the necessary information to allow the consumer to determine how the individual EP performed on those measures.

There were also some general concerns about QCDR data including concerns that QCDR data are too new, not comparable to PQRS measures, not accurate and reliable, and potentially confusing to consumers. One commenter suggested holding public reporting of QCDR data until more specialties are able to report via QCDRs.

Response: We appreciate the commenters' feedback on these QCDR proposals. We agree that making QCDR data, both PQRS and non-PQRS measures, available for public reporting helps fill potential gaps left by the currently available PQRS data. We also believe these measures add great value for consumers as they provide a greater diversity of quality information at both the group practice and individual EP levels, and thus, further help consumers make informed decisions about their health care. At this time, it is only possible for CMS to consider measures attributed to either the group practice level or the individual EP level. Other attribution options are not possible at this time, but will be taken under consideration for the future.

It is important to note that data collected at the individual EP level, whether through a QCDR or through other PQRS reporting mechanism will only be publicly reported at the individual EP level, and data collected at the group practice level will only be reported at the group practice level. Group practice data will never be publicly reported on an individual EP profile page because it would not be accurate to attribute the group's performance rates to only one EP.

Regarding the general concerns raised about publicly reporting QCDR data, it is important to emphasize that data submitted by QCDRs must meet the same public reporting standards as all other data submitted to CMS. If a QCDR submits a PQRS measure and that measure data is not deemed comparable to data submitted via other PQRS reporting mechanisms, the data will not be publicly reported because all data publicly reported must be comparable to ensure one measure is evaluating each EP or group in the same way regardless of how the data were collected and submitted to CMS.

It is expected that non-PQRS measures submitted via QCDRs are likely to be unique from the available PQRS data. This is considered one of the greatest benefits of the QCDR data. These measures are likely to be more specific to specialties otherwise less represented in PQRS and to be a strong fit for those reporting them. Considering the measures are relevant to the group or EP they are representing, we believe this provides a benefit to consumers reviewing the data. We appreciate that not all groups or EPs may have the opportunity to participate in a QCDR, but we see significant value in making the data that are now accessible available for public reporting for these reasons. Again, as with all data under consideration for public reporting, consumer testing will be done to ensure measures included on Physician Compare are accurately interpreted and deemed valuable by consumers.

Understanding the value of these data, the opportunity for these data to fill gaps currently in the PQRS program, and the relevancy of these data to many specialties, we are finalizing this proposal to make group practice and individual EP level QCDR data, both PQRS and non-PQRS measures, available for public reporting on Physician Compare annually, including making 2016 data available for public reporting in late 2017.

Each QCDR will 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 plans to 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 will 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 TEP, we proposed (80 FR 41812–41813) to publicly report on Physician Compare an item, or measure-level, benchmark derived using the Achievable Benchmark of Care (ABC™) [7] 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

[7] 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.

the data are available and analyzed. We proposed 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).

As explained, 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 proposed to 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 would produce 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 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 proposed (80 FR 41813) to use the ABC™ methodology to generate a benchmark which could 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.[8] [9] [10]

To summarize, we proposed 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 solicited comments on this proposal.

[8] 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.

[9] 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.

[10] 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.

The following is a summary of the comments we received on our proposal 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.

Comment: Many commenters supported the use of benchmarks to help consumers make informed health care decisions and specifically the proposed ABC™ methodology, noting this is a valuable and useful tool for consumers and a valid and reliable way to approach a benchmark and star ratings. However, some commenters stated it was too soon to publicly report a benchmark and suggested phasing in or testing and sharing the benchmark privately with EPs and group practices for internal improvement first prior to making the benchmark publicly available. Some commenters asked for up to 2 years of internal use prior to public reporting. Other commenters would like CMS to wait to apply a benchmark until MIPS is implemented in order to understand how the methodology would be applied in the context of MIPS.

Some commenters noted concern that measures are currently not risk-adjusted and that the proposed methodology may not be appropriate for all measures. Multiple commenters, both those who support and do not support the specific proposal, noted concerns about the need to stratify any benchmark developed by specialty, stratify by reporting mechanism, and risk-adjust the benchmark. Some commenters urged CMS to educate physicians and consumers on the benchmark methodology. Several commenters appreciated the stakeholder engagement conducted by the Physician Compare team regarding the benchmark methodology selection and encouraged continued engagement in the future.

Several commenters also asked for clarification on how the pared-mean was determined and how this method can be applied to both process measures and outcome measures. Some commenters suggested increasing the pared-mean to 25 percent and commenters suggested other benchmark methodologies, including an approach that recognizes self-improvement over time and peer-to-peer performance. One commenter asked for the opportunity to review the database and provide a clear demonstration of the benchmark's validity. Additional commenters noted that benchmarks using the ABC™ methodology is too complex and will be difficult for consumers to understand,

and encouraged consumer testing to remedy this potential problem. Several commenters urged CMS to use consistent benchmarking across its programs to promote consistency and minimize confusion. Several commenters urged CMS to allow QCDRs to determine their own benchmark approach.

Response: We are particularly appreciative of the collaborative effort of the many stakeholders who took the initiative to participate in the stakeholder outreach process conducted to determine a suitable benchmark methodology to propose for public reporting on Physician Compare. We look forward to continuing this collaborative approach. We also appreciate the concerns raised. Although we see the reasons why some commenters would first like the benchmark to be viewed privately, we reiterate the significant value in adding a benchmark to Physician Compare now. Consumers need tools to best understand the data and to make accurate and appropriate comparisons. A benchmark such as this can provide this valuable tool. We are committed to continually working to make the information on Physician Compare as easy to understand and consumer friendly as possible, and adding a benchmark is a critical next step in this process.

Regarding the commenters' concerns about risk adjustment, we agree that risk adjustment will become increasingly important as we move to more outcome measures, specifically at the individual EP level. We actively encourage measure developers to produce measures that are risk adjusted. We believe that it is most appropriate to approach risk adjustment at the measure development level versus trying to adjust after the fact at the benchmarking stage, especially when data are submitted via reporting mechanisms that do not provide the necessary information to risk adjust after data collection is complete. We will continue to conduct analyses to ensure all data, including the benchmarks, meet the stated public reporting criteria, and therefore, are showing variation in performance and not in other factors, such as region or population of care.

Regarding stratifying the benchmark, one consideration is the negative effect of over-stratification. At this stage in public reporting, looking to stratify by too many criteria can lead to data groupings so small that there can be no meaningful or statistically relevant comparisons made. Also, it is important to remember that searches on Physician Compare are conducted by location and specialty. In this way, when a consumer is evaluating data on the Physician Compare Web site, they are generally looking at health care professionals in the same location practicing in similar or the same specialties. Understanding the limitations to stratifying at this time, there is one stratification consideration that we believe is not only valuable but necessary as we work to ensure data included on the Web site are comparable.

We are in favor of stratifying by reporting mechanism at this time, which would mean creating a benchmark by measure by reporting mechanism. This would help remove the complexity and potential differences between the same measure collected via multiple reporting mechanisms and help solve some of the concerns raised about the available PQRS data. It would also remove the burden of interpretation across mechanisms from consumers. It is important to note that this benchmark proposal does only apply to PQRS data. QCDRs are free to develop their own benchmark methodology and submit their methodology and benchmark rates to Physician Compare for public reporting consideration for non-PQRS measures when and where appropriate.

One of the benefits of the ABC™ methodology is that it has been tested in a number of scenarios and the pared-mean has been found to be statistically reliable, valid, and accurate when producing a truly achievable benchmark that can be used to measure and improve quality performance. We appreciate the recommendation to look at a pared-mean that includes more than the top 10 percent of patients served by the top performers. However, we believe that increasing this percentage is likely to dilute the benchmark and overstate quality performance on a given measure. That said, we are conducting ongoing testing evaluating this methodology as applied to the available PQRS data, and we will actively reach out to stakeholders to share information about the results of this statistical analysis, as well as ongoing consumer testing, to ensure stakeholders are aware of the specific application of the benchmark and the reliability, validity, and accuracy of the benchmark for the available PQRS process and outcome measures. We will use the most current data to ensure the benchmark is the best measure of timely quality care. Therefore, additional specifics about the application of the benchmark in terms of the specific star attribution, including but not limited to statistical analysis of the 2016 data, star display, and consumer testing, will depend on data that have not been collected yet. We will provide this information as it is available but in advance of publicly reporting the benchmark. It is important to note that initial consumer testing indicated an ABC™ derived benchmark could be well received and understood by consumers on Physician Compare.

We do appreciate the comments that requested that CMS evaluate using a consistent benchmark methodology across programs. We are continually evaluating ways to align where and as possible, and will take this recommendation into consideration for the future. One benefit of the ABC™ methodology is that it is potentially applicable across care settings and measure types.

After considering the comments and stakeholder and expert feedback, as well as testing conducted to date, and for the reasons we noted, we are finalizing our proposal to publicly report on Physician Compare an item, or measure-level, benchmark derived using the ABC™ methodology annually based on the PQRS performance rates most recently available stratified by reporting mechanism for both group practice and individual EP level measures.

In addition to receiving comments about using the ABC™ methodology to derive the benchmark, we also received comments on our proposal to use the ABC™ derived benchmark to systematically assign stars for the Physician Compare 5 star rating. The following is a summary of these comments.

Comment: Several commenters supported the systematic assigning of a star rating based on the proposed benchmark methodology. Other commenters opposed star ratings, generally, noting that they are concerned such ratings oversimplify performance data. These commenters also raised concerns that disparate quality scores could result in inappropriate distinctions of quality for physicians whose performance scores are not statistically different. Several commenters asked for additional details on how the stars will be assigned and urged CMS to provide clear explanations to the public about how to interpret the star ratings.

Response: We are committed to moving to a star rating system on Physician Compare as this is a consumer friendly way to share such complex information as the quality measure data being made available. As with all information available for public reporting on Physician Compare, the benchmark information and the resulting star ratings need to meet the public reporting standards of statistically valid, accurate, reliable, and

comparable data. The goal of using a benchmark such as one derived from the ABC™ methodology is to have a star rating system that distinguishes statistically significant quality differences. Using this methodology can help us ensure that five star performance is statistically different than four star performance, etc. As noted in this section, additional details based on ongoing analysis with the most recently available data will be shared with stakeholders. In addition, information about how stars will be specifically assigned using the ABC™ methodology, star display, and plain language will be shared when the relevant data are available. Finally, we will continue to work to ensure that the star rating system used is accurately understood and interpreted by consumers. Consumer testing is therefore ongoing.

Understanding the value of a star rating system for consumers, we are finalizing our proposal to use the ABC™ derived benchmark to systematically assign stars for the Physician Compare 5 star rating.

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, 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 proposed (80 FR 41813) 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 CAHPS for PQRS reported data will be included on the Web site in 2017). The patient experience data available that we proposed to make available for public reporting are the CAHPS for PQRS measures, which include the CG–CAHPS core measures. For group practices, we proposed to annually make available for public reporting a representation of the top box performance rate [11] 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 solicited comments on this proposal.

The following is a summary of the comments we received on our proposal to publicly report CAHPS for PQRS data for group practices of 2 or more EPs that meet all stated public reporting criteria.

Comment: Many commenters supported expanding public reporting of CAHPS for PQRS measures, noting that patient experience data is highly relevant to consumers. Commenters stated that other patients' assessments of their experience with a given group practice or health care professional are no doubt helpful in the health care decision making process. Some commenters supported including a benchmark for the CAHPS summary measures. Several commenters also urge CMS to collect and report individual EP level patient experience data. Some commenters opposed the proposal, citing concerns around consumer interpretation of patient reported data and that these data may not capture patient experience related to all specialties, such as hospitalists, other hospital-based professionals, and surgical practices. One commenter had concerns with the ''Stewardship of Patient Resources'' measure because the measure does not address the numerous barriers to patients accessing to care. Several commenters supported adding other types of patient experience data to Physician Compare, including Surgical CAHPS® and experience data collected via other sources. Another commenter suggested reporting patient experience data for primary care physicians and only clinical quality performance for specialists.

Response: We agree that these patient experience data are very valuable to consumers, and as noted, consumer testing has consistently shown that these measures aid decision making and are wanted by consumers. Consumer testing has also shown that these measures are generally well understood and accurately interpreted by consumers. CAHPS measures are extensively tested and proven to be statistically valid. We are confident these measures are an appropriate and statistically relevant indicator of patient satisfaction.

We do appreciate the comments regarding other types of patient experience data, as well as the inclusion of a CAHPS benchmark, and will consider these recommendations for the future. We do understand that not all measures under consideration for public reporting equally apply to all types of professionals included on Physician Compare. However, we do believe that the CAHPS for PQRS measures apply to the large majority of professionals currently represented on the site. We also appreciate the request for CAHPS for PQRS measures at the individual EP level. This is something consumers have also requested in testing. Unfortunately, at this time, CAHPS for PQRS measures are only available and tested at the group practice level.

Again, as with all measures available for inclusion on Physician Compare, the measures must meet the stated public reporting standards. Any concerns about specific measures are reviewed against these criteria prior to consideration for public reporting.

After considering the comments received and given that CAHPS for PQRS data are highly valued by consumers, we are finalizing our proposal to make all twelve summary survey CAHPS for PQRS measures available for public reporting on Physician Compare annually for groups of 2 or more EPs reporting via a CMS certified CAHPS vendor.

h. Downloadable Database

(a) Addition of VM Information

To further aid in transparency, we also proposed (80 FR 41813–41814) to add new data elements to the Physician Compare downloadable database at *https://data.medicare.gov/data/physician-compare*. Currently, the downloadable database includes all quality information publicly reported on Physician Compare, including quality program participation. In addition, the downloadable database includes all measures submitted and reviewed and found to be statistically valid and reliable. We proposed (80 FR 41813) to add to the Physician Compare downloadable database for group

[11] 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.

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 proposed (80 FR 41813) 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 analysts, and researchers who are familiar with 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 can be packaged and explained in such a way that it is accurately interpreted, understood, and useful to average consumers. We solicited comments on this proposal.

The following is a summary of the comments we received on our proposal to include this additional VM data to the Physician Compare downloadable database.

Comment: Several commenters expressed significant concerns about adding this VM data to the Physician Compare downloadable database for group practices and individual EPs because the VM is not well-understood by the public, and is perceived as not providing value to the consumer or accurately portraying quality and cost. One commenter noted that consumers can still access this data in the downloadable database. Several commenters were concerned that this data could be misused by researchers or media. One commenter suggested that VM information should be shared with specialty societies rather than publicly reported. Many commenters were also opposed to this proposal due to concerns with the VM calculation methodology and the portion of group practices and health care professionals that will receive ''average'' scores for the cost and/or quality composite. One commenter urged CMS to put in place a 30-day period for EPs and group practices to review any VM information that will be added to the downloadable database. Conversely, several commenters supported adding VM information to the downloadable database, noting that it promotes transparency and provides useful data to the public. Some commenters also noted that these data support research and generate further learnings about the VM methodology.

Response: We do understand the concerns raised about making VM data publicly available. Our experience shows that average consumers are not the primary audience for the downloadable database. In fact, testing has shown that most average consumers do not want or believe they know what to do with that level of detailed data. Therefore, we are not concerned that adding these data to the downloadable database will disadvantage consumers. We do appreciate that these or any data provided in the downloadable database could be misused. However, we do believe that the benefits of transparency and potential learnings for health care professionals, specialty societies, researchers, and other stakeholders, as noted by some commenters, outweigh these concerns. As noted by commenters, making these data available to the informed public could lead to improvements in the methodology and greater understanding of cost and quality. Regarding the request for these data to be made available for preview, we do not currently provide a preview period for the downloadable database, but the cost and quality scores included will match those provided in existing feedback reports. These reports are generally made available for private review more than 30 days prior to publicly reporting the data on Physician Compare.

As a result of our commitment to increased transparency and the other reasons we noted, and after considering the public comments, we are finalizing this proposal to add cost and quality tier, as well as adjustment, information to the Physician Compare downloadable database for the 2018 VM based on 2016 quality and cost data.

(b) Addition of Utilization Data

In addition, we proposed (80 FR 4183–4184) 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 Health care 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, enacted April 16, 2015), beginning with 2016, the Secretary shall integrate utilization data information on Physician Compare. This 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 proposed 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 solicited comments on this proposal.

The following is a summary of the comments we received on our proposal to include utilization data in the Physician Compare downloadable database.

Comment: Some commenters supported the addition of utilization data to the public downloadable database, noting that these data support transparency and may be useful to researchers for analysis. They do however note that these data are not intended for the average Medicare consumer. Several commenters expressed concern with the accuracy of these data and the potential for misinterpretation or misuse of the data. Some commenters request that these data include disclaimers about the limitations of utilization data and request that physicians be allowed to submit corrections where the data are inaccurate or outdated. Several commenters also felt that utilization data are not only not intended for consumer use but do not align with Physician Compare's goals. Some commenters noted that utilization data are already available on a different CMS Web site. One commenter suggested developing a profile based on patient characteristics from the data. Another commenter requests safeguards or summary conclusions from the claims data that would be meaningful for consumers. One commenter urged CMS to limit the release of these data to professional societies and work to determine the most appropriate use.

Response: We agree that these data are not intended for or well understood by the average Medicare consumer. This has been illustrated in consumer testing

to date. Again, it is important to note that consumers are not a primary audience for the downloadable data file. These data are potentially of great value to many stakeholders. The data are already public on another CMS Web site, as mentioned, but including them with the other Physician Compare data could help provide useful context that could better ensure more appropriate use of the data. As noted above, all data shared publicly could potentially be misused. But, again, we believe the benefits of transparency outweigh these concerns and we will work to determine the best method for displaying the data. We appreciate the recommendations for alternative ways to use or include these data on the consumer-facing site or ways additional context could be added to these data. We will review these recommendations for the future.

Given that section 104(e) of MACRA mandates integration of these data on Physician Compare and because we believe that adding these data to the downloadable database advances our transparency goals, we are finalizing our proposal to include utilization data in the Physician Compare downloadable database. Not all available data will be included. The specific HCPCS codes included will be determined based on analysis of the available data, focusing on the most used codes. Additional details about the specific HCPCS codes that will be included in the downloadable database will be provided to stakeholders.

(i) Board Certification

Finally, we proposed (80 FR 41813) 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 proposed 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 ABMS Osteopathic certification. In general, we reviewed interest from boards as it was brought to our attention, and if the necessary data were available and appropriate arrangements and agreements could 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 specifically proposed to include ABO and AOA Board Certification information on Physician Compare. We solicited comments on this proposal.

The following is a summary of the comments we received on our proposal to adding additional Board Certification information to Physician Compare, specifically adding ABO and AOA Certification.

Comment: Commenters supported adding ABO and AOA Board Certification to Physician Compare. One commenter recommended that the name of the certifying board be included on the site so it is clear whether the certificate is issued by an ABMS Member Board or another board. Another commenter urged CMS to consider multiple certifications within a specialty and to develop a tool for Medicare beneficiaries and other health care consumers to view a comparison of the multiple certifications on the site. Several commenters requested the addition of other boards, including the American Board of Audiology (ABA), a Certificate of Clinical Competence in Audiology (CCC–A), American Board of Physician Specialties (ABPS), American Board of Physical Therapy Specialties (ABPTS), ASHA Certificate of Clinical Competence in Speech-Language Pathology (CCC–SLP), Board Certified Specialist in Child Language and Language Disorders, Board Certified Specialist in Fluency and Fluency Disorders, Board Certified Specialist in Swallowing and Swallowing Disorders, and Board Certified Specialist in Intraoperative Monitoring from ASHA. One commenter noted that there is no category for specialized certifications for professionals other than physicians on Physician Compare and requested the opportunity to provide input should such a category be under consideration. Another commenter requested that the site include information about hospitalists who choose to pursue a Focused Practice in Hospital Medicine (FPHM) Maintenance of Certification (MOC).

Response: We particularly appreciate the many suggestions provided for additional Boards to consider for inclusion on the Web site and for additional suggestions regarding how to display this information on the Web site. We also appreciate the comment regarding the need to evaluate including information for EPs beyond physicians. All of these recommendations will be taken under consideration for the future to evaluate if they are feasible and/or considered a value added through consumer testing. For those Boards that have specifically requested being considered for inclusion on the Web site, we will work with each Board to assess if the Board has the data available and comparable information needed to include the Certification information on the Web site and consider whether such boards would be appropriate for consideration in future rulemaking.

As a result of the overall support for adding additional Board Certification information to Physician Compare and for the reasons we specified above, we are finalizing our proposal to add this specifically ABO and AOA Board Certification information.

Table 26 summarizes the Physician Compare measure and participation data proposals finalized in this final rule.

TABLE 26—SUMMARY OF MEASURE AND PARTICIPATION DATA FINALIZED FOR PUBLIC REPORTING

Data collection year*	Publication year*	Data type	Reporting mechanism	Quality measures and data finalized 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 under PQRS in support of Million Hearts.
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 finalized to be reported annually. The table only provides the first year in which these data 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. Public Comment Solicited on Issues for Possible Future Rulemaking

a. Quality Measures

In addition to the proposals we made in the proposed rule, we solicited comment on several new data elements for possible inclusion on the individual EP and group profile pages of Physician Compare through future rulemaking. 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 stated that 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 sought comment on potential measures that would benefit future public reporting on Physician Compare. We are working to identify possible data sources and we sought 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.

The following is a summary of the comments we received on our request for comment on future quality measure needs.

Comment: We received comments on potential measures to report on Physician Compare in the future. Commenters supported including outcome measures, including clinical outcomes and patient-reported outcomes. One commenter noted that outcome measures must include a risk adjustment methodology. Other commenters supported patient safety, care coordination, cross-cutting, and patient and family experience of care measures. Commenters suggested specialty specific measures, including audiology, urology, and neurology measures. One commenter recommended the continued partnership with the professional associations, contractors, and CMS for future measure determination, and noted that measures used for Physician Compare should be included in the proposed rule for public comment. One commenter suggested measures for appropriate access to the health care professional/group practice offices, culturally and linguistically competent services including successful trainings attended, availability of appropriate transportation with equipment, geriatrics specialty/training, patient experience measures with qualitative data, and patient reported measures, including ones that capture patient activation. One commenter suggested a common set of EP level performance measures that would apply across all payment programs, and another urged CMS to incorporate the Core Quality Measures Collaborative's aligned

measure sets. One commenter opposed the future public reporting of performance information for any quality measures that are not reported under federally required quality reporting programs.

Response: We will review all comments and consider these suggestions for possible future rulemaking.

b. Medicare Advantage

We also sought comment on adding Medicare Advantage information to Physician Compare individual EP and group practice profile pages. Specifically, we sought 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 could help ensure that consumers have access to all of the quality data available to make an informed health care decision.

The following is a summary of the comments we received on our request about possibly integrating Medicare Advantage information with Physician Compare information in the future.

Comment: Several commenters supported adding Medicare Advantage information to the Physician Compare individual EP and group practice profile pages, noting that it would further assist consumers with health care decision making and fill a current gap in the available data. One commenter noted that certain services are provided outside of the scope of benefits under traditional FFS Medicare, so it is critical that Physician Compare incorporate the full scope of performance.

However, many commenters opposed adding Medicare Advantage data due to concerns with data accuracy and comparison to FFS quality data. One commenter suggested alignment of physician and physician group quality measures across traditional FFS Medicare, Medicare ACOs, and Medicare Advantage. Another commenter asked where information on Medicare Advantage professionals would be obtained and how often the database would be updated. Commenters were concerned that adding Medicare Advantage data to Physician Compare would be complicated and difficult for both consumers and health care professionals to understand. One commenter asked for additional information on how this information would be messaged to the consumer.

Response: We appreciate that there are many health care professionals providing services through Medicare Advantage, and consumers have regularly indicated an interest in knowing which Medicare Advantage plans, if any, health care professionals on Physician Compare are associated. However, we also appreciate the concerns raised regarding data access and the technical concerns regarding the ability to appropriately link to Plan Finder. We will further evaluate all of the information shared and questions asked concerning the inclusion of Medicare Advantage data, and we will consider these issues for potential future rulemaking.

c. Value Modifier

We also sought comment on including additional VM cost and quality data on Physician Compare. Specifically, we sought 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 sought 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 sought 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 needed time to establish the best method for public reporting and to ensure this information is accurately understood and interpreted by consumers. Therefore, we only sought comment at this time.

The following is a summary of the comments we received regarding potentially including additional VM information on Physician Compare in the future.

Comment: A few commenters supported potentially including an indicator of downward and neutral adjustments under the VM on physician profile pages in the future. Several commenters opposed including additional VM data on profile pages because of concerns around the current VM methodology, the complexity of the program, and concerns about the meaningfulness of the cost and quality composite scores to consumers. One commenter noted that the VM cost and quality composites will be of limited future utility due to the movement towards MIPS.

Response: As noted above, we appreciate the concerns raised about sharing VM data with consumers, and we acknowledge that the payment adjustment under the VM end after CY 2018. We will further review all comments and suggestions regarding this data and consider for potential future rulemaking.

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 sought 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 sought comment on adding these data to Physician Compare, to the extent it is feasible and appropriate. Prior to considering a formal proposal, we 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 sought comment at this time.

The following is a summary of the comments we received regarding possible future inclusion of Open Payments data on Physician Compare.

Comment: Commenters both supported and opposed making Open Payments data available on Physician Compare. Some commenters supported

public access to Open Payments data, but opposed adding it to Physician Compare. Some commenters supported linking to the existing Open Payments Web site, and others noted that the data are already publicly available so adding these data to Physician Compare is redundant. Several commenters urged CMS to provide context for the data to ensure the data are interpreted correctly or to include general information regarding Open Payments rather than the actual Open Payments data. A commenter urged CMS should make clear that manufacturers are not responsible for Physician Compare data and physicians can only log complaints about Open Payments data through the dispute and correction process applicable to the Open Payments program. One commenter suggested establishing additional nature of payment categories for (i) stock option buy outs and (ii) transfers of value not otherwise covered by the existing nature of payment categories. Many commenters noted that Physician Compare serves a different purpose than the Open Payments Web site and it would be misleading to include this information on Physician Compare as it is unrelated to the quality of care. Commenters were also concerned with the accuracy of Open Payments data.

Response: We understand that Open Payments data are different from the quality of care data included on Physician Compare, and we appreciate that these data require context to be fully understood. As noted, we do continue to test these data with consumers, and we will take the comments and recommendations provided under consideration and if appropriate, address in possible future rulemaking.

e. Measure Stratification

Finally, we sought comments on including individual EP and group practice level quality measure data stratified by race, ethnicity, and gender on Physician Compare, if feasible and appropriate (that is, statistically appropriate, etc.). By stratification, we mean that we would 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 sought 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 section 4302 of the Affordable Care Act).

The following is a summary of the comments we received about including individual EP and group practice level quality measure data stratified by race, ethnicity, and gender on Physician Compare.

Comment: Commenters who supported stratifying measures noted that this information is important in determining and tracking health equity, increasing transparency and accountability, and helping identify and reduce known and persistent health care disparities. Some commenters also noted this would allow consumers to make informed choices based on their preferences and give stakeholders valuable information on gaps and trends in the system based on demographics. Several commenters suggested including primary language, disability status, gender identity, and sexual orientation could also add value. Commenters who opposed stratification noted that consumers may misinterpret the data. Other concerns included over-diluting the data, data collection burden, and privacy issues. One commenter noted that it is not the function of Physician Compare to ''monitor trends in health equity.'' Another commenter noted that calculation of stratified quality data would require significant research to ensure that the information provided was both meaningful and accurate.

Response: As with all items presented for comment only, we will review the comments and suggestions and consider whether these data sets are appropriate for inclusion on Physician Compare. Any data recommended in these areas and found suitable for public disclosure on Physician Compare would be addressed through separate notice-and-comment rulemaking.

5. Additional Comments Received

We received additional comments which are summarized and addressed below.

Comment: Commenters noted that the absence of measure data on Physician Compare due to limited available or meaningful measures may mislead consumers. Commenters requested disclaimers be added or additional education be conducted to explain that there could be the absence of measure data due to measure limitations and not poor quality. Some commenters added that these explanations should be in plain language at a 6th grade reading level. Several commenters expressed concern with publicly reporting any data until measure limitations can be analyzed or addressed. A few commenters recommended language explaining the significance of QCDR reporting.

Response: We understand that the limited availability of PQRS measures may make it difficult for some specialties to report. We hope that the introduction of additional measures, such as QCDR measures and patient experience measures, will help mitigate concerns regarding quality data availability in the short term. It is important to realize that most searches on Physician Compare are specialty based. If a given specialty does not have measures, users will only evaluate physicians or other health care professionals that do not have measures. This specialty based search can mitigate some of these concerns. Finally, we also understand that disclaimers and other types of explanatory language are necessary to help inform health care consumers as they use the Web site. We will continue to work to ensure that the language included on Physician Compare addresses the concerns raised and helps users understand that there are a number of reasons a physician or other health care professional may not have quality data on the Web site. We are continually working to update all language on the Web site to ensure it is plain language that can be easily understood.

Comment: Several commenters are concerned with the use of physician-centric language in the proposed rule and on Physician Compare, noting that the name of the Web site could be more inclusive of all eligible health care professionals. One commenter suggested providing information throughout the Web site about the full array of qualified professionals included on the Web site. One commenter asked CMS to assure that audiologists are meaningfully represented and can be easily identified by other professionals and patients.

Response: The name of the site is generally specified in section 10331(a)(1) the Affordable Care Act. Throughout the site we do note that both physicians and other health care professionals are available to search and view. If a professional is in approved status in PECOS and has submitted Medicare FFS claims in their name in the last 12 months, they will be included on Physician Compare. They will be listed by the specialty or other

health care professional designation that they enrolled under when joining Medicare.

I. Physician Payment, Efficiency, and Quality Improvements—Physician Quality Reporting System

This section contains the 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 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 continued to focus on alignment as we developed our proposals for the 2018 PQRS payment adjustment.

In addition, please note that, in our quality programs, we have begun 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) suggested that CMS place an emphasis on higher quality measures, such as functional outcome measures. For example, in the PQRS, we 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 proposed 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 Web Interface as the reporting mechanism. In addition, we proposed to continue to require the reporting of at least 1 applicable cross-cutting measure if an EP sees at least 1 Medicare patient. When reporting measures via a QCDR, we emphasized the reporting of outcome measures, as well as resource use, patient experience of care, efficiency/appropriate use, or patient safety measures.

Furthermore, we note that our proposals related to the 2018 PQRS payment adjustment are similar to the requirements we previously established for the 2017 PQRS payment adjustment. We received comments in previous years, as well as during the comment period for the proposed rule, requesting that CMS not make any major changes to the requirements for PQRS, and we believe these final requirements address these commenters' desire for stable requirements. Indeed, we received many comments related to our proposals for the 2018 PQRS payment adjustment, and we will address those comments with specificity below. Please note, however, that we received comments on the PQRS that were outside the scope of the proposed rule, as they were not related to our specific proposals for the 2018 PQRS payment adjustment. While we will take these comments into consideration, primarily when we begin to develop policies and requirements for the Merit-based Incentive Payment System (or MIPS), we will not specifically respond to those comments here.

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 sought 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 employees 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 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 did not propose 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 did not propose to require the collection of these data elements, we solicited comments regarding the facilitators and obstacles providers and vendors may face in collecting and reporting these attributes. Additionally, we solicited 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. 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. We sought 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 noted 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 8:00 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. Although 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.

The following is a summary of the comments we received regarding this proposal:

Comment: We received many comments in support of our proposal to open the QCDR self-nomination period on December 1 of the prior year to allow more time for entities to self-nominate.

Response: Based on the rationale provided and the positive comments we received, we are finalizing this proposal. 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. Please note, however, that the deadline for an entity becoming a QCDR to submit a self-nomination statement is still 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).

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 proposed 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 invited public comment on this proposal.

Comment: Some commenters opposed this proposal. One commenter stated this one-year waiting period ensures that the entity is established and credible. Another commenter expressed concern that we may be including entities that are ''untested'' should we modify this requirement.

Response: While the commenters' concerns regarding modifying this requirement are understood, based on our analysis of requests for entities to become a QCDR, we believe that a ''waiting period'' is not necessary for entities that are in existence as of January 1. From our experience, at least some of the newer entities requesting to become a QCDR were entities that have had previous experience under a formerly existing QCDR. As such, we do not believe a waiting period is necessary. Therefore, based on the rationale provided, we are finalizing this proposal. Therefore, 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).

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 proposed 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 invited but received no public comment on this proposal. We are finalizing 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 proposed 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 measure specifications the entity submitted. Please note that this does not prevent the entity from providing supplemental information if requested by CMS.

We solicited and received the following public comment on this issue:

Comment: Commenters generally opposed this proposal. The commenters believed that vendors needed more time than proposed to gather its QCDR measures information. As such, the commenters believe the proposed January 31 date occurs too soon in the year.

Response: We understand the commenters concerns regarding needing more time to gather measures information. However, in order for CMS to more closely analyze these potential QCDR measures due to the issues we have found in the past, we must finalize our January 31 deadline, as proposed. Therefore, we are finalizing our proposal 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), as proposed.

Data Validation Requirements for QCDRs: 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 proposed 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. e.s.t. on June 30, 2016. The email subject should be ''PY2015 Qualified Registry Data Validation Execution Report.''

We received the following comments on these proposed validation requirements:

Comment: Some commenters opposed these proposed requirements to provide the QCDR the above data for auditing purposes. The commenters stated that vendors do not have enough time to gather all this information currently, as some vendors do not have this full information. The commenters therefore requested that vendors be given more time to implement these requirements. Commenters also believed that EP verification of NPI and TIN information should be considered sufficient for purposes of the data validation requirements, because QCDRs may have different strategies to meet the data validation requirements. Requiring all QCDRs to collect NPI and tax documentation from each EP as part of a data validation strategy is unduly burdensome.

Response: We understand the commenters' concerns associated with not having received full information from its clients. We note, however, that it is important to implement these requirements in order for CMS to ensure the accuracy of the data collected by these vendors. We also note that, while vendors may not have all this information currently, the vendors have several months, until June 30, 2016, to obtain this information from its clients. We believe this provides vendors with enough time to gather this information. With respect to commenters' belief that EP verification of NPI and TIN information should be considered sufficient for purposes of the data validation requirements, while CMS encourages vendors to check the accuracy of the data being submitted to them, we believe it is also necessary for CMS to have the ability to validate the data received. Therefore, based on the rationale provided, we are finalizing these above requirements for data validation, as proposed. Please note that a vendor will, therefore, need to collect all necessary information by June 30, 2016.

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 proposed that QCDRs also have the ability to submit quality measures data for group practices.

We received the following comments on this proposal:

Comment: Commenters were generally supportive of the newly proposed group practice reporting option via a QCDR and its proposed requirements. Some commenters stressed the importance of maintaining and extending use of the QCDR reporting mechanism.

Response: Based on the positive feedback and the rationale provided, we are finalizing this proposal, as proposed.

b. 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 proposed 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 invited and received the following public comment on this proposal.

Comment: Commenters generally supposed our proposal to use a web-based check box mechanism as a way 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, because it is an efficient method to attest.

Response: Based on the comments received and the rationale provided, we are finalizing our proposals related to attestation statements for registries submitting quality measures data, as proposed.

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 proposed 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. We invited but received no public comment on this proposal. Therefore, we are finalizing this proposal 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, as proposed.

Please note that we are finalizing our proposals related to attestation statements for registries submitting quality measures data, as proposed.

Data Validation Requirements for Qualified Registries: 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 proposed 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.''

Comment: Some commenters opposed these proposed requirements to provide the above data for auditing purposes. The commenters stated that vendors do not have enough time to gather all this information currently, as some vendors do not have this full information. The commenters therefore requested that vendors be given more time to implement these requirements.

Response: We understand the commenters concerns associated with the registry not having received full information from its clients. We note,

however, that it is important to implement these requirements in order for CMS to ensure the accuracy of the data collected by these vendors. We also note that, while vendors may not have all this information currently, the vendors have several months, until June 30, 2016, to obtain and collect this information from its clients. We believe this provides vendors with enough time to gather this information. Therefore, based on the rationale provided, we are finalizing these above requirements for data validation, as proposed.

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 cooperate with this audit process. In order to ensure that CMS has adequate information to perform an audit of a vendor, we proposed 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 (data submission vendor)) 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 invited public comment on these proposals. The following is a summary of the comments we received regarding these proposals.

Comment: Some commenters opposed these proposed requirements that CMS has proposed for auditing purposes. As with the proposed data validation requirements for QCDRs and qualified registries, the commenters stated that vendors do not have enough time to gather all this information currently, as some vendors do not have this full information. The commenters therefore requested that vendors be given more time to implement these requirements.

Response: We understand the commenters concerns associated with not having received full information from its clients. We note, however, that it is important to implement these requirements in order for CMS to ensure the accuracy of the data collected by these vendors. We also note that, while vendors may not have all this information currently, we believe these vendors have enough time to gather this information. Therefore, based on the rationale provided, we are finalizing the requirements we proposed for auditing purposes, as proposed. Please note that, as proposed, these requirements will apply to all vendors submitting PQRS data: qualified registries, QCDRs, direct EHR vendors, or DSV vendors.

3. 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. 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 defined that term in the proposed rule, 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 proposed 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 proposed to define that term in this section, 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 requiring reporting of at least 1 cross-cutting measure, we proposed 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 solicited and received the following public comments on our proposed satisfactory reporting criteria for individual EPs reporting via claims or registry for the 2018 PQRS payment adjustment:

Comment: Commenters generally supported our proposed reporting criteria for individual EPs reporting via claims or registry for the 2018 PQRS payment adjustment, primarily because commenters did not want CMS to propose drastic changes to the criteria for satisfactory reporting. Maintaining similar reporting criteria helps EPs and vendors, as they are already familiar with the reporting criteria. Commenters also generally supported continuing use of the claims-based reporting mechanism as an option to meet the criteria for satisfactory reporting under the PQRS.

Response: Based on the rationale provided and the comments received, we are finalizing our proposed satisfactory reporting criteria for individual EPs reporting via claims or registry for the 2018 PQRS payment adjustment, as proposed.

b. 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 proposed 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 solicited and received the following public comments on this proposal:

Comment: Some commenters supported our proposed requirement for satisfactory reporting for the 2018 PQRS payment adjustment via the EHR reporting mechanism. One commenter supported our proposal to keep the requirements similar to the requirement for satisfactory reporting for the 2017 PQRS payment adjustment, as well as our proposal to align reporting options with the CQM component of the EHR Incentive Program.

Response: We appreciate the commenters' positive feedback on this proposal. Based on the rationale provided and the comments received, we are finalizing our proposed satisfactory reporting criteria for individual EPs reporting via direct EHR product and EHR data submission vendor product for the 2018 PQRS payment adjustment, as proposed.

c. 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 proposed 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 solicited and received the following public comment on our proposed satisfactory reporting criterion for individual EPs reporting measures groups via registry for the 2018 PQRS payment adjustment:

Comment: Commenters generally supported our proposed satisfactory reporting criterion for individual EPs reporting measures groups via registry for the 2018 PQRS payment adjustment, primarily because commenters did not want CMS to propose drastic changes to the criteria for satisfactory reporting. Commenters stated that maintaining similar reporting criteria helps EPs and vendors, as they are already familiar with the reporting criteria.

Response: Based on the comments received and for the rationale provided, we are finalizing our proposed satisfactory reporting criterion for individual EPs reporting measures groups via registry for the 2018 PQRS payment adjustment, as proposed.

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. Criterion for the Satisfactory Participation for Individual EPs in a QCDR for the 2018 PQRS payment adjustment

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 proposed 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 of the 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 solicited and received the following public comments on this proposal:

Comment: We received many comments generally in support of the QCDR reporting mechanism. Commenters also generally supported our proposed criterion for individual EPs to satisfactorily participate in a QCDR for the 2018 PQRS payment adjustment, as the commenters urged us not to propose drastic changes to the criteria for satisfactory participation in a QCDR. The commenters were especially concerned with not making drastic changes to the QCDR option, as it is the newest reporting option available in the PQRS.

Response: We appreciate the commenters' feedback. Based on the comments received and the rationale provided, we are finalizing the proposed criterion for individual EPs to satisfactorily participate in a QCDR for the 2018 PQRS payment adjustment, as proposed.

5. 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.I.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

Explanation of CAHPS for PQRS: 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.

Requirements for CAHPS for PQRS for the 2016 Reporting Period: 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 proposed to require group practices of 25 or more EPs that register to participate in the GPRO and select the Web Interface as the reporting mechanism to select a CMS-certified survey vendor to report CAHPS for PQRS. We believe this is consistent with our effort to collect CAHPS for PQRS data whenever possible. However, we excluded 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 still proposed to keep CAHPS for PQRS reporting as an option for all group practices. We noted 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 invited and received the following public comment on this proposal:

Comment: One commenter generally supported requiring the administration of the CAHPS for PQRS survey. However, the majority of commenters were opposed to this requirement. Some commenters oppose requiring the reporting of the CAHPS for PQRS survey. One commenter is particularly concerned with the timing of the release of the final list of vendors approved to administer the CAHPS for PQRS survey for the 2015 reporting period. The list was not released until after the GPRO registration period closed, not providing group practices with enough time to make a full business decision on whether to administer CAHPS for PQRS prior to the close of GPRO registration. Other commenters are concerned with the cost associated with administering the CAHPS for PQRS survey, particularly for smaller group practices.

Response: We understand the commenters' concerns regarding not being able to receive the list of CAHPS for PQRS vendors for the 2015 reporting period until after registration had closed. We will work to make this list available earlier next year. We also understand that the cost of administering the CAHPS for PQRS survey may be burdensome to smaller group practices. Therefore, as a result of the comments, we are modifying this proposal.

First, we are finalizing our proposal to allow all group practices to voluntarily elect to administer the CAHPS for PQRS survey.

Second, regarding our proposal to require group practices of 25 or more EPs that register to participate in the GPRO and select the Web Interface as the reporting mechanism to select a CMS-certified survey vendor to report CAHPS for PQRS, we are not finalizing this proposal with respect to group practices of 25–99 EPs. We are, however, finalizing this proposal with respect to group practices of 100 or more EPs. Thus, we are requiring that, for the reporting periods occurring in 2016, all group practices of 100 or more EPs that register to participate in the GPRO select a CMS-certified survey vendor to report CAHPS for PQRS, regardless of the reporting mechanism the group practice uses. We note that, for reporting periods occurring in 2015, we currently require all group practices of 100 or more EPs that register to participate in the GPRO select a CMS-certified survey vendor to report CAHPS for PQRS, regardless of the reporting mechanism the group practice uses. Therefore, as it was a previously established requirement, and as group practices of 100 or more EPs were logically included in our proposal to require group practices of 25 or more EPs to report CAHPS for PQRS, we believe it was foreseeable that we would finalize this requirement with respect to group practices of 100 or more EPs. We also believe that this modification addresses the commenters' desire to keep the reporting requirements unchanged. As we specify below, since we are not finalizing this proposal with respect to group practices of 25–99 EPs, we will modify our proposed criteria for satisfactory reporting related to requiring the administering of the CAHPS for PQRS survey for group practices of 25–99 EPs.

In addition, we noted that we finalized a 12-month reporting period for the administration of the CAHPS for PQRS survey. However, as group practices 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 provide an adequate sample of the 12-month reporting period.

b. Criteria for Satisfactory Reporting on PQRS Quality Measures Via the 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 Web Interface (*see* Table 51 at 79 FR 67797)—we proposed 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 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 Web Interface. Although the criteria proposed above are specified for groups practices of 25 or more EPs, please note

that, given our finalized requirement that group practices of 100 or more EPs report the CAHPS for PQRS survey (rather than group practices of 25 or more EPs, as originally proposed), the criteria proposed above would apply to a group practices of 100 or more EPs only if the CAHPS for PQRS survey does not apply to the group practice.

Comment: We solicited and received support for this reporting criterion, mainly because commenters urged us to keep the reporting requirements unchanged.

Response: We appreciate the commenters' feedback, and, based on the rationale provided and the comments received, are finalizing this proposed criterion, as proposed.

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.I.4.a., we proposed to require that group practices of 25 or more EPs who elect to report quality measures via the 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 proposed 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 Web Interface and for which the CAHPS for PQRS survey applies. Specifically, if a group practice chooses to use the Web Interface in conjunction with reporting the CAHPS for PQRS survey measures, we proposed to specify the following 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 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.

We solicited and received the following public comment on this proposal:

Comment: We did not receive specific comments on this proposed criterion. Please note, however, that we received general comments on the requirement to report CAHPS for PQRS, as discussed in section III.I.5.a. of this final rule with comment period.

Response: As we stated in section III.I.5.a. of this final rule with comment period, because we are finalizing our proposal to require group practices to report CAHPS for PQRS only with respect to group practices of 100 or more EPs, we are modifying this proposal as follows:

For group practices of 25–99 EPs that registered to participate in the GPRO for the 12-month reporting period for the 2018 PQRS payment adjustment using the Web Interface and for which the CAHPS for PQRS survey applies, administration of the CAHPS for PQRS survey will be *OPTIONAL* for 2016. Therefore, we are finalizing the following criterion as an option for these group practices if they voluntarily elect to administer the CAHPS for PQRS survey in conjunction with the Web Interface: 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 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 group practices of 100+ EPs that registered to participate in the GPRO for the 12-month reporting period for the 2018 PQRS payment adjustment using the Web Interface and for which the CAHPS for PQRS survey applies, administration of the CAHPS for PQRS survey will be *REQUIRED* for 2016. Therefore, we are finalizing the following criterion for these group practices: 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 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 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 proposed to continue using the attribution methodology used for the VM for the Web Interface beneficiary assignment methodology for the 2018 PQRS payment adjustment and future years. We solicited and received the following public comment on this proposal:

Comment: One commenter opposed the use of the VM's attribution methodology for purposes of the Web Interface beneficiary assignment and methodology. Specifically, the commenter believed that the VM's attribution methodology penalizes providers for costs beyond their control.

Response: We do not believe that the VM's attribution methodology penalizes providers for costs beyond their control. Please note that the cost measures that must be separately reported for the VM are not reported for the PQRS. Therefore, cost is not associated with the attribution methodology we proposed. Based on the rationale provided, we are finalizing our proposal to continue using the attribution methodology used for the VM for the Web Interface beneficiary assignment methodology for the 2018 PQRS payment adjustment.

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 Web Interface. Therefore, to meet the criteria for satisfactory reporting using the Web Interface, a group practice must be assigned and have sampled at least 1 Medicare patient for any of the applicable Web Interface measures. If a group practice does not typically see Medicare patients for which the 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 Web Interface, we advise the group practice to participate in the PQRS via another reporting mechanism.

c. 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 proposed 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 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 proposed 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 invited and received the following public comments on these proposals.

Comment: We received general support for the 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. Some commenters specifically supported continued use of the registry-based reporting mechanism. With respect to reporting CAHPS for PQRS, please note, we received general comments on the requirement to report CAHPS for PQRS, as discussed in section III.I.5.a. of this final rule with comment period.

Response: As we stated in section III.I.5.a. of this final rule with comment period, because we are finalizing our proposal to require group practices to report CAHPS for PQRS only with respect to group practices of 100 or more EPs, we are modifying this proposal as follows:

For group practices of 2–99 EPs registered to participate in the GPRO via registry for the 2018 PQRS payment adjustment: The administration of the CAHPS for PQRS survey is *OPTIONAL.* Therefore, if reporting via registry, these group practices may meet the criteria for satisfactory reporting for the 2018 PQRS payment adjustment in one of two ways:

OPTION 1 (group practices that do not voluntarily elect to administer the CAHPS for PQRS survey in conjunction with the registry): 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 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.

OPTION 2 (group practices that voluntarily elect to administer the CAHPS for PQRS survey in conjunction with the registry): For the 12-month reporting period for the 2018 PQRS payment adjustment, 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.

For group practices of 100+ EPs registered to participate in the GPRO via registry for the 2018 PQRS payment adjustment: The administration of the CAHPS for PQRS survey is *REQUIRED.* Therefore, if reporting via registry, these group practices must meet the following criterion for satisfactory reporting for the 2018 PQRS payment adjustment: For the 12-month reporting period for the 2018 PQRS payment adjustment, 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.

d. 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 proposed 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 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 (since CAHPS for PQRS is in one NQS domain). We invited and received the following public comments on these proposals:

Comment: We received general support for the 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. Some commenters specifically supported continued use of the EHR-based reporting mechanism. With respect to reporting CAHPS for PQRS, please note, we received general comments on the requirement to report CAHPS for PQRS, as discussed in section III.I.5.a. of this final rule with comment period.

Response: As we stated in section III.I.5.a. of this final rule with comment period, because we are finalizing our proposal to require group practices to report CAHPS for PQRS only with respect to group practices of 100 or more EPs, we are modifying this proposal as follows:

For group practices of 2–99 EPs registered to participate in the GPRO via EHR for the 2018 PQRS payment adjustment: The administration of the CAHPS for PQRS survey is OPTIONAL. Therefore, if reporting via EHR, these group practices may meet the criteria for satisfactory reporting for the 2018 PQRS payment adjustment in one of two ways:

OPTION 1 (group practices that do not voluntarily elect to administer the CAHPS for PQRS survey in conjunction with EHR): 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.

OPTION 2 (group practices that voluntarily elect to administer the CAHPS for PQRS survey in conjunction with EHR): For the 12-month reporting period for the 2018 PQRS payment adjustment, 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.

For group practices of 100+ EPs registered to participate in the GPRO via EHR for the 2018 PQRS payment adjustment: The administration of the CAHPS for PQRS survey is REQUIRED. Therefore, if reporting via EHR, these group practices must meet the following criterion for satisfactory reporting for the 2018 PQRS payment adjustment: For the 12-month reporting period for the 2018 PQRS payment adjustment, 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.

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 requires 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. Reporting Period for the Satisfactory Participation by Group Practices 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, requires 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 proposed 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 proposed 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 invited 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.

The following is a summary of the comments we received regarding our proposal.

Comment: Commenters generally supported the proposed 12-month 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, as it is consistent with the reporting period for other criteria for satisfactory reporting, as well as satisfactory participation in a QCDR in the PQRS.

Response: As a result of the supportive comments, we are finalizing this reporting period, as proposed. Therefore, we are revising § 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.

g. 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 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 proposed 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.

We solicited and received the following public comments on these proposals:

Comment: Commenters generally supported the option to report quality measures data via a QCDR as a group practice. One commenter opposed the proposal to require group practices using a QCDR to report on at least 9 measures. The commenter noted that when the QCDR option was first introduced to as a reporting method for individuals, EPs were only required to report at least three measures.

Response: We appreciate the commenters' concerns regarding the requirement to report at least 9 measures. However, we believe that group practices should be required to report on the same amount of measures as an individual EP. Based on the positive feedback and the rationale provided, we are finalizing the proposed criterion for satisfactory participation in a QCDR for group practices registered to participate in the GPRO via a QCDR for the 2018 PQRS payment adjustment, as proposed.

Tables 27 and 28 reflect our criteria for satisfactory reporting—or, in lieu of satisfactory reporting, satisfactory participation in a QCDR—for the 2018 PQRS payment adjustment:

TABLE 27—SUMMARY OF 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 28—SUMMARY OF 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).	25–99 EPs; 100+ EPs (if *CAHPS for PQRS does not apply).	Individual GPRO Measures in the Web Interface.	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 28—SUMMARY OF 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).	25–99 EPs that elect CAHPS for PQRS; 100+ EPs (if CAHPS for PQRS applies).	Individual GPRO Measures in the Web Interface + CAHPS for PQRS.	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 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 Web Interface, the group practice must administer the CAHPS for PQRS survey in addition to reporting the Web Interface measures.
12-month (Jan 1–Dec 31, 2016).	2–99 EPs; 100+ EPs (if CAHPS for PQRS does not apply).	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).	2–99 EPs that elect CAHPS for PQRS; 100+ EPs (if CAHPS for PQRS applies).	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).	2–99 EPs; 100+ EPs (if CAHPS for PQRS does not apply).	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).	2–99 EPs that elect CAHPS for PQRS; 100+ EPs (if CAHPS for PQRS applies).	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 28—SUMMARY OF 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 a ''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.

As such, we may exercise our authority under section 1848(k)(2)(C)(ii) of the Act to propose and finalize a measure because a feasible and practical measure has not been endorsed by the

NQF for a specified topic, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary.

a. PQRS Quality Measures

Taking into consideration the statutory and non-statutory criteria we described previously, this section discusses the inclusion or removal of measures in PQRS for 2016 and beyond. We classified all 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.

In addition, CMS considers the MAP's recommendations as part of the comprehensive assessment of each measure considered for inclusion in the program. Additional elements under consideration include a measure's fit within the program, if a measure fills clinical gaps, changes or updates to clinical guidelines and other program needs. As such, while CMS strongly considers the MAP's recommendations, MAP support is not required for inclusion in PQRS.

Please note that the PQRS quality measure specifications for any given PQRS individual quality measure may differ from specifications for the same quality measure used in prior years. For example, for the 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 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 noted 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 used 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 noted that the NQF process incorporates an opportunity for public comment and engagement in the measure maintenance process. We revised the Specifications Manual and posted notices to clearly identify the updates and provide links to where additional information on the updates can be found. Updates are also 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 31, we proposed 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 noted 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 proposed to keep the measure available for reporting under the PQRS and therefore not finalize our proposal to remove the measure. We stated that we would discuss any such instances in the CY 2016 PFS final rule with comment period.

In addition, we noted 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 began 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.

b. 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 29, we proposed the following measures to be added to the current PQRS cross-cutting measure set. Please note that our rationale for each of these measures is found below the measure description. We solicited and received public comments on these measures. A summary of the comments, our responses, as well as final decisions are in Table 29. Please note that these proposed measures in Table 30 are in addition to the 19 previously finalized cross-cutting measures. As such, for 2016, there will be a total of 23 cross-cutting measures in PQRS.

TABLE 29: Individual Quality Cross-Cutting Measures for the PQRS to be Available for Satisfactory Reporting via Claims, Registry, and EHR beginning in 2016

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description[¥]	Measure Steward	Other Quality Reporting Programs
Measures Finalized as Proposed					
2152/ 431	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. This measure was 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. While several commenters agreed this measure was appropriately classified as cross-cutting, one commentor suggested this measure be delayed for implementation as cross-cutting to allow providers time to standardize documentation processes. CMS continues to believe this is a broadly applicable measure reportable by several provider types and should be relatively easy for providers to document. For this reason, CMS is finalizing its proposal to make this measure reportable as a cross-cutting measure for 2016 PQRS.	American Medical Association – Physician Consortium for Performance Improvement	
2372/ 112	125v4	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. 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 was 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. Several commenters agreed this measure was appropriately classified as cross-cutting. One commenter suggested that designating this measure as cross-cutting "may be viewed as an endorsement of a reduction in the frequency of screening and may compromise patient care". CMS believes that designating a measure as cross-cutting would not impact patient access to appropriate care. CMS believes that providers should adhere to clinical guidelines and not treat patients based on quality measures. CMS continues to believe this is a broadly applicable measure reportable by a number of providers. For these reasons, CMS is finalizing its proposal to include this measure as cross-cutting beginning in 2016 for PQRS.	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. 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.	National Committee for Quality Assurance/ American Medical Association – Physician Consortium	

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description¥	Measure Steward	Other Quality Reporting Programs
			This measure was proposed as a cross-cutting measure for PQRS for CY 2016 PFS as it is applicable to a variety of physician specialties and should be integrated into the standard of care for providers who serve patients with a history of falls. Commenters agreed this measure was appropriately classified as cross-cutting. For this reason, CMS is finalizing its proposal to make this measure reportable as a cross-cutting measure for 2016 PQRS.	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. 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 was proposed as a cross-cutting measure for PQRS for CY 2016 as it is applicable to a variety of physician specialties and should be integrated into the standard of care for providers who serve patients with a history of falls. Commenters agreed this measure was appropriately classified as cross-cutting. For this reason, CMS is finalizing its proposal to make this measure reportable as a cross-cutting measure for 2016 PQRS.	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. New PQRS Measures Available for Reporting for 2016 and Beyond and Changes to Existing PQRS Measures

Table 30 contains additional measures we proposed to include in the PQRS measure set for CY 2016 and beyond. We 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 proposed 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, although we take these recommendations into consideration, in these instances, we believe the rationale provided for the addition of a measure outweighs the MAP's recommendation.

TABLE 30: 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 and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
Measures Finalized as Proposed or with Modifications												
N/A/ 403	N/A	Person and Caregiver-Centered Experience and Outcomes	**Adult Kidney Disease: Referral to Hospice:** Percentage of patients aged 18 years and older with a diagnosis of end-stage renal disease (ESRD) who withdraw from hemodialysis or 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.	Several commenters supported the inclusion of this measure in PQRS. However, one commenter was concerned the nephrologist will have to engage palliative care providers prior to the decision to withdraw from dialysis and that not all patients who are referred to hospice choose to immediately withdraw from dialysis. CMS continues to believe this is a valuable measure that fills a clinical gap in the program. As indicated in the measure specification, this measure is assessing if a referral to hospice is made for those patients who withdraw from dialysis and as such CMS does not believe palliative care must be engaged prior to this decision. For these reasons, CMS is finalizing this measure for reporting in 2016 PQRS.	Renal Physicians Association/ American Medical Association – Physician Consortium for Performance Improvement			X			
N/A/ 439	N/A	Efficiency and Cost Reduction	**Age Appropriate Screening Colonoscopy:** The percentage of patients greater than 85 years of age who received a screening colonoscopy from January 1 to December 31.	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	The title of this measure has been updated since appearing in the CY 2016 PFS proposed rule (originally entitled "Unnecessary Screening Colonoscopy in Older Adults" in Table 23 at 80 FR 41832 through	American Gastroenterological Association/ American Society for Gastrointestinal Endoscopy/ American College of Gastroenterology			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
				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.	41857) and conforms to the measure steward's most current measure specification. Commenters supported the inclusion of this measure in PQRS and urged CMS to encourage measure developers to obtain NQF-endorsement as soon as possible. CMS is exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to finalize this measure because a feasible and practical measure has not been endorsed by the NQF for a specified topic, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Another commenter was concerned with CMS not proposing this measure for claims reporting option, noting that not all eligible professionals have the resources to implement registry reporting. CMS appreciates the commenter's concerns and believes that exclusion of the claims-based reporting option will not negatively impact a significant number of providers reporting this measure. For these reasons, CMS is finalizing this measure for registry reporting in 2016 PQRS.							

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
N/A/ 404	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.	Several commenters were concerned with this measure proposed as registry only reporting option, noting that not all eligible professionals have the resources to implement registry reporting. CMS appreciates the commenters' concerns and believes this measure being reportable by registry only will not negatively impact a significant number of providers. It is CMS's goal to lower the data error rate and decrease provider burden. For these reasons, CMS is finalizing this measure for reporting in 2016 PQRS.	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 and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
N/A/ 421	N/A	Effective Clinical Care	**Appropriate Assessment of Retrievable Inferior Vena Cava Filters for Removal:** Percentage of patients in whom a retrievable IVC filter is placed who, within 3 months post-placement, have a documented assessment for the appropriateness of continued filtration, device removal or the inability to contact the patient with at least two attempts.	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.	The title of this measure has been updated since appearing in the CY 2016 PFS proposed rule (originally entitled "Percentage of Patients with a Retrievable Inferior Vena Cava (IVC) Who Are Appropriately Assessed for Continued Filtration or Device Removal" in Table 23 at 80 FR 41832 through 41857) and conforms to the measure steward's most current measure specification. CMS received supportive comments regarding the inclusion of this measure in PQRS. CMS is finalizing this measure for reporting in 2016 PQRS.	Society of Interventional Radiology			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
N/A/ 405	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.	Commenters supported the inclusion of this measure in PQRS but urged CMS to encourage measure developers to obtain NQF-endorsement as soon as possible. CMS is exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to finalize this measure because a feasible and practical measure has not been endorsed by the NQF for a specified topic, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. For these reasons, CMS is finalizing this measure for reporting in 2016 PQRS.	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 and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
N/A/ 406	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.	Commenters supported the inclusion of this measure in PQRS and urged CMS to encourage measure developers to obtain NQF-endorsement as soon as possible. CMS is exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to finalize this measure because a feasible and practical measure has not been endorsed by the NQF for a specified topic, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. For these reasons, CMS is finalizing this measure for reporting in 2016 PQRS.	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 and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
N/A/ 407	N/A	Effective Clinical Care	**Appropriate Treatment of MSSA Bacteremia:** Percentage of patients with sepsis due to MSSA bacteremia who received beta-lactam antibiotic (e.g. nafcillin, oxacillin or cefazolin) as definitive therapy.	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.	The description of this measure has been updated since appearing in the CY 2016 PFS proposed rule (Table 23 at 80 FR 41832 through 41857) and conforms to the measure steward's most current measure specification. Commenters supported the inclusion of this measure in PQRS. CMS continues to believe that this measure represents a strong clinical need and PQRS measure gap. For this reason, CMS is finalizing this measure for reporting in 2016 PQRS.	Infectious Diseases Society of America	X		X			
N/A/ 408	N/A	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during	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	The title and description of this measure has been updated since appearing in the CY 2016 PFS Proposed rule (originally entitled "Chronic Opioid Therapy Follow-up Evaluation" in Table 23 at 80 FR 41832 through 41857) and	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 and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
			Opioid Therapy documented in the medical record.	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 measure promotes patient safety within PQRS.	conforms to the measure steward's most current measure specification. Commenters supported the inclusion of this measure in PQRS. CMS continues to believe this is an analytically robust and clinically sound measure that identifies the importance of patient safety. For this reason, CMS is finalizing this measure for reporting in 2016 PQRS.							
N/A/ 409	N/A	Effective Clinical Care	**Clinical Outcome Post Endovascular Stroke Treatment:** Percentage of patients with a mRs score of 0 to 2 at 90 days following endovascular stroke intervention.	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.	While some commenters supported the inclusion of this measure in the program, one commenter recommended CMS exclude this measure from the program until it has been fully specified and validated. In addition, this commenter maintained this measure should be risk-adjusted for those providers who care for the sickest patients. Measures finalized for inclusions in the program have undergone feasibility, validity and reliability testing. Additionally, measures within PQRS are fully specified prior to implementation. CMS continues to believe this measure assesses improvement based on the therapy	Society of Interventional Radiology			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
					provided. For these reasons, CMS is finalizing this measure for reporting in 2016 PQRS.							
0711 / 411	N/A	Communication and Care Coordination	**Depression Remission at Six Months:** Adult patients age 18 years and older with major depression or dysthymia and an initial PHQ-9 score > 9 who demonstrate remission at six months defined as a PHQ-9 score less than 5. This measure applies to both patients with newly diagnosed and existing depression whose current PHQ-9 score indicates a need for treatment.	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.	The description of this measure has been updated since appearing in the CY 2016 PFS proposed rule (Table 23 at 80 FR 41832 through 41857) and conforms to the measure steward's most current measure specification. Commenters supported the inclusion of this measure in PQRS. CMS continues to believe this is an important outcome measure for mental health providers. For this reason, CMS is finalizing this measure for reporting in 2016 PQRS.	Minnesota Community Measurement			X			
N/A/ 412	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 Opioid Therapy 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	The description of this measure has been updated since appearing in the CY 2016 PFS proposed rule (Table 23 at 80 FR 41832 through 41857) and conforms to the measure steward's most current measure specification. Several commenters supported the inclusion of this measure in PQRS. One commenter suggested modifications to the measure specification. CMS uses the measure specifications as approved by the measure stewards and owners. CMS is finalizing this measure for reporting in 2016 PQRS.	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 and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
				clinically robust and not duplicative of any measures in the PQRS.								
N/A/ 413	N/A	Effective Clinical Care	**Door to Puncture Time for Endovascular Stroke Treatment:** Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of less than two hours.	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 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.	Several commenters supported the inclusion of this measure in PQRS. One commenter maintained this measure needs further development and validation prior to implementation, noting the target time may be too long, few facilities will have sufficient volume, and that CMS should consider how transfers are handled. CMS appreciates this commenter's concerns. However, CMS continues to believe this is a relevant measure that fills a clinical gap in the program. For this reason, CMS is finalizing this measure for reporting in 2016 PQRS.	Society of Interventional Radiology			X			
N/A/ 415	N/A	Efficiency and Cost Reduction	**Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18**	Encourage Continued Development Although this measure is not NQF-endorsed, we are exercising our	The title and description of this measure has been updated since appearing in the CY 2016 PFS proposed rule (originally entitled "Imaging in	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 and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
			Years and Older: Percentage of emergency department visits for patients aged 18 years and older who presented within 24 hours of a minor blunt head trauma with a Glasgow Coma Scale (GCS) score of 15 and who had a head CT for trauma ordered by an emergency care provider who have an indication for a head CT.	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.	Adult Emergency Department (ED) Patients with Minor Head Injury" in Table 23 at 80 FR 41832 through 41857) and conforms to the measure steward's most current measure specification. Commenters supported the inclusion of this measure in PQRS and urged CMS to encourage measure developers to obtain NQF-endorsement. CMS is exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to finalize this measure because a feasible and practical measure has not been endorsed by the NQF for a specified topic, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. CMS is finalizing this measure for reporting in 2016 PQRS.							
N/A/ 416	N/A	Efficiency and Cost Reduction	**Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 through 17 Years:** Percentage of emergency department visits for patients aged 2 through 17 years who presented within 24 hours of a minor blunt head	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	The title and description of this measure has been updated since appearing in the CY 2016 PFS proposed rule (originally entitled "Imaging in Pediatric ED Patients Aged 2 through 17 Years with Minor Head Injury" in Table 23 at 80 FR 41832 through 41857) and conforms to the measure steward's most	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 and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
			trauma with a Glasgow Coma Scale (GCS) score of 15 and who had a head CT for trauma ordered by an emergency care provider who are classified as low risk according to the PECARN prediction rules for traumatic brain injury.	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.	current measure specification. Commenters supported the inclusion of this measure in PQRS but urged CMS to encourage measure developers to obtain NQF-endorsement as soon as possible. CMS is exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to finalize this measure because a feasible and practical measure has not been endorsed by the NQF for a specified topic, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. CMS continues to believe this measure is clinically robust, analytically feasible and fills a clinical gap as it addresses the importance of radiation safety within the adolescent population. For these reasons, CMS is finalizing this measure for reporting in 2016 PQRS.							
N/A/ 414	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,	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	The description of this measure has been updated since appearing in the CY 2016 PFS proposed rule (Table 23 at 80 FR 41832 through 41857) and conforms to the measure steward's most current measure specification. Commenters supported the	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 and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
			SOAAP-R) or patient interview documented at least once during Opioid Therapy in the medical record.	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.	inclusion of this measure in PQRS. CMS continues to believe this measure fills a clinical gap and addresses the importance of patient safety. For this reason, CMS is finalizing this measure for reporting in 2016 PQRS.							
0053 /418	N/A	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis.	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 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.	Although no comments were received regarding the proposal of this measure, CMS continues to believe that NQF # 0053 represents a more harmonized and up-to-date measure than NQF # 0048, which we are removing in Table 32 of this final rule with comment period. CMS is finalizing this measure for reporting in 2016 PQRS.	National Committee for Quality Assurance/ American Medical Association-Physician Consortium for Performance Improvement	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 and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
N/A/ 419	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 whom advanced brain imaging was not ordered.	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.	The description of this measure has been updated since appearing in the CY 2016 PFS proposed rule (Table 23 at 80 FR 41832 through 41857) and conforms to the measure steward's most current measure specification. Commenters supported the inclusion of this measure in PQRS but urged CMS to encourage measure developers to obtain NQF-endorsement as soon as possible. CMS is exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to finalize this measure because a feasible and practical measure has not been endorsed by the NQF for a specified topic, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. CMS continues to believe this measure fulfills a clinical gap as it addresses the overuse of neuroimaging and its relation to patient safety. For these reasons, CMS is finalizing this measure for reporting in 2016 PQRS.	American Academy of Neurology	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 and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
N/A/ 428	N/A	Effective Clinical Care	**Pelvic Organ Prolapse: Preoperative Assessment of Occult Stress Urinary Incontinence:** 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.	The title of this measure has been updated since appearing in the CY 2016 PFS proposed rule (originally entitled "Preoperative Assessment of Occult Stress Urinary Incontinence Prior to any Pelvic Organ Prolapse Repair" in Table 23 at 80 FR 41832 through 41857) and conforms to the measure steward's most current measure specification. Commenters supported the inclusion of this measure in PQRS. CMS continues to believe this measure fills a clinical gap as it addresses patients who do not receive preoperative assessment of occult stress urinary incontinence prior to pelvic organ prolapse repair. For this reason, CMS is finalizing this measure for reporting in 2016 PQRS.	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 and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
N/A/ 429	N/A	Patient Safety	**Pelvic Organ Prolapse: Preoperative Screening for Uterine Malignancy:** Percentage of patients who are screened for uterine malignancy 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.	The title and description of this measure has been updated since appearing in the CY 2016 PFS proposed rule (originally entitled "Preoperative Exclusion of Uterine Malignancy Prior to any Pelvic Organ Prolapse Repair" in Table 23 at 80 FR 41832 through 41857) and conforms to the measure steward's most current measure specification. Commenters supported the inclusion of this measure in PQRS. CMS continues to believe that this measure fills a clinical gap as it addresses patients who receive preoperative exclusion of uterine malignancy prior to any pelvic organ prolapse repair. For this reason, CMS is finalizing this measure for reporting in 2016 PQRS.	American Urogynecologic Society	X		X			
2063 / 422	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 hysterectomy for pelvic organ prolapse.	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	This measure is now NQF #2063. Commenters supported the inclusion of this measure in PQRS. CMS continues to believe that this measure fills a clinical gap as it addresses injury during hysterectomy procedures. For this reason, CMS is finalizing this measure for reporting in 2016 PQRS.	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 and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
				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.								
0465 / 423	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.	Commenters supported the concept of this measure but urged CMS to encourage measure developers to obtain NQF-endorsement as soon as possible. CMS is exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to finalize this measure because a feasible and practical measure has not been endorsed by the NQF for a specified topic, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. This measure fills a clinical gap as it promotes prevention of secondary vascular disease beyond surgery. CMS is finalizing this measure for reporting in 2016 PQRS.	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 and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
2671 / 424	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.	This measure is now NQF #2671. CMS received several comments concerning the lack of measures proposed with the claims-based reporting option. Commenters noted that not all eligible professionals have the resources to implement registry or EHR reporting. CMS appreciates the commenters' concerns and believes that the use of registry-only reporting will not impact a significant number of providers reporting these measures. Additionally, CMS's goal in data reporting includes a decrease in data error rate and provider burden. For these reasons, CMS is finalizing this measure for reporting in 2016 PQRS.	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 and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
N/A/ 425	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 of colon cancer. Additionally, this measure would be applicable for gastroenterology specialists to report.	Commenters supported the inclusion of this measure in PQRS. CMS continues to believe this measure fills a clinical gap as photodocumentation of cecal intubation aids in the prevention of colon cancer. For this reason, CMS is finalizing this measure for reporting in 2016 PQRS.	American College of Gastroenterology / American Gastroenterological Association/ 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 and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
N/A/ 426	N/A	Communication and Care Coordination	**Post-Anesthetic Transfer of Care Measure: Procedure Room to a Post Anesthesia Care Unit (PACU):** Percentage of patients, regardless of age, who are under the care of an anesthesia practitioner and are admitted to a PACU in which a post-anesthetic formal transfer of care protocol or checklist which includes the key transfer of care elements is utilized.	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.	The description of this measure has been updated since appearing in the CY 2016 PFS proposed rule (Table 23 at 80 FR 41832 through 41857) and conforms to the measure steward's most current measure specification. Several commenters CMS received several comments concerning the lack of measures proposed with the claims-based reporting option. . Commenters noted that not all eligible professionals have the resources to implement registry or EHR reporting. CMS appreciates the commenters' concerns and believes that the use of registry-only reporting will not impact a significant number of providers reporting these measures. Additionally, CMS's goal in data reporting includes a decrease in data error rate and provider burden. For these reasons, CMS is finalizing this measure for reporting in 2016 PQRS.	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 and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
N/A/ 427	N/A	Communication and Care Coordination	**Post-Anesthetic Transfer of Care: Use of Checklist or Protocol for Direct Transfer of Care from Procedure Room to Intensive Care Unit (ICU):** Percentage of patients, regardless of age, who undergo a procedure under anesthesia and are admitted to an Intensive Care Unit (ICU) directly from the anesthetizing location, who have a documented use of a checklist or protocol for the transfer of care from the responsible anesthesia practitioner to the responsible ICU team or team member.	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.	The title of this measure has been updated since appearing in the CY 2016 PFS proposed rule (originally entitled "Post-Anesthetic Transfer of Care Measure: Use of Checklist or Protocol for Direct Transfer of Care from Procedure Room to Intensive Care Unit (ICU)" in Table 23 at 80 FR 41832 through 41857) and conforms to the measure steward's most current measure specification. CMS received several comments concerning the lack of measures proposed with the claims-based reporting option. Commenters noted that not all eligible professionals have the resources to implement registry or EHR reporting. CMS appreciates the commenters' concerns and believes that the use of registry-only reporting will not impact a significant number of providers reporting these measures. Additionally, CMS's goal in data reporting includes a decrease in data error rate and provider burden. For these reasons, CMS is finalizing this measure for reporting in 2016 PQRS.	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 and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
N/A/ 430	N/A	Patient Safety	**Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy:** Percentage of patients, aged 18 years and older, who undergo a procedure under an inhalational general anesthetic, AND who have three or more risk factors for post-operative nausea and vomiting (PONV), who receive combination therapy consisting of at least two prophylactic pharmacologic antiemetic agents of different classes preoperatively or intraoperatively.	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.	CMS received several comments concerning the lack of measures proposed with the claims-based reporting option. Commenters noted that not all eligible professionals have the resources to implement registry or EHR reporting. CMS appreciates the commenters' concerns and believes that the use of registry-only reporting will not impact a significant number of providers reporting these measures. Additionally, CMS's goal in data reporting includes a decrease in data error rate and provider burden. For these reasons, CMS is finalizing this measure for reporting in 2016 PQRS.	American Society of Anesthesiologists			X			
2152 / 431	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.	Encourage Continued Development This measure will replace PQRS #173 "Preventive Care and 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.	Commenters supported the inclusion of this measure in PQRS. CMS continues to believe it is a more clinically robust measure for unhealthy alcohol use than the measure it replaces, PQRS #173 "Preventive Care and Screening Unhealthy Alcohol Use-Screening." For this reason, CMS is finalizing this measure for reporting in 2016 PQRS.	American Medical Association – Physician Consortium for Performance Improvement			X			X

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N/A/ 432	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.	Several commenters supported the inclusion of this measure in PQRS. However, after further review, CMS determined that it is not analytically feasible to report this measure through claims and as such CMS is finalizing this measure as registry reportable only in 2016 PQRS.	American Urogynecologic Society			X			
N/A/ 433	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 time of index surgery that is recognized intraoperative 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	Several commenters supported the inclusion of this measure in PQRS. However, after further review, CMS determined that it is not analytically feasible to report this measure through claims and as such CMS is finalizing this measure as registry reportable only in 2016 PQRS.	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 and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
				program, as it address injury while performing pelvic organ prolapse surgeries. This outcomes measure is reportable by surgeons.								
N/A/ 434	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.	Commenters supported the inclusion of this measure in PQRS. However, after further review, CMS determined that it is not analytically feasible to report this measure through claims and as such CMS is finalizing this measure as registry reportable only in 2016 PQRS.	American Urogynecologic Society			X			
N/A/ 410	N/A	Person and Caregiver-Centered Experience and Outcomes	**Psoriasis: Clinical Response to Oral Systemic or Biologic Medications:** Percentage of psoriasis patients receiving oral systemic or biologic therapy who meet minimal physician- or patient-reported disease activity levels. It is implied that establishment and	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	The title of this measure has been updated since appearing in the CY 2016 PFS proposed rule (originally entitled "Clinical Response to Oral Systemic or Biologic Medications" in Table 23 at 80 FR 41832 through 41857) and conforms to the measure steward's most current measure specification.	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 and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
			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.	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.	Commenters supported the inclusion of this measure in PQRS. CMS continues to believe this outcome measure represents a domain gap in the program. For this reason, CMS is finalizing this measure for reporting in 2016 PQRS.							
N/A/ 435	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.	Although commenters supported the inclusion of this measure in PQRS, a commenter requested the tool used to measure quality of life be specified. CMS relies on the information and guidance of subject matter experts and measure specifications as approved by the measure stewards and owners, when implementing measures in PQRS. The measure specification does not specify which tool should be used to allow for flexibility by Eligible Professionals to choose the tools that work best in their clinical settings. CMS is finalizing this measure for reporting in 2016 PQRS.	American Academy of Neurology	X		X			
N/A/ 436	N/A	Effective Clinical Care	**Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques:**	This measure appeared on the 2013 MUC list. MAP's recommendation in their 2014	Commenters supported the inclusion of this measure in PQRS but urged CMS to encourage measure	American College of Radiology/ American Medical Association –	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 and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
			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	report was 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 targets a provider group currently under represented in the program, radiologists. This measure also fills a current gap within the program for inpatient care.	developers to obtain NQF-endorsement as soon as possible. CMS is exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to finalize this measure because a feasible and practical measure has not been endorsed by the NQF for a specified topic, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. CMS continues to believe this measure fills a current gap within the program for patient safety and targets an under represented provider group. For these reasons, CMS is finalizing this measure for reporting in 2016 PQRS.	Physician Consortium for Performance Improvement / National Committee for Quality Assurance						
1523 / 417	N/A	Patient Safety	**Rate of Open Repair of Abdominal Aortic Aneurysms (AAA) Where Patients Are Discharged Alive:** Percentage of patients undergoing open repair of abdominal aortic aneurysms (AAA) who are discharged alive.	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	This measure is now NQF #1523. Further, title and description of this measure has been updated since appearing in the CY 2016 PFS proposed rule (originally entitled "In-Hospital Mortality Following Elective Open Repair of AAAs" in Table 23 at 80 FR 41832 through 41857) and conforms to the measure steward's most current measure specification No comments were received regarding the proposal of this measure. CMS continues to believe this outcome measure	Society for Vascular Surgeons			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
				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.	fills a clinical gap in the program as it assesses mortality rate in AAA repair. CMS is finalizing this measure for reporting in 2016 PQRS.							
N/A/ 437	N/A	Patient Safety	**Rate of Surgical Conversion from Lower Extremity Endovascular Revascularization Procedure:** Inpatients assigned to endovascular treatment for obstructive arterial disease, the percent of patients who undergo unplanned major amputation or surgical bypass within 48 hours of the index procedure.	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 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.	Commenters supported the inclusion of this measure in PQRS. CMS continues to believe this measure fills a clinical gap as it addresses unplanned complications in major amputation or surgical bypass. For this reason, CMS is finalizing this measure for reporting in 2016 PQRS.	Society of Interventional Radiology	X		X			
N/A/ 438	N/A	Effective Clinical Care	**Statin Therapy for the Prevention and**	Encourage Continued Development	Several commenters support the concept of this measure,	Centers for Medicare & Medicaid			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 and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
			Treatment of Cardiovascular Disease: Percentage of the following patients—all considered at high risk of cardiovascular events—who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years with a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL	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.	noting it fills an important clinical gap in the program. Two commenters were concerned this measure is not NQF endorsed. CMS is exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to finalize this measure because a feasible and practical measure has not been endorsed by the NQF for a specified topic, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Other commenters noted concern regarding adherence to clinical guidelines, the need for additional testing and the potential for a small denominator. This measure reflects CMS's effort to adhere to current clinical guidelines. Based on feedback and guidance from the technical expert panel and measure owner, CMS, this measure is the most advantageous and analytically feasible way to address the clinical guidelines. CMS also appreciates commenters concern regarding broadening the measure to include other therapies beyond statin, however, current clinical guidelines indicate statin therapy is the appropriate standard of care. One	Services/ Mathematica/ Quality Insights of Pennsylvania						

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
					commenter also expressed concern that this measure requires further testing and may not cover all components of the current guidelines. CMS requires that all measures included in the program undergo feasibility, validity and reliability testing. Further, CMS recognizes the measure incorporates three of the four components of the guidelines. However, for its initial implementation, the measure provides an opportunity to fill a key clinical gap in the program. CMS may consider updating this measure in future rulemaking years to address the fourth component of the guidelines. After further review, CMS determined this measure is not analytically feasible to report through claims. Therefore, CMS is finalizing its proposal to include this measure as Web Interface, measures groups and registry reportable in 2016 PQRS.							
N/A/ 420	N/A	Effective Clinical Care	**Varicose Vein Treatment with Saphenous Ablation: Outcome Survey:** Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an	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	The title of this measure has been updated since appearing in the CY 2016 PFS proposed rule (originally entitled "Percentage of Patients Treated for Varicose Veins who are Treated with Saphenous Ablation and Receive an Outcomes Survey Before and after Treatment" in Table 23 at 80 FR 41832	Society of Interventional Radiology			X			

NQF/ PQRS	CMS E-Measure ID	NQS Domain	Measure Title and Description ¥ (Includes Numerator, Denominator, Exclusion Criteria, and Exceptions Information)	2015 MAP Recommendation and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
			improvement on a disease specific patient reported outcome survey instrument after treatment.	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.	through 41857) and conforms to the measure steward's most current measure specification. CMS received supportive comments regarding the inclusion of this measure in the program. CMS continues to believe the measure provides a measurement tool for successful varicose vein therapy. CMS is finalizing this measure for reporting in 2016 PQRS.							
Measures Not Finalized as Proposed												
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 reportable by EPs that provide care	One commenter was concerned with CMS' proposal to add this measure to 2016 PQRS, noting that this measure is not ready for implementation. After further consideration, CMS agrees with the commenter and believes this measure requires further testing and may not be feasible to be reported via Registry. As such, CMS is not finalizing this measure for inclusion in 2016 PQRS.	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 and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
				to pediatric patients.								
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 high-risk elderly patients with cognitive impairment. This measure supports a variety of EPs that support this high-risk Medicare patient population.	Some commenters supported CMS' proposal to add this measure to 2016 PQRS, noting that the measure aligns with current clinical guidelines. CMS found that this measure was developed and tested for eCQMs only. Furthermore, PQRS would be out of alignment with Meaningful Use should this measure be finalized as a Registry measure. As such, CMS is not finalizing this measure for inclusion in 2016 PQRS.	Centers for Medicare & Medicaid Services			X			
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	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	While one commenter supported the intent of this measure, they urged CMS to include this measure only when electronic medical record systems are able to support this measure. After further review, CMS found that this measure was developed and tested for eCQMs only. As such, CMS is not finalizing this measure for inclusion in 2016 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 and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
			provider attempted to communicate with the patient's primary care provider or their specialist about the patient's visit to the emergency department.	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.								
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 care proxy during the measurement period.	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 cognitive impairment care to Medicare patients. This measure promotes the clinical concept of interdisciplinary communication within the PQRS as a whole.	Some commenters supported the inclusion of this measure. However, after further review, CMS found that this measure was developed and tested for eCQMs only. As such, CMS is not finalizing this measure for inclusion in 2016 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 and NPRM Rationale	Public Comments and Responses	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.	One commenter supported CMS' proposal to add this measure to 2016 PQRS, noting that they agree with adopting additional measures addressing imaging services. However, the measure steward of this measure withdrew support for this measure, indicating data suggest that the variation/gap in care does not justify continuation of the measure. As such, CMS is not finalizing this measure for inclusion in 2016 PQRS.	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 and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
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.	While some commenters supported the inclusion of this measure in PQRS, after further review CMS determined this measure would be considered a basic standard of care and thus would not fill a quality gap in the program. For this reason, CMS is not finalizing this measure for reporting in 2016 PQRS.	American College of Gastroenterology / American Gastroenterological Association/ American Society for Gastrointestinal Endoscopy	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	Commenters supported CMS' proposal to add this measure to 2016 PQRS, noting that the measure is clinically sound and represents an important screening concept. However, after further consideration, CMS determined this measure requires additional testing. As such, CMS is not finalizing this measure for inclusion in 2016 PQRS.	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 and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
				partnership. This measure is clinically-sound and represents an 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	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	Commenters supported CMS' proposal to add this measure to 2016 PQRS, noting that the measure is clinically sound and represents an important screening concept. However, after further review, CMS determined the measure, in its current form, needs further development prior to implementation. As such, CMS is not finalizing this measure for inclusion in 2016 PQRS.	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 and NPRM Rationale	Public Comments and Responses	Measure Steward	Claims	Certified Survey Vendor (CSV)	Registry	EHR	GPRO Web Interface	Measures Groups
				reportable by a variety of specialists, including primary care physicians, family practice doctors, OB-GYNs, urologists, and internal medicine physicians.								

¥ 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 31, we provided our proposals for a NQS domain change for measures that are currently available for reporting under the PQRS.

TABLE 31: 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
Measures Finalized as Proposed				
0089/ 019	142v4	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. 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 proposed 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. Commenters supported the domain change for PQRS #019 from Effective Clinical Care to Communication and Care Coordination. CMS is finalizing its proposal to change the domain of this measure for 2016 PQRS.
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. 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 proposed 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. No comments were received for the proposed domain change for PQRS #131 for 2016. CMS is finalizing its proposal to change the domain of this measure for 2016 PQRS.

NQF/ PQRS	CMS E-Measure ID	Previously Finalized NQS Domain	Proposed New NQS Domain	Measure Title and Description
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. 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 proposed 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. One commentor supported the proposed domain change for PQRS #243 for 2016. CMS is finalizing its proposal to change the domain of this measure for 2016 PQRS.
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 for reporting through registryin the PQRS in the CY 2014 PFS final rule (78 FR 74638). CMS proposed 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. No comments were received for the proposed domain change for PQRS #330 for 2016. CMS is finalizing its proposal to change the domain of this measure for 2016 PQRS.
N/A/ 378	75v4	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 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 proposed 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. No comments were received for the proposed domain change for PQRS #378 for 2016. CMS is finalizing its proposal to change the domain of this measure for 2016 PQRS.

¥ 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 32, we proposed to remove the following measures from reporting under the PQRS.

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TABLE 32: Measures 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
Measures Finalized as Proposed										
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. 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 proposed 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). Some commenters disagreed with CMS' proposal to remove PQRS #033 based on the rationale that PQRS #033 is duplicative of PQRS #032 (Stroke and Stroke Rehabilitation: Discharged on Antithrombotic Therapy). Commenters maintained the denominator of this measure is suffciently different from the denominator of PQRS #032 and that removing this measure may result in inappropriate treatment and increased risk of stroke. CMS believes PQRS #032 is the more broadly applicable measure and patients captured in the denominator of PQRS #033 would also be included in the denominator of PQRS #032, and that #033 therefore remains duplicative. Furthermore, CMS maintains that providers should be providing services and care based on clinical guidelines and not quality measures, and as such CMS does not agree removal of this measure will negatively impact treatment.For these reasons, CMS is finalizing its proposal to remove this measure for 2016 PQRS.	American Academy of Neurology			X				

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
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. 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 proposed 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 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). No comments were received regarding the proposal to remove this measure. CMS is finalizing its proposal to remove this measure for 2016 PQRS.	National Committee for Quality Assurance/American Medical Association-Physician Consortium for Performance Improvement	X		X				
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. 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 proposed 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	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
		to 100%, suggesting there is no gap in care. Commenters disagreed with CMS' proposal to remove PQRS #081 based on high performance, noting that it measures the core function of dialysis and that adequate dialysis dose is strongly associated with better health outcomes. CMS maintains that eligible professionals are consistently meeting performance on this measure with performance rates close to 100%, suggesting there is no gap in care. CMS is finalizing its proposal to remove this measure for 2016 PQRS.								
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. 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). CMS proposed 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. Commenters disagreed with CMS' proposal to remove PQRS #081 based on high performance, noting that it measures the core function of dialysis and that adequate dialysis dose is strongly associated with better health outcomes. CMS maintains that eligible professionals are consistently meeting performance on this measure with performance rates close to 100%, suggesting there is no gap in care. CMS is finalizing its proposal to remove this measure for 2016 PQRS.	Renal Physicians Association			X				
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	Society for Vascular Surgeons	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
		vascular access documented by surgeon to have received autogenous AV fistula. 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 proposed 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. Two commenters disagreed with CMS' proposal to remove PQRS #172, suggesting this measure has helped foster increased use of Arterial Venous fistula and decreased catheter placement. CMS maintains that eligible professionals are consistently meeting performance on this measure with performance rates close to 100%, suggesting there is no gap in care. CMS is finalizing its proposal to remove this measure for 2016 PQRS.									
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. 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 reporting methods. CMS proposed 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. No comments were received regarding the proposal to remove this measure. CMS is finalizing its proposal to remove this measure for 2016 PQRS.	American Medical Association-Physician Consortium for Performance Improvement			X			X	
N/A/ 193	Patient Safety	**Perioperative Temperature Management:** Percentage of patients, regardless of age, undergoing surgical or therapeutic procedures under	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
		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. 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 proposed 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 proposed removal due to EPs consistently meeting performance on this measure with performance rates close to 100%, suggesting there is no gap in care. No comments were received regarding the proposal to remove this measure. CMS is finalizing its proposal to remove this measure for 2016 PQRS.									
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. 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 proposed 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	American Society of Clinical Oncology			X				

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		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. Some commenters disagreed with the proposal to remove PQRS #194 suggesting "performance on this measure by oncology practices engaged in quality reporting continues to show considerable variation and potential for improvement and retaining this measure will eliminate unwanted variability in performance of this staging measure." However, CMS continues to believe this measure is a basic standard of care and as such is finalizing its proposal to remove this measure for 2016 PQRS.								
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. 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 proposed removal of PQRS #285 in the CY 2016 PFS proposed rule as it was believed that this measure was duplicative of PQRS #134 (Preventive Care and Screening: Screening for Clinical Depression and Follow-up), which includes screening for depression. One commenter requested the standardized screening tool used in PQRS #134 be applicable to patients with dementia if CMS is to finalize its proposal to remove PQRS #285. Although PQRS #134 may not be completely duplicative of PQRS #285, CMS found that #134 is a more clinically robust measure, as it addresses a follow-up plan. CMS is finalizing its proposal to remove PQRS #285 in 2016 PQRS.	American Academy of Neurology / American Psychological Association						X	
0076/34 9	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, statin medication unless valid contraindication or exception, tobacco-	Minnesota Community Measurement			X				

NQF/ PQRS	NQS Domain	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)*	Measures Groups	Other Quality Reporting Programs
		free status, and daily oral aspirin or anti-platelet use unless valid contraindication or exception. 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 proposed removal in the CY 2016 PFS proposed rule as parts of this composite measure are duplicative of Million Hearts measures. One commenter requested CMS retain this measure in the program and instead work with the Million Hearts program to "acknowledge reporting of these clinical areas via the composite rather than the related Million Hearts measures." CMS appreciates the commenter's concerns; however, CMS is not able to make changes to the Million Hearts program. This measure continues to be duplicative of the related Million Hearts measures reportable through PQRS, and to maintain alignment with this program, CMS is finalizing its proposal to remove this measure for 2016 PQRS.								
Measures Not Finalized as Proposed										
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. **This measure was finalized for inclusion in 2014 PQRS in the CY 2014 PFS Final Rule (see Table 52 at 78 FR 74646).** CMS proposed removal in the CY 2016 PFS proposed rule due to measure steward indicating they will no longer maintain this measure. Currently, the measure steward is still AMA-PCPI, and the measure is ready for CY 2016 implementation. We have tentatively identified a new measure steward who will maintain the measure for purposes of CY 2017 reporting and beyond, and for this reason CMS is not finalizing its proposal to remove this measure from reporting in 2016	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
		PQRS.								
N/A/ 336	Communicatio n 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. **This measure was finalized for inclusion in 2014 PQRS in the CY 2014 PFS Final Rule (see Table 52 at 78 FR 74647).** CMS proposed removal in the CY 2016 PFS proposed rule due to measure steward indicating they will no longer maintain this measure. Currently, the measure steward is still AMA-PCPI, and the measure is ready for CY 2016 implementation. We have tentatively identified a new measure steward who will maintain the measure for purposes of CY 2017 reporting and beyond, and for this reason CMS is not finalizing its proposal to remove this measure from reporting in 2016 PQRS.	American Medical Association-Physician Consortium for Performance Improvement			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 33, we proposed to change the mechanism(s) by which an EP or group practice may report a respective PQRS measure beginning in 2016.

TABLE 33: 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
Measures Finalized as Proposed									
0088/ 018	167 v3	**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. 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 proposed 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. No comments were received regarding the proposal to add this measure to the Diabetic Retinopathy Measures Group. CMS is finalizing its proposal to change the reporting option of this measure for 2016 PQRS.	American Medical Association – Physician Consortium for Performance Improvement / National Committee for Quality Assurance				X		X
0089/ 019	142 v3	**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. 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 proposed to add this measure to the Diabetes	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
		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 – UKPDS). No comments were received regarding the proposal to add this measure to the Diabetic Retinopathy Measures Group. CMS is finalizing its proposal to change the reporting option of this measure for 2016 PQRS.							
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. 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 proposed 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. Several commenters were concerned with this measure proposed to remove the claims reporting option, noting that not all eligible professionals have the resources to implement registry reporting. CMS appreciates the commenters' concerns and believes this measure being reportable by registry only will not negatively impact a significant number of providers. It is CMS's goal to lower the data error rate and decrease provider burden. For these reasons, CMS is finalizing the removal of the claims reporting option for reporting in 2016 PQRS.	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. 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 proposed 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. Several commenters were concerned with this measure proposed to remove the claims reporting option, noting that not all eligible professionals have the resources to implement registry reporting. CMS appreciates the commenters' concerns and believes this measure being reportable by registry only will not negatively impact a significant number of providers. It is CMS's goal to lower the data error rate and decrease provider burden. For these	National Committee for Quality Assurance			X	X		X

NQF/ PQRS	CMS E-Measure ID	Measure Title and Description¥	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups
		reasons, CMS is finalizing the removal of the claims reporting option for reporting in 2016 PQRS.							
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. 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 proposed 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. Commenters supported the proposal to include this measure in the Diabetes Measures Group. CMS is finalizing its proposal to change the reporting option of this measure for 2016 PQRS.	American Podiatric Medical Association			X			X
0056/ 163	123v 4	**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 proposed 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 Program, under which this measure is also available for reporting in 2016, CMS proposed to maintain this measure in PQRS for EHR reporting only, removing all other reporting options. Commenters supported the proposal to remove this measure from the Diabetes Measures Group. CMS is finalizing its proposal to change the reporting option of this measure for 2016 PQRS.	National Committee for Quality Assurance				X		
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. 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 proposed to make this individual measure reportable via measures group only in the CY 2016 PFS proposed rule	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
		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. No comments were received regarding the proposal to make this measure reportable via measures groups only. CMS is finalizing its proposal to change the reporting option of this measure for 2016 PQRS.							
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. 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 proposed 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. No comments were received regarding the proposal to make this measure reportable via measures groups only. CMS is finalizing its proposal to change the reporting option of this measure for 2016 PQRS.	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. 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 proposed 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. No comments were received regarding the proposal to make this measure reportable via measures groups only. CMS is finalizing its proposal to change the reporting option of this measure for 2016 PQRS.	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. 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 proposed 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. No comments were received regarding the proposal to make this measure reportable via Measures Groups only. CMS is finalizing its proposal to change the reporting option of this measure for 2016 PQRS.	Society of Thoracic Surgeons						X
0068/ 204	164v 4	**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. 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 proposed 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. Commenters supported the proposal to add this measure to the Cardiovascular Prevention Measures Group. CMS is finalizing its proposal to change the reporting option of this measure for 2016 PQRS.	National Committee for Quality Assurance	X		X	X	X	X
0018/ 236	165v 4	**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. 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.	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
		CMS proposed 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. Commenters supported the proposal to add this measure to the Cardiovascular Prevention Measures Group. CMS is finalizing its proposal to change the reporting option of this measure for 2016 PQRS.							
0022/ 238	156v 4	**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. 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 proposed 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. No comments were received regarding the proposal to add this measure to the Multiple Chronic Conditions Measures Group. CMS is finalizing its proposal to change the reporting option of this measure for 2016 PQRS.	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. 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 proposed 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. No comments were received regarding the proposal to make this measure reportable via measures group only. CMS is finalizing its proposal to change the reporting option of this measure for 2016 PQRS.	American College of Cardiology/American Heart Association/ American Medical Association-Physician Consortium for Performance Improvement						X

NQF/ PQRS	CMS E-Measure ID	Measure Title and Description[¥]	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups
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. 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 proposed 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. No comments were received regarding the proposal to remove the claims reporting option from this measure. CMS is finalizing its proposal to change the reporting option of this measure for 2016 PQRS.	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. 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 proposed 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. No comments were received regarding the proposal to remove the claims reporting option from this measure. CMS is finalizing its proposal to change the reporting option of this measure for 2016 PQRS.	American Society of Breast Surgeons			X			
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. 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 proposed 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

NQF/ PQRS	CMS E-Measure ID	Measure Title and Description¥	Measure Steward	Claims	CSV	Registry	EHR	GPRO (Web Interface)	Measures Groups
		One comment was received regarding the proposal to add this measure to the Rheumatoid Arthritis Measures Group suggesting CMS delay this addition for one year to allow providers time to create data collection mechanisms. CMS continues to believe this measure is an appropriate addition to this measures group and that providers can continue to report this measure as an individual measure, if needed.For these reasons, CMS is finalizing its proposal to change the reporting option of this measure for 2016 PQRS.							
0710/ 370	159v 4	**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. 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 Web Interface reporting method. CMS proposed 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 proposed rule. No comments were received regarding the proposal to add registry as a reporting option for this measure. CMS is finalizing its proposal to change the reporting option of this measure for 2016 PQRS.	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.

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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 proposed to add the following 3 new measures groups as shown in Tables 34, 35 and 36 that will be available for reporting in the PQRS beginning in 2016. Please note that, in these tables, we provided the PQRS measure numbers for the measures within these measures groups that were previously finalized in the PQRS. New measures within these measures groups that were proposed to be added, as indicated in Table 29, do not have a PQRS number. Therefore, in lieu of a PQRS number, an ''NA'' is indicated. We solicited and received the following public comments on these proposed measures groups:

- *Multiple Chronic Conditions Measures Group:* We proposed 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.

Comment: Commenters supported the inclusion of this measure groups in PQRS.

Response: Based on the comments and rationale provided, CMS is finalizing its proposal to include this measures group for reporting in the PQRS beginning in 2016.

- *Cardiovascular Prevention Measures Group (Millions Hearts):* We proposed 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.

Comment: Commenters supported the inclusion of this measures group in PQRS.

Response: Based on the comments and rationale provided, CMS is finalizing its proposal to include this measures group for reporting in the PQRS beginning in 2016.

• *Diabetic Retinopathy Measures Group:* We proposed 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.

Comment: Commenters supported the inclusion of this measures group in PQRS.

Response: Based on the comments and rationale provided, CMS is finalizing its proposal to include this measures group for reporting in the PQRS beginning in 2016.

TABLE 34—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/ Mathematica/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/ Mathematica/Quality Insights of Pennsylvania.
N/A/438	Statin Therapy for the Prevention and Treatment of Cardiovascular Disease: Percentage of the following patients—all considered at high risk of cardiovascular events—who were prescribed or were on statin therapy during the measurement period:. • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR. • Adults aged ≥21 years with a fasting or direct low-density lipoprotein cholesterol (LDL–C) level ≥ 190 mg/dL; OR. • Adults aged 40–75 years with a diagnosis of diabetes with a fasting or direct LDL–C level of 70–189 mg/dL. This is a new measure described in Table 22 above	Centers for Medicare & Medicaid Services/ Mathematica/Quality Insights of Pennsylvania.

TABLE 35—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 35—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 18–75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal or dilated eye exam (no evidence of retinopathy) in the 12 months 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/ Mathematica/Quality Insights of Pennsylvania.

TABLE 36—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/ Mathematica/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/ Mathematica/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/ Mathematica/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 36—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 proposed to amend the following previously finalized measures groups (in Table 37 through Table 41) for reporting in the PQRS beginning in 2016. Please note that, in these tables, we provided the PQRS measure numbers for the measures within these proposed measures groups that were previously finalized in the PQRS. New measures within these measures groups that were proposed to be added, as indicated in Table 29, do not have a PQRS number. Therefore, in lieu of a PQRS number, an ''NA'' is indicated.

TABLE 37—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.	Centers 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 proposed to amend the Dementia Measures Group for reporting in the PQRS beginning in 2016 by adding Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan (PQRS# 134) and removing Dementia: Screening for Depressive Symptoms (PQRS #285). We solicited and received the following public comment on this measures group.

Comment: One commenter encouraged CMS to retain the nine dementia-specific measures included in the Dementia Measures Group for continued use in the PQRS program even though measures that are not NQF-endorsed are typically removed. The commenter stated that these measures address gaps in the PQRS measure set, reflect the services furnished by a particular specialty, impact chronic conditions, and have a high impact on health care and support CMS' priorities for improved care quality and efficiency and should be retained in future program years.

Response: In response to the comment requesting CMS retain the nine measures of the Dementia Measures Group, please note CMS proposed to remove only one measure but retain the remaining eight dementia measures in this group. CMS is finalizing its proposal to remove PQRS #285 ''Dementia: Screening for Depressive Symptoms'' as CMS believes it is duplicative of PQRS #134 ''Preventive Care and Screening: Screening for Clinical Depression and Follow-up'', which includes screening for depression and is a more robust measure. For this reason, we are finalizing the proposed changes to this measures group for reporting in the PQRS beginning in 2016, as proposed. The final Dementia Measures Group is shown on Table 38.

TABLE 38—DEMENTIA MEASURES GROUP FOR 2016 AND BEYOND

[CMS is finalizing its proposal to add PQRS# 134 Preventive Care and Screening: Screening for Clinical Depression and Follow-up Plan 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.
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/Mathematica/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.

We proposed to amend the Diabetes Measures Group for reporting in the PQRS beginning in 2016 by adding Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy—Neurological Evaluation (PQRS #126) and removing Diabetes: Foot Exam (PQRS #163). We solicited and received the following public comment on this measures group.

Comment: One commenter supported the proposed changes to the Diabetes Measures Group.

Response: Based on the comments and rationale provided, we are finalizing the proposed changes to this measures group for reporting in the PQRS beginning in 2016, as proposed. The final Diabetes Measures Group is shown in Table 39.

TABLE 39—DIABETES MEASURES GROUP FOR 2016 AND BEYOND

[CMS is finalizing its proposal 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 18–75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal or dilated eye exam (no evidence of retinopathy) in the 12 months 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.

TABLE 39—DIABETES MEASURES GROUP FOR 2016 AND BEYOND—Continued

[CMS is finalizing its proposal 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
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.

We proposed to amend the Preventative Care Measures Group for reporting in the PQRS beginning in 2016 by adding Preventive Care and Screening: Unhealthy Alcohol Use: Screening & Brief Counseling (NQF #2152) and removing Preventive Care and Screening: Unhealthy Alcohol Use—Screening (PQRS #173). We solicited and received the following public comment on this measures group.

Comment: One commenter supported the proposed changes to the Preventative Care Measures Group.

Response: Based on the comments and rationale provided, CMS is finalizing the proposed changes to this measures group for reporting in the PQRS beginning in 2016, as proposed. The final Preventative Care Measures Group is shown in Table 40.

TABLE 40—PREVENTIVE CARE MEASURES GROUP FOR 2016 AND BEYOND

[TMS is finalizing its proposal 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 for 2016 PQRS]

NQF/PQRS	Measure title and description	Measure developer
0046/039 ..	Screening for Osteoporosis for Women Aged 65–85 Years of Age: Percentage of female patients aged 65–85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis. The title and description of this measure has been updated since appearing in the CY 2016 PFS proposed rule (originally entitled ''Screening or Therapy for Osteoporosis for Women Aged 65 Years and Older'' in Table 29D at 80 FR 41877) and conforms to the measure steward's most current measure specification.	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 50–75 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.	Centers for Medicare & Medicaid Services/Mathematica/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/Mathematica/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.
2152/431 ..	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 22	American Medical Association-Physician Consortium for Performance Improvement.

We proposed to amend the Rheumatoid Arthritis Measures Group for reporting in the PQRS beginning in 2016 by adding Tuberculosis Prevention for Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis Patients on a Biological Immune Response Modifier (PQRS #337). We solicited and received no public comment on this measures

group. Therefore, based on the rationale provided, we are finalizing the proposed changes to this measures group for reporting in the PQRS beginning in 2016, as proposed. The final Rheumatoid Arthritis Measures Group is shown in Table 41.

TABLE 41—RHEUMATOID ARTHRITIS MEASURES GROUP FOR 2016 AND BEYOND

[CMS is finalizing its proposal to add PQRS #337 Tuberculosis Prevention for Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis Patients on a Biological Immune Response Modifier to this measures group for 2016 PQRS]

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 rheumatoid arthritis 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.	Centers for Medicare & Medicaid Services/Mathematica/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.
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.
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 Web Interface

We finalized the measures that are available for reporting in the 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 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 proposed to adopt the Statin Therapy for the Prevention and Treatment of Cardiovascular Disease measure in Table 42 for reporting via the Web Interface beginning in 2016. We solicited and received the following comments on this proposal:

Comment: Several commenters supported the concept of this measure, noting it fills an important clinical gap in the program. Two commenters were concerned this measure is not NQF endorsed. Other commenters noted concern regarding adherence to clinical guidelines, the need for additional testing and the potential for a small denominator.

Response: This measure reflects CMS's effort to adhere to current clinical guidelines. We are exercising our exception authority under section 1848(k)(2)(C)(ii) of the Act to finalize this measure because a feasible and practical measure has not been endorsed by the NQF that has been submitted to the measures application partnership. Based on feedback and guidance from the technical expert panel and measure owner, CMS, this measure is the most advantageous and analytically feasible way to address the clinical guidelines. We also appreciate the commenters concern regarding broadening the measure to include other therapies beyond statin; however, current clinical guidelines indicate statin therapy is the appropriate standard of care. One commenter also expressed concern that this measure requires further testing and may not cover all components of the current guidelines. We require that all measures included in the program undergo feasibility, validity, and reliability testing. Further, we recognize the measure incorporates three of the four components of the guidelines. However, for its initial implementation, the measure provides an opportunity to fill a key clinical gap in the program. After further review, we determined this measure is not analytically feasible to

report through claims. The measure owner, CMS, may consider updating this measure in future rulemaking years to address the fourth component of the guidelines. Therefore, we are finalizing our proposal to include this measure as Web Interface, measures groups and registry reportable in 2016 PQRS. In addition, we are finalizing this measure under the PREV–13 module. Please note that we do not believe finalizing this measure under the PREV–13 module substantively impacts group practices, as group practices must report on all measures in the Web Interface regardless of the modules in which they are placed. This final change is reflected in Table 42.

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TABLE 42: 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
Measure Finalized as Proposed				
Additions				
N/A / 438	PREV	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients—all considered at high risk of cardiovascular events—who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years with a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL Several commenters support the concept of this measure, noting it fills an important clinical gap in the program. Two commenters were concerned this measure is not NQF endorsed. CMS is exercising its exception authority under section 1848(k)(2)(C)(ii) of the Act to finalize this measure because a feasible and practical measure has not been endorsed by the NQF for a specified topic, as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. Other commenters noted concern regarding adherence to clinical guidelines, the need for additional testing and the potential for a small denominator. This measure reflects CMS's effort to adhere to current clinical guidelines. Based on feedback and guidance from the technical expert panel and measure owner, CMS, this measure is the most advantageous and analytically feasible way to address the clinical guidelines. CMS also appreciates commenters concern regarding broadening the measure to include other therapies beyond statin, however, current clinical guidelines indicate statin therapy is the appropriate standard of care. One commenter also expressed concern that this measure requires further testing and may not cover all components of the current guidelines. CMS requires that all measures included in the program undergo feasibility, validity and reliability testing. Further, CMS recognizes the measure incorporates three of the four components of the guidelines. However, for its initial implementation, the measure provides an opportunity to fill a key clinical gap in the program. CMS may consider updating this measure in future rulemaking years to address the fourth component of the guidelines. After further review, CMS determined this measure is not analytically feasible to report through claims. Therefore, CMS is finalizing its proposal to include this measure as Web Interface, measures groups and registry reportable in 2016 PQRS.	Centers for Medicare & Medicaid Services/ Mathematica / Quality Insights of Pennsylvania	Shared Savings Program

The FINAL list of all PQRS measures available for reporting in 2016 is below:

TABLE 43: Final Individual Quality Measures and Those Included in Measures Groups for the Physician Quality Reporting System to be Available for Satisfactory Reporting via Claims, Registry, or EHR Beginning in 2016 and Beyond

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
0059/ 001	122v4	Effective Clinical Care	**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. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69215).	National Committee for Quality Assurance
N/A/002	163v4	Effective Clinical Care	**Diabetes: Low Density Lipoprotein (LDL-C) Control (<100 mg/dL):** Percentage of patients 18–75 years of age with diabetes whose LDL-C was adequately controlled (< 100 mg/dL) during the measurement period. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 94 at 77 FR 69209).	National Committee for Quality Assurance
0081/005	135v4	Effective Clinical Care	**Heart Failure (HF): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy either within a 12 month period when seen in the outpatient setting OR at each hospital discharge. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69215).	American Medical Association-Physician Consortium for Performance Improvement/ American College of Cardiology Foundation/ American Heart Association
0067/006	N/A	Effective Clinical Care	**Coronary Artery Disease (CAD): Antiplatelet Therapy:** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease (CAD) seen within a 12 month period who were prescribed aspirin or clopidogrel. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69215).	American College of Cardiology/American Heart Association/ American Medical Association-Physician Consortium for Performance Improvement
0070/007	145v4	Effective Clinical Care	**Coronary Artery Disease (CAD): Beta-Blocker Therapy – Prior Myocardial Infarction (MI) or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have prior MI OR a current or prior LVEF < 40% who were prescribed beta-blocker therapy. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69216).	American Medical Association-Physician Consortium for Performance Improvement/ American College of Cardiology Foundation/ American Heart Association

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
0083/008	144v4	Effective Clinical Care	**Heart Failure (HF): Beta-Blocker Therapy for Left Ventricular Systolic Dysfunction (LVSD):** Percentage of patients aged 18 years and older with a diagnosis of heart failure (HF) with a current or prior left ventricular ejection fraction (LVEF) < 40% who were prescribed beta-blocker therapy either within a 12 month period when seen in the outpatient setting OR at each hospital discharge. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69216).	American Medical Association-Physician Consortium for Performance Improvement/ American College of Cardiology Foundation/ American Heart Association
0105/ 009	128v4	Effective Clinical Care	**Anti-Depressant Medication Management:** Percentage of patients 18 years of age and older who were diagnosed with major depression and treated with antidepressant medication, and who remained on antidepressant medication treatment. Two rates are reported a. Percentage of patients who remained on an antidepressant medication for at least 84 days (12 weeks). b. Percentage of patients who remained on an antidepressant medication for at least 180 days (6 months). This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69216).	National Committee for Quality Assurance
0086/012	143v4	Effective Clinical Care	**Primary Open-Angle Glaucoma (POAG): Optic Nerve Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) who have an optic nerve head evaluation during one or more office visits within 12 months. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69216).	American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance
0087/014	N/A	Effective Clinical Care	**Age-Related Macular Degeneration (AMD): Dilated Macular Examination:** Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration (AMD) who had a dilated macular examination performed which included documentation of the presence or absence of macular thickening or hemorrhage AND the level of macular degeneration severity during one or more office visits within 12 months. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69216).	American Academy of Ophthalmology
0088/018	167v4	Effective Clinical Care	**Diabetic Retinopathy: Documentation of Presence or Absence of Macular Edema and Level of Severity of Retinopathy:** Percentage of patients aged 18 years and older with a diagnosis of diabetic retinopathy who had a dilated macular or fundus exam performed which included documentation of the level of severity of retinopathy and the presence or absence of macular edema during one or more office visits within 12 months. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69216).	American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance
0089/019	142v4	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	American Medical Association-Physician Consortium for

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
			macular or fundus exam at least once within 12 months. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69217).	Performance Improvement/ National Committee for Quality Assurance
0268/021	N/A	Patient Safety	**Perioperative Care: Selection of Prophylactic Antibiotic – First OR Second Generation Cephalosporin:** Percentage of surgical patients aged 18 years and older undergoing procedures with the indications for a first OR second generation cephalosporin prophylactic antibiotic, who had an order for a first OR second generation cephalosporin for antimicrobial prophylaxis. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69217).	American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance
0271/022	N/A	Patient Safety	**Perioperative Care: Discontinuation of Prophylactic Parenteral Antibiotics (Non-Cardiac Procedures):** Percentage of non-cardiac surgical patients aged 18 years and older undergoing procedures with the indications for prophylactic parenteral antibiotics AND who received a prophylactic parenteral antibiotic, who have an order for discontinuation of prophylactic parenteral antibiotics within 24 hours of surgical end time. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69217).	American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance
0239/023	N/A	Patient Safety	**Perioperative Care: Venous Thromboembolism (VTE) Prophylaxis (When Indicated in ALL Patients):** Percentage of surgical patients aged 18 years and older undergoing procedures for which VTE prophylaxis is indicated in all patients, who had an order for Low Molecular Weight Heparin (LMWH), Low-Dose Unfractionated Heparin (LDUH), adjusted-dose warfarin, fondaparinux or mechanical prophylaxis to be given within 24 hours prior to incision time or within 24 hours after surgery end time. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69218).	American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance
0045/024	N/A	Communication and Care Coordination	**Communication with the Physician or Other Clinician Managing On-going Care Post-Fracture for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older treated for a fracture with documentation of communication, between the physician treating the fracture and the physician or other clinician managing the patient's on-going care, that a fracture occurred and that the patient was or should be considered for osteoporosis treatment or testing. This measure is reported by the physician who treats the fracture and who therefore is held accountable for the communication. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69218).	National Committee for Quality Assurance/ American Medical Association-Physician Consortium for Performance Improvement
0325/032	N/A	Effective Clinical Care	**Stroke and Stroke Rehabilitation: Discharged on Antithrombotic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of ischemic stroke or transient ischemic attack (TIA) with documented permanent, persistent, or paroxysmal atrial fibrillation who were prescribed an antithrombotic at discharge. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69219).	American Academy of Neurology

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
0046/039	N/A	Effective Clinical Care	**Screening for Osteoporosis for Women Aged 65-85 Years of Age:** Percentage of female patients aged 65-85 years of age who ever had a central dual-energy X-ray absorptiometry (DXA) to check for osteoporosis. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69219).	National Committee for Quality Assurance / American Medical Association-Physician Consortium for Performance Improvement
N/A/041	N/A	Effective Clinical Care	**Osteoporosis: Pharmacologic Therapy for Men and Women Aged 50 Years and Older:** Percentage of patients aged 50 years and older with a diagnosis of osteoporosis who were prescribed pharmacologic therapy within 12 months. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69220).	National Committee for Quality Assurance / American Medical Association-Physician Consortium for Performance Improvement
0134/043	N/A	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Use of Internal Mammary Artery (IMA) in Patients with Isolated CABG Surgery:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who received an IMA graft. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69220).	Society of Thoracic Surgeons
0236/044	N/A	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Preoperative Beta-Blocker in Patients with Isolated CABG Surgery:** Percentage of isolated Coronary Artery Bypass Graft (CABG) surgeries for patients aged 18 years and older who received a beta-blocker within 24 hours prior to surgical incision. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69220).	Centers for Medicare & Medicaid Services/ Quality Insights of Pennsylvania
0097/046	N/A	Communication and Care Coordination	**Medication Reconciliation Post-Discharge:** The percentage of discharges from any inpatient facility (e.g. hospital, skilled nursing facility, or rehabilitation facility) for patients 18 years and older of age seen within 30 days following discharge in the office by the physician, prescribing practitioner, registered nurse, or clinical pharmacist providing on-going care for whom the discharge medication list was reconciled with the current medication list in the outpatient medical record. This measure is reported as three rates stratified by age group: • Reporting Criteria 1: 18-64 years of age • Reporting Criteria 2: 65 years and older • Total Rate: All patients 18 years of age and older. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69220).	National Committee for Quality Assurance / American Medical Association-Physician Consortium for Performance Improvement
0326/047	N/A	Communication and Care Coordination	**Care Plan:** Percentage of patients aged 65 years and older who have an advance care plan or surrogate decision maker documented in the medical record or documentation in the medical record that an advance care plan was discussed but the patient did not wish or was not able to name a surrogate decision maker or provide an advance care plan. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS	National Committee for Quality Assurance / American Medical Association-

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
			Final Rule (see Table 95 at 77 FR 69221).	Physician Consortium for Performance Improvement
N/A/048	N/A	Effective Clinical Care	**Urinary Incontinence: Assessment of Presence or Absence of Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older who were assessed for the presence or absence of urinary incontinence within 12 months. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69221).	National Committee for Quality Assurance / American Medical Association-Physician Consortium for Performance Improvement
N/A/050	N/A	Person and Caregiver-Centered Experience and Outcomes	**Urinary Incontinence: Plan of Care for Urinary Incontinence in Women Aged 65 Years and Older:** Percentage of female patients aged 65 years and older with a diagnosis of urinary incontinence with a documented plan of care for urinary incontinence at least once within 12 months. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69221).	National Committee for Quality Assurance / American Medical Association-Physician Consortium for Performance Improvement
0091/051	N/A	Effective Clinical Care	**Chronic Obstructive Pulmonary Disease (COPD): Spirometry Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of COPD who had spirometry results documented. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69221).	American Thoracic Society
0102/052	N/A	Effective Clinical Care	**Chronic Obstructive Pulmonary Disease (COPD): Inhaled Bronchodilator Therapy:** Percentage of patients aged 18 years and older with a diagnosis of COPD and who have an FEV1 less than 60% predicted and have symptoms who were prescribed an inhaled bronchodilator. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69221).	American Thoracic Society
0047/053	N/A	Effective Clinical Care	**Asthma: Pharmacologic Therapy for Persistent Asthma - Ambulatory Care Setting:** Percentage of patients aged 5 years and older with a diagnosis of persistent asthma who were prescribed long-term control medication. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69222).	American Academy of Allergy, Asthma, and Immunology/ American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance
0090/054	N/A	Effective Clinical Care	**Emergency Medicine: 12-Lead Electrocardiogram (ECG) Performed for Non-Traumatic Chest Pain:** Percentage of patients aged 40 years and older with an emergency department discharge diagnosis of non-traumatic chest pain who had a 12-lead electrocardiogram (ECG) performed.	American Medical Association-Physician

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
			This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69222).	Consortium for Performance Improvement/ National Committee for Quality Assurance
0069/065	154v4	Efficiency and Cost Reduction	**Appropriate Treatment for Children with Upper Respiratory Infection (URI):** Percentage of children 3 months through 18 years of age who were diagnosed with upper respiratory infection (URI) and were not dispensed an antibiotic prescription on or three days after the episode. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69222).	National Committee for Quality Assurance
0002/066	N/A	Efficiency and Cost Reduction	**Appropriate Testing for Children with Pharyngitis:** Percentage of children 3-18 years of age who were diagnosed with pharyngitis, ordered an antibiotic and received a group A streptococcus (strep) test for the episode. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69223).	National Committee for Quality Assurance
0377/067	N/A	Effective Clinical Care	**Hematology: Myelodysplastic Syndrome (MDS) and Acute Leukemia: Baseline Cytogenetic Testing Performed on Bone Marrow:** Percentage of patients aged 18 years and older with a diagnosis of myelodysplastic syndrome (MDS) or an acute leukemia who had baseline cytogenetic testing performed on bone marrow. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69223).	American Medical Association-Physician Consortium for Performance Improvement/ American Society of Hematology
0378/068	N/A	Effective Clinical Care	**Hematology: Myelodysplastic Syndrome (MDS): Documentation of Iron Stores in Patients Receiving Erythropoietin Therapy:** Percentage of patients aged 18 years and older with a diagnosis of myelodysplastic syndrome (MDS) who are receiving erythropoietin therapy with documentation of iron stores within 60 days prior to initiating erythropoietin therapy. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69223).	American Medical Association-Physician Consortium for Performance Improvement/ American Society of Hematology
0380/069	N/A	Effective Clinical Care	**Hematology: Multiple Myeloma: Treatment with Bisphosphonates:** Percentage of patients aged 18 years and older with a diagnosis of multiple myeloma, not in remission, who were prescribed or received intravenous bisphosphonate therapy within the 12-month reporting period. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69223).	American Medical Association-Physician Consortium for Performance Improvement/ American Society of Hematology
0379/070	N/A	Effective Clinical Care	**Hematology: Chronic Lymphocytic Leukemia (CLL): Baseline Flow Cytometry:** Percentage of patients aged 18 years and older seen within a 12 month reporting period with a diagnosis of chronic lymphocytic leukemia (CLL) made at any time during or prior to the reporting period who had baseline flow cytometry studies performed and documented in the chart. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69223).	American Medical Association-Physician Consortium for Performance Improvement/ American Society of Hematology

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
0387/071	140v4	Effective Clinical Care	**Breast Cancer: Hormonal Therapy for Stage IC -IIIC Estrogen Receptor/Progesterone Receptor (ER/PR) Positive Breast Cancer:** Percentage of female patients aged 18 years and older with Stage IC through IIIC, ER or PR positive breast cancer who were prescribed tamoxifen or aromatase inhibitor (AI) during the 12-month reporting period. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69224).	American Medical Association-Physician Consortium for Performance Improvement/ American Society of Clinical Oncology/ National Comprehensive Cancer Network
0385/072	141v5	Effective Clinical Care	**Colon Cancer: Chemotherapy for AJCC Stage III Colon Cancer Patients:** Percentage of patients aged 18 through 80 years with AJCC Stage III colon cancer who are referred for adjuvant chemotherapy, prescribed adjuvant chemotherapy, or have previously received adjuvant chemotherapy within the 12-month reporting period. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69224).	American Medical Association-Physician Consortium for Performance Improvement/ American Society of Clinical Oncology/ National Comprehensive Cancer Network
N/A/076	N/A	Patient Safety	**Prevention of Central Venous Catheter (CVC)-Related Bloodstream Infections:** Percentage of patients, regardless of age, who undergo central venous catheter (CVC) insertion for whom CVC was inserted with all elements of maximal sterile barrier technique, hand hygiene, skin preparation and, if ultrasound is used, sterile ultrasound techniques followed. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69224).	American Society of Anesthesiologists
0395/084	N/A	Effective Clinical Care	**Hepatitis C: Ribonucleic Acid (RNA) Testing Before Initiating Treatment:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who started antiviral treatment within the 12 month reporting period for whom quantitative hepatitis C virus (HCV) ribonucleic acid (RNA) testing was performed within 12 months prior to initiation of antiviral treatment. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69225).	American Medical Association-Physician Consortium for Performance Improvement/ American Gastroenterological Association
0396/085	N/A	Effective Clinical Care	**Hepatitis C: Hepatitis C Virus (HCV) Genotype Testing Prior to Treatment:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who started antiviral treatment within the 12 month reporting period for whom hepatitis C virus (HCV) genotype testing was performed within 12 months prior to initiation of antiviral treatment. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69225).	American Medical Association-Physician Consortium for Performance Improvement/ American Gastroenterological Association
0398/087	N/A	Effective Clinical Care	**Hepatitis C: Hepatitis C Virus (HCV) Ribonucleic Acid (RNA) Testing Between 4-12 Weeks After Initiation of Treatment:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who are receiving antiviral treatment for whom quantitative hepatitis C virus (HCV) ribonucleic acid (RNA) testing was performed between 4-12 weeks after the initiation of antiviral treatment.	American Medical Association-Physician Consortium for Performance

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
			This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69225).	Improvement/ American Gastroenterological Association
0653/091	N/A	Effective Clinical Care	**Acute Otitis Externa (AOE): Topical Therapy:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were prescribed topical preparations. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69226).	American Academy of Otolaryngology-Head and Neck Surgery
0654/093	N/A	Efficiency and Cost Reduction	**Acute Otitis Externa (AOE): Systemic Antimicrobial Therapy – Avoidance of Inappropriate Use:** Percentage of patients aged 2 years and older with a diagnosis of AOE who were not prescribed systemic antimicrobial therapy. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69226).	American Academy of Otolaryngology-Head and Neck Surgery
0391/099	N/A	Effective Clinical Care	**Breast Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade:** Percentage of breast cancer resection pathology reports that include the pT category (primary tumor), the pN category (regional lymph nodes), and the histologic grade. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69226).	College of American Pathologists
0392/100	N/A	Effective Clinical Care	**Colorectal Cancer Resection Pathology Reporting: pT Category (Primary Tumor) and pN Category (Regional Lymph Nodes) with Histologic Grade:** Percentage of colon and rectum cancer resection pathology reports that include the pT category (primary tumor), the pN category (regional lymph nodes) and the histologic grade. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69226).	College of American Pathologists
0389/102	129v5	Efficiency and Cost Reduction	**Prostate Cancer: Avoidance of Overuse of Bone Scan for Staging Low Risk Prostate Cancer Patients:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at low risk of recurrence receiving interstitial prostate brachytherapy, OR external beam radiotherapy to the prostate, OR radical prostatectomy, OR cryotherapy who did not have a bone scan performed at any time since diagnosis of prostate cancer. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69226).	American Medical Association-Physician Consortium for Performance Improvement
0390/104	N/A	Effective Clinical Care	**Prostate Cancer: Adjuvant Hormonal Therapy for High Risk or Very High Risk Prostate Cancer:** Percentage of patients, regardless of age, with a diagnosis of prostate cancer at high or very high risk of recurrence receiving external beam radiotherapy to the prostate who were prescribed adjuvant hormonal therapy (GnRH [gonadotropin-releasing hormone] agonist or antagonist). This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69226)	American Medical Association-Physician Consortium for Performance Improvement/ American Urological Association Education and Research

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
0104/ 107	161v4	Effective Clinical Care	**Adult Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) with a suicide risk assessment completed during the visit in which a new diagnosis or recurrent episode was identified. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69227).	American Medical Association-Physician Consortium for Performance Improvement
0054/108	N/A	Effective Clinical Care	**Rheumatoid Arthritis (RA): Disease Modifying Anti-Rheumatic Drug (DMARD) Therapy:** Percentage of patients aged 18 years and older who were diagnosed with rheumatoid arthritis and were prescribed, dispensed, or administered at least one ambulatory prescription for a disease-modifying anti-rheumatic drug (DMARD). This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69227).	National Committee for Quality Assurance
N/A/109	N/A	Person and Caregiver-Centered Experience and Outcomes	**Osteoarthritis (OA): Function and Pain Assessment:** Percentage of patient visits for patients aged 21 years and older with a diagnosis of osteoarthritis (OA) with assessment for function and pain. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69227).	American Academy of Orthopedic Surgeons
0041/110	147v5	Community/ Population Health	**Preventive Care and Screening: Influenza Immunization:** Percentage of patients aged 6 months and older seen for a visit between October 1 and March 31 who received an influenza immunization OR who reported previous receipt of an influenza immunization. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69227).	American Medical Association-Physician Consortium for Performance Improvement
0043/111	127v4	Community/ Population Health	**Pneumonia Vaccination Status for Older Adults:** Percentage of patients 65 years of age and older who have ever received a pneumococcal vaccine. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69227).	National Committee for Quality Assurance
2372/112	125v4	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. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69227).	National Committee for Quality Assurance
0034/113	130v4	Effective Clinical Care	**Colorectal Cancer Screening:** Percentage of patients 50 - 75 years of age who had appropriate screening for colorectal cancer. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69228).	National Committee for Quality Assurance
0058/116	N/A	Efficiency and Cost Reduction	**Antibiotic Treatment for Adults with Acute Bronchitis: Avoidance of Inappropriate Use:** Percentage of adults 18 through 64 years of age with a diagnosis of acute bronchitis who were not prescribed or dispensed an antibiotic prescription on or 3 days after the episode. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69228).	National Committee for Quality Assurance

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
0055/117	131v4	Effective Clinical Care	**Diabetes: Eye Exam:** Percentage of patients 18 - 75 years of age with diabetes who had a retinal or dilated eye exam by an eye care professional during the measurement period or a negative retinal or dilated eye exam (no evidence of retinopathy) in the 12 months prior to the measurement period. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69228).	National Committee for Quality Assurance
0066/118	N/A	Effective Clinical Care	**Coronary Artery Disease (CAD): Angiotensin-Converting Enzyme (ACE) Inhibitor or Angiotensin Receptor Blocker (ARB) Therapy -- Diabetes or Left Ventricular Systolic Dysfunction (LVEF < 40%):** Percentage of patients aged 18 years and older with a diagnosis of coronary artery disease seen within a 12 month period who also have diabetes OR a current or prior Left Ventricular Ejection Fraction (LVEF) < 40% who were prescribed ACE inhibitor or ARB therapy. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69228).	American College of Cardiology/American Heart Association/ American Medical Association-Physician Consortium for Performance Improvement
0062/119	134v4	Effective Clinical Care	**Diabetes: Medical Attention for Nephropathy:** The percentage of patients 18-75 years of age with diabetes who had a nephropathy screening test or evidence of nephropathy during the measurement period. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69228).	National Committee for Quality Assurance
N/A/121	N/A	Effective Clinical Care	**Adult Kidney Disease: Laboratory Testing (Lipid Profile):** Percentage of patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) who had a fasting lipid profile performed at least once within a 12-month period. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69228).	Renal Physicians Association
N/A/122	N/A	Effective Clinical Care	**Adult Kidney Disease: Blood Pressure Management:** Percentage of patient visits for those patients aged 18 years and older with a diagnosis of chronic kidney disease (CKD) (stage 3, 4, or 5, not receiving Renal Replacement Therapy [RRT]) with a blood pressure < 140/90 mmHg OR ≥ 140/90 mmHg with a documented plan of care. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69228).	Renal Physicians Association
0417/126	N/A	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Peripheral Neuropathy – Neurological Evaluation:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who had a neurological examination of their lower extremities within 12 months. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69229).	American Podiatric Medical Association
0416/127	N/A	Effective Clinical Care	**Diabetes Mellitus: Diabetic Foot and Ankle Care, Ulcer Prevention – Evaluation of Footwear:** Percentage of patients aged 18 years and older with a diagnosis of diabetes mellitus who were evaluated for proper footwear and sizing. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69229).	American Podiatric Medical Association

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
0421/128	69v4	Community/ Population Health	**Preventive Care and Screening: Body Mass Index (BMI) Screening and Follow-Up Plan:** Percentage of patients aged 18 years and older with a BMI documented during the current encounter or during the previous 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. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69229).	Centers for Medicare & Medicaid Services/ Mathematica/ Quality Insights of Pennsylvania
0419/130	68v5	Patient Safety	**Documentation of Current Medications in the Medical Record:** Percentage of visits for patients aged 18 years and older for which the eligible professional attests to documenting a list of current medications using all immediate resources available on the date of the encounter. This list must include ALL known prescriptions, over-the-counters, herbals, and vitamin/mineral/dietary (nutritional) supplements AND must contain the medications' name, dosage, frequency and route of administration. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69229).	Centers for Medicare & Medicaid Services/ Mathematica/ Quality Insights of Pennsylvania
0420/131	N/A	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. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69230).	Centers for Medicare & Medicaid Services/ Quality Insights of Pennsylvania
0418/134	2v5	Community/ Population Health	**Preventive Care and Screening: Screening for Clinical Depression and Follow-Up Plan:** Percentage of patients aged 12 years and older screened for clinical depression on the date of the encounter using an age appropriate standardized depression screening tool AND if positive, a follow-up plan is documented on the date of the positive screen. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69230).	Centers for Medicare & Medicaid Services/ Mathematica/ Quality Insights of Pennsylvania
0650/137	N/A	Communication and Care Coordination	**Melanoma: Continuity of Care – Recall System:** Percentage of patients, regardless of age, with a current diagnosis of melanoma or a history of melanoma whose information was entered, at least once within a 12 month period, into a recall system that includes: • A target date for the next complete physical skin exam, AND • A process to follow up with patients who either did not make an appointment within the specified timeframe or who missed a scheduled appointment. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69230).	American Academy of Dermatology/ American Medical Association-Physician Consortium for Performance Improvement
N/A/138	N/A	Communication and Care Coordination	**Melanoma: Coordination of Care:** Percentage of patient visits, regardless of age, with a new occurrence of melanoma who have a treatment plan documented in the chart that was communicated to the physician(s) providing continuing care within one month of diagnosis. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69230).	American Academy of Dermatology/ American Medical Association-Physician Consortium for Performance Improvement

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
0566/140	N/A	Effective Clinical Care	**Age-Related Macular Degeneration (AMD): Counseling on Antioxidant Supplement:** Percentage of patients aged 50 years and older with a diagnosis of age-related macular degeneration (AMD) or their caregiver(s) who were counseled within 12 months on the benefits and/or risks of the Age-Related Eye Disease Study (AREDS) formulation for preventing progression of AMD. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69230).	American Academy of Ophthalmology
0563/141	N/A	Communication and Care Coordination	**Primary Open-Angle Glaucoma (POAG): Reduction of Intraocular Pressure (IOP) by 15% OR Documentation of a Plan of Care:** Percentage of patients aged 18 years and older with a diagnosis of primary open-angle glaucoma (POAG) whose glaucoma treatment has not failed (the most recent IOP was reduced by at least 15% from the pre- intervention level) OR if the most recent IOP was not reduced by at least 15% from the pre- intervention level, a plan of care was documented within 12 months. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69231).	American Academy of Ophthalmology
0384/143	157v4	Person and Caregiver-Centered Experience and Outcomes	**Oncology: Medical and Radiation – Pain Intensity Quantified:** Percentage of patient visits, regardless of patient age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy in which pain intensity is quantified. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69231).	American Medical Association-Physician Consortium for Performance Improvement
0383/144	N/A	Person and Caregiver-Centered Experience and Outcomes	**Oncology: Medical and Radiation – Plan of Care for Pain:** Percentage of visits for patients, regardless of age, with a diagnosis of cancer currently receiving chemotherapy or radiation therapy who report having pain with a documented plan of care to address pain. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69231).	American Society of Clinical Oncology
N/A/145	N/A	Patient Safety	**Radiology: Exposure Time Reported for Procedures Using Fluoroscopy:** Final reports for procedures using fluoroscopy that document radiation exposure indices, or exposure time and number of fluorographic images (if radiation exposure indices are not available). This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69231).	American College of Radiology/ American Medical Association-Physician Consortium for Performance Improvement
0508/146	N/A	Efficiency and Cost Reduction	**Radiology: Inappropriate Use of "Probably Benign" Assessment Category in Mammography Screening:** Percentage of final reports for screening mammograms that are classified as "probably benign". This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69231).	American College of Radiology/ American Medical Association-Physician Consortium for Performance Improvement
N/A/147	N/A	Communication and Care Coordination	**Nuclear Medicine: Correlation with Existing Imaging Studies for All Patients Undergoing Bone Scintigraphy:** Percentage of final reports for all patients, regardless of age, undergoing bone scintigraphy that include physician documentation of correlation with existing relevant imaging studies (e.g., x-ray, MRI, CT, etc.) that were performed.	American Medical Association-Physician Consortium for Performance

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
			This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69231).	Improvement/ Society of Nuclear Medicine and Molecular Imaging
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. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69232).	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. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69232).	National Committee for Quality Assurance/ American Medical Association-Physician Consortium for Performance Improvement
0382/156	N/A	Patient Safety	**Oncology: Radiation Dose Limits to Normal Tissues:** Percentage of patients, regardless of age, with a diagnosis of breast, rectal, pancreatic or lung cancer receiving 3D conformal radiation therapy who had documentation in medical record that radiation dose limits to normal tissues were established prior to the initiation of a course of 3D conformal radiation for a minimum of two tissues. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69232).	American Society for Radiation Oncology
0405/160	52v4	Effective Clinical Care	**HIV/AIDS: Pneumocystis Jiroveci Pneumonia (PCP) Prophylaxis:** Percentage of patients aged 6 weeks and older with a diagnosis of HIV/AIDS who were prescribed Pneumocystis Jiroveci Pneumonia (PCP) prophylaxis. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69233).	National Committee for Quality Assurance
0056/163	123v4	Effective Clinical Care	**Diabetes: Foot Exam:** Percentage of patients aged 18-75 years of age with diabetes who had a foot exam during the measurement period. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69233).	National Committee for Quality Assurance
0129/164	N/A	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Prolonged Intubation:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require postoperative intubation > 24 hours. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69233).	Society of Thoracic Surgeons
0130/165	N/A	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Deep Sternal Wound Infection Rate:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who, within 30 days postoperatively, develop deep sternal wound infection involving muscle, bone, and/or mediastinum requiring operative intervention.	Society of Thoracic Surgeons

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
			This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69234).	
0131/166	N/A	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Stroke:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who have a postoperative stroke (i.e., any confirmed neurological deficit of abrupt onset caused by a disturbance in blood supply to the brain) that did not resolve within 24 hours. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69234).	Society of Thoracic Surgeons
0114/167	N/A	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Postoperative Renal Failure:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery (without pre-existing renal failure) who develop postoperative renal failure or require dialysis. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69234).	Society of Thoracic Surgeons
0115/168	N/A	Effective Clinical Care	**Coronary Artery Bypass Graft (CABG): Surgical Re-Exploration:** Percentage of patients aged 18 years and older undergoing isolated CABG surgery who require a return to the operating room (OR) during the current hospitalization for mediastinal bleeding with or without tamponade, graft occlusion, valve dysfunction, or other cardiac reason. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69234).	Society of Thoracic Surgeons
N/A/176	N/A	Effective Clinical Care	**Rheumatoid Arthritis (RA): Tuberculosis Screening:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have documentation of a tuberculosis (TB) screening performed and results interpreted within 6 months prior to receiving a first course of therapy using a biologic disease-modifying anti-rheumatic drug (DMARD). This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69235).	American College of Rheumatology
N/A/ 177	N/A	Effective Clinical Care	**Rheumatoid Arthritis (RA): Periodic Assessment of Disease Activity:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment and classification of disease activity within 12 months. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69235).	American College of Rheumatology
N/A/178	N/A	Effective Clinical Care	**Rheumatoid Arthritis (RA): Functional Status Assessment:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) for whom a functional status assessment was performed at least once within 12 months. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69235).	American College of Rheumatology
N/A/179	N/A	Effective Clinical Care	**Rheumatoid Arthritis (RA): Assessment and Classification of Disease Prognosis:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have an assessment and classification of disease prognosis at least once within 12 months. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS	American College of Rheumatology

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
			Final Rule (see Table 95 at 77 FR 69235).	
N/A/180	N/A	Effective Clinical Care	**Rheumatoid Arthritis (RA): Glucocorticoid Management:** Percentage of patients aged 18 years and older with a diagnosis of rheumatoid arthritis (RA) who have been assessed for glucocorticoid use and, for those on prolonged doses of prednisone ≥ 10 mg daily (or equivalent) with improvement or no change in disease activity, documentation of glucocorticoid management plan within 12 months. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69236).	American College of Rheumatology
N/A/181	N/A	Patient Safety	**Elder Maltreatment Screen and Follow-Up Plan:** Percentage of patients aged 65 years and older with a documented elder maltreatment screen using an Elder Maltreatment Screening Tool on the date of encounter AND a documented follow-up plan on the date of the positive screen. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69236).	Centers for Medicare & Medicaid Services/ Quality Insights of Pennsylvania
2624/182	N/A	Communication and Care Coordination	**Functional Outcome Assessment:** Percentage of visits for patients aged 18 years and older with documentation of a current functional outcome assessment using a standardized functional outcome assessment tool on the date of encounter AND documentation of a care plan based on identified functional outcome deficiencies on the date of the identified deficiencies. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69236).	Centers for Medicare & Medicaid Services/ Quality Insights of Pennsylvania
0399/183	N/A	Community/ Population Health	**Hepatitis C: Hepatitis A Vaccination:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C who have received at least one injection of hepatitis A vaccine, or who have documented immunity to hepatitis A. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69236).	American Medical Association-Physician Consortium for Performance Improvement/ American Gastroenterological Association
0659/185	N/A	Communication and Care Coordination	**Colonoscopy Interval for Patients with a History of Adenomatous Polyps – Avoidance of Inappropriate Use:** Percentage of patients aged 18 years and older receiving a surveillance colonoscopy, with a history of a prior adenomatous polyp(s) in previous colonoscopy findings, who had an interval of 3 or more years since their last colonoscopy. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69236).	American Medical Association-Physician Consortium for Performance Improvement/ American Gastroenterological Association/ American Society for Gastrointestinal Endoscopy/ American College of Gastroenterology

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
N/A/187	N/A	Effective Clinical Care	**Stroke and Stroke Rehabilitation: Thrombolytic Therapy:** Percentage of patients aged 18 years and older with a diagnosis of acute ischemic stroke who arrive at the hospital within two hours of time last known well and for whom IV t-PA was initiated within three hours of time last known well. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69237).	American Heart Association/ American Society of Anesthesiologists/ The Joint Commission
0565/191	133v4	Effective Clinical Care	**Cataracts: 20/40 or Better Visual Acuity within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and no significant ocular conditions impacting the visual outcome of surgery and had best-corrected visual acuity of 20/40 or better (distance or near) achieved within 90 days following the cataract surgery. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69237).	American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance
0564/192	132v4	Patient Safety	**Cataracts: Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures:** Percentage of patients aged 18 years and older with a diagnosis of uncomplicated cataract who had cataract surgery and had any of a specified list of surgical procedures in the 30 days following cataract surgery which would indicate the occurrence of any of the following major complications: retained nuclear fragments, endophthalmitis, dislocated or wrong power IOL, retinal detachment, or wound dehiscence. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69238).	American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance
0507/195	N/A	Effective Clinical Care	**Radiology: Stenosis Measurement in Carotid Imaging Reports:** Percentage of final reports for carotid imaging studies (neck magnetic resonance angiography [MRA], neck computed tomography angiography [CTA], neck duplex ultrasound, carotid angiogram) performed that include direct or indirect reference to measurements of distal internal carotid diameter as the denominator for stenosis measurement. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69238).	American College of Radiology/ American Medical Association-Physician Consortium for Performance Improvement
0068/204	164v4	Effective Clinical Care	**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. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69239).	National Committee for Quality Assurance
0409/205	N/A	Effective Clinical Care	**HIV/AIDS: Sexually Transmitted Disease Screening for Chlamydia, Gonorrhea, and Syphilis:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS for whom chlamydia, gonorrhea and syphilis screenings were performed at least once since the diagnosis of HIV infection. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69239)	National Committee for Quality Assurance/ American Medical Association-Physician Consortium for Performance Improvement

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
0422/217	N/A	Communication and Care Coordination	**Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Knee Impairments:** Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the knee in which the change in their Risk-Adjusted Functional Status is measured. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69241).	Focus on Therapeutic Outcomes, Inc.
0423/218	N/A	Communication and Care Coordination	**Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Hip Impairments:** Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the hip in which the change in their Risk-Adjusted Functional Status is measured. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69241).	Focus on Therapeutic Outcomes, Inc.
0424/219	N/A	Communication and Care Coordination	**Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Lower Leg, Foot or Ankle Impairments:** Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the lower leg, foot or ankle in which the change in their Risk-Adjusted Functional Status is measured. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69241).	Focus on Therapeutic Outcomes, Inc.
0425/220	N/A	Communication and Care Coordination	**Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Lumbar Spine Impairments:** Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the lumbar spine in which the change in their Risk-Adjusted Functional Status is measured. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69241).	Focus on Therapeutic Outcomes, Inc.
0426/221	N/A	Communication and Care Coordination	**Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Shoulder Impairments:** Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the shoulder in which the change in their Risk-Adjusted Functional Status is measured. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69242).	Focus on Therapeutic Outcomes, Inc.
0427/222	N/A	Communication and Care Coordination	**Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Elbow, Wrist or Hand Impairments:** Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the elbow, wrist or hand in which the change in their Risk-Adjusted Functional Status is measured. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69242).	Focus on Therapeutic Outcomes, Inc.
0428/223	N/A	Communication and Care Coordination	**Functional Deficit: Change in Risk-Adjusted Functional Status for Patients with Neck, Cranium, Mandible, Thoracic Spine, Ribs, or Other General Orthopedic Impairments:** Percentage of patients aged 18 or older that receive treatment for a functional deficit secondary to a diagnosis that affects the neck, cranium, mandible, thoracic spine, ribs, or other general orthopedic impairment in which the change in their Risk-Adjusted Functional Status is measured. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69242).	Focus on Therapeutic Outcomes, Inc.

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
0562/224	N/A	Efficiency and Cost Reduction	**Melanoma: Overutilization of Imaging Studies in Melanoma:** Percentage of patients, regardless of age, with a current diagnosis of stage 0 through IIC melanoma or a history of melanoma of any stage, without signs or symptoms suggesting systemic spread, seen for an office visit during the one-year measurement period, for whom no diagnostic imaging studies were ordered. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69242).	American Academy of Dermatology/ American Medical Association-Physician Consortium for Performance Improvement
0509/225	N/A	Communication and Care Coordination	**Radiology: Reminder System for Screening Mammograms:** Percentage of patients undergoing a screening mammogram whose information is entered into a reminder system with a target due date for the next mammogram. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69242).	American College of Radiology/ American Medical Association-Physician Consortium for Performance Improvement
0028/226	138v4	Community/ Population Health	**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. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69242).	American Medical Association-Physician Consortium for Performance Improvement
0018/236	165v4	Effective Clinical Care	**Controlling High Blood Pressure:** Percentage of patients 18-85 years of age who had a diagnosis of hypertension and whose blood pressure was adequately controlled (<140/90 mmHg) during the measurement period. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69243).	National Committee for Quality Assurance
0022/238	156v4	Patient Safety	**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. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69244).	National Committee for Quality Assurance
0024/239	155v4	Community/ Population Health	**Weight Assessment and Counseling for Nutrition and Physical Activity for Children and Adolescents:** Percentage of patients 3-17 years of age who had an outpatient visit with a Primary Care Physician (PCP) or Obstetrician/Gynecologist (OB/GYN) and who had evidence of the following during the measurement period. Three rates are reported. - Percentage of patients with height, weight, and body mass index (BMI) percentile documentation - Percentage of patients with counseling for nutrition - Percentage of patients with counseling for physical activity. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69244).	National Committee for Quality Assurance

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
0038/240	117v4	Community/ Population Health	**Childhood Immunization Status:** Percentage of children 2 years of age who had four diphtheria, tetanus and acellular pertussis (DTaP); three polio (IPV), one measles, mumps and rubella (MMR); three H influenza type B (HiB); three hepatitis B (Hep B); one chicken pox (VZV); four pneumococcal conjugate (PCV); one hepatitis A (Hep A); two or three rotavirus (RV); and two influenza (flu) vaccines by their second birthday. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69244).	National Committee for Quality Assurance
N/A/241	182v5	Effective Clinical Care	**Ischemic Vascular Disease (IVD): Complete Lipid Profile and LDL-C Control (< 100 mg/dL):** 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 each of the following during the measurement period: a complete lipid profile and LDL-C was adequately controlled (< 100 mg/dL). This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69244).	National Committee for Quality Assurance
N/A/242	N/A	Effective Clinical Care	**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. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69244).	American College of Cardiology/American Heart Association/ American Medical Association-Physician Consortium for Performance Improvement
0643/243	N/A	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. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69245).	American College of Cardiology Foundation/ American Heart Association
1854/249	N/A	Effective Clinical Care	**Barrett's Esophagus:** Percentage of esophageal biopsy reports that document the presence of Barrett's mucosa that also include a statement about dysplasia. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69246).	College of American Pathologists
1853/250	N/A	Effective Clinical Care	**Radical Prostatectomy Pathology Reporting:** Percentage of radical prostatectomy pathology reports that include the pT category, the pN category, the Gleason score and a statement about margin status.	College of American Pathologists

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
			This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69246).	
1855/251	N/A	Effective Clinical Care	**Quantitative Immunohistochemical (IHC) Evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) for Breast Cancer Patients:** This is a measure based on whether quantitative evaluation of Human Epidermal Growth Factor Receptor 2 Testing (HER2) by immunohistochemistry (IHC) uses the system recommended in the current ASCO/CAP Guidelines for Human Epidermal Growth Factor Receptor 2 Testing in breast cancer. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69246).	College of American Pathologists
0651/254	N/A	Effective Clinical Care	**Ultrasound Determination of Pregnancy Location for Pregnant Patients with Abdominal Pain:** Percentage of pregnant female patients aged 14 to 50 who present to the emergency department (ED) with a chief complaint of abdominal pain or vaginal bleeding who receive a trans-abdominal or trans-vaginal ultrasound to determine pregnancy location. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69246).	American College of Emergency Physicians
N/A/255	N/A	Effective Clinical Care	**Rh Immunoglobulin (Rhogam) for Rh-Negative Pregnant Women at Risk of Fetal Blood Exposure:** Percentage of Rh-negative pregnant women aged 14-50 years at risk of fetal blood exposure who receive Rh-Immunoglobulin (Rhogam) in the emergency department (ED). This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69247).	American College of Emergency Physicians
1519/257	N/A	Effective Clinical Care	**Statin Therapy at Discharge after Lower Extremity Bypass (LEB):** Percentage of patients aged 18 years and older undergoing infra-inguinal lower extremity bypass who are prescribed a statin medication at discharge. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69247).	Society for Vascular Surgeons
N//A/258	N/A	Patient Safety	**Rate of Open Repair of Small or Moderate Non-Ruptured Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #7):** Percent of patients undergoing open repair of small or moderate sized non-ruptured abdominal aortic aneurysms who do not experience a major complication (discharge to home no later than post-operative day #7). This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69247).	Society for Vascular Surgeons
N/A/259	N/A	Patient Safety	**Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Abdominal Aortic Aneurysms (AAA) without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of patients undergoing endovascular repair of small or moderate non-ruptured abdominal aortic aneurysms (AAA) that do not experience a major complication (discharged to home no later than post-operative day #2). This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69247).	Society for Vascular Surgeons

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
N/A/260	N/A	Patient Safety	**Rate of Carotid Endarterectomy (CEA) for Asymptomatic Patients, without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CEA who are discharged to home no later than post-operative day #2. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69247).	Society for Vascular Surgeons
N/A/261	N/A	Communication and Care Coordination	**Referral for Otologic Evaluation for Patients with Acute or Chronic Dizziness:** Percentage of patients aged birth and older referred to a physician (preferably a physician specially trained in disorders of the ear) for an otologic evaluation subsequent to an audiologic evaluation after presenting with acute or chronic dizziness. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69248).	Audiology Quality Consortium
N/A/262	N/A	Patient Safety	**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. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69248).	American Society of Breast Surgeons
N/A/263	N/A	Effective Clinical Care	**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. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69248).	American Society of Breast Surgeons
N/A/264	N/A	Effective Clinical Care	**Sentinel Lymph Node Biopsy for Invasive Breast Cancer:** The percentage of clinically node negative (clinical stage T1N0M0 or T2N0M0) breast cancer patients who undergo a sentinel lymph node (SLN) procedure. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69248).	American Society of Breast Surgeons
N/A/265	N/A	Communication and Care Coordination	**Biopsy Follow-Up:** Percentage of new patients whose biopsy results have been reviewed and communicated to the primary care/referring physician and patient by the performing physician. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69248).	American Academy of Dermatology
1814/268	N/A	Effective Clinical Care	**Epilepsy: Counseling for Women of Childbearing Potential with Epilepsy:** All female patients of childbearing potential (12 - 44 years old) diagnosed with epilepsy who were counseled or referred for counseling for how epilepsy and its treatment may affect contraception OR pregnancy at least once a year. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69249).	American Academy of Neurology

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
N/A/270	N/A	Effective Clinical Care	**Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Sparing Therapy:** Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease who have been managed by corticosteroids greater than or equal to 10 mg/day of prednisone equivalents for 60 or greater consecutive days or a single prescription equating to 600 mg prednisone or greater for all fills that have been prescribed corticosteroid sparing therapy within the last twelve months. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69249).	American Gastroenterological Association
N/A/271	N/A	Effective Clinical Care	**Inflammatory Bowel Disease (IBD): Preventive Care: Corticosteroid Related Iatrogenic Injury – Bone Loss Assessment:** Percentage of patients aged 18 years and older with an inflammatory bowel disease encounter who were prescribed prednisone equivalents greater than or equal to 10 mg/day for 60 or greater consecutive days or a single prescription equating to 600mg prednisone or greater for all fills and were documented for risk of bone loss once during the reporting year or the previous calendar year. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69249).	American Gastroenterological Association
N/A/274	N/A	Effective Clinical Care	**Inflammatory Bowel Disease (IBD): Testing for Latent Tuberculosis (TB) Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease (IBD) for whom a tuberculosis (TB) screening was performed and results interpreted within six months prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69250).	American Gastroenterological Association
N/A/275	N/A	Effective Clinical Care	**Inflammatory Bowel Disease (IBD): Assessment of Hepatitis B Virus (HBV) Status Before Initiating Anti-TNF (Tumor Necrosis Factor) Therapy:** Percentage of patients aged 18 years and older with a diagnosis of inflammatory bowel disease (IBD) who had Hepatitis B Virus (HBV) status assessed and results interpreted within one year prior to receiving a first course of anti-TNF (tumor necrosis factor) therapy. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69250).	American Gastroenterological Association
N/A/276	N/A	Effective Clinical Care	**Sleep Apnea: Assessment of Sleep Symptoms:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea that includes documentation of an assessment of sleep symptoms, including presence or absence of snoring and daytime sleepiness. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69250).	American Academy of Sleep Medicine/ American Medical Association-Physician Consortium for Performance Improvement
N/A/277	N/A	Effective Clinical Care	**Sleep Apnea: Severity Assessment at Initial Diagnosis:** Percentage of patients aged 18 years and older with a diagnosis of obstructive sleep apnea who had an apnea hypopnea index (AHI) or a respiratory disturbance index (RDI) measured at the time of initial diagnosis. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69250).	American Academy of Sleep Medicine/ American Medical Association-Physician Consortium for Performance Improvement

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
N/A/278	N/A	Effective Clinical Care	**Sleep Apnea: Positive Airway Pressure Therapy Prescribed:** Percentage of patients aged 18 years and older with a diagnosis of moderate or severe obstructive sleep apnea who were prescribed positive airway pressure therapy. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69250).	American Academy of Sleep Medicine/ American Medical Association-Physician Consortium for Performance Improvement
N/A/279	N/A	Effective Clinical Care	**Sleep Apnea: Assessment of Adherence to Positive Airway Pressure Therapy:** Percentage of visits for patients aged 18 years and older with a diagnosis of obstructive sleep apnea who were prescribed positive airway pressure therapy who had documentation that adherence to positive airway pressure therapy was objectively measured. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69251).	American Academy of Sleep Medicine/ American Medical Association-Physician Consortium for Performance Improvement
N/A/280	N/A	Effective Clinical Care	**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. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69251).	American Academy of Neurology/ American Psychological Association
N/A/281	149v4	Effective Clinical Care	**Dementia: Cognitive Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of cognition is performed and the results reviewed at least once within a 12 month period. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69251).	American Medical Association-Physician Consortium for Performance Improvement
N/A/282	N/A	Effective Clinical Care	**Dementia: Functional Status Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia for whom an assessment of functional status is performed and the results reviewed at least once within a 12 month period. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69251).	American Academy of Neurology/ American Psychological Association
N/A/283	N/A	Effective Clinical Care	**Dementia: Neuropsychiatric Symptom Assessment:** Percentage of patients, regardless of age, with a diagnosis of dementia and for whom an assessment of neuropsychiatric symptoms is performed and results reviewed at least once in a 12 month period. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69251).	American Academy of Neurology/ American Psychological Association
N/A/284	N/A	Effective Clinical Care	**Dementia: Management of Neuropsychiatric Symptoms:** Percentage of patients, regardless of age, with a diagnosis of dementia who have one or more neuropsychiatric symptoms who received or were recommended to receive an intervention for neuropsychiatric symptoms within a 12 month period. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69251).	American Academy of Neurology/ American Psychological Association

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
N/A/286	N/A	Patient Safety	**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. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69252).	American Academy of Neurology/ American Psychological Association
N/A/287	N/A	Effective Clinical Care	**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. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69252).	American Academy of Neurology/ American Psychological Association
N/A/288	N/A	Communication and Care Coordination	**Dementia: Caregiver Education and Support:** Percentage of patients, regardless of age, with a diagnosis of dementia whose caregiver(s) were provided with education on dementia disease management and health behavior changes AND referred to additional sources for support within a 12 month period. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69252).	American Academy of Neurology/ American Psychological Association
N/A/289	N/A	Effective Clinical Care	**Parkinson's Disease: Annual Parkinson's Disease Diagnosis Review:** All patients with a diagnosis of Parkinson's disease who had an annual assessment including a review of current medications (e.g., medications that can produce Parkinson-like signs or symptoms) and a review for the presence of atypical features (e.g., falls at presentation and early in the disease course, poor response to levodopa, symmetry at onset, rapid progression [to Hoehn and Yahr stage 3 in 3 years], lack of tremor or dysautonomia) at least annually. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69252).	American Academy of Neurology
N/A/290	N/A	Effective Clinical Care	**Parkinson's Disease: Psychiatric Disorders or Disturbances Assessment:** All patients with a diagnosis of Parkinson's disease who were assessed for psychiatric disorders or disturbances (e.g., psychosis, depression, anxiety disorder, apathy, or impulse control disorder) at least annually. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69252).	American Academy of Neurology
N/A/291	N/A	Effective Clinical Care	**Parkinson's Disease: Cognitive Impairment or Dysfunction Assessment:** All patients with a diagnosis of Parkinson's disease who were assessed for cognitive impairment or dysfunction at least annually. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69253).	American Academy of Neurology
N/A/292	N/A	Effective Clinical Care	**Parkinson's Disease: Querying about Sleep Disturbances:** All patients with a diagnosis of Parkinson's disease (or caregivers, as appropriate) who were queried about sleep disturbances at least annually. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69253).	American Academy of Neurology

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
N/A/293	N/A	Communication and Care Coordination	**Parkinson's Disease: Rehabilitative Therapy Options:** All patients with a diagnosis of Parkinson's disease (or caregiver(s), as appropriate) who had rehabilitative therapy options (e.g., physical, occupational, or speech therapy) discussed at least annually. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69253).	American Academy of Neurology
N/A/294	N/A	Communication and Care Coordination	**Parkinson's Disease: Parkinson's Disease Medical and Surgical Treatment Options Reviewed:** All patients with a diagnosis of Parkinson's disease (or caregiver(s), as appropriate) who had the Parkinson's disease treatment options (e.g., non-pharmacological treatment, pharmacological treatment, or surgical treatment) reviewed at least once annually. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69253).	American Academy of Neurology
1536/303	N/A	Person and Caregiver-Centered Experience and Outcomes	**Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older in sample who had cataract surgery and had improvement in visual function achieved within 90 days following the cataract surgery, based on completing a pre-operative and post-operative visual function survey. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69254).	American Academy of Ophthalmology
N/A/304	N/A	Person and Caregiver-Centered Experience and Outcomes	**Cataracts: Patient Satisfaction within 90 Days Following Cataract Surgery:** Percentage of patients aged 18 years and older in sample who had cataract surgery and were satisfied with their care within 90 days following the cataract surgery, based on completion of the Consumer Assessment of Healthcare Providers and Systems Surgical Care Survey. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69254).	American Academy of Ophthalmology
0004/305	137v4	Effective Clinical Care	**Initiation and Engagement of Alcohol and Other Drug Dependence Treatment:** Percentage of patients 13 years of age and older with a new episode of alcohol and other drug (AOD) dependence who received the following. Two rates are reported. a. Percentage of patients who initiated treatment within 14 days of the diagnosis. b. Percentage of patients who initiated treatment and who had two or more additional services with an AOD diagnosis within 30 days of the initiation visit. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69254).	National Committee for Quality Assurance
0032/309	124v4	Effective Clinical Care	**Cervical Cancer Screening:** Percentage of women 21-64 years of age, who received one or more Pap tests to screen for cervical cancer. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69255).	National Committee for Quality Assurance
0033/310	153v4	Community/ Population Health	**Chlamydia Screening for Women:** Percentage of women 16-24 years of age who were identified as sexually active and who had at least one test for chlamydia during the measurement period. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69255).	National Committee for Quality Assurance

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
0036/311	126v4	Effective Clinical Care	**Use of Appropriate Medications for Asthma:** Percentage of patients 5-64 years of age who were identified as having persistent asthma and were appropriately prescribed medication during the measurement period. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69255).	National Committee for Quality Assurance
0052/312	166v5	Efficiency and Cost Reduction	**Use of Imaging Studies for Low Back Pain:** Percentage of patients 18-50 years of age with a diagnosis of low back pain who did not have an imaging study (plain X-ray, MRI, CT scan) within 28 days of the diagnosis. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69256).	National Committee for Quality Assurance
N/A/316	61v5 & 64v5	Effective Clinical Care	**Preventive Care and Screening: Cholesterol – Fasting Low Density Lipoprotein (LDL-C) Test Performed AND Risk-Stratified Fasting LDL-C:** Percentage of patients aged 20 through 79 years whose risk factors* have been assessed and a fasting LDL test has been performed AND percentage of patients aged 20 through 79 years who had a fasting LDL-C test performed and whose risk-stratified fasting LDL-C is at or below the recommended LDL-C goal. *There are three criteria for this measure based on the patient's risk category. 1. Highest Level of Risk: Coronary Heart Disease (CHD) or CHD Risk Equivalent OR 10-Year Framingham Risk >20% 2. Moderate Level of Risk: Multiple (2+) Risk Factors OR 10-Year Framingham Risk 10-20% 3. Lowest Level of Risk: 0 or 1 Risk Factor OR 10-Year Framingham Risk <10%. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69256).	Centers for Medicare & Medicaid Services/ Quality Insights of Pennsylvania
N/A/317	22v4	Community/ Population Health	**Preventive Care and Screening: Screening for High Blood Pressure and Follow-Up Documented:** Percentage of patients aged 18 years and older seen during the reporting period who were screened for high blood pressure AND a recommended follow-up plan is documented based on the current blood pressure (BP) reading as indicated. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69256).	Centers for Medicare & Medicaid Services/ Mathematica/ Quality Insights of Pennsylvania
0101/318	139v4	Patient Safety	**Falls: Screening for Fall Risk:** Percentage of patients 65 years of age and older who were screened for future fall risk at least once during the measurement period. This measure was finalized for inclusion in 2013 PQRS in the CY 2012 PFS Final Rule (see Table 95 at 77 FR 69256).	National Committee for Quality Assurance
0658/320	N/A	Communication and Care Coordination	**Appropriate Follow-Up Interval for Normal Colonoscopy in Average Risk Patients:** Percentage of patients aged 50 to 75 years of age receiving a screening colonoscopy without biopsy or polypectomy who had a recommended follow-up interval of at least 10 years for repeat colonoscopy documented in their colonoscopy report. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74631).	American Medical Association-Physician Consortium for Performance Improvement/ American Gastroenterological Association/ American Society for Gastrointestinal Endoscopy/ American College of

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
				Gastroenterology
0005 & 0006/321	N/A	Person and Caregiver-Centered Experience and Outcomes	**CAHPS for PQRS Clinician/Group Survey:** • 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 Your to Take Medication as Directed; and • Stewardship of Patient Resources. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74632).	Agency for Healthcare Research & Quality
N/A/322	N/A	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Preoperative Evaluation in Low-Risk Surgery Patients:** Percentage of stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), or cardiac magnetic resonance (CMR) performed in low risk surgery patients 18 years or older for preoperative evaluation during the 12-month reporting period. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74633).	American College of Cardiology
N/A/323	N/A	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Routine Testing After Percutaneous Coronary Intervention (PCI):** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in patients aged 18 years and older routinely after percutaneous coronary intervention (PCI), with reference to timing of test after PCI and symptom status. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74633).	American College of Cardiology
N/A/324	N/A	Efficiency and Cost Reduction	**Cardiac Stress Imaging Not Meeting Appropriate Use Criteria: Testing in Asymptomatic, Low-Risk Patients:** Percentage of all stress single-photon emission computed tomography (SPECT) myocardial perfusion imaging (MPI), stress echocardiogram (ECHO), cardiac computed tomography angiography (CCTA), and cardiovascular magnetic resonance (CMR) performed in asymptomatic, low coronary heart disease (CHD) risk patients 18 years and older for initial detection and risk assessment. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74634).	American College of Cardiology
N/A/325	N/A	Communication and Care Coordination	**Adult Major Depressive Disorder (MDD): Coordination of Care of Patients with Specific Comorbid Conditions:** Percentage of medical records of patients aged 18 years and older with a diagnosis of major depressive disorder (MDD) and a specific diagnosed comorbid condition (diabetes, coronary artery disease, ischemic stroke, intracranial hemorrhage, chronic kidney disease [stages 4 or 5], End Stage Renal Disease [ESRD] or congestive heart failure) being treated by	American Psychiatric Association/American Medical Association-Physician

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
			another clinician with communication to the clinician treating the comorbid condition. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74635).	Consortium for Performance Improvement
1525/326	N/A	Effective Clinical Care	**Atrial Fibrillation and Atrial Flutter: Chronic Anticoagulation Therapy:** Percentage of patients aged 18 years and older with a diagnosis of nonvalvular atrial fibrillation (AF) or atrial flutter whose assessment of the specified thromboembolic risk factors indicate one or more high-risk factors or more than one moderate risk factor, as determined by CHADS2 risk stratification, who are prescribed warfarin OR another oral anticoagulant drug that is FDA approved for the prevention of thromboembolism. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74635).	American College of Cardiology/American Heart Association/ American Medical Association-Physician Consortium for Performance Improvement
N/A/327	N/A	Effective Clinical Care	**Pediatric Kidney Disease: Adequacy of Volume Management:** Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of End Stage Renal Disease (ESRD) undergoing maintenance hemodialysis in an outpatient dialysis facility have an assessment of the adequacy of volume management from a nephrologist. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74636).	Renal Physicians Association
1667/328	N/A	Effective Clinical Care	**Pediatric Kidney Disease: ESRD Patients Receiving Dialysis: Hemoglobin Level < 10 g/Dl:** Percentage of calendar months within a 12-month period during which patients aged 17 years and younger with a diagnosis of End Stage Renal Disease (ESRD) receiving hemodialysis or peritoneal dialysis have a hemoglobin level < 10 g/dL. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74637).	Renal Physicians Association
N/A/329	N/A	Effective Clinical Care	**Adult Kidney Disease: Catheter Use at Initiation of Hemodialysis:** Percentage of patients aged 18 years and older with a diagnosis of End Stage Renal Disease (ESRD) who initiate maintenance hemodialysis during the measurement period, whose mode of vascular access is a catheter at the time maintenance hemodialysis is initiated. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74637).	Renal Physicians Association
N/A/330	N/A	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. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74638).	Renal Physicians Association
N/A/331	N/A	Efficiency and Cost Reduction	**Adult Sinusitis: Antibiotic Prescribed for Acute Sinusitis (Overuse):** Percentage of patients, aged 18 years and older, with a diagnosis of acute sinusitis who were prescribed an antibiotic within 10 days after onset of symptoms. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74639).	American Academy of Otolaryngology-Head and Neck Surgery

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
N/A/332	N/A	Efficiency and Cost Reduction	**Adult Sinusitis: Appropriate Choice of Antibiotic: Amoxicillin With or Without Clavulanate Prescribed for Patients with Acute Bacterial Sinusitis (Appropriate Use):** Percentage of patients aged 18 years and older with a diagnosis of acute bacterial sinusitis that were prescribed amoxicillin, with or without clavulante, as a first line antibiotic at the time of diagnosis. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74641).	American Academy of Otolaryngology-Head and Neck Surgery
N/A/333	N/A	Efficiency and Cost Reduction	**Adult Sinusitis: Computerized Tomography (CT) for Acute Sinusitis (Overuse):** Percentage of patients aged 18 years and older with a diagnosis of acute sinusitis who had a computerized tomography (CT) scan of the paranasal sinuses ordered at the time of diagnosis or received within 28 days after date of diagnosis. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74642).	American Academy of Otolaryngology-Head and Neck Surgery
N/A/334	N/A	Efficiency and Cost Reduction	**Adult Sinusitis: More than One Computerized Tomography (CT) Scan Within 90 Days for Chronic Sinusitis (Overuse):** Percentage of patients aged 18 years and older with a diagnosis of chronic sinusitis who had more than one CT scan of the paranasal sinuses ordered or received within 90 days after the date of diagnosis. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74644).	American Academy of Otolaryngology-Head and Neck Surgery
N/A/335	N/A	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. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74646).	American Medical Association-Physician Consortium for Performance Improvement
N/A/336	N/A	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. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74647).	American Medical Association-Physician Consortium for Performance Improvement
N/A/337	N/A	Effective Clinical Care	**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. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74648).	American Academy of Dermatology

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
2082/338	N/A	Effective Clinical Care	**HIV Viral Load Suppression:** The percentage of patients, regardless of age, with a diagnosis of HIV with a HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74650).	Health Resources and Services Administration
2083/339	N/A	Effective Clinical Care	**Prescription of HIV Antiretroviral Therapy:** Percentage of patients, regardless of age, with a diagnosis of HIV prescribed antiretroviral therapy for the treatment of HIV infection during the measurement year. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74650).	Health Resources and Services Administration
2079/340	N/A	Efficiency and Cost Reduction	**HIV Medical Visit Frequency:** Percentage of patients, regardless of age with a diagnosis of HIV who had at least one medical visit in each 6 month period of the 24 month measurement period, with a minimum of 60 days between medical visits. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74650).	Health Resources and Services Administration
N/A/342	N/A	Person and Caregiver-Centered Experience and Outcomes	**Pain Brought Under Control Within 48 Hours:** Patients aged 18 and older who report being uncomfortable because of pain at the initial assessment (after admission to palliative care services) who report pain was brought to a comfortable level within 48 hours. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74651).	National Hospice and Palliative Care Organization
N/A/343	N/A	Effective Clinical Care	**Screening Colonoscopy Adenoma Detection Rate Measure:** The percentage of patients age 50 years or older with at least one conventional adenoma or colorectal cancer detected during screening colonoscopy. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74652).	American College of Gastroenterology/ American Gastroenterological Association/ American Society for Gastrointestinal Endoscopy
N/A/344	N/A	Effective Clinical Care	**Rate of Carotid Artery Stenting (CAS) for Asymptomatic Patients, Without Major Complications (Discharged to Home by Post-Operative Day #2):** Percent of asymptomatic patients undergoing CAS who are discharged to home no later than post-operative day #2. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74653).	Society for Vascular Surgeons
1543/345	N/A	Effective Clinical Care	**Rate of Postoperative Stroke or Death in Asymptomatic Patients Undergoing Carotid Artery Stenting (CAS):** Percent of asymptomatic patients undergoing CAS who experience stroke or death following surgery while in the hospital. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74654).	Society for Vascular Surgeons
1540/346	N/A	Effective Clinical Care	**Rate of Postoperative Stroke or Death in Asymptomatic Patients Undergoing Carotid Endarterectomy (CEA):** Percent of asymptomatic patients undergoing CEA who experience stroke or death following surgery while in the hospital. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74656).	Society for Vascular Surgeons

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
1534/347	N/A	Patient Safety	**Rate of Endovascular Aneurysm Repair (EVAR) of Small or Moderate Non-Ruptured Abdominal Aortic Aneurysms (AAA) Who Die While in Hospital:** Percent of patients undergoing endovascular repair of small or moderate abdominal aortic aneurysms (AAA) who die while in the hospital. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74657).	Society for Vascular Surgeons
N/A/348	N/A	Patient Safety	**HRS-3: Implantable Cardioverter-Defibrillator (ICD) Complications Rate:** Patients with physician-specific risk-standardized rates of procedural complications following the first time implantation of an ICD. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74658).	The Heart Rhythm Society
N/A/350	N/A	Communication and Care Coordination	**Total Knee Replacement: Shared Decision-Making: Trial of Conservative (Non-surgical) Therapy:** Percentage of patients regardless of age or gender undergoing a total knee replacement with documented shared decision-making with discussion of conservative (non-surgical) therapy (e.g. Nonsteroidal anti-inflammatory drugs (NSAIDs), analgesics, weight loss, exercise, injections) prior to the procedure. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74661).	American Association of Hip and Knee Surgeons
N/A/351	N/A	Patient Safety	**Total Knee Replacement: Venous Thromboembolic and Cardiovascular Risk Evaluation:** Percentage of patients regardless of age or gender undergoing a total knee replacement who are evaluated for the presence or absence of venous thromboembolic and cardiovascular risk factors within 30 days prior to the procedure (e.g. history of Deep Vein Thrombosis (DVT), Pulmonary Embolism (PE), Myocardial Infarction (MI), Arrhythmia and Stroke). This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74661).	American Association of Hip and Knee Surgeons
N/A/352	N/A	Patient Safety	**Total Knee Replacement: Preoperative Antibiotic Infusion with Proximal Tourniquet:** Percentage of patients regardless of age or gender undergoing a total knee replacement who had the prophylactic antibiotic completely infused prior to the inflation of the proximal tourniquet. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74662).	American Association of Hip and Knee Surgeons
N/A/353	N/A	Patient Safety	**Total Knee Replacement: Identification of Implanted Prosthesis in Operative Report:** Percentage of patients regardless of age or gender undergoing a total knee replacement whose operative report identifies the prosthetic implant specifications including the prosthetic implant manufacturer, the brand name of the prosthetic implant and the size of each prosthetic implant. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74662).	American Association of Hip and Knee Surgeons
N/A/354	N/A	Patient Safety	**Anastomotic Leak Intervention:** Percentage of patients aged 18 years and older who required an anastomotic leak intervention following gastric bypass or colectomy surgery.	American College of Surgeons

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
			This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74663).	
N/A/355	N/A	Patient Safety	**Unplanned Reoperation within the 30 Day Postoperative Period:** Percentage of patients aged 18 years and older who had any unplanned reoperation within the 30 day postoperative period. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74663).	American College of Surgeons
N/A/356	N/A	Effective Clinical Care	**Unplanned Hospital Readmission within 30 Days of Principal Procedure:** Percentage of patients aged 18 years and older who had an unplanned hospital readmission within 30 days of principal procedure. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74663).	American College of Surgeons
N/A/357	N/A	Effective Clinical Care	**Surgical Site Infection (SSI):** Percentage of patients aged 18 years and older who had a surgical site infection (SSI). This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74664).	American College of Surgeons
N/A/358	N/A	Person and Caregiver-Centered Experience and Outcomes	**Patient-Centered Surgical Risk Assessment and Communication:** Percentage of patients who underwent a non-emergency surgery who had their personalized risks of postoperative complications assessed by their surgical team prior to surgery using a clinical data-based, patient-specific risk calculator and who received personal discussion of those risks with the surgeon. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74664).	American College of Surgeons
N/A/359	N/A	Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Utilization of a Standardized Nomenclature for Computed Tomography (CT) Imaging Description:** Percentage of computed tomography (CT) imaging reports for all patients, regardless of age, with the imaging study named according to a standardized nomenclature and the standardized nomenclature is used in institution's computer systems. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74665).	American College of Radiology
N/A/360	N/A	Patient Safety	**Optimizing Patient Exposure to Ionizing Radiation: Count of Potential High Dose Radiation Imaging Studies: Computed Tomography (CT) and Cardiac Nuclear Medicine Studies:** Percentage of computed tomography (CT) and cardiac nuclear medicine (myocardial perfusion studies) imaging reports for all patients, regardless of age, that document a count of known previous CT (any type of CT) and cardiac nuclear medicine (myocardial perfusion) studies that the patient has received in the 12-month period prior to the current study. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74666).	American College of Radiology
N/A/361	N/A	Patient Safety	**Optimizing Patient Exposure to Ionizing Radiation: Reporting to a Radiation Dose Index Registry:** Percentage of total computed tomography (CT) studies performed for all patients, regardless of age, that are reported to a radiation dose index registry AND that include at a minimum selected data elements. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS	American College of Radiology

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
			Final Rule (see Table 52 at 78 FR 74666).	
N/A/362	N/A	Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Computed Tomography (CT) Images Available for Patient Follow-up and Comparison Purposes:** Percentage of final reports for computed tomography (CT) studies performed for all patients, regardless of age, which document that Digital Imaging and Communications in Medicine (DICOM) format image data are available to non-affiliated external healthcare facilities or entities on a secure, media free, reciprocally searchable basis with patient authorization for at least a 12-month period after the study. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74667).	American College of Radiology
N/A/363	N/A	Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Search for Prior Computed Tomography (CT) Studies Through a Secure, Authorized, Media-Free, Shared Archive:** Percentage of final reports of computed tomography (CT) studies performed for all patients, regardless of age, which document that a search for Digital Imaging and Communications in Medicine (DICOM) format images was conducted for prior patient CT imaging studies completed at non-affiliated external healthcare facilities or entities within the past 12-months and are available through a secure, authorized, media free, shared archive prior to an imaging study being performed. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74668).	American College of Radiology
N/A/364	N/A	Communication and Care Coordination	**Optimizing Patient Exposure to Ionizing Radiation: Appropriateness: Follow-up CT Imaging for Incidentally Detected Pulmonary Nodules According to Recommended Guidelines:** Percentage of final reports for computed tomography (CT) imaging studies of the thorax for patients aged 18 years and older with documented follow-up recommendations for incidentally detected pulmonary nodules (e.g., follow-up CT imaging studies needed or that no follow-up is needed) based at a minimum on nodule size AND patient risk factors. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74668).	American College of Radiology
N/A/365	148v4	Effective Clinical Care	**Hemoglobin A1c Test for Pediatric Patients:** Percentage of patients 5-17 years of age with diabetes with a HbA1c test during the measurement period. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74669).	National Committee for Quality Assurance
0108/366	136v5	Effective Clinical Care	**ADHD: Follow-Up Care for Children Prescribed Attention-Deficit/Hyperactivity Disorder (ADHD) Medication:** Percentage of children 6-12 years of age and newly dispensed a medication for attention-deficit/hyperactivity disorder (ADHD) who had appropriate follow-up care. Two rates are reported. a. Percentage of children who had one follow-up visit with a practitioner with prescribing authority during the 30-Day Initiation Phase. b. Percentage of children who remained on ADHD medication for at least 210 days and who, in addition to the visit in the Initiation Phase, had at least two additional follow-up visits with a practitioner within 270 days (9 months) after the Initiation Phase ended. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS	National Committee for Quality Assurance

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
			Final Rule (see Table 52 at 78 FR 74669).	
N/A/367	169v4	Effective Clinical Care	**Bipolar Disorder and Major Depression: Appraisal for Alcohol or Chemical Substance Use:** Percentage of patients with depression or bipolar disorder with evidence of an initial assessment that includes an appraisal for alcohol or chemical substance use. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74670).	Center for Quality Assessment and Improvement in Mental Health
N/A/368	62v4	Effective Clinical Care	**HIV/AIDS: Medical Visit:** Percentage of patients, regardless of age, with a diagnosis of HIV/AIDS with at least two medical visits during the measurement year with a minimum of 90 days between each visit. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74671).	National Committee for Quality Assurance
N/A/369	158v4	Effective Clinical Care	**Pregnant Women that had HBsAg Testing:** This measure identifies pregnant women who had a HBsAg (hepatitis B) test during their pregnancy. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74671).	OptumInsight
0710/370	159v4	Effective Clinical Care	**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. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74671).	Minnesota Community Measurement
0712/371	160v4	Effective Clinical Care	**Depression Utilization of the PHQ-9 Tool:** Adult patients age 18 and older with the diagnosis of major depression or dysthymia who have a PHQ-9 tool administered at least once during a 4 month period in which there was a qualifying visit. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74673).	Minnesota Community Measurement
N/A/372	82v3	Community/ Population Health	**Maternal Depression Screening:** The percentage of children who turned 6 months of age during the measurement year, who had a face-to-face visit between the clinician and the child during child's first 6 months, and who had a maternal depression screening for the mother at least once between 0 and 6 months of life. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74674).	National Committee for Quality Assurance
N/A/373	65v5	Effective Clinical Care	**Hypertension: Improvement in Blood Pressure:** Percentage of patients aged 18-85 years of age with a diagnosis of hypertension whose blood pressure improved during the measurement period. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74675).	Centers for Medicare & Medicaid Services/National Committee for Quality Assurance

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
N/A/374	50v4	Communication and Care Coordination	**Closing the Referral Loop: Receipt of Specialist Report:** Percentage of patients with referrals, regardless of age, for which the referring provider receives a report from the provider to whom the patient was referred. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74677).	Centers for Medicare & Medicaid Services/ Mathematica
N/A/375	66v4	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessment for Knee Replacement:** Percentage of patients aged 18 years and older with primary total knee arthroplasty (TKA) who completed baseline and follow-up (patient-reported) functional status assessments. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74677).	Centers for Medicare & Medicaid Services/National Committee for Quality Assurance
N/A/376	56v4	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessment for Hip Replacement:** Percentage of patients aged 18 years and older with primary total hip arthroplasty (THA) who completed baseline and follow-up (patient-reported) functional status assessments. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74677).	Centers for Medicare & Medicaid Services/National Committee for Quality Assurance
N/A/377	90v4	Person and Caregiver-Centered Experience and Outcomes	**Functional Status Assessment for Complex Chronic Conditions:** Percentage of patients aged 65 years and older with heart failure who completed initial and follow-up patient-reported functional status assessments. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74678).	Centers for Medicare & Medicaid Services/ Mathematica
N/A/378	75v4	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. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74678).	Centers for Medicare & Medicaid Services/ Mathematica
N/A/379	74v5	Effective Clinical Care	**Primary Caries Prevention Intervention as Offered by Primary Care Providers, including Dentists:** Percentage of children, age 0-20 years, who received a fluoride varnish application during the measurement period. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74679).	Centers for Medicare & Medicaid Services/National Committee for Quality Assurance
N/A/380	179v4	Patient Safety	**ADE Prevention and Monitoring: Warfarin Time in Therapeutic Range:** Average percentage of time in which patients aged 18 and older with atrial fibrillation who are on chronic warfarin therapy have International Normalized Ratio (INR) test results within the therapeutic range (i.e., TTR) during the measurement period. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74679).	Centers for Medicare & Medicaid Services/National Committee for Quality Assurance
N/A/381	77v4	Effective Clinical Care	**HIV/AIDS: RNA Control for Patients with HIV:** Percentage of patients aged 13 years and older with a diagnosis of HIV/AIDS, with at least two visits during the measurement year, with at least 90 days between each visit, whose most recent HIV RNA level is <200 copies/mL. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS Final Rule (see Table 52 at 78 FR 74681).	Centers for Medicare & Medicaid Services/National Committee for Quality Assurance
1365/382	177v4	Patient Safety	**Child and Adolescent Major Depressive Disorder (MDD): Suicide Risk Assessment:** Percentage of patient visits for those patients aged 6 through 17 years with a diagnosis of major depressive disorder with an assessment for suicide risk. This measure was finalized for inclusion in 2014 PQRS in the CY 2013 PFS	American Medical Association-Physician Consortium for Performance

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
			Final Rule (see Table 52 at 78 FR 74681).	Improvement
1879/383	N/A	Patient Safety	**Adherence to Antipsychotic Medications for Individuals with Schizophrenia:** Percentage of individuals at least 18 years of age as of the beginning of the measurement period with schizophrenia or schizoaffective disorder who had at least two prescriptions filled for any antipsychotic medication and who had a Proportion of Days Covered (PDC) of at least 0.8 for antipsychotic medications during the measurement period (12 consecutive months). This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67808).	Health Services Advisory Group/ Centers for Medicare & Medicaid Services
N/A/384	N/A	Effective Clinical Care	**Adult Primary Rhegmatogenous Retinal Detachment Surgery: No Return to the Operating Room Within 90 Days of Surgery:** Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment who did not require a return to the operating room within 90 days of surgery. This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67808).	American Academy of Ophthalmology
N/A/385	N/A	Effective Clinical Care	**Adult Primary Rhegmatogenous Retinal Detachment Surgery: Visual Acuity Improvement Within 90 Days of Surgery:** Patients aged 18 years and older who had surgery for primary rhegmatogenous retinal detachment and achieved an improvement in their visual acuity, from their preoperative level, within 90 days of surgery in the operative eye. This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67808).	American Academy of Ophthalmology
N/A/386	N/A	Person and Caregiver-Centered Experience and Outcomes	**Amyotrophic Lateral Sclerosis (ALS) Patient Care Preferences:** Percentage of patients diagnosed with Amyotrophic Lateral Sclerosis (ALS) who were offered assistance in planning for end of life issues (e.g. advance directives, invasive ventilation, hospice) at least once annually. This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67809).	American Academy of Neurology
N/A/387	N/A	Effective Clinical Care	**Annual Hepatitis C Virus (HCV) Screening for Patients who are Active Injection Drug Users:** Percentage of patients regardless of age who are active injection drug users who received screening for HCV infection within the 12 month reporting period. This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67809).	American Medical Association-Physician Consortium for Performance Improvement
N/A/388	N/A	Patient Safety	**Cataract Surgery with Intra-Operative Complications (Unplanned Rupture of Posterior Capsule Requiring Unplanned Vitrectomy:** Percentage of patients aged 18 years and older who had cataract surgery performed and had an unplanned rupture of the posterior capsule requiring vitrectomy. This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67809).	American Academy of Ophthalmology/American College of Healthcare Sciences
N/A/389	N/A	Effective Clinical Care	**Cataract Surgery: Difference Between Planned and Final Refraction:** Percentage of patients aged 18 years and older who had cataract surgery performed and who achieved a final refraction within +/- 1.0 diopters of their planned (target) refraction. This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67810).	American Academy of Ophthalmology/American College of Healthcare Sciences

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description[¥]	Measure Steward
N/A/390	N/A	Person and Caregiver-Centered Experience and Outcomes	**Hepatitis C: Discussion and Shared Decision Making Surrounding Treatment Options:** Percentage of patients aged 18 years and older with a diagnosis of hepatitis C with whom a physician or other qualified healthcare professional reviewed the range of treatment options appropriate to their genotype and demonstrated a shared decision making approach with the patient. To meet the measure, there must be documentation in the patient record of a discussion between the physician or other qualified healthcare professional and the patient that includes all of the following: treatment choices appropriate to genotype, risks and benefits, evidence of effectiveness, and patient preferences toward treatment. This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67810).	American Medical Association-Physician Consortium for Performance Improvement/ American Gastroenterological Association
0576/391	N/A	Communication and Care Coordination	**Follow-Up After Hospitalization for Mental Illness (FUH):** The percentage of discharges for patients 6 years of age and older who were hospitalized for treatment of selected mental illness diagnoses and who had an outpatient visit, an intensive outpatient encounter or partial hospitalization with a mental health practitioner. Two rates are reported: - The percentage of discharges for which the patient received follow-up within 30 days of discharge - The percentage of discharges for which the patient received follow-up within 7 days of discharge. This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67811).	National Committee for Quality Assurance
2474/392	N/A	Patient Safety	**HRS-12: Cardiac Tamponade and/or Pericardiocentesis Following Atrial Fibrillation Ablation:** Rate of cardiac tamponade and/or pericardiocentesis following atrial fibrillation ablation This measure is reported as four rates stratified by age and gender: • Reporting Age Criteria 1: Females less than 65 years of age • Reporting Age Criteria 2: Males less than 65 years of age • Reporting Age Criteria 3: Females 65 years of age and older • Reporting Age Criteria 4: Males 65 years of age and older This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67812).	The Heart Rhythm Society
N/A/393	N/A	Patient Safety	**HRS-9: Infection within 180 Days of Cardiac Implantable Electronic Device (CIED) Implantation, Replacement, or Revision:** Infection rate following CIED device implantation, replacement, or revision. This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67812).	The Heart Rhythm Society
1407/394	N/A	Community/ Population Health	**Immunizations for Adolescents:** The percentage of adolescents 13 years of age who had the recommended immunizations by their 13th birthday. This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67812).	National Committee for Quality Assurance
N/A/395	N/A	Communication and Care Coordination	**Lung Cancer Reporting (Biopsy/Cytology Specimens):** Pathology reports based on biopsy and/or cytology specimens with a diagnosis of primary nonsmall cell lung cancer classified into specific histologic type or classified as NSCLC-NOS with an explanation included in the pathology report. This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67812).	College of American Pathologists
N/A/396	N/A	Communication and Care Coordination	**Lung Cancer Reporting (Resection Specimens):** Pathology reports based on resection specimens with a diagnosis of primary lung carcinoma that include the pT category, pN category and for non-small cell lung cancer, histologic type. This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67812).	College of American Pathologists

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
N/A/397	N/A	Communication and Care Coordination	**Melanoma Reporting:** Pathology reports for primary malignant cutaneous melanoma that include the pT category and a statement on thickness and ulceration and for pT1, mitotic rate. This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67813).	College of American Pathologists
N/A/398	N/A	Effective Clinical Care	**Optimal Asthma Control:** Patients ages 5-50 (pediatrics ages 5-17) whose asthma is well-controlled as demonstrated by one of three age appropriate patient reported outcome tools. This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67813).	Minnesota Community Measurement
2452/399	N/A	Effective Clinical Care	**Post-Procedural Optimal Medical Therapy Composite (Percutaneous Coronary Intervention):** Percentage of patients aged 18 years and older for whom PCI is performed who are prescribed optimal medical therapy at discharge. This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67813).	American College of Cardiology/American Heart Association/ American Medical Association-Physician Consortium for Performance Improvement
N/A/400	N/A	Effective Clinical Care	**One-Time Screening for Hepatitis C Virus (HCV) for Patients at Risk:** Percentage of patients aged 18 years and older with one or more of the following: a history of injection drug use, receipt of a blood transfusion prior to 1992, receiving maintenance hemodialysis OR birthdate in the years 1945-1965 who received a one-time screening for HCV infection. This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67814).	American Medical Association-Physician Consortium for Performance Improvement
N/A/401	N/A	Effective Clinical Care	**Hepatitis C: Screening for Hepatocellular Carcinoma (HCC) in Patients with Cirrhosis:** Percentage of patients aged 18 years and older with a diagnosis of chronic hepatitis C cirrhosis who underwent imaging with either ultrasound, contrast enhanced CT or MRI for hepatocellular carcinoma (HCC) at least once within the 12 month reporting period. This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67814).	American Medical Association-Physician Consortium for Performance Improvement/ American Gastroenterological Association
N/A/402	N/A	Community/ Population Health	**Tobacco Use and Help with Quitting Among Adolescents:** The percentage of adolescents 12 to 20 years of age with a primary care visit during the measurement year for whom tobacco use status was documented and received help with quitting if identified as a tobacco user. This measure was finalized for inclusion in 2015 PQRS in the CY 2014 PFS Final Rule (see Table 53 at 79 FR 67815).	National Committee for Quality Assurance/National Collaborative for Innovation in Quality Measurement
N/A/403 ‡	N/A	Person and Caregiver-Centered Experience and Outcomes	**Adult Kidney Disease: Referral to Hospice:** Percentage of patients aged 18 years and older with a diagnosis of end-stage renal disease (ESRD) who withdraw from hemodialysis or peritoneal dialysis who are referred to hospice care. This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.	Renal Physicians Association/American Medical Association-Physician Consortium for Performance Improvement

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
N/A/439 ‡	N/A	Efficiency and Cost Reduction	**Age Appropriate Screening Colonoscopy:** The percentage of patients greater than 85 years of age who received a screening colonoscopy from January 1 to December 31. This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.	American Gastroenterological Association/ American Society for Gastrointestinal Endoscopy/ American College of Gastroenterology
N/A/404 ‡	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. This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.	American Society of Anesthesiologists
N/A/421 ‡	N/A	Effective Clinical Care	**Appropriate Assessment of Retrievable Inferior Vena Cava Filters for Removal:** Percentage of patients in whom a retrievable IVC filter is placed who, within 3 months post-placement, have a documented assessment for the appropriateness of continued filtration, device removal or the inability to contact the patient with at least two attempts. This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.	Society of Interventional Radiology
N/A/405 ‡	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 This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.	American College of Radiology
N/A/406 ‡	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. This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.	American College of Radiology
N/A/407 ‡	N/A	Effective Clinical Care	**Appropriate Treatment of MSSA Bacteremia:** Percentage of patients with sepsis due to MSSA bacteremia who received beta-lactam antibiotic (e.g. nafcillin, oxacillin or cefazolin) as definitive therapy. This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.	Infectious Disease Society of America
N/A/408 ‡	N/A	Effective Clinical Care	**Opioid Therapy Follow-up Evaluation:** All patients 18 and older prescribed opiates for longer than six weeks duration who had a follow-up evaluation conducted at least every three months during Opioid Therapy documented in the medical record. This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.	American Academy of Neurology

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
N/A/409 ‡	N/A	Effective Clinical Care	**Clinical Outcome Post Endovascular Stroke Treatment:** Percentage of patients with a mRs score of 0 to 2 at 90 days following endovascular stroke intervention. This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.	Society of Interventional Radiology
0711/411 ‡	N/A	Communication and Care Coordination	**Depression Remission at Six Months:** Adult patients age 18 years and older with major depression or dysthymia and an initial PHQ-9 score > 9 who demonstrate remission at six months defined as a PHQ-9 score less than 5. This measure applies to both patients with newly diagnosed and existing depression whose current PHQ-9 score indicates a need for treatment. This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.	Minnesota Community Measurement
N/A/412 ‡	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 Opioid Therapy documented in the medical record. This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.	American Academy of Neurology
N/A/413 ‡	N/A	Effective Clinical Care	**Door to Puncture Time for Endovascular Stroke Treatment:** Percentage of patients undergoing endovascular stroke treatment who have a door to puncture time of less than two hours. This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.	Society of Interventional Radiology
N/A/415 ‡	N/A	Efficiency and Cost Reduction	**Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 18 Years and Older:** Percentage of emergency department visits for patients aged 18 years and older who presented within 24 hours of a minor blunt head trauma with a Glasgow Coma Scale (GCS) score of 15 and who had a head CT for trauma ordered by an emergency care provider who have an indication for a head CT. This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.	American College of Emergency Physicians
N/A/416 ‡	N/A	Efficiency and Cost Reduction	**Emergency Medicine: Emergency Department Utilization of CT for Minor Blunt Head Trauma for Patients Aged 2 through 17 Years:** Percentage of emergency department visits for patients aged 2 through 17 years who presented within 24 hours of a minor blunt head trauma with a Glasgow Coma Scale (GCS) score of 15 and who had a head CT for trauma ordered by an emergency care provider who are classified as low risk according to the Pediatric Emergency Care Applied Research Network prediction rules for traumatic brain injury. This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.	American College of Emergency Physicians
N/A/414 ‡	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 Opioid Therapy in the medical record. This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.	American Academy of Neurology
0053/418 ‡	N/A	Effective Clinical Care	**Osteoporosis Management in Women Who Had a Fracture:** The percentage of women age 50-85 who suffered a fracture and who either had a bone mineral density test or received a prescription for a drug to treat osteoporosis. This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.	National Committee for Quality Assurance/ American Medical

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
				Association-Physician Consortium for Performance Improvement
N/A/419 ‡	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 whom advanced brain imaging was not ordered. This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.	American Academy of Neurology
N/A/428 ‡	N/A	Effective Clinical Care	**Pelvic Organ Prolapse: Preoperative Assessment of Occult Stress Urinary Incontinence:** Percentage of patients undergoing appropriate preoperative evaluation for the indication of stress urinary incontinence per ACOG/AUGS/AUA guidelines. This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.	American Urogynecologic Society
N/A/429 ‡	N/A	Patient Safety	**Pelvic Organ Prolapse: Preoperative Screening for Uterine Malignancy:** Percentage of patients who are screened for uterine malignancy prior to surgery for pelvic organ prolapse. This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.	American Urogynecologic Society
2063/422 ‡	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 hysterectomy for pelvic organ prolapse. This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.	American Urogynecologic Society
0465/423 ‡	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. This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.	Society for Vascular Surgeons
2671/424 ‡	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. This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.	American Society of Anesthesiologists
N/A/425 ‡	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. This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.	American College of Gastroenterology/ American Gastroenterological Association/ American Society for Gastrointestinal Endoscopy

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
N/A/426 ‡	N/A	Communication and Care Coordination	**Post-Anesthetic Transfer of Care Measure: Procedure Room to a Post Anesthesia Care Unit (PACU):** Percentage of patients, regardless of age, who are under the care of an anesthesia practitioner and are admitted to a PACU in which a post-anesthetic formal transfer of care protocol or checklist which includes the key transfer of care elements is utilized. This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.	American Society of Anesthesiologists
N/A/427 ‡	N/A	Communication and Care Coordination	**Post-Anesthetic Transfer of Care: Use of Checklist or Protocol for Direct Transfer of Care from Procedure Room to Intensive Care Unit (ICU):** Percentage of patients, regardless of age, who undergo a procedure under anesthesia and are admitted to an Intensive Care Unit (ICU) directly from the anesthetizing location, who have a documented use of a checklist or protocol for the transfer of care from the responsible anesthesia practitioner to the responsible ICU team or team member. This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.	American Society of Anesthesiologists
N/A/430 ‡	N/A	Patient Safety	**Prevention of Post-Operative Nausea and Vomiting (PONV) – Combination Therapy:** Percentage of patients, aged 18 years and older, who undergo a procedure under an inhalational general anesthetic, AND who have three or more risk factors for post-operative nausea and vomiting (PONV), who receive combination therapy consisting of at least two prophylactic pharmacologic antiemetic agents of different classes preoperatively or intraoperatively. This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.	American Society of Anesthesiologists
2152/431 ‡	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. This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.	American Medical Association-Physician Consortium for Performance Improvement
N/A/432 ‡	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. This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.	American Urogynecologic Society
N/A/433 ‡	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 time of index surgery that is recognized intraoperative or within 1 month after surgery. This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.	American Urogynecologic Society
N/A/434 ‡	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. This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.	American Urogynecologic Society

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
N/A/410 ‡	N/A	Person and Caregiver-Centered Experience and Outcomes	**Psoriasis: Clinical Response to Oral Systemic or Biologic Medications:** Percentage of psoriasis patients receiving oral systemic or biologic therapy who meet minimal physician- or patient-reported disease activity levels. It is implied that establishment and maintenance of an established minimum level of disease control as measured by physician- and/or patient-reported outcomes will increase patient satisfaction with and adherence to treatment. This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.	American Academy of Dermatology
N/A/435 ‡	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. This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.	American Academy of Neurology
N/A/436 ‡	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 This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.	American College of Radiology/ American Medical Association-Physician Consortium for Performance Improvement/ National Committee for Quality Assurance
1523/417 ‡	N/A	Patient Safety	**Rate of Open Repair of Abdominal Aortic Aneurysms (AAA) Where Patients Are Discharged Alive:** Percentage of patients undergoing open repair of abdominal aortic aneurysms (AAA) who are discharged alive. This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.	Society for Vascular Surgeons
N/A/437 ‡	N/A	Patient Safety	**Rate of Surgical Conversion from Lower Extremity Endovascular Revasculatization Procedure:** Inpatients assigned to endovascular treatment for obstructive arterial disease, the percent of patients who undergo unplanned major amputation or surgical bypass within 48 hours of the index procedure. This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.	Society of Interventional Radiology
N/A/438 ‡	N/A	Effective Clinical Care	**Statin Therapy for the Prevention and Treatment of Cardiovascular Disease:** Percentage of the following patients—all considered at high risk of cardiovascular events—who were prescribed or were on statin therapy during the measurement period: • Adults aged ≥ 21 years who were previously diagnosed with or currently have an active diagnosis of clinical atherosclerotic cardiovascular disease (ASCVD); OR • Adults aged ≥21 years with a fasting or direct low-density lipoprotein cholesterol (LDL-C) level ≥ 190 mg/dL; OR • Adults aged 40-75 years with a diagnosis of diabetes with a fasting or direct LDL-C level of 70-189 mg/dL This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.	Centers for Medicare & Medicaid Services/ Mathematica/Quality Insights of Pennsylvania

NQF/ PQRS	CMS E-Measure ID	National Quality Strategy Domain	Measure Title and Description¥	Measure Steward
N/A/420 ‡	N/A	Effective Clinical Care	**Varicose Vein Treatment with Saphenous Ablation: Outcome Survey:** Percentage of patients treated for varicose veins (CEAP C2-S) who are treated with saphenous ablation (with or without adjunctive tributary treatment) that report an improvement on a disease specific patient reported outcome survey instrument after treatment. This measure was finalized for inclusion in 2016 PQRS in the CY 2015 PFS Final Rule.	Society of Interventional Radiology

‡ This measure is new to the Physician Quality Reporting System and has been adopted for reporting beginning in CY 2016.

¥ 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. This column also contains summary of public comments and CMS's responses, if applicable.

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7. Request for Input on the Provisions Included in the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA)

The Medicare Access and CHIP Reauthorization Act of 2015 (Pub. L. 114–10, enacted on April 16, 2015) (MACRA) repealed the Medicare sustainable growth rate (SGR) update formula for payments under the Medicare physician fee schedule, established the Merit-based Incentive Payments System (MIPS) under the physician fee schedule, established incentive payments for participation in certain alternative payment models (APMS), and made other changes affecting Medicare payments to physicians and other eligible professionals. We sought public input on the following provisions of the MACRA in the CY 2016 PFS proposed rule (80 FR 41879 through 41880):

- 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. In the proposed rule, we sought public input on specific provisions related to the MIPS, including (80 FR 41879):

- 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.
- 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.
- Which factors to include, individually or in combination, in determining a low-volume threshold.
- Whether a low-volume threshold similar to ones currently used in other CMS reporting programs would be an appropriate low-volume threshold for the MIPS and the applicability of existing low-volume thresholds used in other CMS reporting programs toward MIPs.
- What activities could be classified as clinical practice improvement activities according to the definition under section 1848(q)(2)(C)(v)(III) of the Act.

b. Alternative Payment Models

Section 101(e) of the 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 certain APMs. The statutory amendments made by this section have payment implications for eligible professionals beginning in 2019. As part of our continued commitment to stakeholder engagement, we broadly sought public comments on the promotion of alternative payment models (APMs) in the proposed rule (80 FR 41879 through 41880). Specifically, we sought comment on approaches for developing and encouraging APMs and on incentive payments for participation in APMs by eligible professionals. We noted that we would be requesting more detailed information in a forthcoming RFI on the following topics: 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 alternative payment entities; quality measures and EHR use requirements; and the definition of nominal financial risk for eligible alternative payment entities.

In response to our solicitation, we received over 90 insightful and informative public comments suggesting matters to consider in our RFI and for

future rulemaking. In addition to seeking public comment through the proposed rule, we published a Request for Information (RFI) on October 1, 2015, (80 FR 59102–59113) available at *https://federalregister.gov/a/2015-24906*, asking for additional public comment on more detailed questions related to both MIPS and APMs. We appreciate the many insights and comments that we received, and look forward to additional comments in response to the RFI. We will consider these public comments in future rulemaking.

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.

In this final rule, we summarize the comments we received based on our proposals for the EHR Incentive Program in the CY 2016 PFS proposed rule (80 FR 41880) and state our final policies based on these proposals and comments. Please note that we received numerous comments related generally to the EHR Incentive Program but not related to our specific proposals for the EHR Incentive Program in the CY 2016 PFS proposed rule. While we may take these comments into consideration when developing proposals in the future, we will not address these comments with specificity here.

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 anticipated 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 anticipated 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.

Accordingly, to allow providers to upgrade to 2015 Edition CEHRT before 2018, we proposed in the CY 2016 PFS proposed rule (80 FR 41880) 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 noted that the proposed CEHRT definition for 2015 through 2017 included in the Stage 3 proposed rule published on March 30, 2015 (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 proposed in the CY 2016 PFS proposed rule (80 FR 41880) 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 proposed 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 invited comment on our proposals. We note that ONC finalized the proposal to adopt a 2015 Edition CQM reporting certification (at 45 CFR 170.315(c)(3)) in its 2015 Edition final rule. The certification criterion requires health IT to be certified to report CQMs using the QRDA Category I and III standards. It also includes an optional provision to report CQMs in the ''form and manner'' that CMS requires for submission. We refer readers to 80 FR 62651 through 62652.

The following is a summary of the comments we received regarding these proposals.

Comment: Commenters were supportive of our proposals to revise the CEHRT definition at § 495.4. The commenters stated that if CMS intends to require EHR products to be able to submit this data either directly or via a certified file format, the proposal to require the optional portion of the CQM reporting criterion for the CEHRT definition is necessary.

Response: We appreciate the commenters' support for our proposals. Based on the comments received and for the reasons stated previously, we are finalizing these proposals made in the CY 2016 PFS proposed rule, as proposed. We are revising the regulation text under § 495.4 to reflect this final policy.

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 9 electronically specified CQMs across 2 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.

In the CY 2016 PFS proposed rule (80 9 FR 41881), we proposed 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 3 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 finalized in the Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 through 2017 final rule (80 FR 62888), EPs in any year of participation may electronically report clinical quality measures for a reporting period in 2016. Therefore, we proposed that for CY 2016, EPs who are part of a 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 noted 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 invited public comment on these proposals.

We received several comments in response to the proposed group reporting option for CPC practice sites for CY 2016.

Comment: Several commenters supported the alignment between CPC and the Medicare EHR Incentive Program. They also supported the inclusion of EPs who are in their first year of participation in the Medicare EHR Incentive Program in the proposal to meet the CQM reporting requirement of the Medicare EHR Incentive Program through successful reporting to CPC. However, a few commenters expressed concern about penalizing first year EPs

who submit 12 months of data rather than 90 days.

Response: We appreciate the support for this proposal. To clarify, we proposed that EPs who are part of a CPC practice site and are in their first year of demonstrating meaningful use [in CY 2016] may report CQMs through the CPC group reporting option for CY 2016, and if submitted successfully in accordance with the requirements established by the CPC Initiative and using CEHRT, their CPC reporting would satisfy the CQM requirement for the Medicare EHR Incentive Program. First-year EPs who successfully report CQMs through the CPC group reporting option for the CY 2016 reporting period and meet all other requirements for the Medicare EHR Incentive Program would avoid the meaningful use payment adjustment under Medicare in CY 2018. We note that in the Medicare and Medicaid Programs; Electronic Health Record Incentive Program-Stage 3 and Modifications to Meaningful Use in 2015 through 2017 final rule (80 FR 62905), we established that in CY 2016, the EHR reporting period for a payment adjustment year for EPs who are new participants is any continuous 90-day period in CY 2016, and an EP who successfully demonstrates meaningful use for this period and satisfies all other program requirements will avoid the payment adjustment in CY 2017 if the EP successfully attests by October 1, 2016. Therefore, to avoid the meaningful use payment adjustment under Medicare in CY 2017, EPs who are demonstrating meaningful use for the first time in CY 2016 and report CQMs through the CPC group reporting option must also successfully report CQMs by attestation through the EHR Incentive Program's Registration and Attestation System for a 90-day reporting period in CY 2016 by October 1, 2016, or apply for a significant hardship exception from the CY 2017 payment adjustment.

Comment: One commenter expressed concern that CPC practice site vendors may not be able to support the CPC CQM reporting requirements.

Response: We understand that some practices found it challenging to meet the CPC CQM reporting requirements due to issues involving their vendors. However, the CPC CQM results from program year 2014 demonstrated that a substantial majority of the CPC practices were able to meet the CPC requirements.

Comment: Two commenters suggested that electronic quality measurement should look across longer periods of time, utilize more data sources, and consider care in settings other than hospitals and ambulatory care such as long-term post-acute care, behavioral health and palliative care.

Response: The Medicare EHR Incentive Program is limited by statute to eligible professionals, eligible hospitals, and critical access hospitals. There are separate CMS programs, however, that require quality reporting from other types of providers. In addition, certain measures in the Medicare EHR Incentive Program include information about care from other settings or for particular conditions, such as behavioral health, and we hope to continue to add measures for a wider range of specialties and settings with a focus on outcomes measures.

After consideration of the comments received, and for the reasons stated previously, we are finalizing the proposals for the group reporting option for CPC practice sites for CY 2016 as proposed.

K. Discussion and Acknowledgement of Public Comments Received on the Potential Expansion of the Comprehensive Primary Care (CPC) Initiative

1. Background

We have been working to develop and test models of advanced primary care under the authority of section 1115A of the Act. Through these models, we plan to evaluate whether advanced primary care results in higher quality and more coordinated care at a lower cost to Medicare. We are currently testing the Comprehensive Primary Care (CPC) initiative.

In the CPC initiative, we are collaborating with commercial payers and state Medicaid agencies to test a payment and service delivery model that includes the payment of monthly non-visit based per beneficiary per month care management fees and shared savings opportunities. The 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 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 primary care practitioner 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. More information on the CPC initiative can be found on the CMS Center for Medicare and Medicaid Innovation's Web site at *http://innovation.cms.gov/initiatives/Comprehensive-Primary-Care-Initiative/*.

In the CY 2016 PFS proposed rule (80 FR 41881 through 41884), we presented a description of the CPC initiative and solicited public comments regarding policy and operational issues related to a potential future expansion of the CPC initiative. Section 1115A(c) of the Act, as added by section 3021 of the Affordable Care Act, provides the Secretary with the authority to expand through rulemaking the duration and scope of a model that is being tested under section 1115A(b) of the Act, such as the CPC initiative (including implementation on a nationwide basis), if the following findings are made, taking into account the evaluation of the model under section 1115A(b)(4) of the Act: (1) The Secretary determines that the expansion is expected to either reduce Medicare spending without reducing the 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. The decision of whether or not to expand 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. Given that further evaluation is needed to

determine its impact on both Medicare cost and quality of care, we did not propose an expansion of the CPC initiative in the CY 2016 PFS proposed rule.

Consistent with our continuing commitment to engaging stakeholders in CMS's work, we solicited public comments on a variety of issues to broaden and deepen our understanding of the important issues and challenges regarding primary care payment and transformation in the health care marketplace. Among other subject-matter areas, we solicited public comments on practice readiness, practice standards and reporting, practice groupings, interaction with state primary care transformation initiatives, learning activities, payer and self-insured employer readiness, Medicaid, quality reporting, interaction with the chronic care management code, and provision of data feedback to practices. In response to our solicitation, we received over 90 timely and informative public comments suggesting matters to consider in a potential future expansion of the CPC initiative, including engagement of electronic health record vendors, coaching on leadership and change management, documentation, beneficiary cost-sharing, care management, further testing of the CPC initiative, eligibility for incentive payments for participation in Alternative Payment Models under MACRA, auditing requirements, aggregation of payer and clinical data, and engagement with providers across the broader medical neighborhood. These comments, submitted by a variety of stakeholders, broadly supported CPC expansion. We appreciate the commenters' views and recommendations. We will consider the public comments we received if the CPC initiative is expanded in the future through rulemaking.

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 addressed the following policies under the Shared Savings Program in the CY 2016 PFS 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 who bill through the TIN of an ACO participant may 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 certain policies related to the quality measures and quality performance standard that we proposed in the CY 2016 PFS proposed rule. Specifically, we proposed 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 billing through the TIN of an ACO participant 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. 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, in the CY 2016 PFS proposed rule we proposed 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 proposed to add a statin therapy 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 45 lists the Shared Savings Program quality measure set, including the one measure we proposed to add, which would be used to assess ACO quality starting in 2016.

- Statin Therapy for the Prevention and Treatment of Cardiovascular Disease

We proposed 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 proposed this measure to continue Shared Savings Program alignment with the PQRS program and Million Hearts® Initiative. We proposed that the multiple denominators would 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 solicited public comment on the implementation of the measure for the Shared Savings Program. We solicited comment on whether the measure should be considered a single measure with weighted denominators or three measures given the multiple denominators that 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 solicited 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 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, which could result in a low number of beneficiaries meeting the measure denominators. Hence, we proposed 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 proposed 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 proposed 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 of the proposed rule (80 FR 41886 through 41888). 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 also solicited 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 solicited 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 the 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.

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 44 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 44 provides a summary of the number of measures by domain and the total points and domain weights that would be used for scoring purposes with the proposed Statin Therapy measure in the Preventive Health domain. Under our proposal, 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 also solicited 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.

TABLE 44—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%
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%

Comment: Most comments we received supported the addition of the Statin Therapy measure to the Preventative Health domain, but some stakeholders recommended changes to the denominators or suggested expanding treatments beyond statins to include other effective treatments. An example of a suggested change to the measure that we received is a recommendation to modify the denominators to report the percentage of the high risk population that is both on a statin and has achieved an LDL < 100. In addition, numerous commenters urged CMS to seek endorsement of the Statin Therapy measure from the National Quality Forum prior to implementation in the Shared Savings Program. Many commenters supported increasing the beneficiary oversample for reporting the measure, but did not think it would resolve the issue of insufficient beneficiaries meeting the multiple denominators and did not provide alternative suggestions. Most commenters supported scoring the measure as a single measure and retaining the measure as pay-for-reporting for the entire agreement period due to concerns with the measure specifications and lack of NQF endorsement. However, some

commenters agreed with our proposal and recommended the measure transition to pay-for-performance after being pay-for-reporting for 2 years.

We also received many comments opposing the addition of the Statin Therapy measure, citing concerns about specifications that are not publicly available and about adding a process measure that has not been tested and still does not conform to the four major statin therapy benefit categories from the 2013 ACC/AHA clinical guidelines. Commenters suggested CMS move toward replacing process measures with health outcome and patient-reported outcome measures.

Response: After reviewing the comments, we are finalizing our proposal for adding the Statin Therapy quality measure to the quality measure set for the Shared Savings Program. As is our standard practice, we intend to make specifications for this measure available prior to the performance year in which it is applicable. We therefore anticipate the final specifications for the Statin Therapy measure will be made public prior to the 2016 performance year. In response to the commenters who expressed concern that this measure requires further testing and may not cover all components of the current clinical guidelines, we note that CMS requires that all measures included in the program undergo feasibility, validity, and reliability testing. CMS tested the measure to assess the technical feasibility of the measure, as well as the extent to which measure scores are valid and reliable. In addition, the measure underwent qualitative testing activities across multiple testing sites to assess the feasibility, face validity and usability of the measure. The testing was conducted in accordance with the processes and principles outlined in CMS's *A Blueprint for the Measures Management System* (*https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/MMS/Measures ManagementSystemBlueprint.html*). This measure also reflects CMS's effort to adhere to current clinical guidelines. The measure incorporates three of the four components of the 2013 ACC/AHA clinical guidelines, and thus, this initial implementation of the measure provides an opportunity to fill a key clinical gap in the program. Based on feedback and guidance from the technical expert panel and measure owner, this measure is the most advantageous and analytically feasible way to address the clinical guidelines. Although, we believe the measure conforms to current guidelines, we understand the ACC is convening stakeholders to further discuss and review the guidelines. CMS will continue to monitor and review updates to guidelines and take these into consideration in the future. We appreciate comments suggesting the use of an NQF-endorsed measure. However, there is no similar, feasible, and practical measure that has been endorsed by the NQF and submitted to the Measure Applications Partnership. While some commenters suggested expanding the measure to other effective treatments, current clinical guidelines indicate statin therapy is the appropriate standard of care. We believe that requiring ACOs to report on the Statin Therapy measure is important to encourage focus on important preventive care and effective treatment for a high prevalence condition. Moreover, inclusion of this measure, as outlined previously, will enhance alignment with PQRS and the Million Hearts ® Initiative, and focus on important preventive care and effective treatments for high prevalence conditions.

We are finalizing our proposal of adding the Statin Therapy measure as a single 3-part measure scored as 2 points with an oversample of 750 beneficiaries. We are increasing the oversample from 616 to 750 beneficiaries for this measure, but the consecutive reporting requirement for measures reported through the CMS web interface will remain at 248 beneficiaries. Although we proposed transitioning the measure to pay-for-performance in the third year of the agreement period, we are finalizing the measure as pay-for-reporting for all reporting years because a majority of commenters supported finalizing the measure as pay-for-reporting only and because ACC and other experts are continuing to discuss non-statin therapy and reducing ASCVD risk. These discussions may, in turn, cause modifications in the measure specifications. For these reasons, we believe 2 years is too short a timeline to transition to pay for performance in accordance with our current rules and therefore will finalize this measure as pay for reporting for all three years. By finalizing the measure as pay-for-reporting in all agreement years we hope to provide ACOs and their ACO participants and ACO providers/suppliers with an opportunity to gain experience and become familiar with the ACC/AHA clinical guidance and multiple denominators of the measure. However, we agree with commenters that stated support for measures of statin therapy and the importance of moving to pay for performance. We therefore intend to revisit this measure in future rulemaking to propose a timeline for phasing in pay for performance. As a result of adding this measure, the total points possible in the Preventive Health domain will increase from 16 points to 18 points and the total measures in the Shared Savings Program measure set reported by ACOs will increase from 33 measures to 34 measures.

TABLE 45: Measures for Use in Establishing Quality Performance Standards that ACOS Must Meet for Shared Savings

Domain	ACO Measure #	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**
	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)		Adapted NQF #2510 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	CMS Web Interface	R	**P**	**P**

				NCQA				
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 CMS	CMS Web Interface	R	**R**	**R**
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 ACO - 41: Diabetes: Eye Exam		NQF #0059 NCQA (individual component)	CMS Web Interface	R	**P**	**P**
	ACO - 41			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**

c. 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, in the CY 2016 PFS proposed rule (80 FR 41889) we proposed to adopt a general policy under which we would 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. In the proposed rule, we explained that we expected to 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 proposed 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 solicited 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.

Comment: Comments supported the proposed policy not to assess ACO performance on measures that no longer align with clinical guidelines or may cause patient harm; however, many commenters suggested the most appropriate method to handle such measures is immediate suspension and further evaluation of the measure by stakeholders or NQF rather than maintaining the measure as pay-for-reporting.

Response: We are finalizing our proposal to 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 practice due to clinical guideline changes or clinical evidence suggesting that the continued collection of the data may result in harm to patients. We believe that maintaining or reverting a measure to pay-for-reporting will ensure ACOs will not be scored on their performance on the measure while CMS and the measure steward assess the measure specifications. CMS may propose to retire such a measure in the next rulemaking cycle, which will offer the public an opportunity to comment and will put ACOs on sufficient notice about the retirement of the measure. We appreciate the comments suggesting immediate suspension and will explore this option further and may consider proposing such an approach in the future.

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 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 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'' 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. In addition, we also updated the measure specifications to include providers who met meaningful use requirements within the past 2 years to account for the changes in meaningful use requirements and to support the progression of HIT adoption and use.

We continue to believe that measures that 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. In October 2015, final rules were issued for ''Stage 3'' of the EHR Incentive program (80 FR 62761), as well as the 2015 Edition of ONC certification criteria (80 FR 62601). Together, these rules 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 *https://www.healthit.gov/sites/default/files/hie-interoperability/nationwide-interoperability-roadmap-final-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. Although we did not propose any changes to the current measure ''Percent of PCPs who Successfully Meet Meaningful Use Requirements'' (ACO–11), we solicited comments 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 welcomed 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?

We appreciate the numerous thoughtful comments on the questions we posed regarding the current measure ''Percent of PCPs who Successfully Meet Meaningful Use Requirements'' (ACO–11) and its evolution as a part of the Shared Savings Program. We will use the feedback as we determine how the measure could be updated and expanded to further incentivize and reward providers for using and adopting more advanced health IT. We would make any modifications necessary to permit the evolution of the measure through future rulemaking.

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 an 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 proposed in the CY 2016 PFS proposed rule (80 FR 41890) 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 indicated that 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.

Comment: We received few comments on this proposal, but all comments supported the proposed changes because the revisions would clarify the reporting requirement and align the policy under the Shared Savings Program with PQRS.

Response: We appreciate the comments in support of our proposal. We agree that the proposed revisions to § 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, will clarify the reporting requirement and align the Shared Savings Program policy with PQRS. As a result, we are finalizing our proposed revisions to § 425.504.

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 proposed 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 Skilled Nursing Facilities (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 E/M 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 November 2014 proposed rule, in some cases, hospitalists that perform E/M 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 suggested excluding SNF visit codes furnished in POS 31 to potentially relieve physicians practicing exclusively in skilled nursing facilities from the requirement that 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. Although 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, in the CY 2016 PFS proposed rule we proposed 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. Although 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. We indicated in the proposal that if we finalized this proposal, we anticipated 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 approach 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 proposed 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. ACO participant TINs that include only ACO professionals that furnish services exclusively in SNFs would not be required to be exclusive to a single ACO. We also note, however, that an ACO participant TIN that includes both ACO professionals that furnish services exclusively in SNFs as well as other ACO professionals that furnish primary care services in non-SNF settings would continue to be required to be exclusive to a single ACO since such an ACO participant TIN would be submitting claims for primary care services that would continue to be used for beneficiary assignment.

The following is a summary of the comments we received regarding these proposals:

Comment: Nearly all commenters that submitted comments supported the proposal to exclude services billed under CPT codes 99304 through 99318 when the claim includes the POS 31 modifier. These commenters agreed that it would increase the accuracy of the beneficiary assignment methodology. Although beneficiaries' care may be coordinated during their time in a 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 care needs. Hospitalists and other physicians providing services in SNFs also indicated their support for the proposal, agreeing that in some circumstances it could relieve them from the requirement that they must be exclusive to a single ACO if their services are considered in assignment. In addition, a commenter opposed the proposal, believing that the proposal fails to recognize the importance in rural areas of SNFs as a vital site of primary care services. This commenter reported that SNF residents in rural areas often have longer stays for chronic conditions requiring intensive maintenance and coordination efforts. As a result, the commenter believes the

proposal would deprive ACO attribution and benefits to a significant portion of the rural ''Medicaid'' population and those in most need of such patient-centered service delivery. Another commenter questioned the validity of excluding SNF visits from the beneficiary assignment process while including any cost savings generated by ACOs through collaborative affiliation with SNFs.

Response: 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 care needs. Further, based on our preliminary analysis and input from commenters, we do not believe removal of these claims will result in a significant reduction of assigned beneficiaries from an ACO, although we recognize that assignment to some ACOs may be more affected than others, depending on the practice patterns of their ACO provider/suppliers.

We disagree with the comment that this approach would deprive ACO attribution and benefits to a significant portion of the rural Medicaid population and those in most need of such patient-centered service delivery. While residing in a SNF, patients are primarily receiving continued acute medical care and rehabilitative services. Further, assignment under the Shared Savings Program is only available to Medicare beneficiaries, and the assignment methodology includes primary care services furnished in RHCs. We believe that it is more appropriate for such patients to be assigned to ACOs based on the primary care professionals in the community (including NFs) who are typically responsible for providing care to meet their true primary care needs. We also disagree with the commenter who questioned the validity of excluding the SNF visits from the beneficiary assignment process while including the cost savings generated by an ACO through collaborative affiliation with SNFs. We believe that including such expenditures as part of determining an ACO's shared savings or losses provides an appropriate incentive for ACOs to coordinate and manage a patient's overall care. We also note this is consistent with the statutory requirements in section 1899(c) of the Act, which requires that beneficiaries be assigned to ACOs based on their utilization of primary care services, and requires that ACOs be accountable for the total cost of the beneficiary's care (that is, both part A and B expenditures).

After considering the comments, we are finalizing the proposal to amend paragraph (2) under § 425.20 to exclude from our definition of primary care services claims billed under CPT codes 99304 through 99318 when the claim includes the POS code 31 modifier. We believe that excluding these services furnished in SNFs from the definition of primary care services will complement our goal of assigning beneficiaries to an ACO based on their utilization of primary care services. We are also finalizing our proposal to make a conforming change to the definition of primary care services 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, which excludes services furnished in SNFs from the definition of primary care services effective starting with the 2017 performance year. To conform to the precedent set by the June 2015 Shared Savings Program final rule (*80 FR 32758*), we will adjust all benchmarks at the start of the first performance year in which the new assignment rules are applied so that the benchmark for an ACO reflects the use of the same assignment rules as would apply in the performance year.

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 the institutional claim submitted by an ETA hospital 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 proposed 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 allows us to continue to accurately assign Medicare FFS beneficiaries to ACOs based on their utilization of primary care services furnished by ACO professionals, including those ACOs that may include ETA hospitals.

We would note that 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 proposed 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 proposed 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 proposed 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 approach 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 proposed 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.

The following is a summary of the comments we received regarding these ETA proposals:

Comment: We received very few comments on these ETA proposals; all these comments supported the proposals.

Response: We appreciate the support for our proposals. We continue to believe that including claims for primary care services furnished in ETA hospitals 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.

Accordingly, we are finalizing our proposals to codify our current practice and guidance regarding the treatment of claims for primary care services submitted by ETA hospitals in the assignment process. We are amending 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 to codify our current practice for performance year 2016 and subsequent performance years. We are revising § 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 will 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. We are also finalizing our proposal 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. In addition, we are also correcting a typographical error in § 425.102(b) by revising ''eligible participate'' to read ''eligible to participate.''

3. Technical Correction

In the 2015 PFS final rule with comment period (79 FR 67931), we finalized corrections to a technical error and a typographical error at § 425.502(d)(2)(ii) that were not subsequently reflected in the regulations text. Specifically, we proposed and finalized a technical correction to eliminate the specific reference to paragraph (c) of § 425.216. The provision at § 425.216, which addresses the actions we may take prior to termination of an ACO from the Shared Savings Program, does not include paragraph (c). We also finalized a correction to a typographical error in § 425.502(d)(2)(ii) by revising ''actions describe'' to read ''actions described.'' In the 2015 PFS final rule with comment period, we noted that we did not receive any objections to correcting the typographical error or the other minor technical correction to § 425.502(d)(2)(ii), and stated that we intended to finalize them as proposed (79 FR 67931). However, we inadvertently neglected to include these corrections in the regulations text section of the 2015 PFS final rule. As a result of this oversight, the CFR was not updated to reflect our final policies. At this time, therefore, we are correcting the oversight by including the previously finalized revisions to § 425.502(d)(2)(ii) in this final rule as they were finalized in the 2015 PFS final rule with comment period.

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 and Physician Feedback program continue CMS' initiative to recognize and reward providers based on the quality and cost of care provided to their patients, increase the transparency of health care

quality information and to assist providers and beneficiaries in improving medical decision-making and health care delivery.

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.

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 Final Rule With Comment Period

As a general summary, in the CY 2016 PFS proposed rule (80 FR 41892 through 41908) we proposed 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 to 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 methodology 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 CY 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 CY 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 solicited comment on, but made 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). Our previously-finalized policy is that, 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 and solo practitioners, respectively, are removed from the PECOS-generated list if during the performance period for the applicable CY payment adjustment period, based on our analysis of claims, the group did not have the required number of EPs that submitted claims or the solo practitioner did not submit claims. 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 through 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 through 67941 and 67951 through 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 proposed 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 proposed to update § 414.1210(c) accordingly.

The following is a summary of the comments we received on these proposals.

Comment: Several commenters supported our proposal to determine a TIN's size 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, recognizing that the result would be that the group would be subject to the lower amount at risk and also lower possible upward payment adjustment.

Response: We appreciate these commenters' support.

Comment: We received a comment suggesting that we consider alternative ways to define ''group'', other than using a single TIN, and allow options for groups to define themselves and use both TIN and NPI as unique identifiers.

Response: In the CY 2013 PFS final rule with comment period (77 FR 69309), we discussed our rationale for identifying a group for purposes of the VM by its Medicare-enrolled TIN. We stated that using TINs makes it possible for us to take advantage of infrastructure and methodologies already developed for PQRS group-level reporting and evaluation and affords us flexibility and statistical stability for monitoring and evaluating quality and outcomes for beneficiaries assigned to the group for quality reporting purposes. As discussed in section III.M.4.h. of this final rule with comment period, CY 2018 will be the final payment adjustment period under the VM; therefore, we do not believe it would be appropriate for us to consider revising how we identify groups during the last year of program. We may take these comments under consideration as we develop policies for the Merit-based Incentive Payment System (MIPS) through future notice and comment rulemaking.

Final Policy: After considering the comments received, we are finalizing our proposal 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 the number of EPs indicated by our analysis of the claims data for purposes of determining the payment adjustment amount under the VM. We are also finalizing the proposed updates to § 414.1210(c) without modification.

In section III.M.4.b. of the proposed rule (80 FR 41895), we proposed 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 the proposed rule (80 FR 41901–41903), we proposed to apply different payment adjustment amounts under the CY 2018 VM based on the composition of a group. Specifically, in that section, we proposed that the PAs, NPs, CNSs, and CRNAs in groups that consist of nonphysician EPs (that is, 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 proposed 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 noted 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 proposed 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. We provided the following examples to illustrate our 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 in section III.M.4.f. of the 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 still 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 in section III.M.4.f. of the 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 welcomed public comment on these proposals. We proposed to revise § 414.1210(c) accordingly. The following is a summary of the comments we received on these proposals.

Comment: One commenter supported our proposal to not apply the VM in CY 2018 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, while another commenter indicated that the VM should apply to all groups and solo practitioners regardless of whether or not the groups and solo practitioners consist only of nonphysician EPs.

Response: In section III.M.4.b. of this final rule with comment period, we are finalizing that we will 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, and not to other types of nonphysician EPs who bill under a group's TIN or who are solo practitioners. Therefore, we do not believe it would be consistent with this final policy to apply the VM 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. As noted in the proposed rule, 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.

Final Policy: After considering the comments received, we are finalizing our proposal for the CY 2018 payment adjustment period 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. Under the policy finalized in section III.M.4.b. of this final rule with comment period, the CY 2018 VM will 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 are also finalizing that the VM will 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. We are also finalizing the proposed revisions to § 414.1210(c) without modification.

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. Also in that prior rule, we finalized that 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, 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 and that 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, in the CY 2015 PFS final rule with comment period, 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.

Subsequent to our having finalized the preceding policies in the CY 2015 PFS final rule with comment period, the MACRA was enacted on April 16, 2015. 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 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. 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 because payment adjustments under the MIPS would not apply to them until 2021. Therefore, we proposed (80 FR 41895) 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 proposed to revise § 414.1210(a)(4) to reflect this proposed policy. We proposed 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 proposed 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 noted 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 did not propose to revise these policies; however, we noted 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 would add regulation text under § 414.1270 to reflect this policy when we established the policies for the VM for the CY 2018 payment adjustment period in future rulemaking. Accordingly, we proposed (80 FR 41895) 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 final rule with comment period, 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 proposed to apply the VM in CY 2018 only to nonphysician EPs who are PAs, NPs, CNSs, and CRNAs.

The following is a summary of the comments we received on these proposals.

Comment: Many commenters supported our proposal and agreed that 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. Several commenters noted the proposal allows a more coordinated transition from the VM to the MIPS in CY 2019 by extending the VM only to the nonphysician EPs who will be transitioned into the MIPS directly and ensuring that the remaining nonphysician EPs are transitioned to a value-based payment program only once (that is, in 2021 under the MIPS).

Few commenters opposed our proposal and stated that CMS is not required by the statute to apply the VM to nonphysician EPs; nonphysician practices typically have fewer resources than physician practices and struggle to meet reporting requirements; and that subjecting the nonphysician EPs to the

VM for only one year is not a valuable use of their practice time and resources since they will need to learn about the MIPS requirements for CY 2019. Two commenters urged CMS to exclude all nonphysician EPs from the VM in CY 2018.

Response: We appreciate the comments that supported our proposal 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 believe that it would be appropriate to apply the VM to PAs, NPs, CNSs, and CRNAs in CY 2018, and not to other nonphysician EPs, because PAs, NPs, CNSs, and CRNAs are the only nonphysician EPs the MIPS will apply to in CY 2019 and CY 2020. With regard to commenters' concerns about nonphysician EPs, we note that nonphysician EPs are subject to the reporting requirements under the PQRS and must meet the criteria to avoid the PQRS payment adjustment in CY 2018, as discussed in section III.I. of this final rule with comment period. We are finalizing the two-category approach for the CY 2018 VM based on participation in the PQRS by groups and solo practitioners (as discussed in section III.M.4.c. of this final rule with comment period). We will also hold harmless PAs, NPs, CNSs, and CRNAs in groups that consist of nonphysician EPs and PAs, NPs, CNSs, and CRNAs who are solo practitioners from downward adjustments under the quality-tiering methodology in CY 2018 (as discussed in section III.M.4.b. of this final rule with comment period). We believe that application of the VM to PAs, NPs, CNSs, and CRNAs in CY 2018 would provide them with incentives to provide high quality and low cost care similar to the incentives offered to physicians under the VM. Consequently, we do not agree with the comments that stated that the VM should not apply to nonphysician EPs in CY 2018.

Comment: A few commenters asked for clarification of the impact of not applying the CY 2018 VM to nonphysician EPs who are not PAs, NPs, CNSs, and CRNAs.

Response: If the VM were not applied to these nonphysician EPs, they would not be subject to any adjustment (upward, downward, or neutral) under the VM in CY 2018. However, these nonphysician EPs are still subject to the reporting requirements under the PQRS. We encourage these EPs to actively participate in the PQRS and become familiar with the criteria they must meet to avoid the PQRS payment adjustment in CY 2018, as discussed in section III.I. of this final rule with comment period. We also encourage these nonphysician EPs to review our future rulemaking for the MIPS in anticipation of the application of the MIPS to them.

Comment: One commenter stated that since quality and cost benchmarks for NPs must be specific to a NP's specialty, we should adopt meaningful specialty designations for NPs.

Response: The quality and cost benchmarks are based on the national mean and are not specialty-specific. Specifically, we finalized in the CY 2013 PFS final rule with comment period (77 FR 69322) that the benchmark for each quality measure would be the national mean of each measure's performance rate during the year prior to the performance year and that the benchmark for each cost measure is the national mean of each measure's performance rate during the performance year. As related to PQRS measures, because we are allowing flexibility on the quality measures that groups and solo practitioners can report, we believe the most appropriate peer group consists of other groups and solo practitioners reporting the same measure regardless of specialty. We note that we finalized in the CY 2014 PFS final rule with comment period (78 FR 74784) that we will use the specialty adjustment methodology to calculate the expected cost for each cost measure, beginning with the CY 2016 VM. This methodology takes into account the differential costs of specialties in making cost comparisons, and the cost measures are also risk adjusted to account for differences in patient characteristics not directly related to patient care, but that may increase or decrease the costs of care.

We appreciate the concerns raised by the commenter and encourage the commenter to review the procedures for obtaining a CMS specialty code, which are available at *https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/MedicareProviderSupEnroll/Taxonomy.html.* As noted above, CY 2018 is the final payment adjustment period for the VM. Policies for application of the MIPS to nonphysician EPs in subsequent years would be finalized through future notice and comment rulemaking.

Comment. Several commenters supported our policy to hold groups that consist of nonphysician EPs and solo practitioners who are nonphysician EPs harmless from downward adjustments under the quality-tiering methodology in CY 2018.

Response: We appreciate the comments supporting the policy we finalized in the CY 2015 PFS final rule with comment period (79 FR 67937) to hold groups and solo practitioners consisting of nonphysician EPs harmless from downward adjustment under the quality-tiering methodology in CY 2018. Because we are finalizing that the VM will apply in CY 2018 only to those nonphysician EPs who are PAs, NPs, CNSs, and CRNAs, we are also finalizing our proposed addition of § 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 final rule with comment period, we discuss the final 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.

Final Policy: After considering the comments received, we are finalizing our proposal 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 are finalizing the proposed revisions to § 414.1210(a)(4) to reflect this policy without modification. Under this policy, we will apply the VM in CY 2018 to the items and services billed under the PFS by all of the physicians, PAs, NPs, CNSs, and CRNAs who bill under a group's TIN based on the TIN's performance during the applicable performance period, which we are finalizing as CY 2016 in section III.M.4.h. of this final rule with comment period. The CY 2018 VM will 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.

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. Because the CY 2018 VM will apply only to certain types of nonphysician EPs, all of the PAs, NPs, CNSs, and CRNAs who bill under a group's TIN will be subject to the same VM adjustment that will apply to the

physicians who bill under that TIN in CY 2018, and physicians, PAs, NPs, CNSs, and CRNAs billing under the same TIN will be subject to the same VM policies established in earlier rulemakings and under subpart N. For example, PAs, NPs, CNSs, and CRNAs 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 also finalizing our proposal 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 are codifying these definitions under § 414.1205 without modification. We are also codifying in § 414.1270(d) without modification 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.

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 proposed (80 FR 41896) 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 proposed 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 the proposed rule. We also proposed 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 shown in Table 20 of the proposed rule. We proposed 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 proposed 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 of the proposed rule, it was unclear whether CMS systems could support this type of assessment as soon as the CY 2017 VM, and thus our proposal was contingent upon operational feasibility. For the CY 2017 VM, we proposed 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 proposed 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 proposed 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. We proposed that, if our systems were not able to accomplish this, then we would 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 proposed to include in Category 1 for the CY 2018 VM those solo practitioners that meet the criteria, in Table 20 of the proposed rule, to avoid the CY 2018 PQRS payment adjustment as individuals,

We proposed that Category 2 would include those groups and solo

practitioners that are subject to the CY 2018 VM and did not fall within Category 1. As discussed in section III.M.4.f. of this final rule with comment period, we proposed 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 final rule with comment period, we proposed to apply the VM in CY 2018 to the nonphysician EPs who are PAs, NPs, CNSs, and CRNAs.

We proposed that 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 the proposed rule, we proposed to use CY 2016 as the performance period for the VM adjustments that will apply during CY 2018. We solicited comment on these proposals.

The following is a summary of the comments we received on these proposals.

Comment: One commenter stated that despite being based on PQRS data, the VM and PQRS programs would continue to have their own sets of regulations, payment adjustments, feedback reports, and deadlines, which result in administrative complexity and redundancy across federal quality programs.

Response: As we stated in the CY 2014 PFS final rule with comment period (78 FR 74767), one of the principles governing our implementation of the VM is to align program requirements to the extent possible. Thus, our proposals for the CY 2018 payment adjustment period for the VM sought to continue to align the VM with the PQRS program requirements and reporting mechanisms to ensure individual EPs s and groups report data on quality measures that reflect their practice. However, the VM and PQRS were created under different statutory authorities and thus must have their own regulations and policies.

As discussed above, under section 101 of the MACRA, CY 2018 will be the final year of the separate PQRS and VM payment adjustments, and the MIPS will apply to payments for items and services furnished on or after January 1, 2019. We believe the creation of the MIPS may help alleviate the concerns raised in the comment, and we encourage the commenter to review our future rulemaking for the MIPS.

Comment: Many commenters supported our proposal to continue to use a two-category approach for the CY 2018 VM based on participation in the PQRS by groups and solo practitioners. Commenters also supported our proposals to consider whether the 50 percent threshold has been met regardless of whether the group registers for a PQRS GPRO, in determining whether a group would be included in Category 1 for the CY 2017 and CY 2018 VM.

Response: We appreciate the commenters' support for our proposals.

Final Policy: We are finalizing all of the policies as proposed. We are finalizing the two-category approach for the CY 2018 VM based on participation in the PQRS by groups and solo practitioners. For purposes of the CY 2018 VM, Category 1 will 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 finalized in Table 28 of this final rule with comment period. We are also finalizing 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 finalized in Table 27 of this final rule with comment period. Under our final policies for the CY 2018 VM, in determining whether a group will be included in Category 1, we will consider whether the 50 percent threshold has been met regardless of whether the group registers for a PQRS GPRO. As noted in the proposed rule, we believe this policy will 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. Please note that if a group registers for a PQRS GPRO and meets the criteria to avoid the PQRS payment adjustment as a group, then the group-level quality data reported through the GPRO reporting mechanism would be taken into account for purposes of applying the CY 2018 VM. Lastly, we are finalizing 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 finalized in Table 27 of this final rule with comment period. Category 2 will include those groups and solo practitioners that are subject to the CY 2018 VM and do not fall within Category 1. We are finalizing the corresponding regulation text at § 414.1270(d)(1) that reflect these policies without modification.

For a group or solo practitioner 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) must be met during the reporting periods occurring in CY 2016 for the CY 2018 PQRS payment adjustment. As finalized in section III.M.4.h. of this final rule with comment period, CY 2016 will be the performance period for the VM adjustments that will apply during CY 2018. In section III.M.4.f. of this final rule with comment period, we discuss the CY 2018 payment adjustment amounts for groups and solo practitioners that fall in Category 1 and Category 2 for the CY 2018 VM.

We are also finalizing our proposal to revise the criteria for groups to be included in Category 1 for the CY 2017 VM. We determined that it is operationally feasible for our system to utilize data reported through a mechanism other than the one through which a group registered to report under PQRS GPRO. Therefore, for the CY 2017 VM, we are finalizing that Category 1 will 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. Category 1 will also include 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. Under our final policies for the CY 2017 VM, in determining whether a group will be included in Category 1, we will consider whether the 50 percent threshold has been met regardless of whether the group registered to participate in the PQRS GPRO in CY 2015. We believe this policy will 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 2017 VM. Please note that if a group registers for a PQRS GPRO and meets the criteria to avoid the PQRS payment adjustment as a group, then the quality data reported

by the group would be taken into account for purposes of applying the CY 2017 VM. We are revising § 414.1270(c)(1)(i) to reflect this change in policy for the CY 2017 VM.

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. That is, 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 final rule with comment period, 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 proposed to continue to apply the quality-tiering methodology to all groups and solo practitioners in Category 1. We proposed 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 comment 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 proposed to revise § 414.1270 to reflect these proposals. We solicited comments on these proposals. In section III.M.4.f. of this final rule with comment period, we discuss the 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 stated our belief in the proposed rule that 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 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 final rule with comment period, 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. As we stated that we intended to do, in September of 2015, we made annual QRURs, based on CY 2014 data, available to all groups and solo practitioners. The reports show TINs their performance during CY 2014 on all of the quality and cost measures that were used to calculate the CY 2016 VM. Thus, we believe groups with between 2 to 9 EPs and physician solo practitioners will have had 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 received 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 expressed our belief that it would be 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 stated that we would 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.

The following is a summary of the comments we received on these proposals.

Comment: Some commenters supported our proposal to apply the quality-tiering methodology to all groups and solo practitioners that are in Category 1 for the CY 2018 VM. However, other commenters were opposed to the application of the quality-tiering methodology in general. Many commenters had concerns about our proposal to apply the downward adjustment to groups with between 2 to 9 EPs and physician solo practitioners under the quality-tiering methodology in CY 2018 and urged CMS to continue to hold these groups and solo practitioners harmless from downward adjustments under the quality-tiering methodology in CY 2018. Commenters noted methodological concerns (that is, potential small sample size, lack of specialist-specific measures, and episode-based cost measures); perceived lack of awareness of or resources to interpret the QRURs; and need to become familiar with the MIPS requirements after only one year of being subject to downward adjustments under the quality-tiering methodology under the VM.

Response: We appreciate the commenters' support for our proposal to apply upward and downward adjustments under quality-tiering for groups of two to nine EPs consisting of at least one physician and to physician solo practitioners. We disagree that we should not apply downward adjustments under the quality-tiering methodology to physician groups with between 2 to 9 EPs and physician solo practitioners. We believe that applying full quality-tiering to these groups and solo practitioners, coupled with the lower adjustment rates and changes to improve measure reliability, continues momentum to prepare smaller groups and solo practitioners for value-based payment including a smoother transition to the MIPS.

For the comments concerning small sample size, we note that in recent analyses based on the measure specifications used for the 2016 VM and the proposed case sizes for the 2017 VM, average reliabilities for TINs with less than 10 EPs for all claims-based measures, except the all-cause hospital readmissions measure and the Medicare Spending per Beneficiary (MSPB) measure, exceeded the threshold for moderate reliability (that is, 0.4). The average reliability for the all-cause hospital readmissions measure and MSPB measure were near the threshold

for moderate reliability. We were, however, persuaded by commenters' concerns to perform a reliability analysis at a more granular level than the analyses we had previously conducted. We utilized the most recently available performance data, CY 2014, for this analysis, and we looked not only at groups of fewer than ten EPs, but also further broke down the data into a reliability analysis for solo practitioners, groups of two to five EPs, and groups of fewer than ten EPs. The results of this analysis are displayed in Table 46.

TABLE 46—AVERAGE RELIABILITY OF CLAIMS-BASED MEASURES USED FOR THE 2016 VM PAYMENT ADJUSTMENT, BY TIN SIZE

Measure	Minimum Case Size	1 EP	2–5 EPs	Fewer than 10 EPs	10 or more EPs
ACSC Acute Composite	20	0.64	0.72	0.67	0.78
ACSC Chronic Composite	20	0.67	0.71	0.68	0.79
All-Cause Hospital Readmissions	200	0.34*	0.37*	0.37*	0.56
Per Capita Costs for All Attributed Beneficiaries	20	0.74	0.71	0.73	0.80
Medicare Spending per Beneficiary	125	0.40	0.48	0.48	0.67
Medicare Spending per Beneficiary	100	0.37	0.44	0.45	0.64

Note: All measures were computed based on 2014 data using measure specifications for the 2016 Value Modifier.

Our new analysis reveals that, in order for solo practitioners and groups with two to five EPs to meet the average reliability threshold of 0.4 that we discussed in the CY 2013 PFS rulemaking (77 FR 45009, 69322), a minimum number of 125 episodes is required for the MSPB measure, and even at 200 cases, the reliability of the all-cause hospital readmission measure does not meet our threshold for these solo practitioners and small groups. Because these measures do not meet the threshold for what we consider to be moderate reliability for solo practitioners and groups of two to five EPs, we are finalizing our proposed policy to apply upward, neutral, and downward adjustments under quality-tiering in CY 2018 to all physician solo practitioners and groups of physicians, with modifications to address reliability concerns for smaller groups and solo practitioners. For the CY 2017 and CY 2018 payment adjustment periods, we will increase the minimum number of episodes required for inclusion of the MSPB measure in the cost composite of the VM to 125 episodes (discussed in section III.M.4.k. of this final rule), and we will not include the all-cause hospital readmission measure in the calculation of the quality composite of the VM for solo practitioners or groups of two to nine EPs. For 2018 VM payment adjustments, the policies to increase the minimum number of episodes required for inclusion of the MSPB measure to 125 episodes and to remove the all-cause hospital readmission measure in the calculation of the 2018 VM will also apply for nonphysician Eps who are solo practitioners and groups consisting of nonphysician EPs. We continue to believe it is important to apply upward, neutral, or downward adjustments under quality-tiering to these solo practitioners and groups of EPs, in order to maintain the momentum of improving quality and to continue to emphasize the importance of quality and cost performance under the VM and the upcoming MIPS.

With regard to comments that there are an insufficient number of specialist-specific measures, we do not believe that this would disadvantage smaller groups or solo practitioners. We note that our current policies for the VM, as well as our proposals for the CY 2018 payment adjustment period, include all available PQRS reporting mechanisms, including registries that may be specialty-focused. We also note that the VM methodology includes additional safeguards to guard against misclassification—we finalized in the CY 2013 PFS final rule with comment period (77 FR 69325) the adoption of the quality-tiering model where we classify quality composite scores and cost composite scores each into high, average, and low categories based on whether these scores are at least one standard deviation from the mean and are also statistically significantly different from the mean at the 5.0 percent level of significance, in order to apply the VM upward or downward adjustment only when a group's performance is significantly different from the national mean. The result of this focus on outliers is that quality-tiering leads to a small percentage of TINs receiving downward adjustments based on performance— for the 2015 VM, out of the 106 groups that elected quality-tiering and had sufficient data, 11 groups (10.4 percent) received a downward VM adjustment and 14 groups (13.2 percent) received an upward VM adjustment based on performance. Cost measures are also risk-adjusted (77 FR 69318) and specialty-adjusted (78 FR 74784) to account for patient characteristics and specialty-composition of the group, respectively.

As discussed in section III.M.4.m. of this final rule with comment period, we are finalizing the policies that, beginning with the CY 2016 payment adjustment period, a group or solo practitioner subject to the VM will 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. This policy is consistent with the policy we previously finalized in the CY 2015 PFS final rule with comment period (79 FR 67934) that, beginning with the CY 2016 payment adjustment period, a group or solo practitioner subject to the VM will 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.

With regard to commenters' concern about lack of episode-based cost measures, we believe that the total per capita cost measure, condition-specific total per capita cost measures, and MSPB measure provide sufficient cost performance data for VM cost composite calculation and are inclusive of episode cost-based measures.

In the proposed rule (80 FR 41896–41897), we stated that we believe it is appropriate to apply both the upward and the downward payment adjustments under the quality-tiering methodology for the CY 2018 VM to these groups and solo practitioners and also stated the reasons for our belief. We

noted that the proposal 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 is consistent with gradual implementation of the VM, wherein groups with between 10 to 99 EPs (79 FR 67941) and groups with 100 or more EPs (78 FR 74769–74770), consecutively were subject to both upward and downward adjustments under quality-tiering during the second year that the VM applied to them. As discussed in section III.M.4.f. of this final rule with comment period, we are finalizing a policy to set the maximum downward adjustment under the quality-tiering methodology in CY 2018 to −2.0 percent for groups with between 2 to 9 EPs and physician solo practitioners. We expect this level of payment at risk to not have a significant financial impact on small groups and solo practitioners in CY 2018 and is consistent with our approach to gradually phase in the VM over time and increase the amount at risk.

With regard to the commenters' suggestion that smaller groups lack awareness of the VM program, we believe that they have been given sufficient time and data with which to become familiar with the program. In September 2015, we made available QRURs based on CY 2014 data to all groups and 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 2016 payment adjustment period. As discussed in section III.M.5.a. of this final rule with comment period, 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 spring of 2016, we intend to disseminate the 2015 Mid-Year QRURs to all groups and solo practitioners. 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. We strongly encourage EPs subject to the VM to proactively educate themselves about the VM program and QRURs by visiting the VM/QRUR Web site *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/index.html.* The VM/QRUR Web site contains information on the VM policies for each payment adjustment period, including a link to the 2014 QRURs Web site that contains detailed information on the methodology used to calculate the CY 2016 VM shown in the CY 2014 QRURs and how to use the information contained in the QRURs.

We note that we work with medical and specialty associations and have National Provider Calls throughout the year to educate physicians and other professionals about the VM program and the QRURs. Further outreach also will be undertaken by our Quality Improvement Organizations (QIOs), which will provide technical assistance to physicians and groups of physicians in an effort to help them improve quality and consequently, performance under the VM program.

Final Policy: After considering the comments received, we are finalizing that we will apply the quality-tiering methodology to all groups and solo practitioners in Category 1 for the CY 2018 VM. We are also finalizing our proposal that groups and solo practitioners will be subject to upward, neutral, or downward adjustments derived under the quality-tiering methodology (with the exception discussed in section III.M.4.b. of this final rule with comment period, 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), with the following modifications: We are finalizing an increase to the minimum episode number requirement for the MSPB measure in the CY 2017 and 2018 payment adjustment periods to 125 episodes, for solo practitioners and for groups of all sizes, in section III.M.4.k of this final rule with comment period. In that section, we discuss our proposal in the CY 2016 Medicare PFS proposed rule, to raise the episode minimum for inclusion of this measure in the cost composite to 100 episodes (80 FR 41906) and our final policy to raise the minimum number of episodes to 125. We are also finalizing that we will not include the all-cause hospital readmissions measure in the quality composite for solo practitioners and groups of two to nine EPs for the CY 2017 and 2018 payment adjustment periods. We believe that his final policy best addresses commenters' concerns with small sample sizes for solo practitioners and groups of two to nine EPs, while preserving the emphasis on provision of high quality efficient and effective care. We are finalizing revisions to §§ 414.1230, 414.1270, and 414.1265 to reflect these final policies.

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 proposed 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 proposed 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. We provided several examples to illustrate the proposal.

We believe our proposed approach is appropriate because it is straightforward for TINs participating in multiple Shared Savings Program ACOs to understand. The 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. It also allows us to determine peer group means for the purposes of determining statistical significance and determining whether a given quality composite score is at least one standard deviation from the peer group mean. We proposed to make corresponding changes to § 414.1210(b)(2).

In developing this 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 solicited comments on our proposal as well as the alternatives we considered.

The following is a summary of the comments we received on the proposal and alternatives considered:

Comment: We received a few comments in support of our proposal to assign practices the highest quality composite score of the multiple ACOs in which they participated. One commenter expressed the belief that in the instance where a group or individual EP participates in two or more ACOs, it is more appropriate and straightforward to compare the VM adjustments associated with each ACO and apply the highest VM adjustment to the group or individual EP. We received no comments on the alternatives we considered.

Response: We appreciate commenters' support of our proposal to assign TINs participating in multiple Shared Savings Program ACOs the quality composite score of the ACO with the highest numerical quality composite score. We acknowledge the comment that it would be more straightforward to apply the highest VM adjustment instead; however, it would not be possible to assign the highest VM adjustment to these TINs, because movement of a given TIN from one quality designation to another (from average to high quality, for example) would result in recalculation of the peer group mean against which all other TINs subject to the VM are compared, for the purpose of determining their quality designations. Such a recalculation would necessitate an additional analysis of which Shared Savings Program ACO had the highest numerical quality composite score. Likewise, movement of another TIN from one quality designation to another would necessitate the same recalculation. Thus, it would not be feasible for us to concurrently recalculate the VM for every TIN, with each iteration of moving a given TIN in and out of a peer group mean.

Final Policy: After consideration of the comments received, we are finalizing our proposal that, beginning with the CY 2017 payment adjustment period, TINs that participate in multiple Shared Savings Program ACOs in the applicable performance period will receive the quality composite score of the ACO that has the highest numerical quality composite score. We believe that this is the most straightforward and advantageous methodology to acknowledge the highest quality performance among the Shared Savings Program ACOs in which these TINs participate.

(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)). As noted above, ACO participants who do not provide primary care services may participate in multiple Shared Savings Program ACOs, but under section 1899(b)(4) of the Act, providers and suppliers that participate in a Shared Savings Program ACO may not participate in an Innovation Center model that involves shared savings, or any other program or demonstration project that involving shared savings. 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 in section III.M.4.e. of this final rule with comment period. We proposed 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 proposed to make corresponding changes to § 414.1210(b)(2)(i)(E). We solicited comment on this proposal.

The following is a summary of the comments we received on this proposal.

Comment: We received one comment in support of our proposal of applying the VM to groups and solo practitioners who participate in the Medicare Shared Savings Program, even if they also participate in an Innovation Center model. Two commenters were of the opinion that the proposed policy would be a barrier to fostering innovation and expressed the concern that a TIN's performance might be counted multiple

times if it participates in the Shared Savings Program, an Innovation Center initiative, and the VM. Though we made no proposals to do so, the majority of comments on proposals surrounding application of the VM to Shared Savings Program ACO participant TINs expressed support for waiving the VM for these TINs entirely.

Response: We appreciate the commenter's support for our proposal to apply the VM to Shared Savings Program participants, even if they also participate in Innovation Center models, as it would incentivize the provision of high quality care to assigned beneficiaries. We also note that the quality measures used for calculating the VM quality composite score for Shared Savings Program ACO participants are the same measures under which their quality is measured within the Shared Savings Program, and they are assigned a cost composite score of ''average'' under the VM. Consequently, they do not face conflicting quality or cost performance incentives or increased reporting burden. With regard to the comment that application of the VM to Shared Savings Program ACO participants would create a barrier to innovation under Innovation Center models, we disagree. The quality performance of these TINs under the Shared Savings Program is used for purposes of calculating the VM quality composite score. No additional requirements related to cost or quality reporting are imposed on these TINs for purposes of the VM, above what they are already doing under the Shared Savings Program, so no additional barriers to innovation would be created by applying the VM. A TIN's performance under an Innovation Center model is not considered under the VM and is therefore not counted multiple times.

Final Policy: After consideration of the public comments received, we are finalizing our proposal, beginning with the CY 2017 payment adjustment period, to 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 revised § 414.1210(b)(2)(i)(E) to reflect this policy. This will avoid the need to create multiple polices for application of the VM to Shared Savings Program participant TINs and will continue to reinforce the importance of quality performance.

(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 proposed 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 proposed 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 solicited comment on this proposal.

The following is a summary of the comments we received on this proposal.

Comment: We received one comment questioning this proposal, in which the commenter expressed the belief that the proposal would discourage participation in Shared Savings Program ACOs due to the potential to earn a downward payment adjustment under the VM.

Response: We disagree that the proposed policy would discourage participation in Shared Savings Program ACOs. Shared Savings Program ACOs are required to report on quality on behalf of all participants and this provision reinforces that reporting requirement. If these TINs did not participate in a Shared Savings ACO, they would be required to meet quality reporting requirements for the VM through another mechanism. We believe that the proposed policy would emphasize the importance of quality performance while treating Shared Savings Program participant TINs the same as other TINs with regard to the consequence of failing to report quality data.

Final Policy: After consideration of the comments received, we are finalizing our proposal for the CY 2018 payment adjustment period, that if a Shared Savings Program ACO does not successfully report quality data as required by the Shared Savings Program during the performance period for the VM, all groups and solo practitioners participating in the ACO will fall in Category 2 for the VM and will be subject to an automatic downward payment adjustment. We are finalizing the corresponding revisions to § 414.1210(b)(2)(i)(D).

(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 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 proposed a similar policy for the CY 2018 payment adjustment period as discussed in section III.M.4.f. of this final rule with comment period.

Beginning in the CY 2017 payment adjustment period, we proposed 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 proposed 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 proposed corresponding revisions to § 414.1210(b)(2). We solicited 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 noted 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.

The following is a summary of the comments we received on this proposal.

Comments: Commenters were very supportive of this proposal. One commenter encouraged CMS to include aspects of social risk or community risk in the calculations, stating that achieving good quality results for patients who are socially complex (for example, low income, homeless, living alone) or living in unsupportive community environments would justify the same kind of enhanced payment that achieving similar outcomes for clinically complex patients does, which supports the idea of adding an upward payment adjustment in 2017 and subsequent years of the VM program to those treating high-risk beneficiaries.

Response: We acknowledge that beneficiaries' social support systems could potentially have an impact on quality performance. We did not make any proposals to change the definition of high-risk beneficiaries, however, and make no changes in this final rule with comment period.

Final Policy: After consideration of the comments received, we are finalizing our proposal beginning in the CY 2017 payment adjustment period 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 are finalizing corresponding revisions at § 414.1210(b)(2). We note that Shared Savings Program ACO participant TINs are eligible for the +1.0x adjustment under § 414.1210(b)(2) based on the average beneficiary risk score of the attributed patient population of their ACO; they are not eligible for the similar +1.0x adjustment under § 414.1275(d).

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. and the timing and availability of that quality data may not be aligned with the availability of quality data under PQRS that is used in the VM calculations.

(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 the CY 2016 PFS proposed rule, and in consideration of comments previously received, we believed 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 proposed 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) of the Act for this purpose, will no longer apply in CY 2019 when the Value Modifier adjustment under section 1848(p) of the Act has ended. 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. We refer readers to the proposed rule (80 FR 41900) for an explanation of our rationale for proposing to waive the VM for the CPC Initiative and the Pioneer ACO 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 proposed the waiver would apply beginning with the CY 2017 payment adjustment period. We noted 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 noted 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 proposed to revise § 414.1210(b)(3) to reflect these proposals and sought comment on these proposals.

(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 previously finalized 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 proposed 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 determined such a waiver would be 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 noted that this policy and use of the waiver authority under section 1115A(d)(1) of the Act 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 proposed to revise § 414.1210(b)(4) to reflect this proposal. We solicited comment on this proposal.

(a) Application of the VM to Solo Practitioners and Groups with EPs Who Participate in the Comprehensive ESRD Care Initiative (CEC), Oncology Care Model (OCM), 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 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. We refer readers to the proposed rule (80 FR 41901) for an explanation of our determination that these models are similar to the Pioneer ACO Model and the CPC Initiative and our belief that a waiver is necessary to test these models.

We proposed 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 solicited comment on this proposal.

The following is a summary of the comments we received on the proposals to waive application of the VM for the Pioneer ACO Model; CPC Initiative; and other similar Innovation Center models, including the Next Generation ACO Model, Oncology Care Model, and Comprehensive ESRD Care Initiative.

Comment: We received many comments on this proposal, all of which were in support of waiving the VM if at least one EP participated in the Pioneer ACO Model, CPC Initiative, or other similar Innovation Center model, such as Next Generation ACO, Oncology Care Model, or the Comprehensive ESRD Care Initiative. Though we did not make any proposal to do so, several of the commenters also requested that CMS also waive the VM for EPs who participate in the Medicare Shared Savings Program. A few commenters suggested that the Value Modifier be waived for participants in any Alternative Payment Model (APM), even for private (non-CMS) demonstrations, and also suggested waiving the Value Modifier for the Bundled Payments for Care Improvement (BPCI) initiative.

Response: We appreciate commenters' support for our proposal to waive the VM for these models. With regard to the suggestion that we also waive the VM for Shared Savings Program ACO participants, we disagree that such a waiver would be appropriate or necessary to carry out the Shared Savings Program. As stated in the CY

2015 final rule with comment period (79 FR 67941), we believe that alignment of the VM and the Shared Savings Program emphasizes the importance of quality reporting and quality measurement, for improvement of the quality of care provided to Medicare beneficiaries. The Shared Savings Program requires quality reporting through the PQRS GPRO Web Interface, so we have readily available quality data for use in calculating a quality composite score for the VM, whereas such data may not be available for TINs that participate in Innovation Center models. The VM does not impose any different quality performance requirements on Shared Savings Program ACO participants, and thus does not create conflicting quality performance incentives for them. We disagree with the commenters' suggestion that we waive the VM for participants in any APM, BPCI or private (non-CMS) demonstrations. If the commenters are referring to APMs as defined in section 101(e) of MACRA, we note the statutory amendments made by this section have payment implications for EPs beginning in 2019, after the VM has sunset. We established specific criteria for a model to be considered ''similar,'' for the purpose of waiving the VM. The VM is an important initiative for incentivizing high quality efficient care for Medicare beneficiaries. We established specific criteria wherein it could be waived and we do not believe that it would be appropriate to waive this important adjustment in cases where the criteria do not apply. We do not believe BPCI is a ''similar'' model according to the criteria established in the CY 2015 PFS final rule with comment period (79 FR 67949 through 67950), because the model does not require reporting on quality measures outside of the PQRS, does not require reporting on cost measures, and its methodology is not in conflict with the cost and quality metrics used under the VM.

Final Policy: After considering the public comments received, we are finalizing our proposals to waive application of the VM for the Pioneer ACO Model; CPC Initiative; and other similar Innovation Center models, including the Next Generation ACO Model, the Oncology Care Model, and the Comprehensive ESRD Care Initiative, all as proposed without modification. We are finalizing the corresponding revisions to the regulation text at § 414.1210(E)(3)(i)(ii)

(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 finalizing in section III.M.4.e.1. of this final rule with comment period our proposal 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, we stated in the event that we finalize the waiver, we proposed to remove the references to ''CMS initiatives'' from § 414.1210(b)(4). We solicited comment on this proposal, but did not receive comments specific to this proposal.

Final Policy: As a result, we are finalizing our proposal to remove the references to ''CMS initiatives'' from § 414.1210(b)(4).

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 final rule with comment period, 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 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 proposed 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 final rule with comment period that in CY 2018 we proposed 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 proposed 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 proposed 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 percent for groups classified as either low quality/average cost or average quality/high cost. We also proposed 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 (80 FR 41903) of the proposed rule shows the quality-tiering payment adjustment amounts for CY 2018 for physicians, PAs, NPs, CNSs, and CRNAs in groups with 10 or more EPs. These 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 proposed to apply a negative ''−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 negative ''−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 negative ''−1.0'' percent for groups and physician solo practitioners classified as either low quality/average cost or average quality/high cost. We also proposed 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 of the proposed rule (80 FR 41903) shows the 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 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 proposed to apply a negative ''−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 noted in section III.M.4.b. of this final rule with comment period, the nonphysician EPs to which the CY 2018 VM payment adjustments would apply are PAs, NPs, CNSs, and CRNAs. We also proposed 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 of the proposed rule (80 FR 41903) shows the 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 have received 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 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 proposed 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 proposed to revise § 414.1270 and § 414.1275(c)(4) and (d)(3) to reflect the changes to the payment adjustments under the VM for the CY 2018 payment adjustment period. We solicited comments on all of these proposals.

Consistent with the policy adopted in the CY 2013 PFS final rule with comment period (77 FR 69324 through 69325), we noted 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 35 of the proposed rule) would be determined after the performance period has ended based on the aggregate amount of downward payment adjustments.

The following is a summary of the comments we received on these proposals.

Comment: Several commenters expressed appreciation for our efforts to maintain stability in the payment adjustment amounts applicable under the VM in CY 2018 as we transition to the MIPS in CY 2019 and supported our proposal to maintain the payment adjustment amounts in CY 2018 at the same levels as that for the CY 2017 VM. Some commenters suggested alternatives that included maintaining lower downside risk while establishing different upward adjustments based on group size; keeping adjustments constant, regardless of group size; and establishing a 2.0 percent maximum amount at risk for all groups, so that combined with the PQRS adjustment, the total would be consistent with the 4.0 percent at risk under the first year of the MIPS.

Response: We appreciate the commenters' support of our proposals. We believe that any significant change in the payment adjustment amounts under the VM from CY 2017 to CY 2018, which is the final year in which the VM will apply to payments, would not be consistent with our intention to maintain stability as we transition to the MIPS in CY 2019.

Final Policy: As discussed in section III.M.4.c. of this final rule with comment period, for the CY 2018 VM, we are finalizing that we will continue to apply the quality-tiering methodology to all groups and solo practitioners in Category 1. We are also finalizing that groups and solo practitioners will 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 comment period (79 FR 67937), that groups consisting 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. We finalized modifications to ensure that the measures used to

calculate the VM for solo practitioners and groups of all sizes are reliable, in sections III.M.4.c. and III.M.4.k. of this final rule with comment period.

For CY 2018, we are finalizing that we will apply a negative ''−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 will set the maximum downward adjustment under the quality-tiering methodology in CY 2018 to negative ''−4.0'' percent for physicians, PAs, NPs, CNSs, and CRNAs in groups with 10 or more EPs classified as low quality/high cost and set the adjustment to negative ''−2.0'' percent for groups classified as either low quality/average cost or average quality/high cost. We will also 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 set the adjustment to +2.0x for groups classified as either average quality/low cost or high quality/average cost. Table 47 shows the final quality-tiering payment adjustment amounts for CY 2018 for physicians, PAs, NPs, CNSs, and CRNAs in groups with 10 or more EPs. These payment amounts will 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 are finalizing that we will apply a negative ''−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 will set the maximum downward adjustment under the quality-tiering methodology in CY 2018 to negative ''−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 set the adjustment to negative ''−1.0'' percent for groups and physician solo practitioners classified as either low quality/average cost or average quality/high cost. We will also 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 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 48 shows the final 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 payment adjustment amounts will 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 are finalizing that we will apply a negative ''−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 finalized in section III.M.4.b. of this final rule with comment period, the nonphysician EPs to which the CY 2018 VM payment adjustments would apply are PAs, NPs, CNSs, and CRNAs. We are also finalizing 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 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. 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 49 shows the final 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. 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 will be available to all groups and solo practitioners eligible for upward adjustments under the VM. Consequently, the upward payment adjustment factor (''x'' in Tables 47, 48, and 49) will be determined after the performance period has ended based on the aggregate amount of downward payment adjustments.

TABLE 47—FINAL CY 2018 VM AMOUNTS FOR THE QUALITY-TIERING APPROACH FOR PHYSICIANS, PAS, NPS, CNSS, AND CRNAS IN GROUPS OF PHYSICIANS 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 48—FINAL CY 2018 VM AMOUNTS FOR THE QUALITY-TIERING APPROACH FOR PHYSICIANS, PAS, NPS, CNSS, AND CRNAS IN GROUPS OF PHYSICIANS 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 49—FINAL 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.

Comment: Commenters supported our proposal 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 treated the most complex beneficiaries. One commenter urged CMS to apply the additional upward payment adjustment to all providers that serve high-risk patients, and another stated that CMS should include aspects of social risk or community risk in the determination of whether beneficiaries fall into the highest risk category.

Response: The additional upward payment adjustment is intended to be an incentive for groups and solo practitioners that treat high-risk beneficiaries to provide them with higher quality of care at lower costs. Therefore, we do not believe it would be appropriate to provide the additional upward payment adjustment to all groups and solo practitioners that treat high-risk beneficiaries. As discussed in section III.M.4.d. of this final rule with comment period, we did not make proposals to include aspects of social or community risk in the determination of whether a beneficiary would be classified as falling in the top 25 percent of risk scores, such that a TIN treating the beneficiary would be eligible for the additional +1.0X adjustment, and thus make no such adjustments in this final rule with comment period.

Final Policy: We are finalizing our proposal 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.

Comment: One commenter noted the following clarification provided for the PQRS program in section III.I.1. of the proposed rule: ''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.'' The commenter requested that we also clarify that EPs who practice in RHCs and/or FQHCs would not be subject to the VM.

Response: As discussed in the CY 2013 PFS final rule with comment period (77 FR 69309), the VM provides for differential payment to a physician or a group of physicians under the Medicare PFS for items and services furnished. Groups and solo practitioners who furnish items and services paid under the Medicare PFS are subject to the VM for these items and services, regardless of whether they practice in RHCs and/or FQHCs. However, as explained in section III.I.1. of the proposed rule (80 FR 41816), we are currently unable to assess PQRS participation for EPs billing under the PFS who practice in RHCs and/or FQHCs and do not also practice in other settings, such as in physician offices. Under the PQRS, these EPs will be treated as having avoided the PQRS payment adjustment if the EP billing under the PFS reports only place of service codes 50 (FQHC) and/or 72 (RHC) during the applicable reporting period. As discussed in section III.M.4.c. of this final rule with comment period, a TIN will be included in Category 1 if the TIN meets the criteria to avoid the PQRS payment adjustment as a group or at least 50% of the EPs in the TIN meet the criteria to avoid the PQRS payment adjustment as individuals. Further, consistent with the policy we are finalizing in section III.M.4.m. of this final rule with comment period, a group or solo practitioner will 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.

Comment: One commenter was concerned that there is no process that would permit nonparticipating physicians to receive an upward adjustment under the VM.

Response: We refer the commenter to the CY 2015 PFS final rule with comment period (79 FR 67950–67951), in which we explained that the VM will apply to all assigned claims, including those submitted by both participating and non-participating physicians, and nonphysician EPs to the extent the VM is applied to them. Therefore, the VM will affect nonparticipating physicians to the extent that they submit assigned claims, and they may qualify for an upward adjustment under the quality-tiering methodology the same as a participating physician. We will monitor these issues, but we continue to believe that these policies are reasonable. As explained in previous rulemaking (79 FR 67950–67951), if the VM were to be applied to non-assigned services, then the VM would directly affect beneficiary cost sharing and not Medicare payments to physicians, contrary to our intent. We further note that over 99 percent of Medicare physician services are billed on an assignment related basis by both participating and non-participating physicians and other suppliers, with the remainder billed as non-assigned services by non-participating physicians and other suppliers (79 FR 40505).

Final Policy: After considering the comments received, we are finalizing all of the policies discussed in section III.M.4.f. of the proposed rule. We are also finalizing the revisions at § 414.1270 and § 414.1275(c)(4) and (d)(3) to reflect these policies without modification.

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 also proposed a similar

policy for the CY 2018 VM as discussed in section III.M.4.f. of the proposed rule (80 FR 41903). 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 proposed 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 solicited public comment on this proposal.

Final Policy: We did not receive any comments on this proposal. Therefore, we are finalizing our proposal and will 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.

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 proposed to use CY 2016 as the performance period for the VM adjustments that will apply during CY 2018. Accordingly, we proposed 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 solicited comment on this proposal.

The following is a summary of the comments we received on this proposal.

Comment: One commenter supported our proposal to use CY 2016 as the performance period for the 2018 VM, while another commenter objected stating that it is difficult for groups to translate how performance affects payments two years later and urged CMS to eliminate the gap between performance and payment years. One commenter asked that we clarify whether CY 2016 will be the last performance period for the VM program.

Response: In the CY 2012 PFS final rule with comment period (76 FR 73435), CY 2013 PFS final rule with comment period (77 FR 69313–69314), and CY 2014 PFS final rule with comment period (78 FR 74771–74772), we addressed how we considered shortening the gap between the performance period and the payment adjustment period. As we explained in the CY 2012 PFS final rule with comment period (76 FR 73435), we explored different options to close the gap between the performance period and the payment adjustment period, but found that none of them would have permitted sufficient time for physicians and groups of physicians to report measures or have their financial performance measured over a meaningful period, or for us to calculate a VM and notify physicians and groups of physicians of their quality and cost performance and VM prior to the payment adjustment period.

As discussed in section III.M.5.a. of this final rule with comment period, in April 2015, we made available 2014 Mid-Year QRURs to groups of physicians and physician solo practitioners nationwide based on performance from July 1, 2013, through June 30, 2014. We plan to make available the 2015 and 2016 Mid-Year QRURs during the spring of 2016 and 2017, respectively. The Mid-Year QRURs are intended to provide groups and solo practitioners with interim information about their performance on the claims-based quality outcome measures and cost measures that are a subset of the measures that were used to calculate the VM. Therefore, we are finalizing our proposal to use CY 2016 as the performance period for the VM adjustments that will apply during CY 2018.

As discussed in section III.M.4.b. of this final rule with comment period, 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. Therefore, CY 2018 will be the final payment adjustment period and CY 2016 will be the final performance period under the VM.

Final Policy: After considering public comments received, we are finalizing our proposal to use CY 2016 as the performance period for the VM adjustments that will apply during CY 2018 and finalizing the addition of § 414.1215(d) without modification.

i. Quality Measures

(1) PQRS Reporting Mechanisms

In the CY 2016 PFS proposed rule (80 FR 41904), we stated our belief that 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 sought to avoid placing an undue burden on EPs to report such data. Accordingly, for purposes of the VM for CY 2018, we proposed 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 the proposed rule (80 FR, 41825).

(2) PQRS Quality Measures

We proposed 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 the proposed rule (80 FR 41830).

The following is the summary of comments we received on these proposals.

Comment: Commenters supported the continued alignment of the VM with PQRS requirements. However, some commenters raised concerns about the lack of applicable measures for multiple specialties.

Response: We thank the commenters for their support of our continued alignment with PQRS. In previous rulemakings we have committed to expanding the specialty measures available in PQRS to more accurately measure the performance on quality of care furnished by specialists; PQRS now has specialty measure sets (for example; Pathology preferred measure set, radiology preferred measure set, and ophthalmology preferred measure set) that can be utilized as a guide to assist eligible professionals in choosing measures applicable to their specialty. We reaffirm our commitment to using measures of performance across specialties that are valid and reliable for the VM. As discussed in section III.M.4.m. of this final rule with comment period, we are finalizing that beginning in the CY 2016 payment adjustment period, a group or solo practitioner subject to the VM will 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.

Final Policy: After consideration of the comments received, we are finalizing our proposal for the CY 2018 VM to include 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 27 and 28 of this final rule with comment period. Additionally, we are finalizing our proposal 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 quality measures are described in Table 29 through 42 of this final rule with comment period.

(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 made a proposal to address this issue. We referred to quality measures collected through EHRs as ''eCQMs.'' We noted 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 proposed 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 proposed 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 solicited comment on this proposal. The following is a summary of the comments we received on this proposal:

Comment: Commenters were unanimous in their support of this proposal. However, while not directly related to this proposal several commenters asked for clarification on how benchmarks for quality of care measures reported via PQRS QCDRs will be calculated. Specifically, they asked whether QCDR measures would only be benchmarked against identical measures that are reported via a different QCDR or other reporting mechanism. Commenters also requested clarification on whether QCDRs will be allowed to develop their own benchmarking methodology or if CMS plans to calculate the benchmarks using its current methodology.

Response: PQRS measures reported via QCDRs will be benchmarked according to our current VM benchmarking methodology which is defined as follows. The benchmark for quality of care measures reported through the PQRS using the claims, registries, QCDR, 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. Benchmarks for non-PQRS quality of care measures reported via QCDRs would also be calculated as the national mean of the measure's performance rate across all EPs reporting the measure via different QCDRs during the year prior to the performance period. It is important to note that measures reported through a QCDR that are new to PQRS would not be included in the quality composite for the VM because we would not be able to calculate benchmarks for them.

Final Policy: After consideration of the comments received, we are finalizing our proposal to exclude eCQM measures from the overall benchmark for a given measure and create separate eCQM benchmarks, based on the CMS eMeasure ID beginning with the CY 2016 performance period for which the eCQM benchmarks would be calculated based on CY 2015 performance data. We will finalize corresponding changes to § 414.1250(a).

(4) CAHPS Reporting

In our efforts to maintain alignment with the PQRS quality reporting requirements, we noted in the proposed rule that the criteria for administration of the CAHPS for PQRS survey for the CY 2016 performance period will contain 6 months of data (80 FR 41904). 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 VM, should they elect to have CAHPS for PQRS included in their VM calculation. 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 VM (77 FR 69322–69323). We noted that we took a similar approach in the CY 2014 PFS final rule with comment period (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 with comment period (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 proposed to continue this policy for the CY 2016 performance period for the CY 2018 VM. We did not receive comments on this proposal, and therefore, are finalizing our policy that groups with 2 or more EPs could elect to include the patient experience of care measures collected through the PQRS CAHPS survey for the CY 2016 performance period for the CY 2018 VM. We note that this policy for the VM is separate from the CAHPS reporting requirements under the PQRS.

(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 proposed 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 proposed 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 proposed 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 proposed to make corresponding changes to § 414.1210(b)(2)(i)(B). We solicited comment on this proposal.

The following is a summary of the comments we received on this proposal.

Comment: One commenter supported this proposal, and we did not receive any opposing comments.

Response: We thank the commenter for their support.

Final Policy: After consideration of the comments received, we are finalizing our proposal 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 are also finalizing 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 finalized corresponding changes to § 414.1210(b)(2)(i)(B).

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 intended to disseminate reports containing CY 2013 data in fall 2014 to groups of physicians subject to the VM in 2015 and that we would 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) 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 physicians 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 a third-party vendor error or CMS made an error in the calculation of the quality composite. We proposed

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 solicited comment on this proposal.

The following is a summary of the comments we received on this proposal.

Comment: Many commenters supported this proposal; however, several commenters cautioned about the over-reliance on the automatic ''average quality'' designation as it may not accurately reflect the quality of truly high performers and may penalize physicians for errors that are outside of their control. One commenter also suggested extending the review period to ninety days to give practitioners enough time to thoroughly review the QRURs.

Response: We acknowledge commenters' concerns about the ''average quality'' designation; however we continue to believe the proposal to assign ''average quality'' if it is not possible for us to recompute the quality composite is the best alternative in light of the quality data that will be available during the informal inquiry process and prior to application of the VM adjustments. We believe that a 60-day review period allows ample time for practitioners to access and review their QRURs. The 60-day timeframe also enables us to make corrections prior to the start of the payment adjustment period, reducing administrative burden and costs of reprocessing claims for both physicians and CMS.

Final Policy: After consideration of the comments received, for the CY 2017 and CY 2018 payment adjustment periods, we are finalizing 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. We are finalizing the continuation of the process for accepting requests from groups and solo practitioners to correct certain errors made by CMS or a third-party vendor (for example, PQRS-qualified registry). We would continue the approach of the initial corrections process to classify a TIN as ''average quality'' in the event we determine a third-party vendor error or CMS made an error in the calculation of the quality composite and the infrastructure was not available to allow for recomputation of the quality measure data.

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 PQRS 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 PQRS and VM informal review submission periods 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 proposed 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 noted 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 would be classified as ''average quality''; however, if the data is available in a timely manner, then we would recalculate the quality composite.

We solicited comments on this proposal. The following is a summary of the comments we received on this proposal:

Comment: Commenters were unanimous in their support for this proposal.

Response: We thank the commenters for their support.

Final Policy: After consideration of the comments received, we are finalizing our proposal 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 to avoid the PQRS downward payment adjustment for the relevant payment adjustment year. If the group was initially classified as Category 2, then we would not expect to have data for calculating their quality composite, in which case they would be classified as ''average quality''; however, if the data is available in a timely manner, then we would recalculate the quality composite.

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 non-specialty-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 found that the specialty-adjusted measure did not have moderate or high reliability with a 20 episode minimum for many groups (80 FR 41906).

Given that our analysis demonstrated the measure had 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 proposed to increase the episode minimum to 100 episodes beginning with the CY 2017 payment adjustment period and CY 2015 performance period. We also noted that we had 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 noted that, using an episode minimum of 20 for the 2016 VM, the MSPB measure has moderate reliability for the 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).

We believe that it is important to ensure that only reliable measures are included in the VM. We also noted that we had considered increasing the episode minimum to 75 instead of 100. This would have allowed us to include the MSPB measure in the cost composite for a larger number of groups but we stated that we believed that the reliability for solo practitioners with a minimum of 100 episodes was preferable to the reliability when using a 75 episode minimum.

Therefore, we proposed to add § 414.1265(a)(2) to reflect a case minimum of 100 episodes for the MSPB measure beginning with the CY 2017 payment adjustment period and CY 2015 performance period. We solicited comment on this proposal, as well as on a 75-episode minimum or other potential minimum case thresholds for this measure.

The following is a summary of the comments we received on this proposal to establish a case minimum of 100 episodes for the MSPB measure.

Comment: Most commenters that responded to the proposal generally supported the proposal to increase the episode minimum to 100 episodes, given that the results for the specialty-adjusted measure were more reliable at higher episode minimums and that this would result in increased accuracy of the MSPB measure. Many commenters that supported the proposal also suggested that CMS consider an even higher minimum number of episodes (for example, 200 episodes). A few commenters opposed the proposal and/or suggested a lower minimum number of episodes such as 50. These commenters indicated their concern with a scenario we had discussed in the proposed rule in which a group that would have performed well on this measure would no longer have this measure included in its cost composite as a result of the proposal, which could negatively impact their TIN's cost composite score, and ultimately their VM adjustment. Some commenters suggested that any measures that cannot meet a reliability standard of at least 0.7 should be rejected.

Response: We appreciate the commenters' support for our proposal to raise the episode minimum for this measure. As discussed in section III.M.4.c. of this final rule with comment period, commenters expressed concerns over small sample sizes, as they related to application of downward adjustments under quality-tiering for solo practitioners and groups of two to nine EPs. In response to those comments, we conducted a more granular reliability analysis, based on which we determined a minimum of 125 episodes was required in order for this measure to meet our average reliability threshold of 0.4 for solo practitioners and groups of two to nine EPs (see Table 46 in section III.M.4.c. of this final rule with comment period). Based on this new analysis, we believe that a minimum of 125 episodes is preferable to the reliability associated with the other minimum numbers of episodes suggested by some commenters. For example, a 50 or 75 episode minimum 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 and groups of two to five EPs with a minimum of 125 episodes is preferable to the reliability when using a 50 or 75 episode minimum. As discussed in the proposed rule, establishing a higher case minimum reduces the number of groups and solo practitioners for whom we would be able to include an MSPB calculation in the cost composite. Our latest analysis supports this finding, with 6,401 TINs having 125 or more cases for MSPB, as compared to the 7,904 TINs had 100 or more cases, based on 2014 data. However, we do not believe we should use the measure in calculating the cost composite if it is not reliable. Further, we believe that a minimum of 125 episodes is preferable to a higher minimum such as 200 episodes suggested by some other commenters. A higher minimum might slightly increase the reliability of the measure but would further reduce the number of groups and solo practitioners for whom we would be able to include an MSPB calculation in the cost composite.

We acknowledged in the proposed rule (80 FR 41906) 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 continue to believe that it would not be appropriate to include this measure in the cost composite with a 20-episode minimum at a sample size that does not produce reliable results 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.

Final Policy: After consideration of the comments received, we are finalizing an episode minimum of 125 episodes for the MSPB measure beginning with the CY 2017 payment adjustment period and CY 2015 performance period. We are finalizing an addition at § 414.1265(a)(2) to reflect this final policy.

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 proposed that, beginning with the 2018 VM, we change the definition of index admission used for the MSPB measure 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 in other states. Under this proposal, we would continue to standardize 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 for payment policy changes and updates; any methodological changes made across years are documented in the Appendix of the ''CMS Price

Standardization'' document. We solicited 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.

The following is a summary of the comments we received on this proposal.

Comment: One commenter supported the proposal and we did not receive any opposing comments.

Response: We appreciate the commenter's support for the proposal. This change will allow us to include this measure in the calculation of the cost composite for groups and solo practitioners in Maryland, consistent with what is done in other states.

Final Policy: After consideration of the comments received, we are finalizing the proposal to, beginning with the CY 2018 payment adjustment period, include hospitalizations at Maryland hospitals as an index admission for the MSPB measure for the purposes of the VM.

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 final rule with comment period, beginning with the CY 2017 payment adjustment period, we proposed to increase the minimum number of episodes for inclusion of the MSPB measure in the cost composite to 100 episodes. Therefore, we proposed 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 proposed 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 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 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 proposed 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 proposed 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 final rule with comment period, 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 proposed 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 proposed to specify in § 414.1265(b)(1) that this policy was applicable only for the CY 2015 payment adjustment period.

The following is a summary of the comments we received on this proposal.

Comment: One commenter supported our proposal to classify a quality or cost composite as ''average'' if there is not at least one quality or cost measure that can be calculated reliably. Some commenters were concerned that some practices would be subject to a downward adjustment under the quality-tiering methodology if classified as ''average cost and low quality'' or ''average quality and high cost'' under the proposed policies and recommended that any group or solo practitioner that receive an automatic average designation due to a lack of either quality or cost measure data should be held harmless from any downward payment adjustment under the VM.

Response: After considering comments we received, we are finalizing all of the policies as proposed. We believe that for TINs for which we are not able to calculate a reliable quality (or cost) composite score, it is appropriate to classify the quality (or cost) composite as average under the quality-tiering methodology and determine the VM adjustment based on the TIN's available cost (or quality) data.

In our analysis of the groups that are subject to the 2016 VM (without accounting for the informal inquiry process), we found that no TIN received a downward adjustment under the quality-tiering methodology as a result of being classified as average quality and high cost under this policy. We also found that 2 TINs received an upward adjustment under the quality-tiering methodology as a result of being classified as average quality and low cost under this policy. Therefore, we expect these policies to have minimal negative impact on groups and solo practitioners.

Final Policy: As discussed in section III.M.4.k. of this final rule with comment period, beginning with the CY 2017 payment adjustment period, we are finalizing our proposal to increase the minimum number of episodes for inclusion of the MSPB measure in the cost composite to 125 episodes. Therefore, we are finalizing our

proposed revisions to § 414.1265(b) to indicate that a group or solo practitioner subject to the VM will 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. Consequently, to the extent a group or solo practitioner's quality composite is classified as high, average, or low, the group or solo practitioner's VM will reflect that classification. To improve the organization of the regulation text, we are also finalizing our proposal to move the provisions at § 414.1270(b)(5) and (c)(5) to § 414.1265(b)(3).

We are finalizing that beginning in the CY 2016 payment adjustment period, a group or solo practitioner subject to the VM will 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 will reflect that classification. We are finalizing the incorporation of this policy at § 414.1265(b)(2). This policy is consistent with the policy we finalized in the CY 2015 PFS final rule with comment period (79 FR 67934), that beginning with the CY 2016 payment adjustment period, a group or solo practitioner subject to the VM will 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 and thus a reliable cost composite cannot be calculated for the group or solo practitioner.

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 final policies that 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 and 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, we are also finalizing our proposal 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 proposed 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 physicians 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 noted 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 proposed 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 noted that we were 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).

We did not receive any comments on these proposals, and therefore, we are finalizing these technical changes to the regulation text without modification.

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 physician or other eligible professional. 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. As discussed in section III.M.4.c. of this final rule with comment period, we also note that the VM methodology includes additional safeguards to guard against misclassification—we finalized in the CY 2013 PFS final rule with comment period (77 FR 69325) the adoption of the quality-tiering model where we classify quality composite scores and cost composite scores each into high, average, and low categories based on

whether these scores are at least one standard deviation from the mean and statistically significantly different from the mean at the 5.0 percent level of significance, in order to apply the VM bonus or penalty only when a group's performance is significantly different from the national mean.

We noted that high costs within the post-acute and long-term care settings present a unique opportunity for these professionals to improve performance on cost and quality measures. Although we continue to encourage professionals 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 did not make any proposals on this matter at this time. We solicited feedback on this potential approach, as well as other approaches. The following is a summary of the comments we received on this potential approach.

Comment: Nearly all that provided feedback were supportive of approaches 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. Many of these commenters provided additional suggestions and/or reserve final judgment until an evaluation of the impact of this approach is made public. Some believe that we should address other methodology concerns such as to distinguish between specialists and sub-specialists in the same field or between physicians with similar training but very different practice profiles such as primary care physicians who are office-based versus those who are largely providing care in a hospital, skilled nursing facility or patient's home.

Response: We appreciate the thoughtful suggestions regarding the development of ways 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.

After consideration of the comments received, we will continue to work with stakeholders to further explore options for risk stratified comparisons. If we determine that further changes may be appropriate, we will make a proposal through future rulemaking. We will continue to learn from and incorporate more information about this issue and impacted groups in the annual experience report.

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 expanded 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 made 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 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 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 provides 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 accommodates new PQRS reporting options, including QCDRs and CAHPS for PQRS. In addition, the reports 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 provided more detailed per capita cost of service breakdowns for all six cost measures. The reports also 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 will disseminate 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 invited comment on which aspects of the QRUR reports have been most useful and how we can improve access to and usability of performance reports.

The following is a summary of the comments we received.

Comment: Commenters were supportive of CMS's intention to make QRURs 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 and Shared Savings Program ACO participant TINs and groups that include one or more EPs who participated in a Pioneer ACO or the CPC Initiative. However, commenters expressed concerns about timeliness of reports; the accessibility of the reports; the complexity of the reports, and the outreach regarding the VM program.

Response: In response to previous comments about the timeliness of reports, this year we disseminated the Mid-Year QRURs, the Annual QRURs and the Supplemental QRURs. We believe that these reports provide groups and solo practitioners with more timely and actionable information on the quality and cost of the care they furnish. We acknowledge that there is a

process that must be followed to access the reports and would note that it is important to protect the information contained in the reports. These security measures are necessary to protect the data contained in the reports and ensure that only authorized users are able to access them. We have made strides to simplify the outreach around how to access the reports and would direct readers to the step-by-step instructions at *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/Obtain-2013-QRUR.html.* We also acknowledge that the QRUR reports could be perceived as complex. They contain a significant amount of valuable data to help physicians and other eligible professionals understand and improve the quality and efficiency of care they provide. We have added a performance dashboard to provide a visual snapshot and summary of performance to the beginning of the reports. We encourage all physician groups and solo practitioners to access their report and also encourage QRUR users to submit feedback to the PV helpdesk at 1–888–734–6433 (select option 3) or at *pvhelpdesk@cms.hhs.gov.* We have continued to engage our stakeholders and seek input on how best to refine the reports. We disagree that CMS does not provide adequate outreach about the VM. We conduct National Provider Calls in conjunction with each QRUR release, and we provide education and outreach documents that are accessible on our Web site related the VM, how to access the QRURs, and how to interpret the QRURs. We will continue to engage the stakeholder community to determine how best to educate about value-based payment programs.

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 provided 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 were 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, 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 included 26 major episode measures and 38 sub types of episodes and were made available to over 300,000 groups and solo practitioners. We will continue to seek stakeholder input as we develop the episode framework.

Lastly, we direct readers to the Physician Compare policies in this rule (section III.H. of this final rule with comment period), which did not finalize the proposal to add a green check mark to the profile page of the Physician Compare Web site for physicians and other eligible professionals receiving an upward adjustment under the VM starting in CY 2018. 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; (3) prohibitions on per-unit of service (''per-click'') and percentage-based compensation formulas for determining the rental charges for office space and equipment lease arrangements; and (4) expansion of the definition of ''entity.'' We are aware of the recent D.C. Circuit decision in *Council for Urological Interests v. Burwell,* 790 F.3d 212 (D.C. Cir. 2015), which addressed the prohibition on per-click equipment lease payments found in § 411.357(b)(4)(ii)(B). In accordance with that decision, the regulation has been remanded to the Secretary for further consideration. Accordingly, we are considering our options as to how to comply with the court's decision.

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 to codify and interpret the Affordable Care Act's revisions to section 1877 of the Act.

b. Purpose of this Final Rule with Comment Period

This rule updates 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 those goals, the final rule with comment period 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 the proposed rule, we proposed to establish new policies and revise certain existing policies regarding recruitment assistance and retention payments. Specifically, we proposed a new exception for assistance to physicians to employ nonphysician practitioners (NPPs). In addition, we proposed to clarify for federally qualified health centers (FQHCs) and rural health clinics (RHCs) how to determine the geographic areas that they serve for the 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 also proposed 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 proposed to clarify how parties should calculate the maximum amount for permissible retention payments. Those proposals are described in detail below.

a. Assistance To Compensate 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 to be a member of the hospital's medical staff, subject to certain requirements. This exception is codified at § 411.357(e). In Phase III, we declined to expand § 411.357(e) to cover the recruitment of NPPs into a hospital's service area, including into an existing group practice (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. The demand for primary care is increasing, especially in rural and underserved areas, because the Affordable Care Act expanded health care coverage to the previously uninsured, and because the population is growing and aging. The supply of physicians is projected to not keep pace with the increasing demand for primary care (see 80 FR 41910). We have identified similar trends with respect to mental health care services. NPPs, the fastest growing segment of the primary care workforce, may help to mitigate these shortages. In addition, new and evolving care delivery models, which feature an increased role for NPPs (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 NPP recruitment assistance to physicians, using the authority granted to the Secretary in section 1877(b)(4) of the Act, we proposed a limited exception for hospitals, FQHCs, and RHCs that wish to provide remuneration to a physician to assist with the employment of an NPP.

The proposed exception at § 411.357(x) would permit remuneration from a hospital, FQHC, or RHC to a physician to assist the physician in employing an NPP in the geographic area served by the hospital, FQHC, or RHC providing the remuneration. (See 80 FR 41910 through 41911 for an explanation of how the proposed exception would 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.) The exception as proposed would have applied only where the NPP 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. However, we solicited comments regarding whether we should also permit remuneration to physicians to assist in attracting NPPs 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 NPP have a minimum term, such as 1 year).

Because our goal in proposing the exception at § 411.357(x) was 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 proposed to define ''nonphysician practitioner,'' for the purposes of this exception, to include only physician assistants (PAs), nurse practitioners (NPs), clinical nurse specialists (CNSs), and certified nurse midwives (CNMs). We solicited comments regarding

whether there is a compelling need to expand the scope of the proposed exception to additional types of NPPs who furnish primary care services.

We also proposed at § 411.357(x)(1)(vi) a requirement that the NPP provide only primary care services to patients of the physician's practice. We solicited comments regarding whether we should consider other, more, or fewer types of services to be ''primary care services'' for the purposes of proposed § 411.357(x), whether there is a compelling need to expand the scope of the proposed exception to NPPs 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 proposed two alternatives for establishing the minimum amount of primary care services furnished to patients of the physician's practice by the NPP: (1) At least 90 percent of the patient care services furnished by the NPP must be primary care services; or (2) substantially all of the patient care services furnished by the NPP must be primary care services. We proposed to define ''substantially all'' patient care services consistent with our regulations. (See § 411.352(d) and § 411.356(c)(1).) We solicited comments regarding which of these alternatives is most appropriate and the nature of the documentation necessary to measure the NPP's services.

Because we do not intend to permit remuneration to physicians through ongoing or permanent subsidies of their NPP's compensation and other practice costs, we proposed 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 NPP's employment by the physician. Under § 411.357(x)(1)(iii) as proposed, the amount of remuneration from the hospital, FQHC, or RHC would have been capped at the lower of: (1) 50 percent of the actual salary, signing bonus, and benefits paid by the physician to the NPP; or (2) an amount calculated by subtracting the receipts attributable to services furnished by the NPP from the actual salary, signing bonus, and benefits paid to the NPP by the physician. We proposed 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. Because the proposed exception would protect only remuneration to reimburse a physician for amounts actually paid to the NPP, the hospital, FQHC, or RHC providing the remuneration could not increase it to account for any tax implications to the physician. We solicited 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 NPP should include all receipts for all services furnished by the NPP, regardless of payor and regardless of whether the services were primary care services. We also solicited 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 NPP 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 an NPP. We also solicited comments specifically addressing the time limitations set forth in our proposal.

The proposed exception at § 411.357(x) closely tracked 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 NPPs 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 NPPs.

We proposed requirements to safeguard against program or patient abuse similar to the requirements found in most of our exceptions in § 411.357. Specifically, we proposed 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 NPP. In addition, the arrangement may not be conditioned on the physician's or the NPP'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 NPP (or any other physician or NPP in the physician's practice) or other business generated between the parties. Because 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 the purposes of the requirements of the new exception, we proposed at § 411.357(x)(3) a definition of the term ''referral'' as it relates to NPPs that is modeled closely on the definition of a physician's ''referral'' at § 411.351. We also proposed 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 proposed that records of the actual amount of remuneration provided to the physician (and to the NPP) be maintained for a period of at least 6 years and be made available to the Secretary upon request. We solicited comment regarding whether these ''general'' safeguards are sufficient to protect against program or patient abuse resulting from arrangements to assist with NPP employment, or if additional safeguards are necessary.

We also proposed requirements for the compensation arrangement between the physician receiving remuneration and the NPP that the remuneration assists the physician to recruit. Specifically, we proposed that the aggregate salary, signing bonus, and benefits paid by the physician to the NPP must be consistent with fair market value. In addition, we proposed a requirement that the physician may not impose practice restrictions on the NPP that unreasonably restrict the NPP's ability to provide patient care services in the geographic area served by the hospital, FQHC, or RHC, and stated that we would interpret this provision in the same way that we interpret the requirement at § 411.357(e)(4)(vi) for physician recruitment arrangements.

We proposed to include requirements to prevent gaming by ''rotating'' or ''cycling'' NPPs 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 NPPs to the hospital, FQHC, or RHC. We noted our concern that parties may misuse the exception to shift to a hospital, FQHC, or RHC the costs of an NPP 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 proposed that the hospital, FQHC, or RHC may not provide assistance to a physician to employ an NPP if: (1) the NPP 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 the physician organization in whose shoes the physician stands); or (2) the NPP was employed or otherwise engaged by a physician (or a physician organization in whose shoes the physician stands) 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 (or the physician organization in whose shoes the physician stands), even if the NPP did not provide patient care services in that office. For consistency and to ease administrative burden, we proposed 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 an FQHC or RHC to have the same meaning assigned to this term in proposed § 411.357(e)(6)(ii).

Finally, we solicited 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), including comments addressing whether we should limit the number of times a hospital, FQHC, or RHC may assist the same physician with the employment of NPPs and, if so, during what time period that limitation should apply. We sought comments on whether we should limit the use of the exception to no more than once every 3 years for a particular physician or no more than three times in the aggregate (regardless of time period) for a particular physician. We sought comments as to whether this type of limitation potentially undermines the goal of increased access to primary care in the event the NPP(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 were 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 solicited 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.

With several modifications, described below in response to the comments we received, we are finalizing an exception at § 411.357(x) for remuneration provided by a hospital, FQHC, or RHC to a physician to assist the physician with compensating an NPP to provide primary care services or mental health care services to patients of the physician's practice. The following is a summary of the comments we received.

Comment: Most commenters supported our proposal to permit remuneration from hospitals, FQHCs, and RHCs to assist physicians in employing NPPs, variously noting that this will increase access to quality healthcare nationwide at a time when healthcare workforce shortages are projected to increase, particularly in underserved and rural areas, and in light of a steadily rising tide of insured patients; be of great benefit to institutional providers of services, physicians, and NPPs; and benefit patients who would otherwise need to travel distances to obtain needed health care services.

Response: We agree with the commenters that the new exception codified at § 411.357(x) will both promote beneficiary access to care and remove barriers that could frustrate health care delivery and payment system reform efforts. We believe that the exception, as finalized, includes appropriate safeguards to insure against program or patient abuse, yet is sufficiently flexible to achieve the outcomes described by the commenters. As described elsewhere in this section, we are expanding the scope of the exception to include remuneration from a hospital, FQHC, or RHC to a physician to assist the physician in employing or contracting with an NPP. Therefore, we refer to new § 411.357(x) as an exception for assistance to compensate an NPP. However, because the public comments addressed the proposal to establish an exception for assistance to ''employ'' an NPP, the comment summaries below reflect the use of that terminology. This does not affect final § 411.357(x), which is an exception for assistance to compensate an NPP.

Comment: One commenter stated that we could achieve our policy of permitting a hospital to provide assistance to a physician to employ an NPP simply by permitting NPPs to be included in the existing exception for physician recruitment at § 411.357(e).

Response: We disagree with the commenter. The exception for physician recruitment is statutory and covers only remuneration from a hospital to a physician to induce the physician to relocate his or her medical practice to the geographic area served by the hospital to become a member of the hospital's medical staff. The Secretary's authority in section 1877(e)(5)(C) of the Act permits her to impose on the arrangement between the hospital and the recruited physician other requirements that she determines necessary to protect against program or patient abuse. This authority does not extend to an expansion of the exception to include remuneration to a physician to employ, contract with, or otherwise recruit an NPP.

We are utilizing the authority in section 1877(b)(4) of the Act to establish the exception for assistance from a hospital, FQHC, or RHC to a physician to compensate an NPP. Because the exception for physician recruitment in section 1877(e)(5) of the Act and § 411.357(e) of our regulations only permits remuneration to a physician to induce *the physician* to relocate his or her medical practice and join the medical staff of the recruiting hospital, we believe that a standalone exception addressing recruitment of an NPP is more appropriate.

Comment: Several commenters, although supportive of CMS' ''efforts to think about creative solutions to the severe primary care shortage,'' opposed the proposed exception for NPPs. The commenters voiced concerns that the proposed exception will be used by hospitals to recruit nonphysician providers away from FQHCs, thereby exacerbating the primary care workforce shortage and worsening access issues for vulnerable safety-net populations.

Response: After carefully considering all of the comments, we are persuaded that the availability of the exception for assistance to compensate NPPs will improve access to care by bringing more qualified healthcare providers to areas where they are needed. Although we understand the commenters' concerns, we are finalizing the exception at § 411.357(x) with the modifications described elsewhere in this section.

Comment: Several commenters, using nearly identical language, described our proposed exception for payments to assist a physician in employing an NPP as protecting ''both direct compensation arrangements between the hospital and an individual physician and 'indirect' compensation arrangements between the hospital and a physician 'standing in the shoes' of a physician organization to which the hospital provided remuneration.''

Response: As we explained in the proposed rule (80 FR 41910–11), the exception at § 411.357(x) is available to protect a direct compensation arrangement between a hospital, FQHC, or RHC and a physician, including a compensation arrangement deemed to be a direct compensation arrangement because the physician stands in the shoes of his or her physician organization under § 411.354(c)(1). We do not repeat this analysis here. The exception at § 411.357(x) is not available for a compensation arrangement that qualifies as an ''indirect compensation arrangement'' under § 411.354(c)(2). Parties wishing to except an indirect

compensation arrangement from the law's referral and billing prohibitions must utilize the exception at § 411.357(p).

Comment: One commenter urged CMS to expand the scope of the exception to permit remuneration to advanced practice registered nurses and PAs to employ other advanced practice registered nurses and PAs. Another commenter requested that we expand the exception to permit ''the same incentives'' to a NP practice so that all eligible providers have equal opportunity to provide access to high quality, cost-effective Medicare services. A third commenter suggested that we permit the remuneration to flow ''directly to'' the NPP who is joining a physician practice or ''through'' the physician practice that he or she joins, similar to the exception for physician recruitment at § 411.357(e).

Response: In Phase III, we explained that recruitment payments made by a hospital directly to an NPP would not implicate the physician self-referral law, unless the NPP serves as a conduit for physician referrals or is an immediate family member of a referring physician (72 FR 51049). This is because section 1877 of the Act is implicated only by the existence a financial relationship between a physician (or his or her immediate family member) and an entity to which the physician makes a referral for DHS payable by Medicare. Provided that the NPP is neither a conduit for physician referrals nor an immediate family member of a referring physician, the compensation arrangements described by the first two commenters would not implicate section 1877 of the Act and no exception to the law's referral and billing prohibitions would be necessary. As to the third comment, provided that all of the remuneration from the hospital, FQHC, or RHC remained with the NPP (that is, the physician practice retained none of the remuneration as overhead or other expenses), the arrangement described by the commenter should not implicate the physician self-referral law. We caution, however, that an arrangement involving remuneration to a potential referral source may implicate other laws, including the Federal anti-kickback statute (section 1128B(b) of the Act).

Comment: Three commenters urged CMS to expand the scope of the exception to cover the employment of mental health care providers to address the acute need for mental health care services. Another commenter similarly suggested that we include clinical social workers and clinical psychologists within the scope of the exception.

Response: As described elsewhere in this section, we are finalizing the exception at § 411.357(x) to permit remuneration to a physician who compensates an NPP to provide either primary care services or mental health care services to patients of the physician's practice. Accordingly, we are expanding the definition of ''nonphysician practitioner'' for the purposes of § 411.357(x) to include clinical social workers and clinical psychologists, as well as PAs, NPs, CNSs, and CNMs.

Comment: We received numerous comments regarding the definition of ''nonphysician practitioner'' for the purposes of the new exception at § 411.357(x), which was proposed as including PAs, NPs, CNSs, and CNMs. Several commenters expressed support for the proposed definition of ''nonphysician practitioner,'' and many others requested that we include additional types of NPPs within the scope of the exception. Among the NPPs that commenters suggested we include in the definition of ''nonphysician practitioner'' are physical therapists, CRNAs, registered dieticians, and nutritional professionals. As noted elsewhere, commenters that urged us to permit NPPs to furnish mental health services in addition to primary care services requested the corresponding inclusion of clinical social workers and clinical psychologists in the definition of ''nonphysician practitioner.'' In contrast, one commenter expressed concern regarding any expansion of the exception that would permit assistance to physicians to employ other nonphysicians, such as physical therapists.

In support of its recommended expansion of the definition to include registered dieticians and nutritional professionals, the commenter asserted that these professionals are an important part of the collaborative care system. With respect to expanding the definition of ''nonphysician practitioner'' to include CRNAs, a commenter noted that CRNAs may be licensed in their jurisdictions to furnish evaluation and management (E/M) services, as well as other services that would fit the proposed definition of primary care services, and that, because of this, elsewhere in the proposed rule CMS proposed to add CRNAs to the list of practitioners under section 1834(m)(4)(E) of the Act who may provide Medicare telehealth services. The commenter asserted that CMS should follow the same policy for CRNAs under the proposed exception at § 411.357(x). According to the commenter, CMS has proposed a range of safeguards which, when applied to NPPs, including CRNAs, should alleviate any concerns regarding risk of fraud and abuse. The commenters that supported the inclusion of physical therapists in the definition of ''nonphysician practitioner'' for the purposes of the new exception claimed that a substantial number of primary care practice patients have musculoskeletal complaints.

Response: Except with respect to clinical social workers and clinical psychologists, we decline to expand the definition of ''nonphysician practitioner'' as requested by the commenters. We continue to believe that PAs, NPs, CNSs, and CNMs are the types of NPPs who practice in the areas of general family practice, general internal medicine, pediatrics, geriatrics, and obstetrics and gynecology, which we consider to be primary care services. As discussed elsewhere in this section, we are finalizing the exception at § 411.357(x) to permit remuneration to a physician who compensates an NPP to provide mental health care services to patients of the physician's practice. Therefore, we are finalizing the exception to define NPP for the purposes of § 411.357(x) as a PA (as defined in section 1861(aa)(5) of the Act), a NP or CNS (as defined in section 1861(aa)(5) of the Act), a certified nurse-midwife (as defined in section 1861(gg) of the Act), a clinical social worker (as defined in section 1861(hh) of the Act), or a clinical psychologist (as defined in § 410.71(d)). The reasoning for this determination is set forth below.

Because we are not persuaded that registered dieticians or nutritional professionals provide the types of services we consider to be primary care services or mental health care services for the purposes of the exception, we do not believe that including registered dieticians or nutritional professionals in the definition of NPP would further the goals of increasing access to primary care services and mental health care services. Moreover, the commenters did not demonstrate a compelling need to include such practitioners in the definition of NPP for the purposes of the exception.

With respect to CRNAs, the commenter is correct that we proposed 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 may furnish Medicare telehealth services (80 FR 41784). 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 the purposes*

of furnishing Medicare telehealth services, the term ''practitioner'' has the meaning given that term in section 1842(b)(18)(C) of the Act, which includes a CRNA as defined in section 1861(bb)(2) of the Act. 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 services on the list of Medicare telehealth services, but now recognize that, in some States, CRNAs are licensed to furnish certain services on the telehealth list, including E/M services. Although we are finalizing our proposal to add CRNAs to the list of distant site practitioners for telehealth services in this final rule, we do not believe that it is necessary or appropriate to include CRNAs in the definition of NPP for the purposes of the exception to the physician self-referral law at § 411.357(x).

Not all E/M services are primary care services. The commenter did not provide sufficient information for us to determine whether the ''other services'' which it claims CRNAs are licensed to furnish in certain States would qualify as general family practice, general internal medicine, pediatrics, geriatrics, or obstetrics and gynecology services. Moreover, although some CRNAs may be licensed to furnish some E/M services, we are not convinced that CRNAs generally furnish primary care services to the extent that the exception mandates. We are similarly not convinced that CRNAs would furnish mental health care services under the expanded exception finalized here. Therefore, we see no compelling need to include CRNAs in the definition of ''nonphysician practitioner'' for the purposes of the exception at § 411.357(x).

We do not believe that physical therapists furnish primary care services or mental health care services to patients. The commenters suggested only that physical therapists may serve the needs of patients of a primary care practice, not that they furnish primary care services themselves. We do not find this a compelling reason to expand the scope of the exception to include physical therapists in the definition of ''nonphysician practitioner.''

Comment: One commenter urged that we allow the employment of any NPP that would qualify as a primary care provider under the definition at § 425.20 and § 425.404, which pertain to accountable care organizations (ACOs) in the Shared Savings Program.

Response: Sections 425.20 and 425.404 relate to (1) definitions of a ''primary care physician'' (not an NPP) and ''primary care services'' (not providers) and (2) special assignment conditions for ACOs that include FQHCs and RHCs, respectively. The definition of ''primary care services'' at § 425.20 includes a set of services identified by certain CPT, HCPCS and revenue center codes. We believe that the commenter is suggesting that we include in our definition of NPP for the purposes of new § 411.357(x) any practitioner that furnishes services denoted by the codes that make up ''primary care services'' for the purposes of the Shared Savings Program. We decline to do so because we see no reason to condition compliance with the physician self-referral law on requirements of the Shared Savings Program. However, we note that the primary care ''specialty designations'' of internal medicine, general practice, family practice, geriatric medicine, or pediatric medicine that qualify a physician as a ''primary care physician'' for performance year 2016 under § 425.20 align identically with the services we consider to be primary care services for the purposes of § 411.357(x).

Comment: Two commenters urged CMS to identify PAs, NPs, CNSs, and CNMs by their properly earned credentials. The commenters stated that the use of the term ''nonphysician practitioners'' diminishes the value of these professions by identifying them in the negative.

Response: Our use of the term ''nonphysician practitioner'' is not intended to diminish the value of PAs, NPs, CNSs, certified nurse-midwives, or any other professional who provides services to Medicare beneficiaries. In the interest of clarity and to simplify compliance with the exception, we are retaining the term ''nonphysician practitioner'' to encompass the PAs, NPs, CNSs, CNMs, clinical social workers, and clinical psychologists that are covered by the exception.

Comment: Numerous commenters urged CMS to include independent contractors within the scope of the exception for NPP employment. One of the commenters noted that, especially in rural areas, primary care providers are usually recruited from urban areas as part-time independent contractors, as it can be difficult to attract such individuals as full-time members of the community. Commenters variously maintained that expanding the scope of the exception to independent contractor NPPs would promote flexibility, remove a barrier to attracting needed practitioners to underserved areas, and help insure increased availability of primary care services. Most commenters emphasized that the fact of an independent contractor relationship does not create or pose any greater potential for fraud and abuse than a standard employment relationship. One commenter noted that Medicare does not limit reassignment only to situations in which the physician organization has employed the NPP, and suggested that we should extend the scope of the exception to any arrangement that is lawful and will permit the physician organization to obtain payment for the services furnished by the NPP.

Response: We agree with the commenters that expanding the exception to permit a hospital, FQHC, or RHC to provide assistance to a physician to employ, contract with, or otherwise engage an NPP under a compensation arrangement to furnish primary care services or mental health care services to patients of the physician's practice would support our underlying goal of increasing access to needed care. However, we do not believe that a contractual relationship between a physician (or a physician organization in whose shoes the physician stands) and an NPP would necessarily result in the same nexus or level of accountability as an employment relationship between the parties. In order to safeguard against program or patient abuse that may arise in the absence of the close nexus between employer and employee, we are requiring that, where the NPP is an independent contractor, the contractual relationship for which assistance is provided by a hospital, FQHC, or RHC is *directly* between the physician (or a physician organization in whose shoes the physician stands under § 411.354(c)) and the NPP. Accordingly, the exception finalized at § 411.357(x) would permit both (1) a compensation arrangement between a physician and an NPP for employment and (2) a compensation arrangement directly between a physician and an NPP for contracted services. As noted previously, we refer to new § 411.357(x) as an exception for assistance to compensate an NPP. An arrangement between a physician and a staffing company that has the direct contractual or employment arrangement with the NPP that provides services to patients of the physician's practice would not be permitted under the new exception.

Comment: One commenter requested that we expand the exception to permit assistance to recruit an NPP to become an owner of a physician practice. According to this commenter, given the increasing numbers of NPPs, primary care practices are ''resorting to bringing in NPPs as owners'' of the practices. The commenter also requested that, if we

expand the exception to cover ownership interests within its scope, we establish a different cap on remuneration where the NPP joins the practice as an owner. The commenter did not specify what the ''ownership'' cap should be.

Response: We decline to adopt the commenter's suggestion. We are unclear whether the commenter is requesting that we establish an exception that permits a hospital, FQHC, or RHC to provide remuneration directly to an NPP to purchase an ownership interest in a physician practice, or whether the commenter is requesting that we expand the scope of § 411.357(x) to permit a hospital, FQHC, or RHC to reimburse a physician for amounts loaned to an NPP that purchases an ownership or investment interest in the physician's practice. As to the first alternative, as discussed above, a direct compensation arrangement between a DHS entity and an NPP does not implicate the physician self-referral law unless the NPP serves as a conduit for physician referrals or is an immediate family member of a referring physician. However, such an arrangement may implicate other laws, including the Federal anti-kickback statute (section 1128B(b) of the Act). As to the second alternative, we are not persuaded that facilitating ownership in a physician practice poses no risk of program or patient abuse.

Comment: Two commenters also urged us to expand the types of services listed as primary care services for the purposes of the exception to include mental health care services. In support of this request, one of the commenters stressed the well-documented, pressing need for mental health care in the United States and decreasing access to mental health care. A third commenter noted the compelling need for access to mental health care services, referencing a study indicating that up to 70 percent of primary care visits stem from psychosocial issues; that is, although patients may present with physical health complaints, underlying mental health or substance abuse frequently triggers these visits. The commenter stated that this problem is exacerbated by the fact that many communities have a critical shortage of providers to whom patients with mental health needs can be referred. The commenter cited in support of its recommendations, Collins, C., Hewson, D., Munger, R., Wade, T. (2010), ''Evolving Models of Behavioral Health Integration in Primary Care (Milbank Memorial Fund),'' August 29, 2015, available at *http://www.milbank.org/uploads/documents/10430EvolvingCare/EvolvingCare.pdf.*

Response: We agree with the commenters that there is a severe lack of access to mental health care services, and that the exception should be expanded to permit financial assistance for the compensation of NPPs who furnish mental health care services. We are persuaded by the study cited by the commenter, as well several other studies and surveys showing a high demand for mental health care services and a substantial shortage of providers.

The demand for mental health services is considerable; one in every five adults will suffer from a mental illness or substance abuse disorder in a given year. In 2013, national surveyors found that 43.8 million adults in the United States (18.5 percent of the national population) had a mental illness during the year. (Substance Abuse and Mental Health Administration, *Results from the 2013 National Survey on Drug Use and Health*). Additionally, surveys indicate there are 12.3 million adults in the United States who have a substance abuse disorder without a concurrent mental illness. (*Substance Abuse and Mental Health Administration, Results from the 2014 National Survey on Drug Use and Health*).

A large portion of those suffering from mental illness are not receiving treatment. Of the adults suffering from a mental illness in 2013, only 19.6 million (44.7 percent) received mental health services. (*2013 National Survey*). One of the most significant barriers to care was a lack of mental health care professionals. In fact, 25.5 percent of those who were unable to receive services did not know where to go for help. (*2013 National Survey*). This is because, in many areas, there are few or no mental health care professionals available. Seventy-seven percent of counties in the United States have a severe shortage of mental health workers, and 55 percent of counties have no practicing psychiatrists, psychologists, or social workers. (Substance Abuse and Mental Health Services Administration, *Report to Congress on the Nation's Substance Abuse and Mental Health Workforce Issues*). In 2012, HRSA reported that there were 3,669 mental health care professional shortage areas that collectively contained 91 million people. (*Report to Congress*). This equates to a shortage of 1,846 psychiatrists and 5,931 NPPs. (*Report to Congress*). HRSA projects that by 2020, 16,624 child and adolescent psychologists will be needed, but the expected supply is 8,312 (*Report to Congress*), and that between 2012 and 2025, overall demand will grow by 10 percent while supply will decline by 900 psychologists. (Health Resources and Service Administration, *Health Workforce Projections,* Psychologists).

We agree with the commenters that there is a compelling need for more mental health care professionals. We believe further that permitting hospitals, FQHCs, and RHCs to provide assistance to a physician to compensate NPPs to provide mental health care services to patients of the physician's practice may improve access to such critically needed services. In turn, we anticipate that increased access will promote treatment, improve outcomes, and may reduce the societal costs of mental illness. We are expanding the scope of the exception at § 411.357(x) to permit an NPP for whom a physician receives assistance from a hospital, FQHC, or RHC to furnish mental health care services to patients of the physician's practice.

Comment: Some commenters urged CMS to broaden the exception to include arrangements under which the NPP furnishes any type of care because NPPs contribute to addressing specialty workforce shortages, particularly in underserved and rural areas, remove barriers to needed care, such as ongoing management of chronic conditions by specialists, and address important needs of beneficiaries, including increased access to care. One of these commenters suggested that, provided there is a demonstrated shortage of specialty providers and where additional availability of NPPs may help address the specialty care shortage concerns, payments made to a physician to employ an NPP to furnish specialty care services should be permissible. A different commenter urged us to expand the exception to all specialties because all specialties are feeling increased demand for services created by the Affordable Care Act.

Response: In the proposed rule, we solicited comments regarding whether there is a compelling need to expand the scope of the exception to NPPs who provide services that are not considered primary care services and, if so, safeguards that could be included to ensure no risk of program or patient abuse (80 FR 41911). Other than the studies discussed in a separate comment and response regarding mental health care services, none of the commenters that advocated for an expansion of the scope of the exception to include services that are not considered primary care services provided documentation or other evidence of the compelling need for such an expansion. We do not believe that an increase in demand for specialty services necessarily correlates

to a barrier to access to those specialty services. Although we appreciate the views of these commenters, without support for a compelling need to expand the exception to NPPs who furnish services that are not considered primary care services or mental health care services, we are not inclined to adopt the revisions requested by the commenters. The exception at § 411.357(x), as finalized here, is limited to NPPs who furnish primary care services or mental health care services.

Comment: Several commenters urged us to expand the scope of the exception to permit a hospital, FQHC, or RHC to provide remuneration to a physician to employ NPPs who practice in certain other specialties, including those who provide neurology, urology, cardiology, surgery, and orthopedic services. One commenter stated that there is an acute need for NPPs who provide neurology and urology services in many community hospitals and, further, that it is not unusual for a surgical practice or an anesthesia practice to have the same ''compelling need'' for a hospital's assistance as does a primary care practice. Some commenters suggested that we permit the NPP to practice in *any* specialty. One commenter recommended that CMS ease the requirement on the services furnished by the NPP to include those non-primary care services for which the local jurisdiction licenses NPPs. A different commenter urged CMS to extend the scope of the proposed exception to remuneration provided to physicians who employ NPPs who provide cancer care, noting that such NPPs often provide enhanced primary care and care coordination services to many of their patients. Yet another commenter requested an equal playing field for specialty and subspecialty physician organizations, stating that this would be a more straightforward way for CMS to encourage access to NPPs and the services that they provide as part of care teams.

Response: For the reasons described in the response to the previous comment, we decline to expand the scope of the exception to permit NPPs to furnish services other than primary care services or mental health care services to patients of the practice of the physician receiving the assistance from a hospital, FQHC, or RHC. Moreover, in our view, a physician practice's perceived need for financial assistance does not equate to or necessarily demonstrate a need for health care services in a geographic area. We note that nothing in § 411.357(x) prohibits a hospital, FQHC, or RHC from providing remuneration to a specialty physician who compensates an NPP to furnish primary care services or mental health care services to patients of the physician's practice. We remind readers that the purpose of the exception as finalized is to remove barriers to care that may frustrate certain goals of health care delivery system reform and to promote beneficiary access to primary care services and mental health care services, not to promote access to the services of particular type of care provider (for example, an NPP).

Comment: One commenter expressed concerns with expanding the exception to permit the employment of NPPs who provide services other than primary care services, specifically raising concerns regarding physical therapy furnished by therapists employed by a physician or physician organization.

Response: We are expanding § 411.357(x) only to the extent that the exception permits the a hospital, FQHC, or RHC to provide assistance to a physician to compensate an NPP who furnishes primary care services or mental health care services to patients of the physician's practice. As finalized, § 411.357(x) would not protect assistance to a physician who compensates an NPP to furnish physical therapy services to patients of the physician's practice. As described above, none of the commenters that advocated for an expansion of the scope of the exception to include services that are not considered primary care services provided documentation or other evidence of the compelling need for such an expansion. Without support for a compelling need to expand the exception to NPPs who furnish services that are not considered primary care services or mental health care services, including physical therapy services, we are not inclined to adopt the revisions requested by the commenters.

Comment: Two commenters urged CMS to expand the exception to hospitals that provide remuneration to physicians providing specialty care who employ NPPs. One of these commenters suggested specifically that we expand the exception to permit the employment of NPPs who furnish only primary care services, but furnish such services to the patients of a specialty physician practice. The other commenter suggested that CMS should not use the physician self-referral regulations to support one particular specialty over another, and that an expansion poses no risk of program or patient abuse. Another commenter went so far as to state that it is an abuse of CMS's authority to extend the scope of the exception to only certain physician specialties.

Response: The exception is available to any physician who compensates an NPP to furnish primary care services or mental health services to patients of the physician's practice. The physician's specialty, even if it is not primary care or mental health care, would not prohibit a hospital, FQHC, or RHC from providing assistance to the physician. However, any assistance to the physician must be for the purpose of compensating an NPP to furnish primary care services or mental health care services.

Comment: One commenter sought confirmation that the exception would permit hospitals, FQHCs, and RHCs to provide remuneration to physicians who practice in hospital-based emergency departments. The commenter noted that such physicians provide enhanced primary care and care coordination services to many of their patients, particularly those who present to the emergency department without a primary care provider or those who have limited access to community-based primary care providers. The commenter read our proposal to be limited to assistance to individual physicians.

Response: We understand the commenter to be questioning the availability of the exception for hospitals, FQHCs, and RHCs that wish to provide assistance to private physician practices that specialize in emergency medicine and furnish patient care services in hospital emergency departments. As such, we reiterate that the physician's specialty, even if it is emergency medicine, would not prohibit a hospital, FQHC, or RHC from providing assistance to the physician. However, any assistance to the physician must be for the purpose of compensating an NPP to furnish primary care services or mental health care services, and the arrangement must satisfy all of the requirements of the exception at § 411.357(x).

Comment: One commenter urged us to interpret ''primary care services'' as broadly as possible because, as health care delivery shifts to patient-centered models of care, a greater diversity of services will be necessary to meet the needs of patients in the primary care setting. Other commenters urged us to broaden the definition of ''primary care services'' to include services furnished by allergists, immunologists, and rheumatologists.

Response: After careful consideration of these comments and the comments urging us to permit assistance to a physician to compensate an NPP who furnishes any type of services to patients of the physician's practice, we decline to consider any types of services

other than those in our proposal to be ''primary care services.'' General or family practice, general internal medicine, pediatrics, and obstetrics and gynecology are the four primary care specialties counted by the Health Resources and Services Administration (HRSA) when determining primary care health professional shortage areas (HPSAs). Further, geriatrics is considered an acceptable primary care specialty under the Primary Care Loan program administered by HRSA. We note that nothing in this rule or the exception at § 411.357(x) precludes a qualified professional, including an NPP, from furnishing general family practice, general internal medicine, pediatrics, geriatrics, and obstetrics and gynecology services—which we consider ''primary care services'' for the purposes of § 411.357(x)—regardless of the individual's specialty training or designation.

Comment: One commenter suggested that the term ''only primary care services'' at proposed § 411.357(x)(1)(vi)(B) could generate uncertainty and necessitate additional rulemaking. Another commenter understood ''only primary care services'' to mean that at least 75 percent of the services furnished by the NPP must be primary care services and found this requirement to be reasonable. Other commenters explicitly asked that we adopt a ''substantially all'' test for the primary care services furnished by the employed NPP, stating that this standard is most appropriate and consistent with other CMS regulations. Moreover, according to these commenters, a standard requiring that the NPP provide ''only'' primary care services could hamper the impact of the exception. We received no comments in support of a different standard for the minimum amount of primary care services that an NPP must furnish under the exception.

Response: Proposed § 411.357(x)(1)(vi)(B) set forth a minimum amount of primary care services that must be furnished by the NPP for whose employment a physician receives assistance from a hospital, FQHC, or RHC, and stated that the NPP must provide ''only'' primary care services to patients of the physician practice. In our discussion of this requirement, we proposed two alternatives for establishing the minimum amount of primary care services furnished to patients of the physician's practice by the NPP: (1) At least 90 percent of the patient care services furnished by the NPP must be primary care services; or (2) substantially all of the patient care services furnished by the NPP must be primary care services (80 FR 41911). We stated that we would define ''substantially all'' patient care services consistent with our regulations at § 411.352(d) and § 411.356(c)(1); that is, at least 75 percent of the NPP's services to patients of the physician's practice must be primary care services.

We agree with the commenters that a ''substantially all'' standard is the appropriate standard for the minimum amount of primary care services or mental health care services that an NPP must furnish to patients of the physician's practice. Therefore, we are finalizing § 411.57(x)(1)(vi) to require that substantially all of the patient care services furnished by the NPP must be primary care services or mental health care services. We expect that physician organizations that qualify as ''group practices'' are familiar with this standard, as are rural providers. As we have throughout the physician self-referral regulations, we are defining ''substantially all'' patient care services to mean at least 75 percent of the NPP's services to patients of the physician's practice. To ensure consistency in the interpretation of identical terms used in our regulations, we are requiring that ''patient care services'' be measured by one of the following: (1) The total time the NPP spends on patient care services documented by any reasonable means (including, but not limited to, time cards, appointment schedules, or personal diaries); or (2) any alternative measure that is reasonable, fixed in advance of the performance of the services being measured, uniformly applied over time, verifiable, and documented. See § 411.352(d)(1). For clarity, we are including this requirement in § 411.357(x) as finalized in this final rule.

Comment: Two commenters urged us to adopt only the bright-line test of 50 percent of the actual salary, signing bonus, and benefits paid to the NPP as the limit on the amount of remuneration that a hospital, FQHC, or RHC may provide to a physician to employ an NPP. One of these commenters suggested that the remuneration methodology should be as simple and straightforward as possible, and that the final rule should avoid complicating the exception and exposing hospitals to noncompliance due to incomplete or inaccurate documentation related to receipts for the NPP's services to patients of the physician's practice. Another commenter urged us to permit hospitals to utilize either method of determining the maximum amount of permissible assistance set forth at § 411.357(x)(1)(iii), without regard to which results in the lower amount of remuneration from the hospital, FQHC, or RHC to the physician. The commenter stated that the ''payments less receipts'' methodology (with payments equal to the salary, signing bonus, and benefits paid to the NPP) is speculative at the outset of the compensation arrangement and cannot be determined with certainty at that time to be lower than 50 percent of the actual salary, signing bonus, and benefits paid to the NPP by the physician or physician organization. The commenter also raised the complicating issue of nonphysician services billed incident to a physician's service rather than under the NPI assigned to the NPP. Moreover, having a ''lower of'' standard effectively requires parties to use both methodologies to determine which results in the lower amount of remuneration, even if only one is desired. To avoid ''after-the-fact'' violations of the physician self-referral law, the commenter suggested that hospitals, FQHCs, and RHCs should be given the choice of selecting either of these two methodologies for determining the amount of assistance they will provide to the physician or physician organization.

Response: We agree with the commenters that recommended establishing a clear, objective standard for determining the maximum amount of assistance that a hospital, FQHC, or RHC may provide to a physician would best serve the interests of hospitals, FQHCs, and RHCs that provide assistance to a physician to compensate an NPP. Such a standard would serve to facilitate compliance with the physician self-referral law, which is a primary purpose of certain of these updates to our regulations. Upon further consideration of the ''receipts minus salary, signing bonus, and benefits'' methodology, we are abandoning this option in favor of a bright-line approach that permits a hospital, FQHC, or RHC to provide assistance to a physician in an amount that does not exceed 50 percent of the actual aggregate compensation, signing bonus, and benefits paid to the NPP who joins the physician's practice. We 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. As we stated in the proposed rule, we recognize that compensation 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 finalizing 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 NPP's salary, signing bonus, and benefits be set in advance.

We recognize the challenges posed by a standard under which a hospital's, FQHC's, or RHC's compliance with the law depends on precise determinations of which services are ''attributable'' to an NPP, adequate record keeping of the physician, and the cooperation of the physician in sharing information regarding the receipts for services furnished by the NPP's services. Compliance challenges would be exacerbated where the NPP furnishes services that are incident to a physician's service and billed under the name (or NPI) of the physician. The third commenter's recommended approach of an ''either/or'' standard, rather than a ''lower of'' standard, while providing flexibility to hospitals, FQHCs, and RHCs, does not alleviate the significant compliance challenges posed by the ''receipts minus salary, signing bonus, and benefits'' standard, and we are not adopting it. We note that our goal in establishing the exception at § 411.357(x) is to expand access to critically needed primary care services and mental health care services. The exception is not intended to provide a physician with the means to increase profit from the services of an NPP in his or her practice at the expense of a hospital, FQHC, or RHC. We intend to monitor the use and impact of the exception for potential program or patient abuse.

Comment: One commenter requested that we increase the limit on the amount of salary, signing bonus and benefits for which a hospital, FQHC, or RHC may provide assistance. The commenter stated that 60 percent would be a more appropriate cap, as that percentage is more closely aligned with added overhead associated with adding an NPP to a physician practice. The commenter provided no data to support this statement. Another commenter recommended that we permit remuneration to a physician to cover the cost of the NPP's relocation. This commenter suggested that a hospital, FQHC, or RHC should be permitted to cover such costs if the NPP was located outside the geographic area served by the hospital and moves at least 25 miles to join the physician practice, as measured from the physician practice's primary place of business (or, if multiple locations, the location where the NPP will primarily practice). The commenter did not specify whether the previous location of the NPP refers to his or her practice location or whether remuneration to cover relocation costs should be subject to the overall cap on remuneration provided under the exception.

Response: Nothing in the exception at § 411.357(x) prohibits a hospital, FQHC, or RHC from providing assistance to a physician that includes an amount associated with the relocation costs of the NPP joining the physician's practice, provided that: (1) The amount is included when calculating the aggregate compensation from the physician to the NPP; (2) the assistance from the hospital, FQHC, or RHC does not exceed the cap established at § 411.357(x)(1)(iii)(A); and (3) the compensation to the NPP—including any amount associated with the relocation costs—does not exceed fair market value for the patient care services furnished by the NPP to patients of the physician's practice. In other words, the hospital, FQHC, or RHC may provide remuneration to the physician to cover relocation costs of the nonphysician provider if the relocation costs are included in the calculation of the actual aggregate compensation, signing bonus, and benefits paid by the physician to the NPP, and all other requirements of the exception are satisfied.

Comment: One commenter recommended that we replace the cap on remuneration in proposed § 411.357(x)(1)(iii)(A) with the analogous safeguards in the exception for physician recruitment, namely a limitation on remuneration not to exceed the actual additional incremental costs attributed to the NPP. The commenter claimed that doing so would serve the same goal of limiting any windfall to the physician while having the advantage of administrative simplicity. Another commenter stated that it failed to see any rationale for limiting assistance to only a portion of the additional incremental costs attributable to the NPP, such as 50 percent of the actual salary, signing bonus, and benefits as set forth in proposed § 411.357(x)(1)(iii)(A), and suggested that assistance should be limited to ''no more than'' the actual additional incremental costs attributable to the employed NPP (that is, 100 percent of the actual incremental costs attributable to the NPP). The commenter stated in support that hospitals have experience in using this methodology, but recognized that it could be difficult to determine amounts under an income guarantee if the NPP's services were billed incident to a physician's service.

Response: We decline to adopt a standard that would potentially permit a hospital, FQHC, or RHC to cover 100 percent of the costs attributable to adding an NPP to a physician's practice and thus result in a windfall to the physician. We stated in the proposed rule and continue to believe that hospitals, FQHCs, or RHCs should not bear the full costs of employing (or otherwise compensating) NPPs who work in private physician practices (80 FR 41912). We are establishing the exception at § 411.357(x) using the Secretary's authority in section 1877(b)(4) of the Act, which allows exceptions only for those financial relationships that do not pose a risk of program or patient abuse. Permitting a physician to shift unlimited overhead costs to the hospital, FQHC, or RHC to which he or she refers may pose a risk of program or patient abuse. Moreover, the methodology advocated by the commenters would not further our goal of facilitating compliance and reducing complexity in our regulations.

Comment: One commenter requested that we increase the permissible period for assistance from 2 years to 3 years, noting that it may require more than 2 years for an NPP's practice to develop and for the physician organization to break even on the NPP's employment. The commenter gave the example of a CNM whose services are often not paid for until the baby is delivered, resulting in a lengthy period until his or her practice develops and for the physician organization to realize the revenue for the CNM's services. Another commenter recommended that we expand the permissible period for assistance to at least 3 years, which, in the commenter's view, will help achieve the policy goals of reducing workforce shortages and increasing access to quality care. The commenter stated that adding an additional year to the permissible period of assistance poses no risk of program or patient abuse.

Response: The purpose of the exception at § 411.357(x) is not to permit a hospital, FQHC, or RHC to subsidize a physician until the physician ''breaks even'' or earns a profit on the NPP's employment or contract. Rather, the exception is intended to promote beneficiary access to care and support the goals of health care delivery and payment system reform. As we stated in the proposed rule, we do not intend to permit remuneration to physicians through ongoing or permanent subsidies of their NPP employment (or contracting) and other practice costs (80 FR 41911). As

discussed elsewhere in this section, we are finalizing a 3-year limitation on the frequency of a hospital's, FQHC's, or RHC's use of the exception for a particular physician. In light of this, we believe that the 2-year limit on assistance to employ or contract with an NPP is necessary to prevent the program or patient abuse that may result from ongoing or permanent subsidies of a physician's NPP employment (or contracting) and other practice costs. A 3-year limit on assistance effectively would permit permanent subsidies of physician practices. As we noted in the proposed rule, ongoing or permanent subsidies could serve as a reward for past referrals or an inducement to continue making referrals to the hospital, FQHC, or RHC providing the assistance (80 FR 41912). We disagree with the commenter that stated that adding an additional year to the permissible period of assistance would not pose a risk of program or patient abuse.

Comment: One commenter supported the safeguards we proposed for the new exception, noting that they are appropriate to prevent abuse. The commenter endorsed a limit on the number of times a hospital, FQHC or RHC may assist the same physician with the employment of a nonphysician, noting that once every 3 years is reasonable and consistent with other physician self-referral regulations, but requested that CMS include a waiver of the frequency limit in the event the NPP remains employed by the physician or his or her physician organization for less than 1 year. Another commenter requested that, if we impose a limitation on the frequency of the use of the exception, we include an exception for situations where an NPP leaves his or her employment or otherwise ceases to meet the requirements of the exception. The commenter did not suggest an appropriate time limitation for the NPP's departure from the physician practice. In contrast, two commenters submitted that the general safeguards proposed for the exception are sufficient and that additional safeguards would unnecessarily restrict the usefulness or availability of the exception. One of these commenters stated that physicians will not hire NPPs unnecessarily if doing so will result in a financial loss to the practice. The other of these commenters suggested that a limitation on the frequency or aggregate use of the exception for a particular referring physician is inconsistent with the exception for recruitment of a physician. Another commenter stated that a frequency limitation could potentially undermine the goal of increased access to primary care and also considered it unnecessary to limit the number of times a hospital, FQHC, or RHC may assist the same physician.

Response: We understand the commenters' concerns that a frequency limitation could serve to undermine the goal of increased access to primary care services and mental health care services, but we are not convinced that omitting this safeguard would pose no risk of program or patient abuse. As discussed in response to other comments in this final rule, we believe that ongoing or permanent subsidies of a physician's NPP and other practice costs, which could occur in the absence of a limitation on the number of times a hospital, FQHC, or RHC may assist the same physician, may serve as an inducement to continue making referrals to the hospital, FQHC, or RHC and pose a risk of program or patient abuse. Therefore, we are finalizing a requirement in the new exception that limits the use of the exception for a particular physician to once every 3 years. However, we agree that the goal of increased access to primary care services and mental health care services could be undermined if this limitation prevented a physician from replacing an NPP who left the physician's practice after only a short time. To address this, we are making an exception to the frequency limitation finalized at § 411.357(x)(8) to permit a hospital, FQHC, or RHC to provide assistance to a physician more than once every 3 years in the event that an NPP for whom the physician received assistance (the original NPP) did not remain with the physician's practice for 1 year or more. The 3-year period would begin on the date the hospital, FQHC, or RHC initially provided remuneration to the physician (to compensate the original NPP). Under final § 411.357(x)(8), the hospital, FQHC, or RHC may provide assistance to the physician to compensate a second (or subsequent) NPP, provided that: (1) The aggregate remuneration from the hospital, FQHC, or RHC does not exceed 50 percent of the actual aggregate compensation, signing bonus, and benefits paid to the replacement NPP; and (2) the assistance is limited to the consecutive 2-year period that begins on the date the original NPP commenced employment or a contractual arrangement with the physician (or physician organization in whose shoes the physician stands under § 411.354(c)).

Comment: One commenter opposed an aggregate limitation on the number of times any individual physician could receive assistance. The commenter gave the example of a physician with a long-term career in a single geographic service area and noted that an absolute limit on the use of the exception vis-à-vis this physician could result in failure to meet CMS's goal of facilitating a meaningful increase in access to primary care.

Response: We are not finalizing an aggregate limit on the number of times a hospital, FQHC, or RHC may provide assistance to the same physician to compensate an NPP to furnish primary care services or mental health services to patients of the physician's practice.

Comment: One commenter referred to the limitation on the availability of the exception to situations where the NPP was not employed or otherwise engaged to provide patient care services in the geographic area served by the hospital, FQHC, or RHC for at least 3 years prior to the commencement of the compensation arrangement between the hospital, FQHC, or RHC and the physician as the ''disqualification'' period. The commenter expressed its belief that a 3-year disqualification period is too restrictive and urged CMS to reduce the time period for ''disqualification'' to 1 year. For the same reason, the commenter urged CMS to remove the limitation on employing an NPP who has been employed or otherwise engaged by a physician practice that maintains a medical practice site within the geographic area served by the hospital, FQHC, or RHC, even if the NPP has not provided patient care services at that practice site (or sites). The commenter stated that both of these provisions restrict the mobility of NPPs and will decrease the effectiveness of the exception.

Response: The underlying purpose of the exception is to increase access to primary care services and mental health care services while removing barriers that could frustrate the goals of health care delivery and payment system reform. Although we do not wish to restrict the mobility of NPPs, we are not convinced that we should remove from the exception important requirements that guard against program or patient abuse. We believe that prohibiting assistance from a hospital, FQHC, or RHC to a physician to compensate an NPP who already furnishes patient care services in the geographic area served by the hospital, FQHC, or RHC (or furnishes patient care services to patients of a physician practice that has a medical office site located in the geographic area served by the hospital, FQHC, or RHC) is necessary to guard against shifting the long-term costs of employing and contracting with NPPs

from private physician practices to hospitals, FQHCs, and RHCs.

However, we agree that a 3-year ''disqualification'' period could undermine the important goals of the exception and are finalizing § 411.357(x)(1)(v) to include a 1-year limitation on the NPP's prior practice in the geographic area served by the hospital, FQHC, or RHC. As finalized, the exception would not be available unless the NPP, within 1 year of being compensated by the physician (or the physician organization in whose shoes the physician stands under § 411.354(c)): (1) Has not practiced in the geographic area served by the hospital, FQHC, or RHC providing the assistance; and (2) has not been employed or otherwise engaged to provide patient care services by a physician or physician organization that has a medical practice in the geographic area served by the hospital, FQHC, or RHC providing the assistance, regardless of whether the NPP furnished services at the medical practice site located in the geographic area served by the hospital, FQHC, or RHC. We believe that a 1-year ''disqualification'' period (to use the commenter's terminology) will serve adequately to prevent gaming by rotating or cycling NPPs through multiple physician practices located in the geographic area served by the hospital, FQHC, or RHC. Similarly, retaining the requirement that the NPP may not have been employed or otherwise engaged to provide patient care services by a physician or physician organization that has a medical practice in the geographic area served by the hospital, FQHC, or RHC providing the assistance for at least 1 year prior to the remuneration to the physician, regardless of whether the NPP furnished services at the medical practice site located in the geographic area served by the hospital, FQHC, or RHC, will serve to prevent physicians from shifting the cost of currently employed NPPs to hospitals, FQHCs, and RHCs. In addition, these limitations may serve to protect against potentially competitive practices, such as a physician luring an NPP from another physician practice using hospital funding.

Comment: Two commenters requested that we include relief in the exception at § 411.357(x) similar to that at § 411.357(e)(3). According to one of these commenters, such an exception to the ''geographic'' requirement would allow a physician or physician practice to employ an NPP who was: (1) Immediately prior to the employment, in training or in practice for less than 1 year; or (2) employed on a full-time basis by a Federal or State entity for at least 2 years immediately prior to the employment. The commenter stated that such a provision would expand the pool from which NPPs could be recruited and open up employment opportunities for NPPs who are either transitioning to private practice or beginning their careers without creating a risk of program or patient abuse. The other commenter also requested that, to recognize that unique circumstances could exist that support the availability of assistance in special cases, we provide in the exception for a waiver of the ''geographic'' requirement and the ''temporal'' requirement (that is, the 3-year ''disqualification'' period) if the Secretary determines in an advisory opinion that the area has a demonstrated need for the NPP.

Response: We decline to adopt the commenters' recommendations. We believe the exception as finalized is sufficiently flexible to achieve its purpose. Although it may benefit NPPs in the way the first commenter suggested, the purpose of the exception at § 411.357(x) is not to facilitate opportunities for NPPs, but rather to increase access to primary care services and mental health care services.

Comment: One commenter urged us not to limit the exception to rural or underserved areas, because providers other than those in rural areas are experiencing shortages. We received no comments in support of limiting the use of the exception to hospitals, FQHCs, and RHCs located in rural or underserved areas.

Response: We did not propose to limit the availability of the exception to hospitals, FQHCs, and RHCs that provide assistance to physicians who compensate NPPs to furnish services only in rural or underserved areas. We are not finalizing such a limitation.

Comment: One commenter suggested that CMS make clear that the definition of ''referral'' in proposed § 411.357(x) applies only to the exception for hospital assistance to a physician to employ an NPP, and not to the physician self-referral regulations in their entirety.

Response: As we explained in the proposed rule, the definition of ''referral'' at § 411.351 relates to the request, ordering of, or certifying or recertifying the need for DHS by a physician (80 FR 41912). This term is used throughout our regulations and is applicable when used in reference to the referrals of a *physician*. Our regulations currently do not include a term that references the request, ordering of, or certifying or recertifying the need for DHS by an NPP. For this reason, solely for the purposes of the requirements of the new exception, we proposed to define the term ''referral,'' *as it relates to NPPs,* as a request by an NPP that includes the provision of any DHS for which payment may be made under Medicare, the establishment of any plan of care by an NPP 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 NPP. We are finalizing this definition at § 411.357(x)(4).

Summary of the provisions in the exception for assistance to compensate an NPP, as finalized at § 411.357(x)

After careful consideration of the comments regarding the exception for assistance from a hospital, FQHC, or RHC to a physician to compensate an NPP, we are finalizing our proposed exception at § 411.357(x) with the following modifications: (1) We are including in the definition of ''nonphysician practitioner,'' for the purposes of the exception at § 411.357(x) clinical social workers and clinical psychologists; (2) we are expanding the type of services that may be furnished by the NPP to patients of the physician's practice to include mental health care services; (3) we are including a requirement that the NPP furnish substantially all primary care services or mental health services (rather than ''only'' such services) to patients of the physician's practice; (4) we are not limiting the type of compensation arrangement between the physician (or physician organization in whose shoes the physician stands) and the NPP, but we are requiring that the contractual relationship for which assistance is provided by a hospital, FQHC, or RHC is directly between the physician (or a physician organization in whose shoes the physician stands under § 411.354(c)) and the NPP; (5) we are establishing a bright-line approach to the amount of permissible remuneration from the hospital, FQHC, or RHC to the physician, limiting it to 50 percent of the actual aggregate compensation, signing bonus, and benefits paid to the NPP; (6) we are finalizing a limit on the frequency with which a hospital, FQHC, or RHC may provide assistance to the same physician and setting the limitation at no more than once every 3 years, with an exception if the NPP does not remain with the physician's practice for at least 1 year; and (7) we are shortening from 3 years to 1 year the period of time that the NPP must not have practiced in the geographic area served by the hospital, FQHC, or RHC providing the assistance.

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 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 and Phase III, we expanded the exception to FQHCs and RHCs, respectively, and revised the definitions of ''geographic area served by a hospital.'' As we explained at 80 FR 41913, the definition of ''geographic area served by a hospital'' adopted in Phase III does not provide guidance as to the geographic area into which an FQHC or RHC may recruit a physician, a concept critical for compliance with the exception's requirements. Therefore, we proposed to revise § 411.357(e)(6) to add a new definition of the geographic area served by an FQHC or RHC.

We proposed two alternative approaches for this policy, which aligns closely with the special optional rule for rural hospitals at § 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 to achieve their goals of providing needed services to the communities that they serve. The first proposed approach closely mirrors our current definition of a rural hospital's geographic service area. It would define the geographic area served by an FQHC or RHC as 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. Under our first proposal, 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 could 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 could 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 proposed to define the geographic area served by an 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. We solicited comments on each of these alternatives, including whether patient encounters is the appropriate measure for determining the geographic area served by an FQHC or RHC. Finally, we solicited 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.

We are finalizing our proposal to define, for the purposes of the exception at § 411.357(e), the geographic area served by an FQHC or RHC as 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. The following is summary of the comments we received.

Comment: Several commenters recommended that CMS use the definition for geographic area served by an FQHC or RHC that does not use contiguity as a factor. These commenters noted that the prior lack of clarity regarding the area into which a physician recruited by an FQHC or RHC must move his or her medical practice may have deterred such entities from making recruitment payments to attract physicians to underserved areas. Another commenter noted concurrence with our proposed approach to defining the geographic area served by an FQHC or RHC, but requested that we allow the FQHC or RHC to include one or more zip codes from which the entity 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. According to the commenter, this would allow an FQHC or RHC to take into account potential patients. The commenter also suggested that we determine service areas based on patients rather than encounters, but gave no reason why this measure would be more appropriate than encounters. A different commenter agreed that patient encounters are the appropriate measure for determining the geographic area served by an FQHC or RHC.

Response: We are finalizing our alternative proposal to define the ''geographic area served'' by an 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. As stated in the proposed rule, 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 (80 FR 41913). Also, under this final rule, the FQHC or RHC is permitted to include one or more zip codes from which the FQHC or RHC draws no patients, provided that such zip codes are entirely surrounded by zip codes in the geographic area from which the FQHC or RHC draws at least 90 percent of its patients. Hospitals that provide recruitment assistance to physicians are provided this flexibility under § 411.357(e)(2)(i). As described at § 411.357(e)(6), the exception applies to remuneration provided by an FQHC or RHC in the same manner as it applies to remuneration provided by a hospital, provided that the arrangement does not violate the Federal anti-kickback statute (section 1128B(b) of the Act) or any Federal or State law or regulation governing billing or claims submission. We see no risk of program or patient abuse in extending the ability to include ''hole'' zip codes (as we described them in Phase III (72 FR 51050)) to FQHCs and RHCs when determining the geographic areas that they serve. We are not persuaded that ''patients'' is a more appropriate measure than ''encounters'' for determining service areas, and are not adopting the change recommended by the commenter who suggested that we determine the geographic area served by an FQHC or RHC based on patients of the FQHC or RHC.

Comment: In response to our solicitation of comments regarding whether the exception at § 411.357(e) for physician recruitment is useful to FQHCs and RHCs, several commenters noted that, in their experience, the existing exception is not widely known or used. The commenters encouraged CMS to better publicize the exception to the rural health community so that it may take advantage of this recruitment tool. Another commenter stated that the exception is of limited utility to FQHCs because, as safety net providers, FQHCs struggle to pay market salaries to attract clinicians, and incentive payments are often financially infeasible for FQHCs.

Response: We appreciate the input of the commenters and will consider ways to provide better outreach to FQHCs and

RHCs regarding the physician self-referral law and its exceptions.

After careful consideration of the comments, we are finalizing our proposal to define the geographic area served by an FQHC or RHC, for the purposes of the exception at § 411.357(e), as 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. We are also permitting FQHCs and RHCs to include one or more zip codes from which they draw no patients, provided that such zip codes are entirely surrounded by zip codes in the geographic area from which the FQHC or RHC draws at least 90 percent of its patients, determined on an encounter basis.

c. Conforming Terminology: ''Takes Into Account''

Several exceptions for compensation arrangements in section 1877(e) of the Act 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).) As we explained in the proposed rule (80 FR 41914), our longstanding policy is to interpret the volume or value standard in all provisions under section 1877(e) of the Act uniformly.

Despite our uniform interpretation of the volume or value standard, the phrase ''takes into account'' is not used consistently in the exceptions for compensation arrangements in § 411.357. 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) and § 411.357(s) 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. See 80 FR 41914. To clarify the regulations, we proposed to modify § 411.357(e)(1)(iii) to conform to the exact language in section 1877(e)(5)(B) of the Act. Specifically, we proposed 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 proposed to amend § 411.357(r) to require that the amount of payment under the arrangement may not take into account the volume or value of any actual or anticipated referrals. Lastly, we proposed to revise the language of § 411.357(m) and (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.

The following is a summary of the comments we received.

Comment: We received several comments supporting our proposal to consistently and uniformly use the phrase ''takes into account'' in reference to the volume or value standard in the exceptions for compensation arrangements in § 411.357. One commenter asked CMS to distinguish between compensation that ''varies with'' the volume or referrals and compensation that ''takes into account'' the volume or value of referrals. Another commenter asked CMS to include in the regulations at § 411.351 a definition of the phrase ''takes into account.''

Response: We are finalizing our proposal to make the use of the phrase ''takes into account'' consistent and uniform throughout the compensation arrangement exceptions in § 411.357. We did not propose to define the term ''takes into account,'' and we decline to do so at this time. Nevertheless, we are considering the commenter's proposed definition of ''takes into account'' and related discussion as part of our solicitation of comments on the perceived need for clarification regarding permissible physician compensation. Likewise, we decline to discuss the meaning of the phrase ''takes into account'' in relation to the phrase ''varies with,'' but we will consider the commenter's discussion of the issue as part of our solicitation of comments on permissible physician compensation.

As a result of the comments, we are finalizing the proposed changes to the regulations at § 411.357(e), (m), (r), and (s). The revision of the regulatory language reflects our policy that the volume or value standard is uniform and consistent in the exceptions for compensation arrangements in § 411.357.

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, FQHC, or RHC 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 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, to avoid confusion due to conflicting regulation text, we proposed to modify our regulations at § 411.357(t)(2)(iv)(A) to reflect the regulatory intent we articulated in Phase III. The following is a summary of the comments we received.

Comment: We received one comment supporting our proposed regulatory change to § 411.357(t). However, the commenter also stated that the current exception is too narrow, and urged CMS to expand the exception to permit retention payments as long as the hospital has a good faith belief that the physician is considering relocating his or her practice.

Response: We appreciate the commenter's support, and we are finalizing the proposed revision of § 411.357(t). We are not making any other changes to the exception at this time.

After reviewing the comments, we are finalizing our proposal to modify our regulations at § 411.357(t)(2)(iv)(A). The revised regulatory text clearly states our intention, as formulated in Phase III, that entities contemplating retention payments must consider the entire 24-month period prior to the payment.

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 requirement 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 final rule with comment period clarifies the writing requirement 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 requirements in many exceptions. In addition, to reduce regulatory burden, we proposed to except certain holdover arrangements, provided that certain safeguards are met.

a. The Writing Requirement 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 (b)) require that a lease be set out in writing. Several other compensation exceptions have a similar writing requirement: 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) 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 section 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 (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. (For a similar discussion regarding arrangements among components of an academic medical center, see Phase II (69 FR 16110).)

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 at § 411.357(a)(1) and (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 proposed to substitute the term ''lease arrangement'' for the term ''agreement'' at § 411.357(a)(1) and (b)(1). We believe that this revision underscores the fact that the writing requirement at § 411.357(a)(1) and (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 proposed 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).

In light of our proposal to clarify the writing requirement at § 411.354(d)(1), (d)(4)(i), (a)(1), (b)(1), (e)(4)(i), and (1)(1) by removing the term ''agreement,'' we proposed to make conforming changes where possible to other provisions in the compensation exceptions and the special rules on compensation. Specifically, we proposed to replace the term ''agreement'' with the term ''lease arrangement'' in § 411.357(a)(2), (a)(4), (a)(5), (a)(6), (b)(3), (b)(4), and (b)(5). We proposed to replace the term ''agreement'' with the term ''arrangement'' in § 411.357(c)(3) (the exception for *bona fide* employment relationships) and § 411.357(f)(2) (exception for isolated transactions). Likewise, we proposed 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 proposed to revise § 411.354(d)(4) by replacing the word ''contract'' as it relates to personal service arrangements with the word ''arrangement,'' and we proposed similar changes to § 411.357(e)(1)(iv) and (r)(2)(v), both of which refer back to § 411.354(d)(4). We proposed 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 proposed 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 did not propose 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 (w) are aligned with the Federal anti-kickback statute safe harbors at § 1001.952(x) and (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 (w). However, we believe that the principles elucidated above regarding the writing requirement of the other compensation exceptions to the physician self-referral law also apply to § 411.357(v) and (w).

We are finalizing the proposed changes to clarify that parties need not reduce the key terms of an arrangement to a single formal contract to satisfy the writing requirement of the compensation exceptions at § 411.357 that require a writing. The following is a summary of the comments we received.

Comment: All the commenters addressing this issue supported our statement in the preamble that a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties, may satisfy the writing requirement of various compensation exceptions. Two commenters complained that the writing and signature requirements, when interpreted narrowly, elevate form over substance. Several commenters requested that CMS confirm that our statement regarding a collection of documents is a clarification of existing policy, and that parties need not self-disclose arrangements where the writing requirement was satisfied by multiple documents (and all other requirements of the applicable exception were satisfied), even if the conduct occurred prior to the finalization of this rule.

Response: CMS' existing policy is that a collection of documents, including contemporaneous documents evidencing the course of conduct between the parties, may satisfy the writing requirement of the exceptions for compensation arrangements that require a writing. Our proposal to substitute the word ''arrangement'' for ''agreement'' throughout the exceptions for compensation arrangements was intended to clarify and confirm this existing policy regarding the writing requirement. Parties considering submitting self-disclosures to the SRDP for conduct that predates the proposed rule may rely on guidance provided in the proposed rule to determine whether the party complied with the writing requirement of an applicable exception. To determine compliance with the writing requirement, the relevant inquiry is whether the available contemporaneous documents (that is, documents that are contemporaneous with the arrangement) would permit a reasonable person to verify compliance with the applicable exception at the time that a referral is made.

Comment: Some commenters stated that State law contract principles should determine what constitutes an arrangement ''set out in writing'' for the purposes of the physician self-referral law. The commenters stated that health care providers and suppliers typically rely on State law principles to determine the validity and enforceability of written agreements, and that it would reduce the burden on providers and suppliers to use the same principles to determine compliance with the physician self-referral law.

Response: We decline to adopt the commenters' recommendation that State contract law principles should determine what constitutes an arrangement that is ''set out in writing'' for the purposes of the physician self-referral law. We are concerned that

reliance on State contract law would result in different standards for compliance for different States and territories. In addition, the requirements for a contract to be valid and enforceable under State law may differ substantively from the requirements of the physician self-referral law. For example, in certain instances, a short term service contract may be valid and enforceable under State law even if the agreement is not reduced to writing. In contrast, if the parties sought to protect the arrangement under the exception for fair market value compensation at § 411.357(l), the arrangement would have to be set out in writing to satisfy the requirements of the exception. Similarly, a contract for the provision of items may be enforceable under State law even if the price for the items is not in writing. In contrast, if the parties sought to protect the arrangement under the exception for fair market value compensation at § 411.357(l), the price of the items would have to be in writing to satisfy the requirements of the exception. Finally, we believe that it may be possible in some instances that writings documenting an arrangement may satisfy the writing requirement of the physician self-referral law, yet not form an enforceable contract under State law. In this context, we are concerned that reliance on State law contract principles may unduly narrow the scope of permissible arrangements under the physician self-referral law.

Although State law contract principles do not definitively determine compliance with the writing requirement of the physician self-referral law, the physician self-referral law does not negate or preempt State contract law. (See 72 FR 51049). Nothing prevents a party from drawing on State law contract principles, as well as other bodies of relevant law, to inform the analysis of whether an arrangement is set out in writing. The important point is this: What determines compliance with the writing requirement of the physician self-referral law is not whether the writings form a valid and enforceable contract under State law, but rather whether the contemporaneous writings would permit a reasonable person to verify that the arrangement complied with an applicable exception at the time a referral is made. For this reason, a written contract that is enforceable under State law may not satisfy the writing requirement if the actual arrangement differed in material respects from the terms and conditions of the written contract.

Comment: Two commenters pointed out that the preamble discussion of the writing requirement did not address the corresponding signature requirement in various compensation arrangement exceptions. The commenters noted that the ''collection of documents'' that may satisfy the writing requirement would still have to be signed by the parties for the arrangement to comply with the applicable exception. The commenter indicated that it is not clear to the commenter what is required to satisfy the signature requirement when parties are relying on a collection of documents to satisfy the writing requirement. Two commenters requested confirmation that a party's signature need only be included on one of the documents in the collection. Another commenter suggested that we draw on State law principles to clarify what constitutes a signed writing for the purposes of the physician self-referral law.

Response: As explained elsewhere in this section, we do not believe that State law principles determine compliance with the physician self-referral law, including compliance with the signature requirement. Regarding the signature requirement as it relates to a collection of documents, we note that the proposed rule clarified that a single written contract is not necessary to satisfy the writing requirement of an applicable exception. We substituted the word ''arrangement'' for ''agreement'' in the compensation exceptions to underscore the fact that it is the arrangement (that is, the underlying financial relationship between the parties) that must be set out in writing; there is no requirement that this writing take the form a formal contract between the parties. Likewise, under the proposed rule—which is a clarification of our existing policy—it is the arrangement that must be signed by the parties to satisfy the exception. (See, for example, the proposed language for § 411.357(a)(1) (''The lease arrangement . . . is signed by the parties . . . .'')). For the same reason that parties do not need a *single* formal written contract to comply with the writing requirement, parties also do not need to sign a *single* formal written contract to comply with the signature requirement of an applicable exception. Nor do we expect every document in a collection of documents to bear the signature of one or both parties. To satisfy the signature requirement, a signature is required on a contemporaneous writing documenting the arrangement. The contemporaneous signed writing, when considered in the context of the collection of documents and the underlying arrangement, must clearly relate to the other documents in the collection and the arrangement that the party is seeking to protect.

Comment: Some commenters asked for concrete examples of the kinds of documents (other than formal written agreements) that may satisfy the writing requirement of various compensation exceptions. In addition, one commenter specifically requested that CMS recognize that electronic documents, such as email communications, may be used to satisfy the writing requirement.

Response: Because compliance with the writing requirement is fact-specific, we decline to give an example of a collection of documents that would, taken as a whole, satisfy the writing requirement. However, we are providing some examples of individual documents that a party might consider as part of a collection of documents when determining whether a compensation arrangement complied with the writing requirement of an applicable exception: Board meeting minutes or other documents authorizing payments for specified services; written communication between the parties, including hard copy and electronic communication; fee schedules for specified services; check requests or invoices identifying items or services provided, relevant dates, and/or rate of compensation; time sheets documenting services performed; call coverage schedules or similar documents providing dates of services to be provided; accounts payable or receivable records documenting the date and rate of payment and the reason for payment; and checks issued for items, services, or rent. This list of examples is not exhaustive, and we emphasize that, depending on the facts and circumstances, a party could have documents of each type listed and nevertheless not satisfy the writing requirement of an applicable exception. Among other things, the documents must clearly relate to one another and evidence one and the same arrangement between the parties.

Comment: One commenter stated that parties should be permitted a 60- or 90-day grace period for satisfying the writing requirement of various compensation exceptions. The commenter stated that such a grace period is needed for last minute arrangements between physicians and DHS entities.

Response: We decline to adopt the commenter's suggestion. A grace period for the writing requirement would not incent parties to document the terms and conditions of the arrangement promptly. For this reason, we believe that a grace period for the writing requirement poses a risk of program or

patient abuse. For example, to the extent that the rate of compensation is not documented before a physician provides services to a DHS entity, the entity could adjust the rate of compensation during the proposed grace period in a manner that takes into account the volume or value of the physician's referrals. In this context, we note that the special rule at § 411.353(g)(1) for temporary noncompliance applies only to noncompliance with the signature requirement of an applicable exception. All other elements of an applicable exception, including the applicable writing requirement, must be satisfied once a compensation arrangement between the parties is established (that is, as soon as items, services, or compensation under the arrangement passes between the parties) and the physician makes referrals to the DHS entity.

We remind parties that DHS entities have the burden of proof to establish that services were not furnished as a result of prohibited referrals, and that all requirements of an exception must be met at the time a referral is made. (See § 411.353(c)(2)(i) and 73 FR 48703.) If an arrangement with a physician fails to comply with the writing requirement of an applicable exception when the arrangement commences, then the entity is not permitted to bill for DHS furnished as a result of the physician's referrals unless and until the arrangement is sufficiently documented over the course of the arrangement (and all other requirements of the applicable exception are met). Contemporaneous documents evidencing the course of conduct between the parties cannot be relied upon to protect referrals that predate the documents. Likewise, parties cannot meet the set in advance requirement from the inception of an arrangement if the only documents stating the compensation term of an arrangement were generated after the arrangement began; however, depending on the facts and circumstances, if parties create contemporaneous documents during the course of the arrangement, and the documents set the compensation out in writing, then parties may be able to satisfy the set in advance requirement for referrals made *after* the contemporaneous documents are created. We reiterate that the surest and most straightforward means of complying with the writing requirement of the physician self-referral law is to reduce the key facts of an arrangement to a single signed writing before either party provides items, services, space, or compensation to the other party under the arrangement.

After careful consideration of the comments, we are finalizing our proposal to substitute the word ''arrangement'' for ''agreement'' in various provisions of § 411.354 and § 411.357 identified in the proposed rule. The revision of the regulatory language reflects our existing policy that a single formal contract is not required to satisfy the writing requirement of those compensation exceptions at § 411.357 that require a writing.

b. Term Requirements in Certain Compensation Arrangements Exceptions

The exceptions at § 411.357(a), (b), and (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 proposed to revise § 411.357(a)(2), (b)(3), and (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, respectively, require that the lease arrangement 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 (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 section, we interpreted ''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'' at § 411.357(a)(2) and (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), (b)(3), and (d)(1)(iv), as applicable. As is the case with the writing requirement in these and other exceptions, 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, 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 (b)(3), we proposed 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).

We are finalizing revised regulatory language that clearly reflects the policy stated in the proposed rule, namely that an arrangement need only last at least 1 year as a matter of fact to satisfy the 1-year term requirement at § 411.357(a)(2), (b)(3), and (d)(1)(iv). The following is a summary of the comments we received.

Comment: All those that commented on this issue (38, 50, 68, 73, 80) supported our statement in the preamble that arrangements that last for at least 1 year satisfy the 1-year term requirement. One commenter requested that CMS confirm that the statement in the preamble regarding the 1-year requirement is a clarification of existing law. Another commenter (38) recommended that CMS further revise the regulatory language at § 411.357(a)(2), (b)(3), and (d)(1)(iv), to make it more clear that arrangements need only last as a matter of fact for at

least 1 year satisfy the 1-year requirement.

Response: To clarify that the length of an arrangement need not be stated explicitly in a formal contract, we proposed to revise the 1-year term provisions at § 411.357(a)(2), (b)(3), and (d)(1)(iv), by substituting the word ''arrangement'' for the word ''agreement.'' In the preamble, we explained that an arrangement that lasts as a matter of fact for at least 1 year would satisfy this requirement. We agree with the commenter that the proposed regulatory language does not unambiguously express our intent, as it was stated in the preamble. Specifically, we believe the word ''term'' in the phrase ''the term of the lease arrangement is at least 1 year'' is ambiguous. ''Term'' could mean either the duration of the arrangement as a matter of fact or the formal term provision of the arrangement as prescribed by contract. To clarify in the regulatory text that arrangements that last for at least 1 year as a matter of fact satisfy the requirement, we are further modifying § 411.357(a)(2), (b)(3), and (d)(1)(iv). We are removing the word ''term'' and simply stating that the duration of the arrangement must be at least 1 year. Finally, we are taking this opportunity to clarify that our statement in the preamble regarding compliance with the 1-year term requirement represents CMS' existing policy.

Comment: One commenter generally supported our proposal, but suggested that CMS rely on State law contract principles to determine compliance with the 1-year term requirement of the physician self-referral law.

Response: As stated elsewhere in this section, we do not believe that State law principles are appropriate for determining compliance with the physician self-referral law, including the 1-year requirement.

Upon review and consideration of the comments regarding the 1-year term requirement, we are finalizing revised regulatory language for the exceptions at § 411.357(a)(2), (b)(3), and (d)(1)(iv). The revised language at § 411.357(a)(2) provides that the duration 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 a new lease arrangement for the same space during the first year of the original lease arrangement. We are finalizing similar language for § 411.357(b)(3) and (d)(iv). The revised regulatory text clearly states our current policy that an arrangement need only last 1 year to satisfy the 1-year term requirement of the exceptions for the rental of office space, the rental of equipment, and personal service arrangements.

c. Holdover Arrangements

The exceptions at § 411.357(a), (b), and (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 proposed to amend the holdover provisions at § 411.357(a)(7), (b)(6), and (d)(1)(vii) to permit indefinite holdovers, provided that certain additional safeguards are met. In the alternative, we proposed 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 proposed 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), (b), and (d) developed over the course of our rulemaking in *Response*: to inquiries regarding the expiration, termination, and renewal of arrangements. See 80 FR 41916 through 41917 for a discussion of the development of the holdover provisions.

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 reconsidered our previous position and proposed 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 that take into account 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), (b)(3), or (d)(1)(iv) (or it must satisfy the requirements of the exception for fair market value compensation at § 411.357(l), if applicable). 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 proposed to revise the holdover provisions at § 411.357(a)(7), (b)(6), and (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 proposed 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 arrangement would be considered renewed for a new 2-year period). We stated in the proposed rule our belief 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 sought 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), (b)(6), and (d)(1)(vii), we proposed 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. Currently, the renewed arrangement must continue to satisfy all the requirements of the exception, including the requirement that the compensation is consistent with fair market value. We proposed 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. In addition, as is the case currently, 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 solicited 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.

We are finalizing the proposed indefinite holdover provisions for the exceptions at § 411.357(a)(7), (b)(6), and (d)(1)(vii). We are also finalizing our proposal to remove the phrase ''made for less than 1 year'' at § 411.357(l)(2). The following is a summary of the comments we received.

Comment: The majority of commenters supported our proposal to permit indefinite holdovers of arrangements that continue on the same terms and conditions as an expired arrangement, provided all elements of the applicable exception continue to be satisfied during the holdover. No commenter suggested that additional safeguards would be necessary, and no commenter favored holdover provisions with potentially shorter durations, such as 1, 2, or 3 years. One commenter stated that additional safeguards for holdovers arrangements are not necessary, because, according to the commenter, an arrangement that continues after the expiration of a term in a contract, but is contemporaneously documented during the ''holdover'' period, may satisfy the writing requirement of an exception even if there is no special regulatory provision relating to holdovers.

Response: We appreciate the commenters' support, and we are finalizing the proposed indefinite holdover provisions. We agree with the commenter that, even without a holdover provision, an arrangement that continued after a contract expired on its own terms could potentially satisfy the writing requirement of an applicable exception, provided that the parties had sufficient contemporaneous documentation of the arrangement. Nevertheless, we believe that the proposed holdover provision will facilitate compliance without posing a risk of program or patient abuse. If a written contract with an explicit term provision expires on its own terms, but the parties nevertheless continue the arrangement past the expiration, the expired written contract by its own terms does not apply to the continued arrangement. For this reason, without a holdover provision, an expired written contract, on its own, could not satisfy the writing requirement of an applicable exception. Without additional supporting documentation, there may be gaps in compliance, as it may take some time after the expiration of the written contract to generate sufficient documents evidencing the course of conduct between the parties after the contract expired. In contrast, with a holdover provision, parties can rely in part on the expired written contract to satisfy the writing requirement for the holdover period. We note, however, that parties relying on the holdover provisions must still have contemporaneous documents establishing that the holdover continued on the same terms and conditions as the immediately preceding arrangement. That is, a party must be able to establish that it satisfied the requirements for the holdover provisions at § 411.357(a)(7), (b)(6), or (d)(1)(vii) for referrals made during the holdover period.

Comment: One commenter objected to our statement in the proposed rule that, if rental amounts fall below fair market value during a holdover, the lease arrangement would no longer satisfy the fair market value requirement of the exception at § 411.357(a). According to the commenter, our statement implies that an arrangement that falls out of fair market value during its term loses protection under the exception. The commenter suggested that we retract the statement in the final rule. Another commenter supported our proposal to require holdover arrangements to continue to satisfy the applicable fair market value requirement during the holdover, but requested that CMS confirm that fair market value is determined at the commencement of the arrangement, taking into account the length of the term.

Response: The statement cited by the commenter regarding rental amounts falling below fair market value referred only to the application of the relevant fair market value requirement during a holdover. We believe that ongoing compliance with the fair market value requirement during the holdover is necessary to prevent program or patient abuse. Regarding the fair market value requirement during the original term, we expect parties to make a determination of fair market value at the time the financial relationship is created. (See 73 FR 48739.) The exception at § 411.357(a)(4) requires rental charges to be consistent with fair market value ''over the term of the arrangement,'' but we note that fair market value is expressed as a range of values. We caution that rental payments may cease to be consistent with fair market value in long-term arrangements.

Comment: One commenter stated that it may be difficult for an arrangement to satisfy the fair market value requirement during a holdover that lasts for more than 1 year. The commenter requested guidance on how the fair market value requirement should be analyzed in a multiple year holdover.

Response: As noted elsewhere in this section, the requirement that an arrangement continue to meet the fair market value requirement throughout the holdover is necessary to prevent program or patient abuse. Parties relying on a holdover provision bear the risk of fluctuations in the relevant market that may cause an arrangement to no longer satisfy the applicable fair market value requirement. In most instances, fair market value is expressed as a range, and minor fluctuations in market value may not cause an arrangement to

become noncompliant. (See 73 FR 48739.) However, as soon as a holdover arrangement ceases to meet all the requirements of an applicable exception, including the fair market value requirement, referrals for DHS by the physician to the entity that is a party to the arrangement are no longer permissible. It is up to the parties to determine the best way to analyze fair market value during a holdover. The best means of ensuring ongoing compliance is to enter into a new agreement in a timely manner after a previous contract expires, and to reassess fair market value to the extent that is necessary at the time of the renewal.

Comment: One commenter requested that CMS permit changes to the terms and conditions of an arrangement during a holdover, provided that the changes do not impact compliance with the elements of an applicable exception.

Response: Under the revised regulations, an indefinite holdover lease arrangement or personal service arrangement is permitted if the arrangement continues on the same terms and conditions as the immediately preceding arrangement. As stated in the proposed rule, the holdover arrangement must continue on the same terms and conditions because frequent renegotiation of short term arrangements poses a risk of program or patient abuse. (See 80 FR 41917). If parties were permitted to amend the terms and conditions of an arrangement in the course of the holdover, then parties would be able to frequently renegotiate the terms of the arrangement during the holdover in a manner that could take into account the volume or value of referrals. Thus, parties are not permitted to amend the terms and conditions of an arrangement during a holdover, because such changes pose a risk of program or patient abuse.

Comment: One commenter stated that many leases provide that the rental amount will increase if the tenant holds over after the lease expires on its own terms. The commenter requested guidance on how the fair market value requirement would apply to increased rental amounts during the holdover period.

Response: In Phase III, we stated that lessors can charge a holdover premium, ''provided that the amount of the premium was set in advance in the lease agreement (or in any subsequent renewal) at the time of its execution and the rental rate (including the premium) remains consistent with fair market value and does not take into account the volume or value of referrals or other business generated between the parties.'' (See 72 FR 51045). The same principles apply to the indefinite holdover provisions that we are finalizing. The rental amount with the holdover premium must satisfy the fair market value requirement when the original agreement expires and throughout the holdover.

We caution that, depending on the facts and circumstances, the failure to apply a holdover premium that is legally required by the original arrangement may constitute a change in the terms and conditions of the original arrangement. In such circumstances, the ''holdover'' arrangement will not meet the requirement at § 411.357(a)(7)(ii) that the arrangement continue on the same terms and conditions as the immediately preceding arrangement. In addition, the failure to charge a holdover premium may constitute the forgiveness of a debt, thus creating a secondary financial relationship between the parties that must satisfy the requirement of an applicable exception.

Comment: One commenter supported the proposal to allow parties to renew arrangements of any duration, including arrangements of 1 year or more, under the exception for fair market value compensation at § 411.357(l). Several other commenters requested that an indefinite holdover provision, similar to the proposal for lease arrangements and personal service arrangements, be applied to the exception for fair market value compensation. The commenters stated that the exception for fair market value compensation is similar in many respects to the exceptions for lease arrangements and personal service arrangements, and therefore, the commenters saw no reason to include an indefinite holdover provision in the latter exceptions while not including such a provision in the exception for fair market value compensation.

Response: We believe that permitting parties to renew arrangements of any length under the exception for fair market value compensation, provided that the terms of the arrangement and the compensation for the same items or services do not change, affords parties sufficient flexibility without posing a risk of program or patient abuse. For this reason, we do not believe that a separate holdover provision is necessary for the exception for fair market value compensation. We note that nothing in the exception requires parties to renew the arrangement in writing. However, the parties must have written documentation establishing that the renewed arrangement was on the same terms and conditions as the original arrangement.

Comment: One commenter stated that the exception at § 411.357(l) as it is currently worded does not prohibit the renewal of arrangements with a term of more than 1 year. The commenter stated that our proposed revision was unnecessary and requested clarification in the final rule that the exception has always permitted the renewal of arrangements of more than 1 year.

Response: The exception as it is currently written permits arrangement for less than 1 year to be renewed any number of times if the terms of the arrangement and compensation for the same items or services do not change. There is no requirement that the arrangement of less than 1 year be renewed in writing. The arrangement can be renewed by course of conduct, and the writing requirement for the renewal period would be satisfied (assuming that it was satisfied for the initial term) if the parties had documents establishing that the arrangement continued on the same terms and conditions. Under our proposed rule, arrangements for 1 year or longer could also be renewed by course of conduct, provided that the parties have documentation establishing that the terms of the arrangement and the compensation for the same items or services do not change during the renewal.

It is true that the exception as currently written does not expressly prohibit parties from renewing arrangements of 1 year or longer. Nonetheless, given the purpose of the exception when it was first established, we believe the better reading of the exception does not rely on reading missing words into the text and, therefore, we are not retracting our statement from the proposed rule.

Comment: One commenter stated that the exception for fair market value compensation currently requires that the term of the arrangement must be specified in writing. The commenter requested that CMS create a ''safe harbor'' timeframe of 6 months for arrangements that do not specify the timeframe in writing.

Response: We decline to create a ''safe harbor'' timeframe for the exception for fair market value compensation. We note, however, that the timeframe can be specified in a collection of documents setting out the arrangement in writing.

After reviewing the comments, we are finalizing the proposed indefinite holdover provisions for the exceptions at § 411.357(a)(7), (b)(6), and (d)(1)(vii). We are also finalizing our proposal to remove the phrase ''made for less than 1 year'' at § 411.357(l)(2). We believe

that lease arrangements and personal service arrangements that continue on the same terms and conditions and satisfy the requirements for the new holdover provisions (including ongoing compliance with all the requirements of an applicable exception) do not pose a risk of program and patient abuse. We also believe that allowing renewals of an arrangement of any timeframe under the exception for fair market value compensation at § 411.357(l), provided the arrangement is renewed on the same terms and conditions, affords DHS entities additional flexibility in their arrangements and facilitates compliance, without posing a risk of program or patient abuse; we remind stakeholders that the renewed arrangement must satisfy all the requirements of the exception at the time a referral for DHS is made.

The indefinite holdover provisions will be available to parties on the effective date of this final rule. Parties who are in a valid holdover arrangement under the current 6-month holdover provisions on the effective date of this final rule may make use of the indefinite holdover provisions that we are finalizing, provided that all the requirements of the new holdover provisions are met. On the other hand, if an arrangement does not qualify for the 6-month holdover under the current regulations at § 411.357(a)(7), (b)(6), or (d)(1)(vii) on the effective date of this rule (for example, if the holdover has lasted for more than 6 months as of the effective date of the rule), then the parties cannot make use of the indefinite holdover provisions.

4. Definitions

In the proposed rule, we proposed to revise several definitions in our regulations to improve clarity and ensure proper application of our policies. We describe below the specific proposals. We are now finalizing the revised definitions as proposed, without additional modification.

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. As explained at 80 FR 41918, we proposed to revise the definition of ''remuneration'' at § 411.351 to make it clear that the provision of an item, device, or supply that is used for one or more of the six purposes listed in the statute, and no other purpose, does not constitute remuneration.

We received two comments in support of our proposed revision of the definition of ''remuneration.'' We are finalizing the revisions to § 411.351 as proposed.

Although we did not propose regulatory revisions, we noted in the proposed rule that we are concerned about potential confusion 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 several written inquiries 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 the purposes of the physician self-referral law. We are taking the opportunity afforded by this rulemaking to address this issue.

In a ''split bill'' arrangement, a physician makes use of a DHS entity's resources (for example, examination rooms, nursing personnel, and supplies) to treat the DHS entity's patients. The DHS entity 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 the 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.

The following is a summary of the comments we received.

Comment: The overwhelming majority of those that commented on the issue of split billing and remuneration agreed that a physician's use of hospital resources when treating hospital patients does not constitute remuneration between the parties for the purposes of the physician self-referral law, if the hospital bills the appropriate payor for the resources and services it provides and the physician bills the payor for his or her services. One commenter asked CMS to confirm that our statement is a clarification of existing law. Several other commenters requested that we codify our position in regulatory text. Two commenters requested that we confirm our interpretation by amending the definition of ''remuneration'' at § 411.351.

Response: Our discussions in the preamble to the proposed rule and in this final rule regarding remuneration and split bill arrangements is a statement of CMS' existing policy. We did not propose any regulatory revisions in the proposed rule because we did not think it necessary, and therefore, we cannot make revisions to the regulatory text at this time.

Comment: One commenter asked whether a hospital's promise to grant a physician organization exclusive use of the hospital's space constituted remuneration for the purposes of the physician self-referral law, if the hospital bills the appropriate payor for the space it provides and the physician bills the payor for his or her services. According to the commenter, in Kosenske the hospital promised a physician group exclusive use of the hospital's space.

Response: Our clarification regarding split bill arrangements and remuneration applied only to the use of a hospital's space, items, and equipment. We are not addressing exclusive use of space in this final rule with comment period.

Following our review of the comments, we are confirming our existing policy that a physician's use of a hospital's resources (for example, examination rooms, nursing personnel, and supplies) when treating hospital patients does not constitute remuneration under the physician self-referral law, 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 emphasize that this statement reflects our interpretation of the term ''remuneration'' and policy on the issue.

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 the 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 the 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 the 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 the 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 proposed 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 the 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 (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 the 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, we proposed to 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.

The following is a summary of the comments we received.

Comment: One commenter disliked the proposed revisions to the ''stand in the shoes'' regulations at § 411.354(c)(3)(i), stating that, prior to

the revision, a physician who did not stand in the shoes of his or her physician organization was not a ''party'' to any compensation arrangement between the physician organization and a DHS entity. The commenter recognized that such a physician's referrals had to be considered when determining the compliance of the compensation arrangement with the volume or value standard in various exceptions, but did not agree that the identifier ''party'' should be applied to a physician who does not stand in the shoes of his or her physician organization. Another commenter was concerned that this revision would create direct compensation arrangements between a DHS entity and the physician employees of a physician organization who do not stand in the shoes of the physician organization under the current regulations.

Response: We disagree that the revised regulation at § 411.354(c)(3)(i) will have the effect of transforming physicians who do not stand in the shoes of their physician organizations into ''parties'' to a compensation arrangement between a DHS entity and the physician organization. In many exceptions, the volume or value standard (described in detail elsewhere in this section) is expressed by prohibiting compensation that is determined in a manner that takes into account the volume or value of referrals or other business generated ''between the parties.'' Most exceptions also include a requirement that the writing evidencing the arrangement be signed by the ''parties.'' In interpreting the physician self-referral exceptions, we attach the same meaning to a term or phrase wherever it is used, unless otherwise specified explicitly in the regulation text. To do otherwise would introduce confusion into the regulations, as a single term or phrase could have different meanings in different exceptions, or even in the same exception if the term or phrase is used more than once. Therefore, if a physician is considered a ''party'' for the purposes of the volume or value standard, he or she would be considered a ''party'' for the purposes of the signature requirement.

As the commenter correctly recognized, the referrals of all physicians in a physician organization—regardless of whether the physicians stand in the shoes of the physician organization—must be considered when determining compliance with the volume or value standard in the exceptions at § 411.355 and § 411.357. Thus, the physicians who do not stand in the shoes of the physician organization would nonetheless be considered ''parties'' for the purposes of analyzing compliance with the volume or value standard. Given our uniform interpretation of terms and phrases used in the physician self-referral regulations, under our current regulations, even physicians who do not stand in the shoes of their physician organizations may be required to meet the signature requirements for ''parties.'' We do not believe there is a need to include these physicians as ''parties'' that must sign the writing evidencing the arrangement between a DHS entity and a physician organization. The revision to § 411.354(c)(3)(i) is merely intended to alleviate the burden on physician organizations related to the signature requirements in many of the exceptions at § 411.355 and § 411.357 that would otherwise require the signatures of physicians who do not stand in the shoes of their physician organizations. It does not affect the regulations at § 411.354(c)(1)(ii) or (c)(2)(iv), which identify physicians who are deemed to stand in the shoes of their physician organizations and have the same compensation arrangements as their physician organizations. Moreover, we note that our determination of which physicians are ''parties'' for the purposes of applying the exceptions at § 411.355 and § 411.357 should not affect which physicians and entities are considered parties to a contract under State or any other law.

Comment: One commenter requested additional clarification regarding our statements in the proposed rule regarding the ''stand in the shoes'' provisions at § 411.354(c)(3)(i). Specifically, the commenter was concerned that the language in the proposed rule could be construed as conflating what it understands to be two separate analyses: (1) The analysis of a direct compensation arrangement between a DHS entity (and the resulting ''deemed'' direct compensation arrangements between the DHS entity and the physicians who stand in the shoes of the physician organization); and (2) the potential existence of an indirect compensation arrangement between the DHS entity and non-owner physicians of the physician organization (employees, independent contractors, and titular owners). As to the second analysis, the commenter recognized that the question of whether aggregate compensation to a non-owner physician (that is, one who does not stand in the shoes of the physician organization) varies with or takes into account the volume or value of referrals or other business generated for the DHS entity must be considered for the purposes of identifying any indirect compensation arrangements, but questioned why ''downstream compensation'' to non-owner physicians would factor into analyzing the direct compensation arrangement between the DHS entity and the physician organization (and the ''deemed'' direct compensation arrangements between the DHS entity and the physicians who stand in the shoes of the physician organization).

Response: Current § 411.354(c)(3)(i) states 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. Further, when applying the exceptions at § 411.355 and § 411.357 to arrangements where a physician stands in the shoes of his or her physician organization, § 411.354(c)(3)(i) states that the relevant referrals and other business generated ''between the parties'' are referrals and other business generated between the DHS entity and the physician organization, including all members, employees, and independent contractor physicians. In the first analysis noted by the commenter, the parties must consider whether the compensation under the arrangement between the DHS entity and the physician organization takes into account the volume or value of referrals or other business generated by any physician in the physician organization, regardless of whether the physician stands in the shoes of the physician organization. Because a physician who stands in the shoes of his or her physician organization has the same compensation arrangements as the physician organization, the result of this analysis would be the same for any ''deemed'' direct compensation arrangement between the DHS entity and a physician who stands in the shoes of the physician organization. Where no direct or ''deemed'' direct compensation arrangement exists between a physician and a DHS entity, parties should consider whether an indirect compensation arrangement exists under § 411.354(c)(2). Nothing in revised § 411.354(c)(3)(i) impacts the analysis regarding whether an indirect compensation arrangement exists between a physician and a DHS entity.

We are uncertain what ''downstream compensation'' the commenter believes is factored into the analysis of the direct compensation between a DHS entity and the physician organization with which it has a compensation arrangement. As noted earlier, compensation between a

DHS entity and a physician organization may not be determined in a manner that takes into account the volume or value of *referrals and other business generated* by any physician in the physician organization, including physicians who do not stand in the shoes of the physician organization. The *compensation from the physician organization to its employed or contracted physicians* is relevant to whether an indirect compensation arrangement exists between the DHS entity and a physician.

Comment: One commenter opposed the proposed revisions to the ''stand in the shoes'' rules at § 411.354(c)(3)(i), stating that the effect of considering all referrals from a physician organization when determining whether the compensation under a particular compensation arrangement takes into account the volume or value of referrals between the parties would be to convert presently lawful transactions into a violation of the physician self-referral law.

Response: The ''stand in the shoes'' regulations, including § 411.357(c)(3)(i) specifically, were established in Phase III and became effective on December 4, 2007 (72 FR 51028). Our Phase III policy considered all physicians in a physician organization to stand in the shoes of the physician organization, and § 411.354(c)(3)(i) originally stated that for the purposes of 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 the entity furnishing DHS and the physician organization (including all members, employees, or independent contractor physicians). Both the policy and § 411.354(c)(3)(i) were amended in the FY 2009 IPPS final rule and became effective on October 1, 2008. The regulation currently states that when applying the exceptions in § 411.355 and § 411.357 of this part 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). Thus, at all times, the regulation at § 411.354(c)(3)(i) has required parties to consider the referrals of all physicians in a physician organization—regardless of whether they stand in the shoes of the physician organization—when analyzing whether the compensation under a particular compensation arrangement takes into account the volume or value of referrals or other business generated ''between the parties.'' We do not believe that, under any iteration of § 411.354(c)(3)(i) or the regulation finalized in this final rule, an arrangement between a DHS entity and a physician organization could comply with the volume or value standard in an applicable exception if the compensation under the arrangement is determined in a manner that takes into account the volume or value of referrals or other business generated by the physicians who do not stand in the shoes of the physician organization.

As a result of the comments, we are finalizing our proposed revisions to the ''stand in the shoes'' regulations at § 411.354(c)(3)(i).

c. Locum Tenens Physician (§ 411.351)

The term ''*locum tenens* physician'' was first defined for the purposes of the physician self-referral law in Phase I (66 FR 954). The definition of ''*locum tenens* physician'' adopted in Phase I used the phrase ''stand in the shoes.'' (See 80 FR 41919 through 41920.) 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'' provisions are specific to compensation arrangements and described in our regulations at § 411.354(c).

We proposed 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 at § 411.354(c) are specific to compensation arrangements and are separate and distinct from the definition of a *locum tenens* physician. However, to eliminate unnecessary verbiage and to avoid any potential ambiguity, we proposed to revise the definition of *locum tenens* physician at § 411.351 by removing the phrase ''stands in the shoes.''

We received no comments opposing our proposal to revise the definition of *locum tenens* at § 411.351 by removing the phrase ''stands in the shoes,'' and we are finalizing the revisions to § 411.351 as proposed.

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. The exception applies to several categories of securities, including securities that are traded under the automated interdealer quotation system operated by the National Association of Securities Dealers (NASD). This exception is codified in our regulations at § 411.356(a), which closely mirrors section 1877(c) of the Act.

Through a question posed to us by a stakeholder, 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 researched 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. (See 80 FR 41920 for a summary of our research).

We proposed 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 did not propose 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 solicited comments 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.

We received no comments on our proposal to update the provision at § 411.356(a)(1) to except ownership or investment interest in securities listed for trading on an electronic stock market or over-the-counter quotation system, provided that quotations are published on a daily basis and trades are standardized and publicly transparent. We are finalizing the revisions to § 411.356(a) as proposed.

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 areas, 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 (l), the exceptions for payments by a physician and fair market value compensation, respectively. We note that the commenter specifically described lease arrangements where the lessee had exclusive, but only periodic, use of the premises, equipment, and personnel. In response, we declined to permit office space lease arrangements 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 office 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 another person or entity'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 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 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.

In general, a license—or permission—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, giving the lessee an exclusive ''right against the world'' (including a right against the lessor) with respect to the leased property, but a license is a mere privilege to act on another's property and does not confer a possessory interest in the property. A license may be granted in writing or orally, and ordinarily does not convey an exclusive right. For a license to convey the right

to exclusive use, it must be specified in the writing that documents the license. As with a license, a ''timeshare'' arrangement, as we use the term in this final rule, does not transfer dominion and control over the premises, equipment, personnel, items, supplies, and services of their owner, but rather confers a privilege to use (during specified periods of time) the premises, equipment, personnel, items, supplies, and services that are the subject of the arrangement.

c. New Exception

Under our current regulations, an arrangement that includes the use of office space, as timeshare arrangements commonly do, must be analyzed under the exception for the rental of office space. The exceptions for payments by a physician and fair market value compensation arrangements 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 permit the use of office space, equipment, personnel, items, supplies, or services 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 health care services (especially in rural and underserved areas), we proposed a new exception at § 411.357(y) that would have applied to 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 E/M 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 E/M services, (ii) is used only to furnish DHS that is incidental to the physician's E/M services and furnished at the time of such E/M 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 have applied 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 solicited comments 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 also solicited comments on whether the exception should be limited to arrangements in rural and underserved areas.

We proposed to protect only those timeshare arrangements under which the physician uses the licensed premises, equipment, personnel, items, supplies, and services predominantly for the E/M 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 solicited comments 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 proposed 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 E/M visit and furnished contemporaneously with that visit. We noted that such a requirement would not affect the manner in which the DHS is billed (for example, ''incident to'' a physician's service or directly by an NPP). Because we believe that DHS that is ''incidental to'' the patient's E/M 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, we proposed 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 proposed to require that the equipment be located on the licensed premises; that is, in the office suite. We solicited comments on these requirements and limitations. Specifically we solicited 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 proposed to prohibit certain per unit-of-service and percentage compensation methodologies for determining the license fees under timeshare arrangements. Under the exception as proposed, parties could 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 solicited 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 solicited comments on the proposed new exception for timeshare arrangements and any additional criteria that may be necessary to safeguard against program or patient abuse.

We are finalizing an exception at § 411.357(y) for timeshare arrangements with several modifications to our proposal. Importantly, the exception as

finalized is not available for arrangements that transfer control—that is, a ''right against the world''—over the premises that are the subject of the arrangement. Rather, the exception protects only those arrangements that grant a right or permission to use the premises, equipment, personnel, items, supplies, or services of another person or entity without establishing a possessory leasehold interest (akin to a lease) in the medical office space that constitutes the premises. However, because the public comments addressed the proposal to establish an exception for remuneration provided by a licensee to a licensor under an arrangement for the use of the licensor's premises, equipment, personnel, items, services, or supplies, the comment summaries below reflect the use of ''licensor'' and ''licensee'' terminology. This does not affect final § 411.357(y), which is an exception for ''remuneration provided under an arrangement for the use of premises, equipment, personnel, items, supplies, or services,'' and does not use the terms ''license,'' ''licensee,'' or ''licensor.'' In our responses to the public comments, we refer to the party granting a right or permission to use its premises, equipment, personnel, items, supplies, or services variously as the ''grantor'' or ''party granting permission.''

The following is a summary of the comments we received.

Comment: Citing a variety of reasons, the majority of commenters supported the establishment of an exception for timeshare arrangements. Many commenters stated that the exception for timeshare arrangements will promote important policy goals. One commenter commended CMS for recognizing the need for arrangements that support specialists who would like to provide services in rural areas that cannot maintain a full-time specialist. Another commenter expressed a belief that the exception will help to provide E/M services that may be needed on only a periodic basis to assist a physician in diagnosing or treating his or her patients. A third commenter stated that the exception will facilitate patient convenience and coordination and continuity of care. Two commenters that supported the establishment of the exception described how current arrangements for the limited use of space and equipment must be structured to fit within some combination of the existing exceptions for the rental of office space, rental of equipment, personal service arrangements, and fair market value compensation, which creates scheduling and other operational difficulties. One of these commenters identified certain requirements of these exceptions that reduce flexibility and potentially inhibit patient access, such as the ''exclusive use'' requirement in the exceptions for the rental of office space and the rental of equipment. In the commenters' view, the new exception for timeshare arrangement offers the promise of simplicity and will allow for much greater functionality and creativity in arrangements for patient services. However, one of these commenters proclaimed the proposed exception too narrow.

Response: After careful consideration of the comments we received in response to the proposed exception, and for the reasons discussed in the proposed rule (80 FR 41921–22), we continue to believe that timeshare arrangements may serve to ensure adequate access to needed health care services. We are finalizing the exception for timeshare arrangements at § 411.357(y) with the following modifications: (1) Regardless of which party grants and which party receives permission to use the premises, equipment, personnel, items, supplies, and services of the other party, a timeshare arrangement must be between a physician (or the physician organization in whose shoes the physician stands under § 411.354(c)) and: (i) A hospital or (ii) a physician organization of which the physician is not an owner, employee, or contractor; (2) equipment included under the timeshare arrangement may be in the same building (as defined at § 411.351) as the office suite where E/M services are furnished; and (3) all locations under the timeshare arrangement, including the premises where E/M services are furnished and the premises where DHS are furnished, must be used on identical schedules. In addition, the exception as finalized protects only those arrangements that grant a right or permission to use the premises, equipment, personnel, items, supplies, or services of another person or entity without establishing a possessory leasehold interest (akin to a lease) in the medical office space that constitutes the premises. We believe that the other safeguards in the exception finalized here are necessary at this time to protect against program or patient abuse. In order not to inhibit flexibility for parties to arrangements involving office space, equipment, personnel, items, supplies or services, the existing exceptions to the physician self-referral law remain available to parties that wish to structure their arrangements in a way that satisfies all of the requirements of the applicable exception(s).

Comment: One commenter stated that its clients ''successfully and without any type of abuse long utilized 'Time Share Agreements' with a physician organization either as the landlord (licensor) or as a tenant (licensee)'' prior to the publication of Phase III. The commenter described a timeshare arrangement as one under which a physician is ''embedded'' in another party's medical practice with permission to use the space, equipment and personnel of the practice for a fair market payment. The commenter depicted the Phase III commentary as prohibiting such arrangements unless they can be arranged so that the embedded physician has the exclusive use of patient care areas and equipment of the practice into which the physician is embedded. Based on its reading of the Phase III commentary, the commenter welcomed the proposed exception for timeshare arrangements, declaring that the new exception is warranted because the types of arrangements it would cover are different from the lease arrangements described at § 411.357(a) and (b).

Response: The Phase III remarks referenced by this commenter related to an arrangement described to CMS in response to the Phase II rulemaking as including the exclusive—but only periodic—use of office space, personnel, waiting areas, furnishings, and equipment. Based on our prior guidance, we declined to permit office space leases to be eligible for the exceptions for fair market value compensation at § 411.357(l) and payments by a physician at § 411.357(i) (72 FR 51044 through 51045). Our position regarding the availability of the exceptions for fair market value compensation at § 411.357(l) and payments by a physician at § 411.357(i) for arrangements involving the rental of offices space has not changed.

As we described in the proposed rule, we believe that timeshare arrangements may improve access to needed care, especially in rural and underserved areas, by facilitating part-time or periodic access to physicians in communities where the need for the physician is not great enough to support the full-time services of the physician or where physicians, for various legitimate reasons, do not require or are not interested in a traditional office space lease arrangement (80 FR 41921). The new exception at § 411.357(y) is intended to promote access to needed services and provide parties with an option for structuring arrangements in the way that best suits the needs of the parties and the community in which the timeshare arrangement is located.

We note that we do not agree with the commenter's description of a timeshare arrangement as one in which a physician is embedded in another party's medical practice with permission to use the space, equipment, and personnel of the practice for a fair market payment. Although such an arrangement may qualify as a timeshare arrangement under the new exception depending on the facts and circumstances, we do not intend to limit the types of arrangements that may qualify as timeshare arrangements to those in which a physician is located within another physician's practice.

Comment: A commenter expressed concern that the use of the terms ''licensor'' and ''licensee'' could prohibit use of the exception for otherwise qualifying arrangements that, through a quirk of State law or the arrangement, are something other than a ''license'' under State law. Another commenter feared that compliance with the physician self-referral law could turn on considerations such as how an arrangement might be classified under landlord/tenant law or technical ''lease'' versus ''license'' considerations.

Response: Nothing in § 411.357(y) is meant to impact parties' rights and obligations as construed under State law. The exception is intended to address the challenge of satisfying the requirements of an available exception to the physician self-referral law in the case of arrangements that merely permit the use of office space without conveying a possessory leasehold interest in the premises or a ''right against the world'' with respect to the office space that is the subject of the arrangement.

We used the term ''license'' in the proposed exception at § 411.357(y) to describe the type of arrangement that could qualify for the exception. Generally, a license grants permission to do something which, without the license, would not be allowable. *See Barnett v. Lincoln*, 162 Wash. 613, 299 P. 392, 394. It is merely a personal privilege or permissive use of the licensor's premises, equipment, personnel, items, supplies, or services. We contrast this with a ''tenancy'' or ''possessory leasehold interest'' which implies some interest in the office space leased. *See Klein v. City of Portland*, 106 Or. 686, 213 P. 147, 150; Vicker v. Byrne, 155 Wis. 281, 143 N.W. 186, 188. One fundamental way that a license differs from a lease is that ownership and control of the property remains with the licensor.

Upon further reflection and after careful consideration of the issues raised by the commenters, we agree that the use of the term ''license'' without a definition that is specific to the exception at § 411.357(y) could introduce unnecessary confusion into the regulations and potentially exclude non-abusive arrangements that we believe should qualify for the exception. The terminology used by the parties in the documentation that describes and supports the timeshare arrangement should not control whether the parties can satisfy the requirements of the exception. Whether the arrangement is styled as a ''license'' or otherwise is not dispositive when determining compliance with new § 411.357(y). Rather, the facts and circumstances of the arrangement are critical to its compliance with the requirements of the exception. Therefore, we are not finalizing § 411.357(y) to include the terms ''license,'' ''licensor,'' or ''licensee.'' As finalized, § 411.357(y) includes a set of requirements for arrangements that we consider to be ''timeshare'' arrangements that do not violate the physician self-referral law's referral and billing prohibitions.

Parties wishing to avail themselves of the exception at § 411.357(y) need not utilize any particular terminology, provided that the arrangement itself grants one party the permission to use the premises, equipment, personnel, items, supplies, or services of the other party to the arrangement. Moreover, the arrangement may qualify for protection under the final exception even if the grant of permission to use the premises, equipment, personnel, items, supplies, or services provides for exclusive use of the premises, equipment, personnel, items, supplies, or services or has a duration of 1 year of more. However, the timeshare arrangement may not convey a possessory leasehold interest in the office space that is the subject of the arrangement. Where control over office space is conferred on a party such as to give that party a ''right against the world'' (including a right against the owner or sub-lessor of the office space), the arrangement must qualify for the exception for the rental of office space at § 411.357(a) in order not to run afoul of the physician self-referral law.

Again, what is imperative for compliance with the physician self-referral law when relying on the exception at § 411.357(y) is that the timeshare arrangement grant to one party the permission to use the premises, equipment, personnel, items, supplies, or services of the other party without conveying a possessory leasehold interest in the office space that is the subject of the arrangement. Of course, the arrangement must also satisfy the other requirements of the exception for timeshare arrangements as finalized at § 411.357(y) in this final rule. And, regardless of the structure of the arrangement or the terminology used by the parties, we do not intend to protect potentially abusive arrangements such as exclusive-use timeshare arrangements that essentially function as full-time leases for medical practice sites; arrangements in which physicians are selected or given preferred time slots based on their referrals to the party granting permission to use the premises, equipment, personnel, items, supplies, or services; or consecutive short-term arrangements that are modified frequently in ways that take into account a physician's referrals.

Comment: One commenter requested clarification that a medical foundation model physician practice would be a permitted licensee under a timeshare arrangement protected by the new exception.

Response: A medical foundation model physician practice may utilize the new exception at § 411.357(y). Because we are not dictating the roles of the parties to a timeshare arrangement, a medical foundation model physician practice may qualify as the party granting permission to use its premises, equipment, personnel, items, supplies, or services, or as the party to whom the permission is granted.

Comment: Many commenters, although supportive of an exception to protect timeshare arrangements, urged CMS not to limit the application of the exception for timeshare arrangements to rural or underserved areas. One of the commenters noted that non-rural areas and areas not determined to be underserved may nonetheless experience a practical shortage in certain specialties. Two of the commenters indicated that the exception for timeshare arrangements will address a longstanding problem that not all physicians are interested in committing to rent or accepting ownership or control over the premises, equipment, personnel, and supplies of a DHS entity. One of these commenters also stated that, although the exception would add much needed flexibility, especially for areas where there are shortages of physicians (and, in particular, specialists), patients in all areas would benefit from these arrangements. This commenter stated its belief that the risk of program abuse would be minimal given the proposed safeguards, which should adequately address any fraud and abuse concerns.

Response: We agree with the commenters. We did not propose to limit the exception to timeshare

arrangements in rural or underserved areas, and are not including such a limitation in the exception at § 411.357(y) finalized here.

Comment: A commenter took issue with our statement in the preamble to the proposed rule indicating that timeshare arrangements structured as licenses ''cannot satisfy the requirements of [the exception for the rental of office space] because a license generally does not provide for exclusive use of the premises.'' The commenter expressed concern that this statement could call into question many existing arrangements that are styled as licenses yet satisfy the requirements of the exception at § 411.357(a), including the ''exclusive use'' requirement. Another commenter recommended that CMS not finalize the proposed exception for timeshare arrangements, stating that it is not necessary because timeshare leases or ''licenses'' fit within the existing exceptions. Both of the commenters were concerned that the establishment of a new exception could cast doubt whether longstanding arrangements have been in compliance with the physician self-referral law. These commenters and a third commenter recommended that we clarify that license arrangements may satisfy the requirements of the exception for the rental of office space, depending on the facts and circumstances of the arrangement.

Response: The establishment of the new exception for timeshare arrangements at § 411.357(y) is not intended to call into question the compliance of any prior or existing arrangement or type of arrangement involving the use of office space, equipment, personnel, items, supplies, or services. Our questioning in the proposed rule of whether an arrangement (as it relates to office space) can satisfy the requirements of the exception at § 411.357(a) pertained only to those arrangements that involve the use of office space on a non-exclusive basis or for a term of less than 1 year. Although we stated our belief that a license generally does not provide for exclusive use of the premises (80 FR 41921), we did not rule out the possibility that it may.

A financial relationship between a physician (or immediate family member of the physician) and a DHS entity must satisfy the requirements of an applicable exception to the physician self-referral law to avoid the law's billing and referral prohibitions. Where more than one exception is available to protect a financial relationship, we do not dictate which exception the parties must use. The exception for timeshare arrangements finalized at § 411.357(y) establishes another—not a replacement—exception for parties to a timeshare arrangement. If a timeshare arrangement includes the exclusive use of office space but does not convey a possessory leasehold interest in the office space that is the subject of the arrangement, the new exception at § 411.357(y) is available to protect the arrangement (provided that all other requirements of the exception are satisfied). Depending on the facts and circumstances of the arrangement, it may also qualify for the exception at § 411.357(a). In short, the parties to a timeshare arrangement may elect to use any available exception(s) to protect the arrangement. However, where control over office space is conferred on a party such as to give that party a ''right against the world'' (including a right against the owner or sub-lessor of the office space), the arrangement must qualify for the exception for the rental of office space at § 411.357(a) in order not to run afoul of the physician self-referral law.

Comment: A commenter requested that we eliminate the proposed restriction on the hospital (or other DHS entity) being the licensee in a timeshare arrangement. The commenter described a scenario where the purpose of the timeshare arrangement is to embed a hospital-employed physician in an independent physician practice, which the commenter maintained is a convenient practice setting for Medicare beneficiaries. The commenter requested that we modify the exception at § 411.357(y) to accommodate timeshare arrangements in which the physician (or a physician organization) is the licensor and the DHS entity is the licensee. A few commenters believed that the proposed requirement that the licensor be a hospital or a physician organization is overly limiting. Two of these commenters noted that hospitals often employ physicians and may require timeshare arrangements that include space in a physician or physician organization's clinic. These commenters requested that we permit hospitals or other entities that employ physicians to be the licensee and still qualify for the protection of the exception. One of the commenters also requested that we permit physician organizations, rather than physicians, to be the licensee under a protected timeshare arrangement. This commenter stated that it is more common for a physician organization or professional corporation to enter into a timeshare arrangement than an individual physician in his or her personal capacity. Another of the commenters noted that many hospitals have affiliates (such as real estate subsidiaries and management service organizations) that act as the licensor in timeshare arrangements. The commenter recommended that hospital affiliates be included as permissible licensors under the exception.

Response: After consideration of the commenters' suggestions, we believe that it would not pose a risk of program or patient abuse to permit timeshare arrangements under which the hospital or physician organization is the party using the premises, equipment, personnel, items, supplies, or services of a physician (or the physician organization in whose shoes the physician stands under § 411.354(c)), provided that the arrangement satisfies all other requirements of the exception. We do not believe, nor did any commenters suggest, that it is necessary to permit other types of DHS entities, such as independent diagnostic testing facilities or laboratories, to be parties to timeshare arrangements to address the potential barriers to access to care described in the proposed rule. As we stated in the proposed rule, we believe that timeshare arrangements offered by independent diagnostic testing facilities or laboratories may serve to lock in referral streams from a physician licensee as a result of the physician's proximity to the DHS furnished by such entities (80 FR 41922). The exception finalized at § 411.357(y) only covers timeshare arrangements under which the DHS entity that is a party to the arrangement is a hospital or physician organization.

As to the request that we permit a physician organization, rather than a physician in his or her personal capacity, to enter into a timeshare arrangement, we refer readers to the discussion in the proposed rule regarding the analysis of arrangements between DHS entities and physician organizations where physicians may stand in the shoes of the physician organizations (80 FR 41911). There, we explained that, 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 exception at § 411.357(y) would be

available to protect a direct compensation arrangement between a physician and a hospital or physician organization of which the physician is not an owner, employee, or contractor, as well as ''deemed'' direct compensation arrangements between a physician standing in the shoes of his or physician organization and a hospital or physician organization of which the physician is not an owner, employee, or contractor. 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 to determine whether an indirect compensation arrangement exists. To protect an indirect compensation arrangement that exists as a result of remuneration provided by the entity furnishing DHS, the arrangement must satisfy the requirements of the exception at § 411.357(p) for indirect compensation arrangements.

Timeshare arrangements between physicians and organizations, such as real estate subsidiaries and management service organizations, that are not themselves DHS entities should be analyzed under the rules regarding indirect compensation arrangements at § 411.354(c). To protect an indirect compensation arrangement that exists as a result of a chain of financial relationships that runs hospital or physician organization—affiliate—physician, the arrangement must satisfy the requirements of the exception at § 411.357(p) for indirect compensation arrangements.

Comment: One commenter urged CMS to finalize a bright-line standard that includes a precise percentage for the minimum amount of E/M services furnished under a timeshare arrangement. The commenter noted that, depending on the volume and types of services furnished, ''predominant'' could be more or less than 50 percent. Another commenter recommended that we define ''predominant use'' to require that more than 50 percent of patients receive E/M services in the timeshare office space.

Response: We decline to adopt either commenter's suggestion. We attribute the common meaning to the term ''predominant'' and an attempt to define this standard further could inadvertently narrow the exception or constrain parties to a timeshare arrangement. We are not prescribing how parties determine compliance with § 411.357(y)(3). Parties may determine predominant use through any reasonable, objective, and verifiable means, which, depending on the circumstances, may include assessing the volume of patients seen, the number of patient encounters, the types of CPT codes billed, or the amount of time spent using the timeshare premises, equipment, personnel, items, supplies, and services. Further, we note that this standard is used in the exception at § 411.357(w) for nonmonetary remuneration (consisting of items and services in the form of software or information technology and training services) that are necessary and used predominantly to create, maintain, transmit, or receive electronic health records, and we are not aware of any difficulty on the part of physicians and entities involved in such arrangements. We remind readers that the use of office space by the physician *solely* or *primarily* to furnish DHS to patients would not be protected by the new exception at § 411.357(y).

Comment: One commenter objected to limiting the DHS furnished on the equipment covered by the timeshare arrangement to DHS that is incidental to the E/M services furnished by the physician at the time of the patient's visit. This commenter gave the example of a cardiologist ordering a test during a patient visit that is to be performed the following week when the ordering cardiologist is elsewhere and another cardiologist from the same physician practice is on the timeshare premises to supervise the test and read the results.

Response: We do not disagree with the commenter that there may be circumstances where a patient would benefit from receiving DHS but does not need an E/M service at the time of the furnishing of the DHS. However, a timeshare arrangement shifts to the party granted the use of the premises, equipment, personnel, items, supplies, or services only minimal financial risk related to the resources used to furnish DHS, and we cannot be certain that a timeshare arrangement would pose no risk of program or patient abuse without a limitation on the amount or scope of the DHS furnished using the timeshare equipment or in the timeshare premises. As we discussed in the proposed rule, our purpose in establishing the exception at § 411.357(y) is to improve access to care and outcomes for our beneficiaries. It is not to facilitate the ability of physicians to furnish a full array of DHS in supplemental medical practice sites. Therefore, we are retaining in the final exception a requirement that the timeshare equipment is not used to furnish DHS other than DHS that are incidental to the patient's E/M visit and furnished contemporaneously with that visit. In light of our determination to permit hospitals and physician organizations to either grant or receive permission to use premises, equipment, personnel, items, supplies, or services under the exception, we are modifying the regulation text slightly to clarify that the DHS furnished using equipment covered by the arrangement must be both: (1) Incidental to the E/M service furnished by the physician using the equipment; and (2) furnished at the time of the E/M service to which it is incidental. We note that the requirement that the DHS be ''incidental'' to E/M services is unrelated to and does not affect the ''incident to'' billing rules elsewhere in our regulations (80 FR 41922).

Comment: Two commenters opposed the exclusion of certain DHS, such as advanced imaging, radiation therapy, and laboratory equipment, from the scope of the exception. One of these commenters stated that limiting the equipment permissible under the exception would hamper patient access to care and immediate diagnosis. This commenter stated that any DHS furnished under a timeshare arrangement would need to satisfy the requirements of the in-office ancillary services exception and stated that safeguards to address potential risks of program or patient abuse from the use of such equipment are already built into that exception. The other of these commenters offered that, provided that fair market value is paid, a licensee physician should be able to use available advanced imaging, radiation therapy, laboratory, or other equipment.

In contrast, two commenters supported our proposal to limit the scope of the exception for timeshare arrangements to those arrangements that do not include the use of radiation therapy equipment, and another supported our proposal to prohibit the use of advanced imaging equipment. A different commenter urged us to prohibit the furnishing of physical therapy services on the premises protected by the new exception.

Response: We decline to remove from the exception finalized at § 411.357(y) the requirement that the equipment covered by the timeshare arrangement is not advanced imaging equipment, radiation therapy equipment, or clinical or pathology laboratory equipment (other than equipment used to perform CLIA-waived laboratory tests). As discussed in the preamble to the proposed rule and elsewhere in this section, the purpose of the exception for timeshare arrangements is to improve access to care and outcomes for our

beneficiaries. In the case of radiation therapy equipment, we do not believe that it is necessary to include the use of such equipment under the exception to improve access to care. Radiation therapy equipment generally is not portable. Thus, any radiation therapy equipment that could be included in a timeshare arrangement would already be available to patients in the community. Including it in a timeshare arrangement would merely permit a physician to bill for the services that are already available to his or her patients from the hospital or physician organization granting the physician permission to use the equipment. As to advanced imaging equipment and laboratory equipment, we are not convinced and the commenter provided no proof that excluding such equipment from the scope of a protected timeshare arrangement would hamper access to care or delay a patient's diagnosis.

We also disagree with the first commenter's statement that DHS furnished under a timeshare arrangement would need to satisfy the requirements of the in-office ancillary services exception and, therefore, the safeguards built into that exception are sufficient to address any risk of program and patient abuse. Other exceptions, such as the exceptions for *bona fide* employment at § 411.357(c) and personal service arrangements at § 411.357(d), may be available to protect referrals from the physicians in a group practice to the group. Further, not every physician organization that would bill for services furnished using premises and equipment under a timeshare arrangement will qualify as a ''group practice'' and have access to the in-office ancillary services exception.

We do not believe that it is necessary at this time to prohibit additional types of equipment under a timeshare arrangement, including equipment that is used to furnish physical therapy services. As discussed in the response to a previous comment, we are finalizing the requirement that the equipment covered by a timeshare arrangement is not used to furnish DHS other than those incidental to the patient's E/M visit and furnished contemporaneously with that visit. To be protected under the exception, physical therapy services furnished using timeshare equipment must be incidental to the patient's E/M services and furnished at the time of the evaluation and management service to which they are incidental. We question whether it would be medically necessary for a patient to receive an E/M service at the time of each physical therapy visit. Moreover, we doubt that a physician furnishes an E/M service prior to each physical therapy session, which would be necessary to satisfy the requirement at final § 411.357(y)(4).

Finally, we note that parties may use the existing exceptions for the rental of office space at § 411.357(a) and the rental of equipment at § 411.357(b), which include different safeguards against program and patient abuse, if they wish to include advanced imaging equipment, radiation therapy equipment, or clinical or pathology laboratory equipment (other than equipment used to perform CLIA-waived laboratory tests) in their arrangements.

Comment: Several commenters requested that we not require that equipment be located in the office suite where E/M services are furnished, suggesting that such a requirement could limit access to needed care, as an office suite may not adequately accommodate the equipment necessary to furnish DHS. One of these commenters noted that permitting the use of equipment in the ''same building'' where the E/M services are furnished is consistent with the requirements of the in-office ancillary services exception. This commenter suggested that, as an additional safeguard, where there are two licensed locations (for example, an office suite with E/M services and a room in the same building with equipment and DHS), CMS could require that the two locations be included in a single arrangement and used on identical schedules.

Response: We do not wish to impose restrictions that hinder the usefulness of the exception for ensuring access to needed care, but we must include requirements sufficient to guard against program or patient abuse when utilizing the Secretary's authority under section 1877(b)(4) of the Act. We agree that the usefulness of the exception for timeshare arrangements would be enhanced if we do not limit the location of the equipment to the office suite where E/M services are furnished to the patient. Accordingly, we are revising the requirement regarding the location of the equipment covered by the timeshare arrangement to require instead that the equipment is located in the same building as the office suite where the E/M services are furnished to the patient. To offset any potential increased risk of program or patient abuse due to this expansion of the exception, we are adopting the commenter's suggestion to include in the exception a requirement that all locations under the timeshare arrangement, including the premises where E/M services are furnished and the premises where DHS are furnished, must be used on identical schedules. A requirement that the use of the premises where E/M services are furnished and the use of the premises where DHS are furnished must be included in a single arrangement would be superfluous because the exception would not protect premises used solely or predominantly for the furnishing of DHS. An arrangement to use premises, equipment, personnel, items, supplies, or services for the furnishing of DHS would satisfy the requirements of the new exception for timeshare arrangements only if the arrangement also includes permission to use the premises, equipment, personnel, items, supplies, or services predominantly for the furnishing of E/M services.

Comment: Three commenters urged us not to limit compensation methodologies or prohibit per-unit of service compensation for timeshare arrangements, stating that, in light of the substantial protections of the other requirements of the exception, a limitation on compensation methodologies is unnecessary and burdensome. Another commenter sought clarification regarding whether the limitation on compensation formulas in the exception would effectively require block lease arrangements. The commenter stated that block lease arrangements are generally not conducive to either the licensor's or the licensee's delivery of services to their respective patients and recommended that we not require block lease arrangements.

Response: We are adopting our proposal to exclude from new § 411.357(y) any timeshare arrangements that incorporate compensation formulas based on: (1) a percentage of the revenue raised, earned, billed, collected, or otherwise attributable to the services provided while using the timeshare; or (2) per-unit of service fees, to the extent that such fees reflect services provided to patients referred by the party granting permission to use the timeshare to the party to which the permission is granted. We are using the authority at section 1877(b)(4) of the Act to establish this exception. Because that authority permits only those exceptions that present no risk of program or patient abuse, we are protecting under new § 411.357(y) only those timeshare arrangements that are based on other forms of compensation, such as those using flat-fee or time-based formulas. Timeshare arrangements that are based on percentage compensation or per-unit of service compensation formulas present a risk of program or patient abuse because they may incentivize

overutilization and patient steering. By way of example, we believe that a per-patient compensation formula could incentivize the timeshare grantor to refer patients (potentially for unnecessary consultations or services) to the party using the timeshare because the grantor will receive a payment each time the premises, equipment, personnel, items, supplies, or services are used. Similarly, a compensation formula that uses services as the unit of measure (for example, a per-CPT code compensation formula) could incentivize the timeshare grantor to refer sicker patients or patients with a likely need for DHS to the party using the timeshare, regardless of the preferences or best interests of the patients, because the grantor will receive a payment for each service furnished in the timeshare premises or using the timeshare equipment.

We recognize that many timeshare arrangements include compensation formulas that are set as a pre-determined amount for each hour, half-day or full-day spent using the premises, equipment, personnel, items, supplies, or services that are covered under the arrangement. We do not believe such compensation formulas raise the same risks as formulas that result in a payment to the party that provides the timeshare premises, equipment, personnel, items, supplies, or services each time that party refers a patient to the party using the timeshare. Under time-based compensation formulas, the ''usage'' fee is paid regardless of the number of patients referred by the timeshare grantor or the number of services furnished to such patients (or any other patients). We do not wish to call into question non-abusive timeshare arrangements with time-based compensation terms. Therefore, we are finalizing the requirement at § 411.357(y)(6)(ii) to require that compensation under a timeshare arrangement is not determined using a formula based on per-unit of service fees, and we expressly do not prohibit compensation using a formula that is time-based (for example, per-hour or per-day). We are not prescribing a minimum amount of time per unit for compensation that utilizes a time-based formula and we remind readers that a compensation formula based on per-unit of service ''usage'' fees is prohibited under the exception only to the extent that such fees reflect services furnished to patients referred by the party granting permission to use its premises, equipment, personnel, items, supplies, or services to the party that receives such permission.

Although not addressed by any commenter, we are also aware of the recent DC Circuit decision in *Council for Urological Interests v. Burwell*, 790 F.3d 212 (D.C. Cir. 2014), which addressed the prohibition on per-click leasing arrangements with respect to the rental-equipment exception found in § 411.357(b)(4)(ii)(B). We established this prohibition in the FY 2009 IPPS final rule using our authority under section 1877(e)(1)(B)(vi) of the Act, which requires an equipment lease to meet such other requirements as the Secretary may impose by regulation as needed to protect against program or patient abuse in order for that lease to qualify for the exception for the rental of equipment. In the same rule, we also discussed certain legislative history contained in a House Conference Report addressing sections 1877(e)(1)(A)(iv) and 1877(e)(1)(B)(iv) of the Act, which establish requirements that rental charges over the term of a lease for office space or rental equipment be set in advance, be consistent with fair market value, and not be determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties. With respect to those statutory conditions, the language in the House Conference Report stated that—

> The conferees intend that charges for space and equipment leases may be based on . . . time-based rates or rates based on units of service furnished, so long as the amount of time-based or units of service rates does not fluctuate during the contract period. (H.R. Rep. No. 103–213, at 814 (1993).)

We noted in the FY 2009 IPPS final rule that CMS had previously interpreted this legislative history as indicating a view that per-click leases do not run afoul of section 1877(e)(1)(B)(iv), but we then stated that this language could also be interpreted as suggesting the Congress's disapproval of per-click leases. We explained, though, that our prohibition on per-click leasing arrangements was ultimately based on our authority to promulgate ''other requirements'' under section 1877(e)(1)(B)(vi) of the Act, and not on an interpretation of section 1877(e)(1)(B)(iv) of the Act.

In the *Council for the Urological Interests* case, the Court agreed with CMS that it had the authority to prohibit per-click leasing arrangements under section 1877(e)(1)(B)(vi) of the Act. The Court concluded that—

> The text of the statute does not unambiguously preclude the Secretary from using her authority to add a requirement that bans per-click leases. (Council for Urological Interests, 790 F.3d at 219.)

The Court further concluded that the relevant language in the House Conference Report merely interpreted section 1877(e)(1)(B)(iv) of the Act, and thus did not preclude CMS from imposing additional requirements under section 1877(e)(1)(B)(vi) of the Act. See id. at 222 (explaining that the legislative history ''simply indicates that, as written, the rental-charge clause [in section 1877(e)(1)(B)(iv)] does not preclude per-click leases'' and ''[n]othing in the legislative history suggests a limit on [CMS's] authority'' to prohibit per-click leases under section 1877(e)(1)(B)(vi) of the Act).

The Court concluded, however, that CMS's revised interpretation of the House Conference Report was arbitrary and capricious, and it remanded the case to the agency to permit a fuller consideration of the legislative history. As previously noted, we are considering options as to how to comply with the court's ruling.

Nonetheless, our current decision to prohibit per-unit of service compensation formulas under § 411.357(y) is not affected by the Court's decision in *Council for Urological Interests.* As explained, the Court did not hold that the House Conference Report requires us to allow per-click arrangements; to the contrary, the Court upheld our authority to prohibit per-click arrangements where we determine that such a prohibition is necessary to protect against program or patient abuse. (See *Council for Urological Interests*, 790 F.3d at 219–22.) Thus, we possess the authority to exclude timeshare arrangements that use a compensation formula based on per-unit of service fees from the new exception at § 411.357(y), and we employ that authority here to ensure that the new exception will not pose a risk of program or patient abuse, as section 1877(b)(4) of the Act requires.

Comment: One commenter recommended that CMS allow the space that is used on a timeshare basis to be used as a provider-based department when it is not licensed to a physician. The commenter stated that this would allow hospitals to use its property and personnel more efficiently than currently allowed.

Response: The commenter's recommendation is outside the scope of this regulation.

Summary of the exception for timeshare arrangements as finalized at § 411.357(y)

After careful consideration of the comments we received in response to the proposed exception, we are

finalizing the exception for timeshare arrangements at § 411.357(y) with the following modifications: (1) regardless of which party grants and which party receives permission to use the premises, equipment, personnel, items, supplies, and services of the other party, a timeshare arrangement must be between a physician (or the physician organization in whose shoes the physician stands under § 411.354(c)) and: (i) a hospital or (ii) a physician organization of which the physician is not an owner, employee, or contractor; (2) equipment covered by the timeshare arrangement may be in the same building (as defined at § 411.351) as the office suite where E/M services are furnished; and (3) all locations under the timeshare arrangement, including the premises where E/M services are furnished and the premises where DHS are furnished, must be used on identical schedules. In addition, the exception as finalized protects only those arrangements that grant a right or permission to use the premises, equipment, personnel, items, supplies, or services of another person or entity without establishing a possessory leasehold interest (akin to a lease) in the medical office space that constitutes the premises.

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). In the proposed rule, we proposed 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 also proposed to revise § 411.353(g) to include reference to the new regulatory exceptions for payments to a physician to employ an NPP and timeshare arrangements that we proposed 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 for the same referring physician. Given these safeguards, we believe that the proposed revision poses no risk of program or patient abuse. We are finalizing our proposed revision to the special rule at § 411.353(g).

The following is a summary of the comments we received.

Comment: The vast majority of commenters on this issue supported our proposal to allow all parties up to 90 days to obtain required signatures, regardless of whether the failure to obtain the signatures was inadvertent or not inadvertent. Several commenters requested that we remove the provision at § 411.353(g)(2) that limits the use of the temporary noncompliance rule to once every 3 years for the same referring physician.

Response: We appreciate the commenters' support, and we are finalizing our proposal. However, we decline to remove the limitation on the use of the special rule to once every 3 years for the same physician. The signature requirement of certain compensation exceptions is statutory, and we believe that the requirement plays a role in preventing fraud and abuse. Among other things, the signature of the parties creates a record of the fact that the parties to an arrangement were aware of and assented to the key terms and conditions of the arrangement. Requiring parties to sign an arrangement encourages parties to monitor and review financial relationships between DHS entities and physicians. In contrast, permitting parties to make frequent use of the special rule for noncompliance with signature requirements would not incent parties to exercise diligence with our rules. (See 73 FR 48707). We believe that repeated use of the special rule (that is, use more than once in a 3-year period) for the same physician may pose a risk of program or patient abuse.

Comment: One commenter requested clarification that the temporary noncompliance provision can be used more than once every 3 years for different physicians within the same group practice. According to the commenter, a party should be permitted to use the temporary noncompliance provision for an arrangement with a group practice for the services of one physician without precluding the party from using the temporary noncompliance provision within 3 years for another arrangement with the same group practice involving the services of a different physician.

Response: The ''stand in the shoes'' provisions at § 411.354(c) determine whether a party may use the rule at § 411.353(g)(1) more than once in 3 years for physicians associated with a physician organization. Assume a physician organization consists of 2 non-titular owners (Drs. A and B), and that a DHS entity enters into a compensation arrangement with the physician organization for the services of Dr. A on January 1, 2014.

The compensation arrangement with the physician organization is deemed to be a compensation arrangement with Dr. A and a compensation arrangement with Dr. B. If the parties do not sign the arrangement until February 15, 2014, but the arrangement otherwise satisfies the requirements of § 411.353(g), the DHS entity may bill the program for DHS performed as a result of referrals by both Dr. A and Dr. B for the period from January 1, 2014 through February 14, 2014. That is to say that the special rule at § 411.353(g) affords the DHS entity protection for referrals from each of the physicians who stand in the shoes of the physician organization. For precisely this reason, however, if the DHS entity enters into a different arrangement with the physician organization on March 1, 2015 for Dr. B's services, and the parties do not sign the arrangement until May 1, 2015, the entity may not rely on the rule at § 411.353(g) for either Dr. A or Dr. B for the period of March 1, 2015 through April 30, 2015. The entity already made use of the special rule for Dr. A and Dr. B's referrals from January 1, 2014 through February 14, 2014. On the other hand, if the DHS entity entered into direct compensation

arrangements with Drs. A and B (that is, arrangements with the physicians as opposed to arrangements with the physician organization), then the DHS could use the rule at § 411.353(g) to protect referrals from Dr. A for the period from January 1, 2014 through February 14, 2014, and to protect referrals from Dr. B for the period from March 1, 2015 through April 30, 2015.

Comment: According to two commenters, a contract can be binding under State law even if it is missing the signature of one or more parties. The commenters urged CMS to adopt a similar rule for the physician self-referral law. Specifically, the commenters requested that CMS deem an arrangement to be signed, for the purposes of the physician self-referral law, even if one or more of the parties did not sign the arrangement, as long as the agreement is binding under State law. Another commenter asked CMS to establish that clear assent of the parties as to the terms of the arrangement is sufficient to satisfy the signature requirement.

Response: As noted elsewhere in this section, State contract law principles do not determine compliance with the physician self-referral law. The commenters' suggestion illustrates a problem with relying exclusively on State law principles, namely that the requirements for a contract to be enforceable under State law may differ substantively from the requirements of the physician self-referral law. By statute, the exceptions for the rental of office space, the rental of equipment, and personal service arrangements require an arrangement to be signed ''by the parties.'' (See section 1877(e) of the Act.) The commenters' suggestion that an arrangement should be deemed to comply with the signature requirement if one or more of the parties have not signed the arrangement is inconsistent with the plain language of the statute. In addition, as noted elsewhere in this section, we believe that the requirement that the parties sign an arrangement plays a role in preventing fraud and abuse. In this context, it is not enough that the course of conduct between the parties could support an inference of assent to the terms. Rather, a signature is necessary to provide a written record of the assent of the parties to the arrangement.

Comment: One commenter requested clarification as to what would satisfy the signature requirement of various compensation exceptions. The commenter specifically asked whether any of the following would satisfy the requirement that an arrangement be signed by the parties: an electronic signature; a typed name; the name of the sender in the ''from'' line of an email; the signature of the maker of a check; and the signature of a person endorsing a check. Another commenter asked CMS to explicitly allow electronic signatures. A third commenter suggested that State law principles should determine what constitutes a signed writing for the purposes of the physician self-referral law.

Response: As noted elsewhere in this section, State law principles do not determine whether a party complies with the physician self-referral law, including compliance with the signature requirement. Nevertheless, parties may look to State law and other bodies of relevant law, including Federal and State law pertaining to electronic signatures, to inform the analysis of whether a writing is signed for the purposes of the physician self-referral law. Given evolving technologies, we are concerned that a prescriptive statement on our part regarding electronic signatures may unduly limit parties' ability to comply with the physician self-referral law in the future.

We decline to state whether the examples provided by the commenter comply with the signature requirement for the following reasons: First, the exceptions require the arrangement to be signed by the parties. Even a document bearing the handwritten signature of one of the parties will not satisfy this requirement if the document, when considered in the context of the collection of documents and the underlying arrangement, does not clearly relate to the arrangement. Second, the intent of the party purportedly ''signing'' the standalone document is not clear in certain examples provided. Third, we are concerned that, by judging the examples in isolation from their context, we might unduly narrow parties' ability to comply with the signature requirement. In sum, whether an arrangement is signed by the parties depends on the facts and circumstances of the arrangement and the writings that document the arrangement.

After careful consideration of the comments, we are finalizing our proposal to remove the distinction between inadvertent and not inadvertent failure to obtain a signature at § 411.353(g). Under the final regulation, all parties have 90 days to obtain missing signatures. The regulation, as finalized, continues to limit the use of § 411.353(g) by an entity to once every 3 years for a particular physician. At this time, we believe that this limitation is necessary to prevent 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 the 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, 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 proposed 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 proposed 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 proposed 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 proposed 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 solicited public comments 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 solicited 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 solicited 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 proposed 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 proposed 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 proposed to define ''public advertising for the hospital,'' for the 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 proposed 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 proposed 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 sought 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 stated 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 the proposed rule, we clarified 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 proposed to clarify the types of statements that constitute a sufficient statement of physician ownership or investment. Specifically, we proposed 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 sought 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 invited 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 did not propose 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 sought public comment on additional guidance that may be necessary regarding the periods of noncompliance for both disclosure requirements.

We are finalizing without modification our proposals regarding the public Web site and public advertising disclosure requirement at § 411.362(b)(3)(ii)(C). The following is a summary of the comments we received.

Comment: A few commenters largely supported our proposed clarifications and regulations that articulate our existing policy concerning the public Web site and public advertising disclosure requirements. The commenters agreed that our proposed examples of statements that would constitute sufficient disclosure of physician ownership or investment interest demonstrate an appropriate approach to implementing the disclosure requirements.

Response: We appreciate the commenters' support. We are finalizing our proposal 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, as well as our proposed examples of language that would satisfy that standard as specified in the proposed rule (80 FR 41924). We note that our goal in proposing the examples of sufficient disclosure statements was to articulate a common sense understanding of what types of statements would satisfy the requirements.

Comment: One commenter supported our proposal to amend § 411.362(b)(3)(ii)(C) to specify examples of Web sites that, consistent with our existing policy, would not constitute ''public Web sites for the hospital,'' and therefore, would not require a disclosure of physician ownership or investment. However, the commenter requested that we revise the phrase ''social media Web sites'' in proposed amended § 411.362(b)(3)(ii)(C) to read as ''social media or networking Web sites'' and that we include in the regulation specific examples of social media or networking Web sites.

Response: We are finalizing our proposal, without revision, to amend § 411.362(b)(3)(ii)(C) to specify that 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. We are not persuaded to explicitly include ''networking Web sites'' in

§ 411.362(b)(3)(ii)(C). We believe that it is commonly understood that networking Web sites are one form of social media and that our discussion of social media Web sites in the proposed rule is broad enough to include networking Web sites (80 FR 41924). We do not believe that additional guidance is necessary. Furthermore, we are hesitant to identify specific names of Web sites, even as examples, given the pace at which technology develops.

Comment: One commenter supported our specific proposal at § 411.362(b)(3)(ii)(C) to exclude electronic patient payment portals and electronic patient care portals from qualifying as public Web sites for the hospital, because, according to the commenter, disclosing through either type of portal would not meet the disclosure requirement's purpose of providing ownership information to the general public.

Response: We appreciate the commenter's support for our proposal to exclude such portals from qualifying as a ''public Web site for the hospital.'' We agree with the commenter's reasoning, and are finalizing the revisions as proposed.

Comment: One commenter supported our proposed definition of ''public advertising for the hospital'' at § 411.362(a), particularly our clarification in the definition that the advertisement must be ''primarily intended to persuade individuals to seek care at the hospital.'' The commenter also supported our proposed list of examples that, consistent with our existing policy, would not constitute ''public advertising for the hospital'' and therefore would not require disclosure of physician ownership or investment. However, the commenter urged CMS to add ''search engine results'' and ''online listings of area hospitals'' to our proposed list of examples given that, according to the commenter, an individual likely would not make a medical decision based on the limited information provided through either means of communication.

Response: We are finalizing our proposal, without revision, to add our proposed definition of ''public advertising for the hospital'' at § 411.362(a). We are not persuaded to add ''search engine results'' and ''online listings of area hospitals'' to our list of examples. As we noted in the preamble to the proposed rule, our list of examples is not exhaustive, and a determination as to whether a specific communication qualifies as ''public advertising for the hospital'' will depend on the facts and circumstances of the communication (80 FR 41924). We also note that under our finalized policy the standard for whether a communication qualifies as ''public advertising for the hospital'' is, in part, whether the communication ''is primarily intended to persuade individuals to seek care at the hospital'' and not whether an individual is likely to make a medical decision based on the information provided in the communication. Finally, as we noted in our proposed rule, our existing regulations at § 411.362(b)(3)(ii)(C) reference ''public advertising'' without explicitly specifying ''for the hospital,'' and we are finalizing our proposal to include the phrase ''for the hospital'' in our definition at § 411.362(a) and in the disclosure requirement to conform our regulations to the statutory language.

Comment: One commenter requested that we identify a more definitive period of noncompliance for a physician-owned hospital's failure to satisfy the public advertising disclosure requirement. The commenter noted that, as to our example in the proposed rule concerning a physician-owned hospital's failure to include a disclosure in a monthly magazine advertisement, we stated that the period of noncompliance would ''likely'' be the applicable month of circulation despite the fact that the magazine may continue to be available (for example, in physician waiting rooms) for a period beyond the initial circulation.

Response: We are finalizing, without revision, our clarifications regarding the periods of noncompliance associated with a failure to satisfy either the public Web site or public advertising disclosure requirements (80 FR 41925). We decline to identify a more definitive period of noncompliance for a physician-owned hospital's failure to satisfy the public advertising disclosure requirement. We believe that determining the period of noncompliance for a hospital's failure to disclose will depend on the specific facts and circumstances surrounding the hospital's public advertisement. We intended our example in the proposed rule to provide only general guidance and not to delineate a bright-line rule.

After careful review and consideration of the comments, we are finalizing our proposal, without revision, to amend § 411.362(b)(3)(ii)(C) to specify that 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. We are finalizing our proposal, without revision, to add our proposed definition of ''public advertising for the hospital'' at § 411.362(a). We are also finalizing, without revision, our clarifications regarding the periods of noncompliance associated with a failure to satisfy either the public Web site or public advertising disclosure requirements (80 FR 41925).

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 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 stated 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 the 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 stated 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 stated that including only referring physicians in the definition of physician owner or investor for the 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 stated 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 the 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 proposed 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 the 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 sought 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 the purposes of establishing their baseline *bona fide* investment levels and the *bona fide* investment levels generally.

To support our proposal and implement the requirements of the statute, we proposed to amend our existing regulations to specify that, for the purposes of § 411.362 (including for the 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 proposed to effectuate this change by establishing a definition of ownership or investment interest solely for the 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 proposed 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 also proposed 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) better align with the statutory definition of ''physician owner or investor'' in a hospital without unsettling long-standing definitions in our regulations. We solicited public comments 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 solicited public comments on an alternate proposal that we believe also supports our policy and, thereby, effectuates the statute's purpose. Specifically, we solicited public comments 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 invited public comments 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, in the proposed rule we recognized 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

finalized 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 proposed 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 stated that 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 solicited comments on how long we should delay the effective date. We also solicited comments 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.

The following is a summary of the comments we received.

Comment: Four commenters disagreed with the *bona fide* investment level proposal, citing a variety of reasons. For example, two commenters stated that requiring the inclusion of ownership and investment interests held by non-referring physicians in the baseline *bona fide* investment level and every assessment of the *bona fide* investment level thereafter is inconsistent with the purpose of the physician self-referral law. One of these commenters stated that requiring the inclusion of ownership and investment interests held by non-referring physicians in the *bona fide* investment levels would stifle physician investment in physician-owned hospitals and frustrate physician recruitment to communities served by physician-owned hospitals. Another commenter asked us to refrain from finalizing the proposal until we can articulate the precise risk of fraud or abuse that excluding the ownership and investment interests held by non-referring physicians from the *bona fide* investment levels would have on the Medicare program. One commenter stated that requiring the inclusion of ownership and investment interests held by non-referring physicians in the baseline *bona fide* investment level and every assessment of the *bona fide* investment level thereafter impermissibly expands the scope of the physician self-referral law because, according to the commenter, without a ''referral,'' a physician's ownership or investment interest in an entity does not implicate the law and, thus, no applicable exception is needed. This commenter stated that we should create a special carve out for physician-owned hospitals that did not obtain a provider agreement until sometime after March 23, 2010, but by the December 31, 2010 deadline, and that these hospitals should include the ownership and investment interests held by all physicians, regardless of referral status, in the baseline *bona fide* investment level.

Response: We continue to believe that the revised policy articulated in the proposed rule is the only reading of the statute that fully accounts for all relevant provisions of law. We do not believe that we have the authority to continue implementing a policy that is inconsistent with the statute. Accordingly, we are finalizing our proposal, without revision, 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 she 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 the purposes of our regulatory definition of ownership or investment interest at § 411.354). We also are finalizing, without revision, our proposed definition of ''ownership or investment interest'' in § 411.362 to implement our revised policy.

Comment: One commenter stated that requiring the inclusion of the ownership and investment interests held by all physicians, regardless of whether each qualifies as a ''referring'' physician, is a more faithful interpretation of the statute than the policy that we articulated in the CY 2011 OPPS/ASC final rule with comment period (75 FR 72250). The commenter stated, however, that we should implement the statute in a different manner than the proposal set forth in the proposed rule. Specifically, the commenter stated that all ownership and investment interests held by physicians as of March 23, 2010, should be included in a hospital's baseline *bona fide* investment level regardless of whether each physician was referring as of that date, but that a physician-owned hospital should be permitted to exclude the ownership and investment interests held by non-referring physicians in any calculation of the *bona fide* investment level thereafter. The commenter noted that in regulations governing provider agreements at § 489.20(u) and (v), CMS chose to not require disclosure of physician ownership interests for any physician-owned hospital that does not have at least one referring physician.

Response: We agree with the commenter that the proposal better aligns with the statute than the policy articulated in the CY 2011 OPPS/ASC final rule with comment period. However, we disagree that a physician-owned hospital should be permitted to exclude the ownership and investment interests held by non-referring physicians in any calculation of the *bona fide* investment level after March 23, 2010. We believe that the term ''physician owner or investor'' as used in the *bona fide* investment level requirement has a singular, defined meaning and that the Congress provided guidance about that meaning through its broad definition of ''physician owner or investor'' at section 1877(i)(5) of the Act, which is supported by a harmonious reading of multiple statutory provisions. Further, as we noted in the proposed rule, if the term ''physician owner or investor'' was intended to include only referring physicians in the *bona fide* investment level requirement, such qualifying language would have been included in the statute, such as in a separate requirement established by the Affordable Care Act for physician-owned hospitals in section 1877(i)(C)(ii) of the Act. Although the commenter's recommended approach would resolve the issue concerning pre-operational hospitals that we discussed in the proposed rule (80 FR 41925), we do not believe that the statute provides sufficient support for concluding that two separate standards can apply for calculating the baseline *bona fide* investment level and every *bona fide* investment level thereafter. Finally, as to the commenter's statements regarding § 489.20(u) and (v), the regulations that govern provider agreements and our regulations concerning the physician self-referral law are two distinct regulatory schemes. Although the regulations cited by the commenter mention physician-owned hospitals, we are bound by the provisions of the physician self-referral law.

Comment: One commenter requested that we clarify that a physician-owned hospital did not improperly calculate its baseline *bona fide* investment level by including the ownership and investment interests held by all physicians regardless of referral status.

Response: We confirm that a proper calculation of a physician-owned hospital's baseline *bona fide* investment level includes the ownership and investment interests held by all physicians regardless of referral status.

Comment: Two commenters stated that requiring the inclusion of ownership and investment interests held by non-referring physicians in the baseline *bona fide* investment level and the assessment of every *bona fide* investment level thereafter likely would cause financial hardship for any non-referring or retiring physicians who would need to sell their ownership interests at the current fair market value to allow a physician-owned hospital to comply with the new policy. The commenters also stated that physician-owned hospitals likely would have to restructure their governance, given the necessary ownership changes, and that such restructuring likely would be difficult and costly for the hospitals.

Response: We acknowledge the commenters' concerns regarding the potential effect that this policy may have on individual physician owners, as well as physician-owned hospitals. While we do not have the discretion to continue implementing a policy that is inconsistent with the statute, we recognize that we need to give physician-owned hospitals a reasonable amount of time to come into compliance with the revised policy. Accordingly, we are delaying the effective date of this revision for one year from the effective date of this final rule to January 1, 2017.

After consideration of the comments, we are amending our existing regulations to specify that, for the purposes of § 411.362 (including for the 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 are establishing a definition of ownership or investment interest solely for the 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 are defining ''ownership or investment interest'' at § 411.362(a) as a direct or indirect ownership or investment interest in a hospital. Under the final rule, 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. 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.

9. Solicitation of Comments: Perceived Need for Regulatory Revisions or Policy Clarification Regarding Permissible Physician Compensation

a. 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. In our proposed rule, we highlighted certain provisions of the Affordable Care Act that grant the Secretary broad authority to test models implementing health care delivery and payment reform. (See 80 FR 41927–28.)

As noted in our proposed rulemaking, 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.*)

b. 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 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 three-part 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 Medicare Shared Savings Program or certain Center for Medicare and Medicaid Innovation-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 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.

c. Analysis of Comments

To help inform the APM Report and Gainsharing Report required under sections 101(e)(7) and 512(b) of MACRA, respectively, and to aid us in determining whether additional rulemaking or guidance is desirable or necessary, we solicited comments regarding the impact of the physician self-referral law on health care delivery and payment reform. On this subject, we specifically solicited comments regarding the ''volume or value'' and ''other business generated'' standards, but welcomed comments concerning any of our rules for determining physician compensation.

We received a number of thoughtful comments on the issues raised in the solicitation. We thank the commenters for their input, and we will carefully consider their comments as we prepare the reports to Congress required under sections 101(e)(7) and 512(b) of MACRA and determine whether additional rulemaking on these issues is necessary. We would like to note that our silence in this rule should not be viewed as an affirmation of any commenter's interpretations or views.

10. Technical Corrections

We have become aware that some of the manual citations listed in our regulations are no longer correct. We therefore proposed 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 proposed 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), (m)(2) through (m)(3), and (m)(5), § 411.362(c)(2)(iv) through (v) and (c)(5), and § 411.384(b). Lastly, we are removing the hyphen from ''publicly-traded'' at § 411.356(a) and § 411.361(d), and we are correcting a minor typographical error at § 411.357(p)(1)(ii)(A).

After the proposed rule went on display, the term ''Web site'' was inadvertently changed to ''Web site.'' Our intention in the proposed rule was to change all instances of the term ''Web site'' to ''Web site.'' We are making this change in the final rule.

11. Comments Outside the Scope of This Rulemaking

Comment: We received several comments, including suggestions on policy changes that are outside the scope of this rulemaking. For example, one commenter requested revisions to the in-office ancillary services exception. Another commenter requested that we make regulatory protections for electronic health records permanent. We also received a few requests that the physician self-referral law be eliminated entirely. In addition, some commenters described their interpretations of various physician self-referral issues or asked questions about existing regulations.

Response: Although we appreciate the commenters taking the time to present these positions, these comments are beyond the scope of this rulemaking and are not addressed in this final rule with comment period. We express no view on these issues; our silence should not be viewed as an affirmation of any commenter's interpretations or views. If these issues are addressed in the future, we will publish a notice of proposed rulemaking that will be open to public comment at that time. Finally, we refer readers to the final rule regarding our exception for electronic health records at § 411.357(w), published December 27, 2013 (78 FR 78751).

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 Regulation

The private contracting/opt out provisions at section 1802(b) of the Act were recently amended by section 106(a) of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) (Pub. L. 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 MAC. Section 106(a) of the 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 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 proposed 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 proposed 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 proposed to amend §§ 405.410(d), 405.435(d), and 405.445(b)(2) so that the term ''carrier'' is replaced with ''Medicare Administrative Contractor''.

We received 13 comments on our private contracting/opt-out proposal.

Comment: Many commenters supported the proposed rule.

Response: We appreciate the commenters' support.

Comment: One commenter proposed that the rule be modified to permit cancellation of opt-out (with a 30-day notice) any time after the physician's or practitioner's initial 2-year opt-out period concludes. The commenter stated that a physician who cancels opt-out and later chooses to opt-out again should be subject to another initial 2-year opt-out period. The commenter contended that such a standard would be sufficient to prevent abuse without requiring the perpetual monitoring of opt-out renewal dates.

Response: We appreciate the comment, but note that the commenter's proposal is inconsistent with the requirements of section 106(a)(1) of MACRA. As noted earlier in this preamble, the MACRA amendments permit 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 to cancel the automatic extension by notifying us at least 30 days prior to the start of the next 2-year opt-out period. The MACRA amendments changed the procedures for renewing the opt-out period; it now renews automatically unless we receive written notice requesting otherwise. The MACRA amendments, however, did not change the requirement that physicians and practitioners opt-out in 2-year intervals. Therefore, because MACRA does not provide any flexibility to cancel opt-out before the 2 year opt-out period actually ends, we are not modifying the rule based on this comment.

To effectuate the changes made by the MACRA, we are finalizing these provisions of the rule as proposed with the exception of minor editorial changes to § 405.445. These changes clarify this section consistent with plain language principles but do not alter the meaning of the proposal.

P. Physician Self-Referral Prohibition: Annual Update to the List of CPT/HCPCS Codes

1. General

Section 1877 of the Act prohibits a physician from referring a Medicare beneficiary for certain designated health services (DHS) to an entity with which the physician (or a member of the physician's immediate family) has a financial relationship, unless an exception applies. Section 1877 of the Act also prohibits the DHS entity from submitting claims to Medicare or billing the beneficiary or any other entity for Medicare DHS that are furnished as a result of a prohibited referral.

Section 1877(h)(6) of the Act and § 411.351 of our regulations specify that the following services are DHS:

- Clinical laboratory services.
- Physical therapy services.
- Occupational therapy services.
- Outpatient speech-language pathology services.
- Radiology services.
- Radiation therapy services and supplies.
- Durable medical equipment and supplies.
- Parenteral and enteral nutrients, equipment, and supplies.
- Prosthetics, orthotics, and prosthetic devices and supplies.
- Home health services.
- Outpatient prescription drugs.
- Inpatient and outpatient hospital services.

2. Annual Update to the Code List

a. Background

In § 411.351, we specify that the entire scope of four DHS categories is defined in a list of CPT/HCPCS codes (the Code List), which is updated annually to account for changes in the most recent CPT and HCPCS Level II publications. The DHS categories defined and updated in this manner are:

- Clinical laboratory services.
- Physical therapy, occupational therapy, and outpatient speech-language pathology services.
- Radiology and certain other imaging services.
- Radiation therapy services and supplies.

The Code List also identifies those items and services that may qualify for either of the following two exceptions to the physician self-referral prohibition:

- EPO and other dialysis-related drugs furnished in or by an ESRD facility (§ 411.355(g)).
- Preventive screening tests, immunizations, or vaccines (§ 411.355(h)).

The definition of DHS at § 411.351 excludes services for which payment is made by Medicare as part of a composite rate (unless the services are specifically identified as DHS and are themselves payable through a composite rate, such as home health and inpatient and outpatient hospital services). Effective January 1, 2011, EPO and dialysis-related drugs furnished in or by an ESRD facility (except drugs for which there are no injectable equivalents or other forms of administration), have been reimbursed under a composite rate known as the ESRD prospective payment system (ESRD PPS) (75 FR 49030). Accordingly, EPO and any dialysis-related drugs that are paid for under ESRD PPS are not DHS and are not listed among the drugs that could qualify for the exception at § 411.355(g) for EPO and other dialysis-related drugs furnished by an ESRD facility.

Drugs for which there are no injectable equivalents or other forms of administration were scheduled to be paid under ESRD PPS beginning January 1, 2014 (75 FR 49044). However, there have been several delays of the implementation of payment of these drugs under ESRD PPS. Most recently, on December 19, 2014, section 204 of the Achieving a Better Life Experience Act of 2014 (ABLE) (Pub. L. 113–295) was enacted and delayed the inclusion of these drugs under the ESRD PPS until 2025. Until that time, such drugs furnished in or by an ESRD facility are not paid as part of a composite rate and thus, are DHS. For purposes of the exception at § 411.355(g), only those drugs that are required for the efficacy of dialysis may be identified on the List of CPT/HCPCS Codes as eligible for the exception. As we have explained previously in the CY 2010 PFS final rule with comment period (75 FR 73583), we do not believe any of these drugs are required for the efficacy of dialysis. Therefore, we have not included any such drugs on the list of drugs that can qualify for the exception.

The Code List was last updated in Tables 90 and 91 of the CY 2015 PFS final rule with comment period (79 FR 67973–67975).

b. Response to Comments

We received three public comments relating to the Code List that became effective January 1, 2015.

Comment: All of the commenters requested the removal of two disposable negative pressure wound therapy (NPWT) codes, 97607 and 97608. The commenters stated that the definition of ''referral'' does not include services personally performed by the referring/ordering physician and that a typical patient provided with a disposal NPWT device will require significant clinical interaction from the physician to thoroughly clean a wound prior to application of such a device.

Response: We are aware that there are some circumstances under which these codes will not be considered therapy services. The codes in question are not considered therapy services when: (1) It is not appropriate to bill the service under a therapy plan of care; and (2) they are billed by practitioners/providers of services who are not therapists, such as physicians, CNSs, NPs and psychologists; or they are billed to MACs by hospitals for outpatient services which are performed by non-therapists. However, these and certain other codes can also be furnished as therapy services, specifically under a physical therapy, occupational therapy, or speech-language pathology plan of care in accordance with section 1861(p) of the Act. We note that determinations should be made on a case-by-case basis with respect to whether the physician self-referral law is implicated when using these codes. Please refer to the billing rules associated with these codes to avoid violating the physician self-referral law.

c. Revisions Effective for CY 2016

The updated, comprehensive Code List effective January 1, 2016, is available on our Web site at *http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/List_of_Codes.html*.

Additions and deletions to the Code List conform it to the most recent publications of CPT and HCPCS Level II, and to changes in Medicare coverage policy and payment status.

Tables 50 and 51 identify the additions and deletions, respectively, to the comprehensive Code List that become effective January 1, 2016. Tables 50 and 51 also identify the additions and deletions to the list of codes used to identify the items and services that may qualify for the exception in § 411.355(g) (regarding dialysis-related outpatient prescription drugs furnished in or by an ESRD facility) and in § 411.355(h) (regarding preventive screening tests, immunizations, and vaccines).

We will consider comments regarding the codes listed in Tables 50 and 51. Comments will be considered if we receive them by the date specified in the ''DATES'' section of this final rule with comment period. We will not consider any comment that advocates a substantive change to any of the DHS definitions in § 411.351.

TABLE 50—ADDITIONS TO THE PHYSICIAN SELF-REFERRAL LIST OF CPT[1]/HCPCS CODES

CLINICAL LABORATORY SERVICES
G0475 HIV combination assay
G0476 HPV combo assay CA screen
PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND OUTPATIENT SPEECH-LANGUAGE PATHOLOGY SERVICES
{No additions}
RADIOLOGY AND CERTAIN OTHER IMAGING SERVICES
72081 X-ray exam entire spi 1 vw
72082 X-ray exam entire spi 2/3 vw
72083 X-ray exam entire spi 4/5 vw
72084 X-ray exam entire spi 6/> vw
73501 X-ray exam hip uni 1 view
73502 X-ray exam hip uni 2–3 views
73503 X-ray exam hip uni 4/> views
73521 X-ray exam hips bi 2 views
73522 X-ray exam hips bi 3–4 views
73523 X-ray exam hips bi 5/> views
73551 X-ray exam of femur 1
73552 X-ray exam of femur 2/>
74712 Mri fetal sngl/1st gestation
78265 Gastric emptying imag study
78266 Gastric emptying imag study
C9457 Lumason contrast agent
C9458 Florbetaben F18
C9459 Flutemetamol F18
G0297 LDCT for Lung CA screen
RADIATION THERAPY SERVICES AND SUPPLIES
0394T Hdr elctrnc skn surf brchytx
0395T Hdr elctr ntrst/ntrcv brchtx
77767 Hdr rdncl skn surf brachytx
77768 Hdr rdncl skn surf brachytx
77770 Hdr rdncl ntrstl/icav brchtx
77771 Hdr rdncl ntrstl/icav brchtx
77772 Hdr rdncl ntrstl/icav brchtx
C2645 Brachytx planar, p-103
DRUGS USED BY PATIENTS UNDERGOING DIALYSIS
{No additions}
PREVENTIVE SCREENING TESTS, IMMUNIZATIONS AND VACCINES
G0475 HIV combination assay
G0476 HPV combo assay CA screen

[1] CPT codes and descriptions only are copyright 2015 AMA. All rights are reserved and applicable FARS/DFARS clauses apply.

TABLE 51—DELETIONS FROM THE PHYSICIAN SELF-REFERRAL LIST OF CPT[1]/HCPCS CODES

CLINICAL LABORATORY SERVICES
0103T Holotranscobalamin
G0431 Drug screen multiple class
G0434 Drug screen multi drug class
PHYSICAL THERAPY, OCCUPATIONAL THERAPY, AND OUTPATIENT SPEECH-LANGUAGE PATHOLOGY SERVICES
{No deletions}
RADIOLOGY AND CERTAIN OTHER IMAGING SERVICES
72010 X-ray exam of spine
72069 X-ray exam of trunk spine
72090 X-ray exam of trunk spine
73500 X-ray exam of hip
73510 X-ray exam of hip
73520 X-ray exam of hips

TABLE 51—DELETIONS FROM THE PHYSICIAN SELF-REFERRAL LIST OF CPT[1]/HCPCS CODES—Continued

73540 X-ray exam of pelvis & hips
73550 X-ray exam of thigh
RADIATION THERAPY SERVICES AND SUPPLIES
0182T HDR elect brachytherapy
77777 Apply interstit radiat inter
77787 HDR brachytx over 12 chan
DRUGS USED BY PATIENTS UNDERGOING DIALYSIS
{No deletions}
PREVENTIVE SCREENING TESTS, IMMUNIZATIONS AND VACCINES
90669 Pneumococcal vacc 7 val im

[1] CPT codes and descriptions only are copyright 2015 AMA. All rights are reserved and applicable FARS/DFARS clauses apply.

IV. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to publish a 30-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.

In the CY 2016 PFS proposed rule (80 FR 41930 through 41937) we solicited public comment on each of the section 3506(c)(2)(A)-required issues for the following information collection requirements. PRA-related comments were received as indicated below under section IV.B.

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 52 presents the mean hourly wage, the cost of fringe benefits, and the adjusted hourly wage.

TABLE 52—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. Information Collection Requirements (ICRs) Carried Over From the CY 2016 Proposed Rule

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 (MACs).

To be consistent with section 106(a), we revised 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 written request to the MAC. We estimate it will take 60 physicians/practitioners approximately 10 min each for a total of 10 hr. We also estimate that a medical secretary will perform this duty at $32.24/hr for a total cost of $322.40 (10 hr x $32.24/hr).

We did not receive any public comments regarding the proposed requirements or burden and are adopting them without change. 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)

For a clinic that was billing as if it were provider-based to an IHS hospital as of April 7, 2000, and is now a tribally-operated clinic contracted or compacted under the ISDEAA, §§ 405.2462(d) and 405.2463(c)(4) provides that the clinic may seek to become certified as a grandfathered tribal FQHC. To become certified, an eligible tribe or tribal organization must submit an enrollment application (CMS–855A, OMB control number 0938–0685) and all required 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, will 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.*). We did not receive any public comments regarding the exempt information collection requirements and are finalizing the policy as proposed.

3. ICRs Regarding the Payment for RHC and FQHC Services (§ 405.2462)

Section 405.2462(g)(3) requires that RHCs report Healthcare Common Procedure Coding System (HCPCS) and other codes as required in reporting services furnished to a Medicare beneficiary during a RHC visit.

The ongoing burden associated with the requirements under § 405.2462(g)(3) is the time and effort it will 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 some RHC billing staff will need training 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 the training 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 policy may not require any additional coding time since they are already capturing HCPCS coding in their billing or electronic health record systems. For those RHCs that are not already capturing HCPCS coding in their billing or electronic health record systems, they 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 and used BLS wage data (see Table 52).

We did not receive any public comments regarding our proposed burden estimates. We are finalizing the reporting requirement as proposed with an effective date of April 1, 2016, to allow the MACs additional time to implement the necessary claims processing systems changes completely. The burden for the aforementioned requirements will be submitted to OMB for approval under control number 0938–1287 (CMS–10568).

4. ICRs Regarding Exceptions to the Referral Prohibition Related to Compensation Arrangements (§ 411.357)

Section 411.357 is revised to establish two new exceptions: (1) An exception to permit remuneration to independent physicians to assist in compensating nonphysician practitioners in the geographic service area of the hospital, FQHC, or RHC providing the remuneration, and (2) 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 clarified the writing requirements for compensation arrangements in § 411.357(a), (b), (d), (e), (l), (p), and (r). The burden associated with these requirements is 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). Since financial arrangements are usually and routinely documented in writing as a standard good business practice, 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 exempt as a usual and customary business practice.

We did not receive any public comments regarding our position that the burden associated with these requirements is a usual and customary business practice that is exempt from the PRA.

5. ICRs Regarding the Physician Quality Reporting System (PQRS) (§ 414.90 and Section III.I. 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 (1) identifying applicable quality measures for which they can report the necessary information, (2) selecting a reporting option, (3) collecting the necessary information, and (4) 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.

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 (1) review the PQRS Measures List, (2) review the various reporting options, (3) select the most appropriate reporting option, (4) identify the applicable measures or measures groups for which they can report the necessary information, (5) review the measure specifications for the selected measures or measures groups, and (6) incorporate reporting of the selected measures or measures groups into the office work flows. The measures list contains the measure title along with a summary 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, select a reporting option, and select the measures on which to report. If an eligible professional has received training, we believe this will take less time. CMS believes that 3 hr 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 reporting the quality measures will vary depending on the reporting mechanism selected by the eligible professional. As such, we break down our burden estimates by eligible professionals and group practices participating in the GPRO according to the reporting mechanism used.

a. Burden for Reporting by Individual Eligible Professionals: 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 by OMB under control number 0938–0999. This rule does not revise either of these forms. We note that the claims-based reporting option is only available to individual eligible professionals and is not available for group practice reporting under the GPRO.

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 will take approximately 2.25 min (0.25 min × 9) to 108 min (12 min × 9) to perform all of the necessary steps.

At an adjusted labor rate of $83.96/hr for a computer systems analyst, the per measure cost will 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 will 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 will 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 will 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 53 summarizes the range of total annual burden associated with eligible professionals using the claims-based reporting mechanism.

TABLE 53: 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**

We received comments related to the estimates in Table 53 and how they relate to reporting using other reporting mechanisms, such as the registry, EHR, and QCDR reporting mechanisms. Please note that the figures in Table 53 only reflect our estimates for reporting via the claims-based reporting mechanism, and not the other PQRS reporting mechanisms.

b. Burden for Reporting by Individual Eligible Professionals and Group Practices: Qualified Registry-based and QCDR-based Reporting Mechanisms

There is no additional time for individual eligible professionals or group practices to report data to a qualified registry since eligible professionals and group practices opting for qualified registry-based reporting or the use of a QCDR will 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.

Eligible professionals and group practices 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 is 5 min per eligible professional or eligible professional within a group practice.

Based on the assumptions discussed above, Table 54 summarizes the total annual burden associated with eligible professionals and group practices 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 or group practice would not be required to submit this data to CMS since the qualified registry or QCDR would perform this function on their behalf.

TABLE 54: 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**

We did not receive any public comments regarding the proposed requirements or burden and are adopting them without change.

c. Burden for 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 (1) review the quality measures on which we will be accepting PQRS data extracted from EHRs, (2) select the appropriate quality measures, (3) extract the necessary clinical data from his or her EHR, and (4) 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 hr to obtain. Once an eligible professional or eligible professional in a group practice has an account, he or she needs to extract the necessary clinical data from his or her EHR and submit the 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 for the eligible professional or group practice to submit data on quality measures should be minimal since the information should already reside in the eligible professional's or group practice's EHR.

In this rule, group practices with 100 or more eligible professionals must report on CAHPS for PQRS (the survey is approved by OMB under control number 0938–1222, CMS–10450). Therefore, a group practice of 100 or more eligible professionals is 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 55 summarizes the total annual burden 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 since the EHR product would perform this function on the eligible professional's behalf.

TABLE 55: 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**

We did not receive any public comments regarding the proposed requirements or burden and are adopting them without change.

d. Burden for 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. 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).

We estimate that the self-nomination process will require 2 hr for a group practice to review the PQRS GPRO and decide whether to participate as a group or individually. We also estimate an additional 2 hr for a group practice to draft their 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 (BLS occupation: billing and posting clerks) has an adjusted labor rate of $26.68/hr. By projecting 6 hr (per group practice) for the self-nomination process, we estimate a total of 3,000 hr (500 group practices × 6 hr) at a cost of $80,040 (3,000 hr $26.68/hr).

The burden associated with the group practice reporting requirements under the GPRO mechanism is the time and effort for group practices to submit the quality measures data. For physician group practices, this is the time for the physician group to complete the web interface. We believe that the burden associated with using the GPRO web interface is comparable to that of using the Performance Assessment Tool (PAT). The PAT was the precursor to the current PQRS GPRO Web Interface and was used in several physician pay for performance demonstrations. The information collection components of the PAT have been reviewed by OMB and are approved under 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 using the PAT. 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 $6,632.84 (79 hr × $83.96/hr). In aggregate, we estimate 39,500 hr (500 group practices × 79 hr) and $3,316,420 (39,500 hr × $83.96/hr).

Based on the assumptions discussed above, Table 56 summarizes the total annual burden associated with the group practice reporting of quality measures.

TABLE 56: 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**

We did not receive any public comments regarding the proposed requirements or burden and are adopting them without change.

e. Total Estimated Burden of this Information Collection Requirement for 2016

It is difficult to accurately estimate the total annual burden associated with the submission of the quality measure data for the PQRS. Since there are a number of reporting mechanisms that eligible professionals can use to report the PQRS measures, it may be more burdensome for certain practices to use a particular reporting mechanism to report their PQRS measures and/or electronic prescribing measures than others. As indicated, 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 was new for the 2014 PQRS. Therefore, Table 57 provides a range of estimates for individual eligible professionals or group practices using the claims, qualified registry, or EHR-based reporting mechanisms. The upper range represents the sum of the estimated maximum hours and cost per eligible professional from Tables 53, 54, and 55. We are updating our currently approved figures for the upper range of estimates provided in Table 57. Changes to the estimated burden for 2016 are due to updated BLS wage figures, inclusion of benefits and overhead allowance, a change in participation estimates for eligible professionals using the qualified registry (QCDR) and EHR-based reporting mechanisms and a change in reporting requirements in the PQRS for the 2018 PQRS payment adjustment.

TABLE 57: Total Burden for Eligible Professionals and/or Group Practices Using the Claims, Qualified Registry or QCDR, 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
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 burden for group practices, Table 58 reiterates the burden (see Table 56) to participate in PQRS under the group practice reporting option using the GPRO web interface.

TABLE 58: Total Burden 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**

The requirements and burden estimates will be submitted to OMB under control number 0938–1059 (CMS–10276).

6. ICRs Regarding Appropriate Use Criteria for Advanced Diagnostic Imaging Services (§ 414.94)

Consistent with section 1834(q) of Title XVIII of the Act (as amended by section 218(b) of the PAMA), we have adopted specific requirements for the development of appropriate use criteria (AUC) that can be specified under § 414.94 as part of the Medicare program. PLEs that use processes that meet certain requirements and want to be recognized as qualified PLEs for the purpose of this section may apply to CMS.

Applications must be submitted electronically and demonstrate how the organization's processes for developing AUC meet the requirements specified in § 414.94(c)(1) which include: A systematic literature review of the clinical topic and relevant imaging studies; led by at least one multidisciplinary team with autonomous governance; a process for

identifying and resolving conflicts of interest of team members, the PLE and any other party participating in AUC development or modification; publication of individual appropriate use criterion on the qualified PLE's Web site; identification of AUC that are relevant to priority clinical areas; 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 (at least annually); a process for developing, modifying or endorsing AUC publicly posted on the entity's Web site; and the disclosure of external parties involved in the AUC development process.

To be identified as a qualified PLE by CMS, organizations must meet the definition of PLE, and demonstrate adherence to the requirements in their application for CMS review and use the application process identified in § 414.94(c)(2) of the regulations. Applicant PLEs must submit applications documenting adherence to each AUC development requirement; applications will be accepted annually by January 1; all qualified PLEs approved in each year will be posted to the CMS Web site by June 30; and all qualified PLEs must re-apply every 5 years and applications must be submitted by January 1 during the 5th year after the qualified PLE's most recent approval date. If a qualified PLE is found to be non-adherent to the requirements identified above, CMS may terminate its qualified status or may consider this information during re-qualification.

The one-time burden associated with the requirements under § 414.94(c)(2) is the time and effort it will take each of the 30 organizations that have expressed interest in developing AUC to compile, review and submit documentation demonstrating adherence to the 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 hours at $67.38/hr for a business operations specialist to compile, prepare and submit the required information, 5 hours at $99.68/hr for a medical and health services manager to review and approve the submission, and 5 hours at $187.48/hr for a physician to review and approve the submission materials. In this regard, we estimate 30 hours per submission at a cost of $2,783.40 per organization. In aggregate, we estimate 900 hours (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 PLEs 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 PLEs must re-apply every 5 years. Therefore in years 5–10, 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 PLEs will be able to make modifications to their original application which should result in a burden of 10 hours at $67.38/hr for a business operations specialist to compile, prepare and submit the required information, 2.5 hours at $99.68/hr for a medical and health services manager to review and approve the submission, and 2.5 hours at $187.48/hr for a physician to review and approve the submission materials. Annually, we estimate 15 hours per submission at a cost of $1,391.70 per organization. In aggregate, we estimate 450 hours (15 hr × 30 submissions) at $41,751 ($1,391.70 × 30 submissions).

Section 414.94(f)(3) provides that CMS may terminate the qualified status of a PLE if it finds that the PLE is not adherent to the requirements in § 414.94(c). In this instance the PLE would need to re-qualify to reinstate their status. The requalification requirements are associated with an administrative action. In accordance with the implementing regulations of the PRA at 5 CFR 1320.4(a)(2) and (c), the associated burden is exempt from the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). We also estimate that the requalification process would apply to fewer than ten respondents per year. Consequently, the information collection requirements are also exempt under 5 CFR 1320.3(c) of the Paperwork Reduction Act's implementing regulations.

While we received public comments (see below) regarding our proposed requirements and burden, we have considered the comments and are adopting the proposed provisions with minimal changes. The requirements and burden will be submitted to OMB under control number 0938-New (CMS–10570).

Comment: Some commenters disagreed with our proposal to require qualified PLEs to reapply for qualification every 6 years, and were instead in favor of a shorter time frame for review.

Response: We carefully reviewed the timeline for reapplication and have determined that an application submitted by January of the fifth year of approval will receive a determination prior to the start of the qualified PLE's sixth year. Therefore, the cycle of approval for qualified PLEs is every 5 years. This is different than what was proposed as we had originally proposed a cycle that was every 6 years. As finalized, a PLE that becomes qualified for the first 5-year cycle beginning July 2016 would be required to submit an application for requalification by January 2021. A determination would be made by June 2021 and, if approved, the second 5-year cycle would begin in July 2021. For example:

Year 1 = July 2016 to June 2017.
Year 2 = July 2017 to June 2018.
Year 3 = July 2018 to June 2019.
Year 4 = July 2019 to June 2020.
Year 5 = July 2020 to June 2021 (reapplication is due by January 1, 2021).

We believe the reapplication timeline is appropriate and allows for PLEs, CDS mechanism developers and ordering practitioners to enter into longer term agreements without the constant concern that the PLE will lose its qualified status. We will assess whether a qualified PLE consistently has developed evidence-based AUC and met our other requirements at the time of requalification. We note, however, that if qualified PLEs are not maintaining compliance with our requirements for AUC development, we may terminate their qualified status.

Comment: One commenter recommended that CMS create a concise list of AUC development requirements or create a template for entities to use for their application and post the list or template to the CMS Web site.

Response: At least for the first round of applications for qualified PLEs, we will not be making available templates or applications. CMS might consider developing such templates or applications in the future if we find it would be useful, efficient, or necessary.

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 CPC initiative and the Medicare EHR

Incentive Program whereby CPC practice sites are required to report at least nine clinical quality measures across 3 domains in accordance with the requirements established by the CPC initiative, which also satisfies the CQM requirements of the Medicare EHR Incentive Program. The aligned reporting between CPC and the Medicare EHR Incentive Program also allows first year EPs participating in the Medicare EHR Incentive Program to satisfy the CQM requirements of the Medicare EHR Incentive Program through successfully meeting CPC CQM reporting requirements. 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 Annual Burden Estimates

TABLE 59—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	32.24	−29,016
405.445(a)	0938–0730 (CMS–R–234).	60	60	10 min	10	32.24	322
405.2462(g)(3)	0938–1287 (CMS–10568).	4,000	8,964,208	3.5 min	522,912.13	26.68	13,951,296
		350,000 (claims-based reporting).	54 (9 × 6)	5.2 hr (5 hr + 12 min)).	5,528,488	varies (see Table 53).	364,021,000
414.90 and section K of this preamble.	0938–1059 (CMS–10276).	212,000 (qualified registry-based and QCDR-based reporting).	212,000	8.083 hr	1,713,596	varies (see Table 54).	83,157,000
		50,000 (EHR-based reporting).	50,000	9	450,000	varies (see Table 55).	23,462,000
		500 (GPRO web interface).	500	85	42,500	varies (see Table 56).	3,396,460
414.94(c)(1) and (2)	0938–1288 (CMS–10570).	30	30	5 hr	150	187.48	28,122
				5 hr	150	99.68	14,952
				20 hr	600	67.38	40,428
Total					8,257,506		488,042,564

D. Submission of PRA-Related Comments

We have submitted a copy of this rule's information collection and recordkeeping requirements to OMB for review and approval. The 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 identify the rule (CMS–1631–FC) and submit your comments to the OMB desk officer via one of the following transmissions:

Mail: OMB, Office of Information and Regulatory Affairs, Attention: CMS Desk Officer, *Fax Number:* 202–395–5806 OR, *Email: OIRA_submission@omb.eop.gov*. ICR-related comments must be received on/by December 29, 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. Waiver of Proposed Rulemaking and Waiver of Delay in Effective Date

A. PFS provisions

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

We utilize HCPCS codes for Medicare payment purposes. The HCPCS is a national coding system comprised of Level I (CPT) codes and Level II (HCPCS National Codes) that are intended to provide uniformity to coding procedures, services, and supplies across all types of medical providers and suppliers. Level I (CPT) codes are copyrighted by the AMA and consist of several categories, including Category I codes which are 5-digit numeric codes, and Category III codes which are temporary codes to track emerging technology, services, and procedures.

The AMA issues an annual update of the CPT code set each Fall, with January 1 as the effective date for implementing the updated CPT codes. The HCPCS, including both Level I and Level II codes, is similarly updated annually on a CY basis. Annual coding changes are not available to the public until the Fall immediately preceding the annual January update of the PFS. Because of the timing of the release of these new codes, it is impracticable for us to provide prior notice and solicit comment on all of these codes and the RVUs assigned to them in advance of publication of the final rule that implements the PFS. Yet, it is imperative that these coding changes be accounted for and recognized timely under the PFS for payment because services represented by these codes will be provided to Medicare beneficiaries by physicians and non-physician practitioners during the CY in which they become effective. Moreover, regulations implementing HIPAA (42 CFR parts 160 and 162) require that the HCPCS be used to report health care services, including services paid under the PFS. In general, we assign interim RVUs to any new codes based on a review of the AMA RUC recommendations for valuing these services. We also assign interim RVUs to certain codes for which we did not receive specific AMA RUC recommendations, but that are components of new combined codes. We set interim RVUs for the component codes in order to conform them to the value of the combined code. Finally, we assign interim RVUs to certain codes for which we received AMA RUC recommendations for only one component (work or PE) but not both. By reviewing the AMA RUC recommendations for the new codes, we are able to assign RVUs to services based on input from the medical community and to establish payment for them, on an interim basis, that corresponds to the relative resources associated with furnishing the services. We are also able to determine, on an interim final basis, whether the codes will be subject other payment policies. We also note, as explained in section II.A. of this final rule, that we finalized a new process for establishing values for new, revised and potentially misvalued codes in the CY 2015 final rule. In rulemaking to adopt this new process, we assessed the trade-offs involved and determined that, on balance, we should move to a process that involves greater transparency and stakeholder input. We also noted our desire to work with the RUC to receive recommendations for new, revised and potentially misvalued codes within a timeframe to support our new process. CY 2016 is a transition year for this new process, and we anticipate this will be the last year we will need to establish payment for these codes on an interim basis, with the infrequent exception for codes that describe wholly new services. If we did not assign RVUs to new codes on an interim basis, the alternative would be to either not pay for these services during the initial CY or have each Medicare contractor establish a payment rate for these new codes. We believe both of these alternatives are contrary to the public interest, particularly since the AMA RUC process allows for an assessment of the valuation of these services by the medical community prior to our establishing payment for these codes on an interim basis. Therefore, we believe it would be contrary to the public interest to delay establishment of fee schedule payment amounts for these codes until notice and comment procedures could be completed.

For the reasons previously outlined in this section, we find good cause to waive the notice of proposed rulemaking for the interim RVUs for selected procedure codes identified in Addendum C and to establish RVUs for these codes on an interim final basis. We are providing a 60-day public comment period.

Section II.H. of this final rule with comment period discusses our review and decisions regarding the AMA RUC recommendations. Similar to the AMA RUC recommendations for new and revised codes previously discussed, due to the timing of the AMA RUC recommendations for the services identified as potentially misvalued codes, and because, as noted earlier, this is the transition year for the new process for establishing values for new, revised and potentially misvalued codes that we finalized in the CY 2015 final rule, it is impracticable for CMS to provide for notice and comment regarding specific revisions for all codes prior to publication of this final rule with comment period. 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 in order to facilitate continued payment for most services for which we do not receive RUC 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 RUC recommendations in time to propose values.

We believe it is in the public interest to implement the revised RVUs for the codes that were identified as misvalued, and that have been reviewed and re-evaluated by the AMA RUC, on an interim final basis for CY 2016. The revisions of RVUs for these codes will establish a more appropriate payment that better corresponds to the relative resources associated with furnishing these services. A delay in implementing revised values for these misvalued codes would not only perpetuate the known misvaluation for these services, it would also perpetuate a distortion in the payment for other services under the PFS. Implementing the changes on an interim basis allows for a more equitable distribution of payments across all PFS services. We believe a delay in implementation of these revisions would be contrary to the public interest, particularly since the AMA RUC process allows for an assessment of the valuation of these services by the medical community prior to the AMA RUC's recommendation to CMS. For the reasons previously described, we find good cause to waive notice and comment procedures with respect to the misvalued codes and to revise RVUs for these codes on an interim final basis. We are providing a 60-day public comment period.

VI. Regulatory Impact Analysis

A. Statement of Need

This final rule with comment period makes payment and policy changes under the Medicare PFS and makes 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 final rule with comment period rule also makes changes to Part B payment policy and other Part B related policies.

B. Overall Impact

We 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 in this section, that the PFS provisions included in this final rule with comment period 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 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 final rule with comment period 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 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We did not prepare an analysis for section 1102(b) of the Act because we determined, and the Secretary certified, that this final rule with comment period 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 final rule with comment period 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 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 final rule with comment period; 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 final rule with comment period, we proposed 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 final rule with comment period. We are unaware of any relevant federal rules that duplicate, overlap, or conflict with this final rule with comment period. The relevant sections of this final rule with comment period 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 final rule with comment period 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 repealed the previous statutory update formula and specified the update adjustment factors for calendar years 2015 and beyond.

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. 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. We estimate the CY 2016 net reduction in expenditures resulting from adjustments to relative values of misvalued codes to be 0.23 percent. Since this does not meet the 1 percent target established by the Achieving a Better Life Experience Act of 2014 (ABLE), payments under the fee schedule must be reduced by the difference between the target for the year and the estimated net reduction in expenditures (the ''Target Recapture Amount''). As a result, we estimate that the CY 2016 Target Recapture Amount will produce a reduction to the CF of −0.77 percent.

To calculate the conversion factor for the year, we multiply the product of the current year conversion factor and the update adjustment factor by the budget neutrality adjustment, and then adjust that figure by the target recapture amount, if applicable. We estimate the CY 2016 PFS conversion factor to be $35.8279, which reflects the budget neutrality adjustment, the 0.5 percent update adjustment factor specified under the MACRA, and the 0.77 percent target recapture amount required under Section 1848(c)(2)(O)(iv) of the Act and described above. We estimate the CY 2016 anesthesia conversion factor to be $22.3309, which reflect the same adjustments, with the addition of anesthesia-specific PE and MP adjustments.

TABLE 60—CALCULATION OF THE CY 2016 PFS CONVERSION FACTOR

Conversion factor in effect in CY 2015		35.9335
Update Factor	0.5 percent (1.005).	
CY 2016 RVU Budget Neutrality Adjustment	−0.02 percent (0.9998).	
CY 2016 Target Recapture Amount	−0.77 percent (0.9923).	
CY 2016 Conversion Factor		35.8279

TABLE 61—CALCULATION OF THE CY 2016 ANESTHESIA CONVERSION FACTOR

CY 2015 National Average Anesthesia Conversion Factor		22.6093
CY 2016 RVU Budget Neutrality Adjustment	−0.02 percent (0.9998).	
CY 2016 Anesthesia Fee Schedule Practice Expense and Malpractice Adjustment.	−0.445 percent (0.99555).	
CY 2016 Target Recapture Amount	−0.79 percent (0.9923).	
CY 2016 Conversion Factor		22.3309

Table 62 shows the payment impact on PFS services of the proposals contained in this final rule with comment period. 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 62 (CY 2016

PFS Estimated Impact on Total Allowed Charges by Specialty). The following is an explanation of the information represented in Table 62.

- *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 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 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 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 changes in the previous columns. Column F may not equal the sum of columns C, D, and E due to rounding.

TABLE 62—CY 2016 PFS ESTIMATED IMPACT ON TOTAL ALLOWED CHARGES BY SPECIALTY *

Specialty	Allowed charges (mil)	Impact of work RVU changes	Impact of PE RVU changes	Impact of MP RVU changes	Combined impact **
(A)	(B)	(C)	(D)	(E)	(F)
TOTAL	$89,020	0%	0%	0%	0%
ALLERGY/IMMUNOLOGY	$221	0%	0%	0%	0%
ANESTHESIOLOGY	$1,970	0%	1%	−2%	0%
AUDIOLOGIST	$61	0%	−1%	1%	−1%
CARDIAC SURGERY	$343	0%	0%	0%	0%
CARDIOLOGY	$6,498	0%	0%	0%	0%
CHIROPRACTOR	$789	0%	0%	0%	0%
CLINICAL PSYCHOLOGIST	$720	0%	0%	0%	0%
CLINICAL SOCIAL WORKER	$558	0%	0%	0%	0%
COLON AND RECTAL SURGERY	$161	−1%	0%	0%	−1%
CRITICAL CARE	$296	0%	0%	0%	0%
DERMATOLOGY	$3,217	0%	0%	0%	1%
DIAGNOSTIC TESTING FACILITY	$725	0%	0%	0%	0%
EMERGENCY MEDICINE	$3,120	0%	0%	0%	0%
ENDOCRINOLOGY	$454	0%	0%	0%	0%
FAMILY PRACTICE	$6,089	0%	0%	0%	0%
GASTROENTEROLOGY	$1,843	−2%	−1%	−1%	−4%
GENERAL PRACTICE	$478	0%	0%	0%	0%
GENERAL SURGERY	$2,210	0%	0%	0%	0%
GERIATRICS	$216	0%	0%	0%	0%
HAND SURGERY	$169	0%	0%	0%	0%
HEMATOLOGY/ONCOLOGY	$1,788	0%	0%	0%	0%
INDEPENDENT LABORATORY	$834	1%	7%	0%	9%
INFECTIOUS DISEASE	$660	0%	0%	0%	0%
INTERNAL MEDICINE	$11,058	0%	0%	0%	0%
INTERVENTIONAL PAIN MGMT	$720	0%	0%	0%	0%
INTERVENTIONAL RADIOLOGY	$298	0%	1%	0%	1%
MULTISPECIALTY CLINIC/OTHER PHYS	$96	0%	0%	0%	0%
NEPHROLOGY	$2,199	0%	0%	0%	0%
NEUROLOGY	$1,524	0%	−1%	0%	−1%
NEUROSURGERY	$776	0%	0%	−1%	−1%
NUCLEAR MEDICINE	$46	0%	0%	0%	−1%
NURSE ANES/ANES ASST	$1,187	0%	2%	−2%	0%
NURSE PRACTITIONER	$2,551	0%	0%	0%	0%
OBSTETRICS/GYNECOLOGY	$669	0%	0%	0%	0%
OPHTHALMOLOGY	$5,506	0%	0%	0%	−1%
OPTOMETRY	$1,178	0%	0%	0%	0%
ORAL/MAXILLOFACIAL SURGERY	$47	0%	0%	0%	0%
ORTHOPEDIC SURGERY	$3,672	0%	0%	0%	0%
OTHER	$25	0%	0%	0%	0%
OTOLARNGOLOGY	$1,197	0%	0%	0%	0%
PATHOLOGY	$1,330	4%	4%	0%	8%
PEDIATRICS	$59	0%	0%	0%	0%
PHYSICAL MEDICINE	$1,035	0%	0%	0%	−1%
PHYSICAL/OCCUPATIONAL THERAPY	$3,102	0%	0%	0%	0%
PHYSICIAN ASSISTANT	$1,728	0%	0%	0%	0%
PLASTIC SURGERY	$376	0%	0%	0%	1%
PODIATRY	$1,999	0%	0%	0%	0%
PORTABLE X–RAY SUPPLIER	$106	0%	1%	0%	1%

TABLE 62—CY 2016 PFS ESTIMATED IMPACT ON TOTAL ALLOWED CHARGES BY SPECIALTY *—Continued

Specialty	Allowed charges (mil)	Impact of work RVU changes	Impact of PE RVU changes	Impact of MP RVU changes	Combined impact **
(A)	(B)	(C)	(D)	(E)	(F)
PSYCHIATRY	$1,317	0%	0%	0%	0%
PULMONARY DISEASE	$1,780	0%	0%	0%	0%
RADIATION ONCOLOGY	$1,776	0%	−2%	0%	−2%
RADIATION THERAPY CENTERS	$52	0%	−2%	0%	−1%
RADIOLOGY	$4,494	0%	0%	0%	0%
RHEUMATOLOGY	$536	0%	0%	0%	0%
THORACIC SURGERY	$350	0%	0%	0%	0%
UROLOGY	$1,796	0%	0%	0%	0%
VASCULAR SURGERY	$1,019	0%	−1%	0%	−1%

** 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 final rule with comment period, 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 gastroenterology and radiation oncology, 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 proposed 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 62 displays the estimated CY 2016 combined impact on total allowed charges by specialty of all the RVU changes. Table 63 (Impact on CY 2016 Payment for Selected Procedures) shows the estimated impact on total payments for selected high volume procedures of all of the 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 63—IMPACT 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	$25.44	1%	$45.28	$45.50	0%
17000		Destruct premalg lesion.	$53.90	$54.46	1%	$67.20	$67.71	1%
27130		Total hip arthroplasty	$1,407.87	$1,404.45	0%	NA	NA	NA
27244		Treat thigh fracture	$1,277.80	$1,279.41	0%	NA	NA	NA
27447		Total knee arthroplasty	$1,407.52	$1,404.45	0%	NA	NA	NA
33533		Cabg arterial single	$1,952.63	$1,952.62	0%	NA	NA	NA
35301		Rechanneling of artery	$1,203.41	$1,198.80	0%	NA	NA	NA
43239		Egd biopsy single/multiple.	$154.15	$151.19	−2%	$412.52	$405.21	−2%
66821		After cataract laser surgery.	$316.21	$316.00	0%	$334.90	$334.27	0%
66984		Cataract surg w/iol 1 stage.	$650.40	$642.39	−1%	NA	NA	NA
67210		Treatment of retinal lesion.	$508.82	$509.47	0%	$526.79	$527.03	0%
71010		Chest x-ray 1 view frontal.	NA	NA	NA	$22.64	$22.57	0%
71010	26	Chest x-ray 1 view frontal.	$9.34	$9.32	0%	$9.34	$9.32	0%
77056		Mammogram both breasts.	NA	NA	NA	$116.42	$116.44	0%
77056	26	Mammogram both breasts.	$44.56	$44.43	0%	$44.56	$44.43	0%
77057		Mammogram screening.	NA	NA	NA	$83.01	$83.12	0%

TABLE 63—IMPACT 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
77057	26	Mammogram screening.	$35.93	$35.83	0%	$35.93 ..	$35.83 ..	0%
77427		Radiation tx management x5.	$187.57	$187.74	0%	$187.57	$187.74	0%
88305	26	Tissue exam by pathologist.	$39.17	$39.77	2%	$39.17 ..	$39.77 ..	2%
90935		Hemodialysis one evaluation.	$73.66	$73.09	−1%	NA	NA	NA
92012		Eye exam establish patient.	$53.18	$53.38	0%	$86.24 ..	$85.99 ..	0%
92014		Eye exam&tx estab pt 1/>vst.	$80.85	$80.97	0%	$124.69	$124.68	0%
93000		Electrocardiogram complete.	NA	NA	NA	$17.25 ..	$17.20 ..	0%
93010		Electrocardiogram report.	$8.62	$8.60	0%	$8.62	$8.60	0%
93015		Cardiovascular stress test.	NA	NA	NA	$77.26 ..	$75.60 ..	−2%
93307	26	Tte w/o doppler complete.	$45.99	$45.86	0%	$45.99 ..	$45.86 ..	0%
93458	26	L hrt artery/ventricle angio.	$323.76	$323.88	0%	$323.76	$323.88	0%
98941		Chiropract manj 3–4 regions.	$35.21	$34.75	−1%	$41.32 ..	$41.20 ..	0%
99203		Office/outpatient visit new.	$77.98	$77.75	0%	$109.60	$109.28	0%
99213		Office/outpatient visit est.	$51.38	$51.59	0%	$73.30 ..	$73.45 ..	0%
99214		Office/outpatient visit est.	$79.41	$79.18	0%	$108.88	$108.20	−1%
99222		Initial hospital care	$139.06	$138.30	−1%	NA	NA	NA
99223		Initial hospital care	$205.90	$204.22	−1%	NA	NA	NA
99231		Subsequent hospital care.	$39.53	$39.77	1%	NA	NA	NA
99232		Subsequent hospital care.	$73.30	$72.73	−1%	NA	NA	NA
99233		Subsequent hospital care.	$105.64	$104.98	−1%	NA	NA	NA
99236		Observ/hosp same date.	$220.99	$219.63	−1%	NA	NA	NA
99239		Hospital discharge day	$108.88	$108.20	−1%	NA	NA	NA
99283		Emergency dept visit ..	$62.88	$62.70	0%	NA	NA	NA
99284		Emergency dept visit ..	$119.66	$118.95	−1%	NA	NA	NA
99291		Critical care first hour	$227.46	$226.07	−1%	$279.20	$277.67	−1%
99292		Critical care addl 30 min.	$113.55	$113.22	0%	$124.33	$123.96	0%
99348		Home visit est patient	NA	NA	NA	$84.80 ..	$85.27 ..	1%
99350		Home visit est patient	NA	NA	NA	$178.95	$179.14	0%
G0008 ...		Immunization admin ...	NA	NA	NA	$25.51 ..	$25.44 ..	0%

[1] CPT codes and descriptions are copyright 2016 American Medical Association. All Rights Reserved. Applicable FARS/DFARS apply.
[2] Payments based on the July-December 2015 conversion factor of 35.9335.
[3] Payments based on the 2016 conversion factor of $35.8279.

D. Effect of Proposed Changes in Telehealth List

As discussed in section II.I. of this final rule with comment period, we proposed 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 additions.

E. Other Provisions of the Proposed Regulation

1. Ambulance Fee Schedule

As discussed in section III.A.2 of this final rule with comment period, 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 finalizing our proposal to correct the dates in the Code of Federal Regulations (CFR) at § 414.610(c)(1)(ii) and (c)(5)(ii) to conform the regulations to these self-implementing statutory provisions.

As discussed in section III.A.3 of this final rule with comment period, we are finalizing our proposal to continue, for CY 2016 and subsequent CYs,

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). As discussed previously, the continued use of the revised OMB delineations and the updated RUCA codes for CY 2016 and subsequent CYs means 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 will 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 will 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 final rule with comment period, the implementation of the revised OMB delineations and updated RUCA codes for CY 2016 and subsequent CYs will continue to affect whether certain areas are designated as urban or rural, and whether or not transports will be eligible for rural adjustments under the ambulance fee schedule statute and regulations. Descriptions of our final policies and accompanying rationale, as well as our responses to comments, are set forth in more detail in section III.A.3. of the final rule with comment period. We estimate that our continued implementation of the revised OMB delineations and updated RUCA codes for CY 2016 and subsequent CYs will 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 will result in a minimal fiscal impact on ambulance providers and suppliers as compared to CY 2015, because we will 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 continued implementation of the revised OMB delineations and updated RUCA codes will 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 final rule with comment period describing certain impacts associated with implementation of these geographic delineations. As further discussed in section III.A.3. of this final rule with comment period, Table 23 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 August 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, as discussed in section III.A.4. of this final rule with comment period, we are revising § 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 revising the definition of Basic Life Support (BLS) in § 414.605 to include the revised staffing requirements discussed above for § 410.41(b). Since we expect ambulance providers and suppliers are already in compliance with their state and local laws, we expect that these revisions will have a minimal impact on ambulance providers and suppliers. Similarly, we do not expect any significant impact on the Medicare program.

Furthermore, we are revising § 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 more clearly states our current policy. Also, for the reasons discussed in section III.A.4. of this final rule with comment period, we are deleting the last sentence of our definition of BLS in § 414.605. Because these revisions do not change our current policies, we expect they will 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 final rule with comment period, we proposed 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 proposed 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 3.4 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 $60 million in Part B payments. We estimate that the 10-year cost impact of CCM payment in RHCs and FQHCs would be $190 million, of which $30 million is the premium offset and $160 million 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 0.034 (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). This estimate was then phased in based on the current utilization under the physician fee schedule. Table 64 provides the yearly estimates (figures are in millions):

TABLE 64—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		$10	$10	$20	$20	$20	$20	$30	$30	$30	$60	$190
Premium Offset								$(10)	$(10)	$(10)	$—	$(30)
Total Part B		$10	$10	$20	$20	$20	$20	$20	$20	$20	$60	$160

3. Healthcare Common Procedure Coding System (HCPCS) Coding for Rural Health Clinics (RHCs)

As discussed in section III.C. of this final rule with comment period, we proposed to require HCPCS coding for all services furnished by RHCs to Medicare beneficiaries effective for dates of service on or after January 1, 2016. We are finalizing the reporting requirement as proposed with an effective date of April 1, 2016 to allow the MACs additional time to implement the necessary claims processing systems changes completely. There will be no cost impact on the Medicare program since this requirement does not change the payment methodology for RHC services. This requirement 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 final rule with comment period, we proposed 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 proposed 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 did not propose 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 final rule with comment period, we discuss the payment of biosimilar biological products under section 1847A of the Act and the proposal 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 final rule, we had not yet received ASP data for any biosimilar biological products that had been approved under the FDA's biosimilar approval pathway. Information from pharmaceutical pricing compendia for one approved biosimilar product has become available since the proposed rule was written, and a comparison of compendia prices for the biosimilar product and its reference product agrees with our expectation that the Medicare program will see some degree of savings from biosimilars. At this time, it is still not clear how many biosimilar products will be approved, when approval and marketing of various products will occur, or what the market penetration of biosimilars in Medicare will be. It is also not clear what the cost differences between the each of the biosimilars will be or what the price differences between the biosimilars and the reference products will be as the market develops. 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

The Appropriate Use Criteria (AUC) development process requirements, as well as an application process that organizations must comply with to become qualified provider-led entities (PLEs) do not impact CY 2016 physician payments under the PFS.

7. Physician Compare

We do not estimate any impact as a result of the final policies for the Physician Compare Web site.

8. 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.'' [12] 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

[12] 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.

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 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. [13] 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.[14] 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

[13] Id. at XV.

[14] Id. at xvi. *See* Figure 4.

(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 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.[15] 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

[15] Id. at xvi. See Figure 4.

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.[16] 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, 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 final rule with comment period, we proposed 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.[17] 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

[16] 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.*

[17] Id. at XV.

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 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 final rule with comment period, we are finalizing a policy that group practices of 100 or more eligible professionals must report on CAHPS for PQRS. Therefore, a group practice of 100 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.[18] In addition, 144 ACOs participated in the PQRS GPRO through either the Medicare Shared Savings Program (112 ACOs) or Pioneer ACO Model (32 practices).[19] These group practices encompass 134,510 eligible professionals (or approximately 140,000 eligible professionals).[20] 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 Shared Saving Program 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 Medicare Shared Savings Program ACOs. 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 ACOs, and Medicare Shared Savings Program ACOs. 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 $\times$ 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.

[18] Id. at xv.

[19] Id. at xvi.

[20] Id. at 18.

Therefore, the total estimated annual cost per group practice is estimated to be approximately $6,632.84.

9. EHR Incentive Program

The changes to the EHR Incentive Program in section III.J of this final rule with comment period would not impact the current burden estimate for the EHR Incentive Program.

10. Comprehensive Primary Care (CPC) Initiative and Medicare EHR Incentive Program Aligned Reporting

The establishment of an aligned reporting option between CPC and the Medicare EHR Incentive Program does not impact the CY 2016 payments under PFS.

11. 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.

12. 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 finalizing certain conforming changes to align with PQRS, including a change to the quality measure set. We also are finalizing 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 finalizing updates to the assignment methodology to include claims submitted by electing teaching amendment hospitals and to exclude certain claims for services performed in SNFs. Since the finalized 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.

13. 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 as well as those groups of physicians and physicians that fail to avoid the PQRS payment adjustment as a group or as individuals.

Unless specified, the changes to the VM in section III.M of this final rule with comment period 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 EPs 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 65.

TABLE 65: 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*

TABLE 65: 2016 VM AMOUNTS UNDER QUALITY-TIERING—Continued

Cost/quality	Low quality	Average quality	High quality
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 Category 1 groups' downward payment adjustments under quality-tiering, in Table 65 with the Category 2 groups' −2.0 percent automatic downward payment adjustments. 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.

On September 8, 2015, we made the 2014 Annual QRURs available to all groups and solo practitioners based on their performance in CY 2014. We also completed a preliminary analysis (prior to accounting for the informal review process) 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 and present a summary of the findings below. Please note that the impact of the policies for the CY 2018 VM finalized in this final rule with comment period will be discussed in the PFS rule for CY 2018.

Based on the methodology codified in § 414.1210(c), there are 13,785 groups of 10 or more EPs (as identified by their Taxpayer Identification Numbers (TINs)) whose physicians' payments under the Medicare PFS will be subject to the VM in the CY 2016 payment adjustment period. Of these 13,785 groups subject to the CY 2016 VM, preliminary results show that 8,357 groups met the criteria for inclusion in Category 1 and are subject to the quality-tiering methodology in order to calculate their CY 2016 VM. Of the 8,357 groups in Category 1, there are 7,639 groups of physicians with between 10 and 99 EPs and 718 groups of physicians with 100 or more EPs. As noted in this section, these are preliminary numbers and may be subject to change as a result of the informal review process. We release the actual number of upward and downward adjustments, along with the adjustment factor after the conclusion of the informal review process.

Of the 7,639 groups of physicians with between 10 and 99 EPs, preliminary results found that 110 groups are in tiers that will result in an upward adjustment of between +1.0x and +3.0x; 42 of those groups qualify for the additional +1.0x adjustment to their Medicare payments for treating high-risk beneficiaries; and 7,529 groups are in tiers that will result in a neutral adjustment to their payments in CY 2016. Of the 718 groups of physicians with 100 or more EPs, our preliminary results showed that 9 groups are in tiers that will result in an upward adjustment of between +1.0x and +3.0x, with 4 of those groups qualifying for the additional +1.0x adjustment to their Medicare payments for treating high-risk beneficiaries; 54 groups are in tiers that will result in a downward adjustment of between −1.0 and −2.0 percent; and 655 groups are in tiers that will result in a neutral adjustment to their payments in CY 2016. We will announce the final quality-tiering results along with the upward payment adjustment factor (x) in the late 2015 on the CMS Web site at *http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/PhysicianFeedbackProgram/ValueBasedPaymentModifier.html.* Tables 66 shows the preliminary distribution of the groups with between 10 and 99 EPs in Category 1 into the various quality and cost tiers. Tables 67 shows the preliminary distribution of the groups with 100 or more EPs in Category 1 into the various quality and cost tiers.

TABLE 66—PRELIMINARY DISTRIBUTION USING 2014 DATA OF QUALITY AND COST TIERS FOR GROUPS WITH BETWEEN 10 TO 99 EPS (7,639 GROUPS)

Cost/quality	Low quality	Average quality	High quality
Low Cost	0.0% (6)	+[1.0/2.0]x (50)	+[2.0/3.0]x (1)
Average Cost	0.0% (589)	0.0% (6,700)	+[1.0/2.0]x (59)
High Cost	0.0% (32)	0.0% (201)	0.0% (1)

TABLE 67—PRELIMINARY DISTRIBUTION USING 2014 DATA OF QUALITY AND COST TIERS FOR GROUPS WITH 100 OR MORE EPS (718 GROUPS)

Cost/Quality	Low Quality	Average Quality	High Quality
Low Cost	0.0% (0)	+[1.0/2.0]x (6)	+[2.0/3.0]x (0)
Average Cost	−1.0% (31)	0.0% (655)	+[1.0/2.0]x (3)
High Cost	−2.0% (0)	−1.0% (23)	0.0% (0)

Of the 13,785 groups subject to the CY 2016 VM, preliminary results found that 5,428 groups met the criteria for inclusion in Category 2. As noted above, Category 2 includes groups that do not fall within Category 1. Groups in Category 2 will be subject to a −2.0 percent payment adjustment under the VM during the CY 2016 payment adjustment period.

In CY 2016, only the physicians in groups with 10 or more EPs will be subject to the VM.

We note that in the 2014 QRUR Experience Report, which we intend to release in early 2016, we will provide a detailed analysis of the impact of the 2016 VM policies on groups of 10 or more EPs subject to the VM in CY 2016, including findings based on the data contained in the 2014 QRURs for all groups and solo practitioners.

14. Physician Self-Referral Updates

The physician self-referral update provisions are discussed in section III.N. of this final rule with comment period. We did not receive any comments on the physician self-referral updates regulatory impact section of the 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 the physician self-

referral update provisions in this final rule with comment period will reduce burden by clarifying previous guidance. We believe these provisions will allow parties to determine with greater certainty whether their financial relationships comply with an exception.

We are also issuing new exceptions and a new definition that will accommodate legitimate financial arrangements while continuing to protect against program and patient abuse:

- In section III.N.2.a of this final rule with comment period, we discuss a limited new exception for hospitals, FQHCs, and RHCs that wish to provide remuneration to physicians to assist with the compensation of a nonphysician practitioner. This new exception would promote access to primary medical and mental health care services, a goal of the Secretary and the Affordable Care Act.
- In section III.N.2.b of this final rule with comment period, we describe the new definition of the geographic area served by an FQHC or RHC we are adding to physician recruitment exception. This new definition will provide certainty to FQHCs and RHCs that their physician recruitment arrangements satisfy the requirements of the exception.
- In section III.N.7 of this final rule with comment period, we discuss a new exception that will protect timeshare arrangements that meet certain criteria. This new exception will 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 will reduce the potential costs of restructuring such arrangements, and the consequences of noncompliance may be avoided entirely.

- In section III.N.9.b of this final rule with comment period, we discuss the requirement 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 may have revised bona fide investment levels that may exceed the baseline bona fide investment levels calculated under our previous guidance. As discussed in section III.N.9.b, while we do not have the discretion to continue implementing a policy that is inconsistent with the statute, we recognize that we need to give physician-owned hospitals a reasonable amount of time to come into compliance with the revised policy. Accordingly, we are delaying the effective date of this revision for one year from the effective date of this final rule to January 1, 2017.

15. Opt Out Change

We revised 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 final rule with comment period 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 final rule with comment period that would have an effect on beneficiaries. In general, we believe that many of these 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 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 63, the CY 2015 national payment amount in the nonfacility setting for CPT code 99203 (Office/outpatient visit, new) was $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 final rule with comment period, using the CY 2016 CF, the CY 2016 national payment amount in the nonfacility setting for CPT code 99203, as shown in Table 63, is $109.28, which means that, in CY 2016, the proposed beneficiary coinsurance for this service would be $21.86.

H. Accounting Statement

As required by OMB Circular A–4 (available at *http://www.whitehouse.gov/omb/circulars/a004/a-4.pdf),* in Table 66 (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 66—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED EXPENDITURES

Category	Transfers
CY 2016 Annualized Monetized Transfers.	Estimated increase in expenditures of $0.0 billion for PFS CF update.
From Whom To Whom?	Federal Government to physicians, other practitioners and providers and suppliers who receive payment under Medicare.
CY 2016 Annualized Monetized Transfers.	Estimated increase in payment of $0.0 billion.
From Whom To Whom?	Federal Government to eligible professionals who satisfactorily participate in the Physician Quality Reporting System (PQRS).

TABLE 67—ACCOUNTING STATEMENT: CLASSIFICATION OF ESTIMATED COSTS, TRANSFER, AND SAVINGS

Category	Transfer
CY 2016 Annualized Monetized Transfers of beneficiary cost coinsurance.	$0.0 billion
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, 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 amends 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 (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 Cancellation of opt-out and early termination of opt-out.

(a) A physician or practitioner may cancel opt-out by submitting a written notice to each Medicare Administrative Contractor to which he or she would file claims absent the opt-out, not later than 30 days before the end of the current 2-year opt-out period, indicating that the physician or practitioner does not want to extend the application of the opt-out affidavit for a subsequent 2-year period.

(b) * * *

(2) Notify all Medicare Administrative 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 paragraphs (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. Removing in paragraph (b)(2) 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 billing as if it were 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) Eighty (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) Eighty (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 grandfathered tribal FQHCs that are authorized to bill at this rate.

* * * * *

(g) * * *

(3) *HCPCS coding.* FQHCs and RHCs 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), (2), and (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.* This rates is 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, 1395rr, and 1395ddd.

■ 19. Section 410.15, paragraph (a), is amended by—

■ a. In the definition of ''First annual wellness visit providing personalized prevention plan services'', revising paragraph (x) and adding paragraph (xi).

■ b. In the definition of ''Subsequent annual wellness visit providing personalized prevention plan services'', revising paragraph (viii) and adding paragraph (ix).

The revisions and additions read as follows:

§ 410.15 Annual wellness visits providing Personalized Prevention Plan Services: Conditions for and limitations on coverage.

(a) * * *

First annual wellness visit providing personalized prevention plan services

* * *

(x) At the discretion of the beneficiary, furnish advance care planning services to include discussion about future care decisions that may need to be made, how the beneficiary can let others know about care preferences, and explanation of advance directives which may involve the completion of standard forms.

(xi) Any other element determined appropriate through the national coverage determination process.

* * * * *

Subsequent wellness visit providing personalized prevention plan services

* * *

(viii) At the discretion of the beneficiary, furnish advance care planning services to include discussion about future care decisions that may need to be made, how the beneficiary can let others know about care preferences, and explanation of advance directives which may involve the completion of standard forms.

(ix) Any other element determined appropriate through the national coverage determination process.

* * * * *

■ 20. 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, Medicaid and all other federally funded health care programs by the Office of Inspector General or had his or her Medicare enrollment revoked, and meets any applicable requirements to provide incident to services, including licensure, imposed by the State in which the services are being furnished.

* * * * *

(b) * * *

(5) In general, services and supplies must be furnished under the direct supervision of the physician (or other practitioner). Services and supplies furnished incident to transitional care management and chronic care

management services can be furnished under general supervision of the physician (or other practitioner) when these services or supplies are provided by clinical staff. The physician (or other practitioner) supervising the auxiliary personnel need not be the same physician (or other practitioner) who is treating the patient more broadly. However, only the supervising physician (or other practitioner) may bill Medicare for incident to services

* * * * *

■ 21. 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.

* * * * *

■ 22. 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.

* * * * *

■ 23. 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

■ 24. The authority citation for part 411 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).

■ 25. Section 411.351 is amended by—

■ a. In the definition of ''Entity'', 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. In the definition of ''Parenteral and enteral nutrients, equipment, and supplies'', revising paragraphs (1) and (2).

■ d. Revising the definition of ''Physician in the group practice''.

■ e. In the definition of ''Remuneration'', 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.

* * * * *

''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.

* * * * *

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.

* * * * *

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.

* * * * *

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.

* * * * *

■ 26. 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), (b)(1), (d)(1)(i), (e)(1)(i), (e)(4)(i), (l)(1), (p)(2), (q) (incorporating the requirement contained in § 1001.952(f)(4) of this title), (r)(2)(ii), (t)(1)(ii) or (t)(2)(iii) (both incorporating the requirements contained in § 411.357(e)(1)(i)), (v)(7)(i), (w)(7)(i), (x)(1)(i), or (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.

* * * * *

■ 27. 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 paragraph (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.

■ 28. 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 (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.

* * * * *

■ 29. Section 411.357 is amended by—

■ a. Revising paragraphs (a) introductory text, (a)(1) through (4), (a)(5) introductory text, (a)(6) and (7), (b)(1) through (3), (b)(4) introductory text, (b)(5) and (6), (c)(3), (d)(1)(iii), (iv)

and (vii), (e)(1)(iii) and (iv), (e)(4)(i) and (iv), (e)(6), (f)(2), (k)(2), (l) introductory text, (l)(1) and (2), (m)(1) through (3), (m)(5), (p)(1)(ii)(A), (p)(2), (r)(2)(iv) and (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 duration 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 duration 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 duration 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 or noncontiguous 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. 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).

* * * * *

(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 compensate a nonphysician practitioner.* (1) Remuneration provided by a hospital to a physician to compensate 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 50 percent of the actual compensation, signing bonus, and benefits paid by the physician to the nonphysician practitioner during a period not to exceed the first 2 consecutive years of the compensation arrangement between the nonphysician practitioner and the physician (or the physician organization in whose shoes the physician stands); 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 compensation, 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 1 year of the commencement of his or her compensation arrangement with the physician (or the physician organization in whose shoes the physician stands under § 411.354(c))—

(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)(A) The nonphysician practitioner has a compensation arrangement with the physician or the physician organization in whose shoes the physician stands under § 411.354(c); and

(B) Substantially all of the services that the nonphysician practitioner furnishes to patients of the physician's practice are primary care services or mental health care services.

(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, a certified nurse-midwife as defined in section 1861(gg) of the Act, a clinical social worker as defined in section 1861(hh) of the Act, or a clinical psychologist as defined in § 410.71(d) of this subchapter.

(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) For purposes of paragraph (x)(1) of this section, a ''compensation arrangement'' between a physician (or the physician organization in whose shoes the physician stands under § 411.354(c) and a nonphysician practitioner—

(i) Means an employment, contractual, or other arrangement under which remuneration passes between the parties; and

(ii) Does not include a nonphysician practitioner's ownership or investment interest in a physician organization.

(7)(i) This paragraph (x) may be used by a hospital, federally qualified health center, or rural health clinic only once every 3 years with respect to the same referring physician.

(ii) Paragraph (x)(7)(i) of this section does not apply to remuneration provided by a hospital, federally qualified health center, or rural health clinic to a physician to compensate a nonphysician practitioner to provide patient care services if—

(A) The nonphysician practitioner is replacing a nonphysician practitioner who terminated his or her employment or contractual arrangement to provide patient care services with the physician (or the physician organization in whose shoes the physician stands) within 1 year of the commencement of the employment or contractual arrangement; and

(B) The remuneration provided to the physician is provided during a period that does not exceed 2 consecutive years as measured from the commencement of the compensation arrangement between the nonphysician practitioner who is being replaced and the physician (or the physician organization in whose shoes the physician stands).

(8)(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 under an arrangement for the use of 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 arrangement is between a physician (or the physician organization in whose shoes the physician stands under § 411.354(c) and—

(i) A hospital; or

(ii) Physician organization of which the physician is not an owner, employee, or contractor.

(3) The premises, equipment, personnel, items, supplies, and services covered by the arrangement are used—

(i) Predominantly for the provision of evaluation and management services to patients; and

(ii) On the same schedule.

(4) The equipment covered by the arrangement is—

(i) Located in the same building 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 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 referral of patients by the physician who is a party to the arrangement to the hospital or physician organization of which the physician is not an owner, employee, or contractor.

(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 while using the premises, equipment, personnel, items, supplies, or services covered by the arrangement; or

(B) Per-unit of service fees that are not time-based, to the extent that such fees reflect services provided to patients referred by the party granting permission to use the premises, equipment, personnel, items, supplies, or services covered by the arrangement to the party to which the permission is granted.

(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.

(9) The arrangement does not convey a possessory leasehold interest in the office space that is the subject of the arrangement.

■ 30. 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.

* * * * *

■ 31. Section 411.362 is amended by—

a. In paragraph (a):

■ i. Effective January 1, 2017, adding the definition of ''Ownership or investment interest'' in alphabetical order; and

■ ii. Adding the definition of ''Public advertising for the hospital'' in alphabetical order.

■ b. Revising paragraphs (b)(3)(ii)(C), (c)(2)(iv) and (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 (c)(2)(iv), ''sufficient number'' means the number of hospitals, as determined by CMS that would ensure that the determination under this paragraph (c)(2)(iv) 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 (c)(2)(v), ''sufficient number'' means the number of hospitals, as determined by CMS that would ensure that the determination under this paragraph (c)(2)(v) 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.

* * * * *

■ 32. 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

■ 33. 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)).

■ 34. Section 414.90 is amended by—

■ a. Adding paragraphs (j)(8) and (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 paragraph (k)(5).

The additions and revisions read as follows:

§ 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 must 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 must 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 2 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 2 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.

(B) [Reserved]

(viii) If the CAHPS for PQRS survey is applicable to the practice, group practices comprised of 100 or more eligible professionals that register to participate in the GPRO must administer the CAHPS for PQRS survey, regardless of the GPRO reporting mechanism selected.

(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) of this section 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]

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■ 35. 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. An AUC set is a collection of individual appropriate use criteria. An individual criterion 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 conditions, diseases or symptom complexes and associated advanced diagnostic imaging services 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 (PLE) means a national professional medical specialty society or other organization that is comprised primarily of providers or practitioners who, either within the organization or outside of the organization, predominantly provide direct patient care.

Specified applicable appropriate use criteria means any individual appropriate use criterion or AUC set developed, modified or endorsed by a qualified PLE.

(c) *Qualified provider-led entity.* To be qualified by CMS, a PLE must adhere to the evidence-based processes described in paragraph (c)(1) of this section when developing or modifying AUC. A qualified PLE may develop AUC, modify AUC developed by another qualified PLE, or endorse AUC developed by other qualified PLEs.

(1) *Requirements for qualified PLEs developing or modifying AUC.* A PLE must perform all of the following when developing or modifying AUC:

(i) Utilize an evidentiary review process when developing or modifying AUC 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) Utilize at least one multidisciplinary team with autonomous governance, decision-making and accountability for developing or modifying AUC. At a minimum the team must be comprised of seven members including at least one practicing physician with expertise in the clinical topic related to the appropriate use criterion being developed or modified, at least one practicing physician with expertise in the imaging studies related to the appropriate use criterion, at least one primary care physician or practitioner as described in sections 1833(u)(6), 1833(x)(2)(A)(i)(I), and 1833(x)(2)(A)(i)(II) of the Act, at least one expert in statistical analysis and at least one expert in clinical trial design. A given team member may be the team's expert in more than one domain.

(iii) Utilize a publicly transparent process for identifying potential conflicts of interest and for resolving conflicts of interest of members on the multidisciplinary team, the PLE and any other party participating in AUC development or modification, to include recusal or exclusion of individuals as appropriate. The PLE must document the following information and make it available in timely fashion to a public request, for a period of not less than 5 years after the most recent published update of the relevant AUC:

(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 including the PLE and any other party participating in AUC development or modification that may financially benefit from the AUC. These financial relationships may include, for example, compensation arrangements such as salary, grant, speaking or consulting fees, contract, or collaboration agreements.

(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 including the PLE or any other party participating in AUC development or modification that may financially benefit from the AUC.

(iv) Publish each individual criterion on the PLE's Web site and include an identifying title, authors (at a minimum, all members of the multidisciplinary AUC development team must be listed as authors), and key references used to establish the evidence.

(v) Identify each appropriate use criterion or AUC subset that are relevant to a priority clinical area with a statement on the PLE's Web site. To be identified as being relevant to a priority clinical area, the criterion or AUC subset must reasonably address the entire clinical scope of the corresponding priority clinical area.

(vi) Identify key points in an individual criterion as evidence-based or consensus-based, and grade such key points in terms of strength of evidence using a formal, published and widely recognized methodology.

(vii) Utilize a transparent process for the timely and continual updating of each criterion. Each criterion must be reviewed and, when appropriate, updated at least annually.

(viii) Publicly post the process for developing or modifying the AUC on the PLE's Web site.

(ix) Disclose parties external to the PLE when such parties have involvement in the AUC development process.

(2) *Process to identify qualifying PLEs.* PLEs must meet all of the following criteria:

(i) PLEs must submit an application to CMS for review 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 PLEs that meet the definition of PLE in paragraph (b) of this section;

(iii) Applications must be received by CMS annually by January 1;

(iv) All approved qualified PLEs in each year will be included on the list of qualified PLEs posted to the CMS Web site by June 30 of that year; and

(v) Approved PLEs are qualified for a period of 5 years.

(vi) Qualified PLEs are required to re-apply. The application must be received by CMS by January 1 of the 5th year after the PLE's most recent approval date.

(d) *Endorsement.* Qualified PLEs may endorse the AUC set or individual criteria of other qualified PLEs, under agreement by the respective parties, in order to enhance an AUC set.

(e) *Identifying priority clinical areas.* (1) CMS identifies priority clinical areas through annual rulemaking and in consultation with stakeholders.

(2) CMS will consider incidence and prevalence of disease, the volume and variability of use of particular imaging services, and strength of evidence supporting particular 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).

(f) *Identification of non-evidence-based AUC or other non-adherence to requirements for qualified PLEs.* (1) CMS will accept public comment to facilitate identification of AUC sets, subsets or individual criterion that are not evidence-based, giving priority to AUC associated with priority clinical areas and to AUC that conflict with one another. CMS may also independently identify AUC of concern.

(2) The evidentiary basis of the identified AUC may be reviewed by the MEDCAC.

(3) If a qualified PLE is found non-adherent to the requirements in paragraph (c) of this section, CMS may terminate its qualified status or may consider this information during re-qualification.

■ 36. 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]

■ 37. 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''.

■ 38. 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).

■ 39. 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.

* * * * *

■ 40. Section 414.1210 is amended by—

■ a. Revising paragraph (a)(4), (b)(2)(i)(B), (C), and (D), (b)(3), (b)(4), and (c).

■ b. Adding paragraphs (b)(2)(i)(E) and (F).

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 of physicians with 10 or more eligible professionals and equal to −2% for groups of physicians with two to nine eligible professionals and for physician 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 of physician or physician 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 +3 × (rather than +2 ×) if the group has 10 or more eligible professionals or +2 × (rather than +1 ×) for 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 +3 × (rather than +2 ×) if the group of physicians has 10 or more eligible professionals, +2 × (rather than +1 ×) for a physician solo practitioner or if the group of physicians has two to nine eligible professionals, or +2 × (rather than +1 ×) for a solo practitioner who is a nonphysician eligible professional or if the group consists 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 paragraph (b)(2) of this section, 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) *Application of the value-based payment modifier to participants in the Pioneer ACO Model and the Comprehensive Primary Care Initiative.* (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 paragraph (a) of this section, 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.

■ 41. 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.

■ 42. Section 414.1230 is amended by revising paragraph (c) to read as follows:

§ 414.1230 Additional measures for groups and solo practitioners.

* * * * *

(c) Rates of an all-cause hospital readmissions measure, except for groups with between two to nine eligible professionals and solo practitioners starting with the CY 2017 payment adjustment period.

■ 43. Section 414.1235 is amended by adding paragraphs (c)(4) and (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.

■ 44. 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, QCDR, 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 eCQM benchmarks will be developed. 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.

* * * * *

■ 45. 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.

■ 46. Section 414.1265 is amended by adding paragraph (a)(2) and revising paragraphs (a)(1) and (b) to read as follows:

§ 414.1265 Reliability of measures.

* * * * *

(a) * * *

(1) Starting with the CY 2017 payment adjustment period, the exception to this paragraph (a) is the all-cause hospital readmissions measure described at § 414.1230(c). In a performance period, if a group has fewer than 200 cases for this all-cause hospital readmissions measure, that measure is excluded from its domain and the remaining measures in the domain are given equal weight.

(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 125 episodes 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.

■ 47. Section 414.1270 is amended by removing paragraphs (b)(5) and (c)(5), revising paragraph (c)(1)(i), and adding paragraph (d) to read as follows:

§ 414.1270 Determination and calculation of Value-Based Payment Modifier adjustments.

* * * * *

(c) * * *

(1) * * *

(i) Such group does not meet the criteria as a group to avoid the PQRS payment adjustment for CY 2017 as specified by CMS; and

* * * * *

(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).

■ 48. 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 OF PHYSICIANS 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 OF PHYSICIANS 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

■ 49. 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).

■ 50. Section 425.20 is amended in the definition of ''Primary care services'' by revising paragraph (2) introductory text and adding paragraphs (2)(v) and (4) to 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.

* * * * *

■ 51. 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 subchapter to receive payment on a reasonable cost basis for the direct medical and surgical services of their physicians.

* * * * *

■ 52. Section 425.402 is 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.

■ 53. Section 425.502 is amended by—

■ a. Adding paragraph (a)(5)

■ b. In paragraph (d)(2)(ii), removing the reference ''§ 425.216(c)'' and adding in its place the reference ''§ 425.216''.

The addition reads 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]

■ 54. 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

■ 55. 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).

■ 56. In § 495.4 the definition of ''Certified electronic health record technology (CEHRT)'' is amended by revising paragraphs (1)(ii)(B)(3) and (2)(ii)(B) to read as follows:

§ 495.4 Definitions.

* * * * *

Certified electronic health record technology (CEHRT) * * *

(1) * * *

(ii) * * *

(B) * * *

(3) Clinical quality measure certification criteria that support the calculation and reporting of clinical quality measures at 45 CFR 170.314(c)(2) and (3); or 45 CFR 170.315(c)(3)(i) and (ii); and can be electronically accepted by CMS if the provider is submitting electronically.

* * * * *

(2) * * *

(ii) * * *

(B) Clinical quality measure certification criteria that support the calculation and reporting of clinical quality measures at 45 CFR 170.315(c)(2) and (c)(3)(i) and (ii), and can be electronically accepted by CMS.

* * * * *

Dated: October 27, 2015.

Andrew M. Slavitt,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: October 28, 2015.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2015–28005 Filed 10–30–15; 4:15 pm]

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Part III

Securities and Exchange Commission

17 CFR Parts 200, 227, 232, et al.
Crowdfunding; Final Rule

SECURITIES AND EXCHANGE COMMISSION

17 CFR Parts 200, 227, 232, 239, 240, 249, 269, and 274

[Release Nos. 33–9974; 34–76324; File No. S7–09–13]

RIN 3235–AL37

Crowdfunding

AGENCY: Securities and Exchange Commission.

ACTION: Final rule.

SUMMARY: The Securities and Exchange Commission is adopting new Regulation Crowdfunding under the Securities Act of 1933 and the Securities Exchange Act of 1934 to implement the requirements of Title III of the Jumpstart Our Business Startups Act. Regulation Crowdfunding prescribes rules governing the offer and sale of securities under new Section 4(a)(6) of the Securities Act of 1933. Regulation Crowdfunding also provides a framework for the regulation of registered funding portals and broker-dealers that issuers are required to use as intermediaries in the offer and sale of securities in reliance on Section 4(a)(6). In addition, Regulation Crowdfunding conditionally exempts securities sold pursuant to Section 4(a)(6) from the registration requirements of Section 12(g) of the Securities Exchange Act of 1934.

DATES: The final rules and forms are effective May 16, 2016, except that instruction 3 adding part 227 and instruction 15 amending Form ID are effective January 29, 2016.

FOR FURTHER INFORMATION CONTACT: With regard to requirements for issuers, Eduardo Aleman, Julie Davis, or Amy Reischauer, Division of Corporation Finance, at (202) 551–3460, and with regard to requirements for intermediaries, Joseph Furey, Joanne Rutkowski, Timothy White, Devin Ryan, or Erin Galipeau, Division of Trading and Markets, at (202) 551–5550, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549.

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I. Introduction

A. Background

Crowdfunding is a relatively new and evolving method of using the Internet to raise capital to support a wide range of ideas and ventures. An entity or individual raising funds through crowdfunding typically seeks small individual contributions from a large number of people. Individuals interested in the crowdfunding campaign—members of the ''crowd''—may share information about the project, cause, idea or business with each other and use the information to decide whether to fund the campaign based on the collective ''wisdom of the crowd.''

The Jumpstart Our Business Startups Act (the ''JOBS Act''),[1] enacted on April 5, 2012, establishes a regulatory structure for startups and small businesses to raise capital through securities offerings using the Internet through crowdfunding. The crowdfunding provisions of the JOBS Act were intended to help provide startups and small businesses with capital by making relatively low dollar offerings of securities, featuring relatively low dollar investments by the ''crowd,'' less costly.[2] Congress included a number of provisions intended to protect investors who engage in these transactions,[3] including

[1] Pub. L. 112–106, 126 Stat. 306 (2012).

[2] *See, e.g.,* congressional statements regarding crowdfunding bills that were precursors to the JOBS Act: 157 Cong. Rec. S8458–02 (daily ed. Dec. 8, 2011) (statement of Sen. Jeff Merkley) (''Low-dollar investments from ordinary Americans may help fill the void, providing a new avenue of funding to the small businesses that are the engine of job creation. The CROWDFUND Act would provide startup companies and other small businesses with a new way to raise capital from ordinary investors in a more transparent and regulated marketplace.''); 157 Cong. Rec. H7295–01 (daily ed. Nov. 3, 2011) (statement of Rep. Patrick McHenry) (''[H]igh net worth individuals can invest in businesses before the average family can. And that small business is limited on the amount of equity stakes they can provide investors and limited in the number of investors they can get. So, clearly, something has to be done to open these capital markets to the average investor[.]'').

[3] *See, e.g.,* congressional statements regarding crowdfunding bills that were precursors to the JOBS Act: 158 Cong. Rec. S1781 (daily ed. Mar. 19, 2012) (statement of Sen. Carl Levin) (''Our bill creates new opportunities for crowdfunding but establishes

investment limits, required disclosures by issuers, and a requirement to use regulated intermediaries. The provisions also permit Internet-based platforms to facilitate the offer and sale of securities in crowdfunding transactions without having to register with the Commission as brokers.

In the United States, crowdfunding generally has not involved the offer of a share in any financial returns or profits that the fundraiser may expect to generate from business activities financed through crowdfunding. Such a profit or revenue-sharing model—sometimes referred to as the ''equity model'' of crowdfunding—could trigger the application of the federal securities laws because it likely would involve the offer and sale of a security. Under the Securities Act of 1933 (''Securities Act''), the offer and sale of securities is required to be registered unless an exemption is available. Some observers have stated that registered offerings are not feasible for raising smaller amounts of capital, as is done in a typical crowdfunding transaction, because of the costs of conducting a registered offering and the resulting ongoing reporting obligations under the Securities Exchange Act of 1934 (''Exchange Act'') that may arise as a result of the offering. Limitations under existing regulations, including purchaser qualification requirements for offering exemptions that permit general solicitation and general advertising, have made private placement exemptions generally unavailable for crowdfunding transactions, which are intended to involve a large number of investors [4] and not be limited to investors that meet specific qualifications.[5]

Moreover, someone who operates a Web site to effect the purchase and sale of securities for the account of others generally would, under pre-existing regulations, be required to register with the Commission as a broker-dealer and comply with the laws and regulations applicable to broker-dealers.[6] A person that operates such a Web site only for the purchase of securities of startups and small businesses, however, may find it impractical in view of the limited nature of that person's activities and business to register as a broker-dealer and operate under the full set of regulatory obligations that apply to broker-dealers.

B. Title III of the JOBS Act

Title III of the JOBS Act (''Title III'') added new Securities Act Section 4(a)(6),[7] which provides an exemption from the registration requirements of Securities Act Section 5 [8] for certain crowdfunding transactions. To qualify for the exemption under Section 4(a)(6), crowdfunding transactions by an issuer (including all entities controlled by or under common control with the issuer) must meet specified requirements, including the following:

- The amount raised must not exceed $1 million in a 12-month period;
- individual investments in all crowdfunding issuers in a 12-month period are limited to:
  - The greater of $2,000 or 5 percent of annual income or net worth, if annual income or net worth of the investor is less than $100,000; and
  - 10 percent of annual income or net worth (not to exceed an amount sold of $100,000), if annual income or net worth of the investor is $100,000 or more; and
- transactions must be conducted through an intermediary that either is registered as a broker-dealer or is registered as a new type of entity called a ''funding portal.''

In addition, Title III:

- Adds Securities Act Section 4A,[9] which requires, among other things, that issuers and intermediaries that facilitate transactions between issuers and investors in reliance on Section 4(a)(6) provide certain information to investors and potential investors, take other actions and provide notices and other information to the Commission;
- adds Exchange Act Section 3(h),[10] which requires the Commission to adopt rules to exempt, either conditionally or unconditionally, ''funding portals'' from having to register as a broker-dealer pursuant to Exchange Act Section 15(a)(1); [11]
- mandates that the Commission establish disqualification provisions under which an issuer would not be able to avail itself of the Section 4(a)(6) exemption if the issuer or an intermediary was subject to a disqualifying event; and
- adds Exchange Act Section 12(g)(6),[12] which requires the Commission to adopt rules to exempt from the registration requirements of Section 12(g),[13] either conditionally or unconditionally, securities acquired pursuant to an offering made in reliance on Section 4(a)(6).

On October 23, 2013, we proposed new rules and forms to implement Title III of the JOBS Act.[14] We received over 485 comment letters on the Proposing Release, including from professional and trade associations, investor organizations, law firms, investment companies and investment advisers, broker-dealers, potential funding portals, members of Congress, the Commission's Investor Advisory Committee,[15] state securities regulators, government agencies, potential issuers, accountants, individuals and other interested parties. We have reviewed and considered all of the comments that we received on the Proposing Release and on Title III of the JOBS Act.[16] In this

basic regulatory oversight, liability, and disclosure rules that will give investors the confidence to participate in this promising emerging source of money for growing companies.'').

[4] In this release, ''investors'' includes investors and potential investors, as the context requires. *See* Rule 100(d) of Regulation Crowdfunding.

[5] *See Eliminating the Prohibition Against General Solicitation and General Advertising in Rule 506 and Rule 144A Offerings,* Release No. 33–9415 (July 10, 2013) [78 FR 44771 (July 24, 2013)] (adopting rules to implement Title II of the Jumpstart Our Business Startups Act) (''Rule 506(c) Adopting Release''). Title II of the JOBS Act directed the Commission to amend Rule 506 of Regulation D to permit general solicitation or general advertising in offerings made under Rule 506, provided that all purchasers of the securities are accredited investors. Accredited investors include natural persons who meet certain income or net worth thresholds. Although this rule facilitates the type of broad solicitation emblematic of crowdfunding, crowdfunding is premised on permitting sales of securities to any interested person, not just to investors who meet specific qualifications, such as accredited investors.

[6] Exchange Act Section 15(a)(1) generally makes it unlawful for a broker or dealer to effect any transactions in, or induce the purchase or sale of, any security unless that broker or dealer is registered with the Commission pursuant to Exchange Act Section 15(b). 15 U.S.C. 78o(a). *See* discussion in Section II.D.2. Because brokers and dealers both register as broker-dealers (*i.e.,* there is no separate ''broker'' or ''dealer'' registration under Exchange Act Section 15(b)), we use the term ''broker-dealer'' in this release.

[7] 15 U.S.C. 77d(a)(6).

[8] 15 U.S.C. 77e.

[9] 15 U.S.C. 77a.

[10] 15 U.S.C. 78c(h).

[11] 15 U.S.C. 78o(a)(1).

[12] 15 U.S.C. 78l(g)(6).

[13] 15 U.S.C. 78l(g).

[14] *See* Rel. No. 33–9470 (Oct. 23, 2013) [78 FR 66427 (Nov. 5, 2013)] (the ''Proposing Release''), *available at: http://www.sec.gov/rules/proposed/2013/33-9470.pdf.*

[15] The SEC Investor Advisory Committee (''Investor Advisory Committee'') was established in April 2012 pursuant to Section 911 of the Dodd-Frank Wall Street Reform and Consumer Protection Act [Pub. L. 111–203, sec. 911, 124 Stat. 1376, 1822 (July 21, 2010)] (the ''Dodd-Frank Act'') to advise the Commission on regulatory priorities, the regulation of securities products, trading strategies, fee structures, the effectiveness of disclosure, initiatives to protect investor interests and to promote investor confidence and the integrity of the securities marketplace. The Dodd-Frank Act authorizes the Investor Advisory Committee to submit findings and recommendations for review and consideration by the Commission.

[16] To facilitate public input on JOBS Act rulemaking before the issuance of rule proposals, the Commission invited members of the public to make their views known on various JOBS Act initiatives in advance of any rulemaking by submitting comment letters to the Commission's Web site at *http://www.sec.gov/spotlight/*

Continued

release, we are adopting new rules and forms to implement Sections 4(a)(6) and 4A and Exchange Act Sections 3(h) and 12(g)(6). The rules are described in detail below.

II. Final Rules Implementing Regulation Crowdfunding

Regulation Crowdfunding, among other things, permits individuals to invest in securities-based crowdfunding transactions subject to certain thresholds, limits the amount of money an issuer can raise under the crowdfunding exemption, requires issuers to disclose certain information about their offers, and creates a regulatory framework for the intermediaries that facilitate the crowdfunding transactions. As an overview, under the final rules:

- An issuer is permitted to raise a maximum aggregate amount of $1 million through crowdfunding offerings in a 12-month period;
- Individual investors, over the course of a 12-month period, are permitted to invest in the aggregate across all crowdfunding offerings up to:
  - If either their annual income or net worth is less than $100,000, then the greater of:
    - $2,000 or
    - 5 percent of the lesser of their annual income or net worth.
  - If both their annual income and net worth are equal to or more than $100,000, then 10 percent of the lesser of their annual income or net worth; and
- During the 12-month period, the aggregate amount of securities sold to an investor through all crowdfunding offerings may not exceed $100,000.

Certain companies are not eligible to use the Regulation Crowdfunding exemption. Ineligible companies include non-U.S. companies, companies that already are Exchange Act reporting companies, certain investment companies, companies that are disqualified under Regulation Crowdfunding's disqualification rules, companies that have failed to comply with the annual reporting requirements under Regulation Crowdfunding during the two years immediately preceding the filing of the offering statement, and companies that have no specific business plan or have indicated their business plan is to engage in a merger or acquisition with an unidentified company or companies.

Securities purchased in a crowdfunding transaction generally cannot be resold for a period of one year. Holders of these securities do not count toward the threshold that requires an issuer to register its securities with the Commission under Section 12(g) of the Exchange Act if the issuer is current in its annual reporting obligation, retains the services of a registered transfer agent and has less than $25 million in assets.

Disclosure by Issuers. The final rules require issuers conducting an offering pursuant to Regulation Crowdfunding to file certain information with the Commission and provide this information to investors and the relevant intermediary facilitating the crowdfunding offering. Among other things, in its offering documents, the issuer is required to disclose:

- Information about officers and directors as well as owners of 20 percent or more of the issuer;
- A description of the issuer's business and the use of proceeds from the offering;
- The price to the public of the securities or the method for determining the price, the target offering amount, the deadline to reach the target offering amount, and whether the issuer will accept investments in excess of the target offering amount;
- Certain related-party transactions;
- A discussion of the issuer's financial condition; and
- Financial statements of the issuer that are, depending on the amount offered and sold during a 12-month period, accompanied by information from the issuer's tax returns, reviewed by an independent public accountant, or audited by an independent auditor. An issuer relying on these rules for the first time would be permitted to provide reviewed rather than audited financial statements, unless financial statements of the issuer are available that have been audited by an independent auditor.

Issuers are required to amend the offering document during the offering period to reflect material changes and provide updates on the issuer's progress toward reaching the target offering amount.

In addition, issuers relying on the Regulation Crowdfunding exemption are required to file an annual report with the Commission and provide it to investors.

Crowdfunding Platforms. One of the key investor protections of Title III of the JOBS Act is the requirement that Regulation Crowdfunding transactions take place through an SEC-registered intermediary, either a broker-dealer or a funding portal. Under Regulation Crowdfunding, offerings must be conducted exclusively through a platform operated by a registered broker or a funding portal, which is a new type of SEC registrant. The rules require these intermediaries to:

- Provide investors with educational materials;
- Take measures to reduce the risk of fraud;
- Make available information about the issuer and the offering;
- Provide communication channels to permit discussions about offerings on the platform; and
- Facilitate the offer and sale of crowdfunded securities.

The rules prohibit funding portals from:

- Offering investment advice or making recommendations;
- Soliciting purchases, sales or offers to buy securities offered or displayed on its platform;
- Compensating promoters and others for solicitations or based on the sale of securities; and
- Holding, possessing, or handling investor funds or securities.

The rules provide a safe harbor under which funding portals can engage in certain activities consistent with these restrictions.

The staff will undertake to study and submit a report to the Commission no later than three years following the effective date of Regulation Crowdfunding on the impact of the regulation on capital formation and investor protection. The report will include, but not be limited to, a review of: (1) Issuer and intermediary compliance; (2) issuer offering limits and investor investment limits; (3) incidence of fraud, investor losses, and compliance with investor aggregates; (4) intermediary fee and compensation structures; (5) measures intermediaries have taken to reduce the risk of fraud, including reliance on issuer and investor representations; (6) the concept of a centralized database of investor contributions; (7) intermediary policies and procedures; (8) intermediary recordkeeping practices; and (9) secondary market trading practices.

A. Crowdfunding Exemption

Section 4(a)(6) provides an exemption from the registration requirements of Securities Act Section 5 for certain crowdfunding transactions. To qualify for this exemption, crowdfunding transactions by an issuer must meet specified requirements, including limits on the dollar amount of the securities that may be sold by an issuer and the dollar amount that may be invested by an individual in a 12-month period. The crowdfunding transaction also must be conducted through a registered

jobsactcomments.shtml. The comment letters relating to Title III of the JOBS Act submitted in response to this invitation are located at *http://www.sec.gov/comments/jobs-title-ii/jobs-title-iii.shtml.*

intermediary that complies with specified requirements.[17] Title III also provides limitations on who may rely on the exemption and establishes specific liability provisions for material misstatements or omissions in connection with Section 4(a)(6) exempt transactions. As discussed below, the rules we are adopting are designed to aid issuers, investors and intermediaries in complying with these various limitations and requirements.

1. Limit on Capital Raised

a. Proposed Rules

The exemption from registration provided by Section 4(a)(6) is available to a U.S. issuer provided that ''the aggregate amount sold to all investors by the issuer, including any amount sold in reliance on the exemption provided under [Section 4(a)(6)] during the 12-month period preceding the date of such transaction, is not more than $1,000,000.'' Under Securities Act Section 4A(h), the Commission is required to adjust the dollar amounts in Section 4(a)(6) ''not less frequently than once every five years, by notice published in the **Federal Register**, to reflect any change in the Consumer Price Index for All Urban Consumers published by the Bureau of Labor Statistics.''

Consistent with the statute, we proposed in Rule 100(a) of Regulation Crowdfunding to limit the aggregate amount sold to all investors by the issuer in reliance on the new exemption to $1 million during a 12-month period. Capital raised through other exempt transactions would not be counted in determining the aggregate amount sold in reliance on Section 4(a)(6).

We also provided guidance clarifying our view that offerings made in reliance on Section 4(a)(6) will not be integrated[18] with other exempt offerings made by the issuer, provided that each offering complies with the requirements of the applicable exemption that is being relied upon for the particular offering.

Under Section 4(a)(6), the amount of securities sold in reliance on Section 4(a)(6) by entities controlled by or under common control with the issuer must be aggregated with the amount to be sold by the issuer in the current offering to determine the aggregate amount sold in reliance on Section 4(a)(6) during the preceding 12-month period. Under the proposed rules, for purposes of determining whether an entity is ''controlled by or under common control with'' the issuer, an issuer would be required to consider whether it has ''control'' based on the definition in Securities Act Rule 405.[19] As proposed, the amount of securities sold in reliance on Section 4(a)(6) also would include securities sold by any predecessor of the issuer in reliance on Section 4(a)(6) during the preceding 12-month period.

b. Comments on the Proposed Rules

A few commenters supported a $1 million limit on capital raised by an issuer in reliance on Section 4(a)(6),[20] while many other commenters believed that the proposed $1 million limit was too low and, in some instances, recommended higher limits.[21] Several commenters urged that the $1 million limit be net of fees charged by the intermediary to host the offering on the intermediary's platform,[22] while other commenters generally opposed this idea.[23]

Commenters were divided on the proposed guidance that other exempt offerings should not be integrated when determining the amount sold during the preceding 12-month period for purposes of the $1 million limit, with some supporting this approach,[24] and others opposing it.[25]

c. Final Rules

We are adopting as proposed rules that limit to $1 million the aggregate amount that may be sold to all investors by the issuer in a 12-month period in reliance on the new exemption.[26] We continue to believe this approach is consistent with the statute and will provide for a meaningful addition to the existing capital formation options for smaller companies while maintaining important investor protections. Moreover, Regulation Crowdfunding is a novel method of raising capital for smaller companies, and we are concerned about expanding the offering limit of the exemption beyond the level specified in Section 4(a)(6) at the outset of the adoption of final rules. Some commenters suggested that the $1 million limit be net of fees charged by the intermediary to host the offering on the intermediary's platform,[27] which would be an indirect way of increasing the $1 million limit. We are concerned that expanding the offering limit in this way would provide less certainty and could raise interpretive questions, which would make the exemption more costly for issuers to comply with. If a funding portal's fees are not known in advance, for example, this may create uncertainty for issuers about how much capital they would be able to raise. Therefore, we are adopting as proposed the limit on the aggregate amount sold.

[17] *See* Section II.C for a discussion of the intermediary requirements. *See also* Section II.D for a discussion of the additional funding portal requirements.

[18] The integration doctrine seeks to prevent an issuer from improperly avoiding registration by artificially dividing a single offering into multiple offerings such that Securities Act exemptions would apply to multiple offerings that would not be available for the combined offering. *See, e.g.,* Final Rule: Nonpublic Offering Exemption, Release No. 33–4552 (Nov. 6, 1962).

[19] *See* 17 CFR 230.405 (''The term control (including the terms controlling, controlled by and under common control with) means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of a person, whether through the ownership of voting securities, by contract, or otherwise.''). Exchange Act Rule 12b–2 contains the same definition. *See* 17 CFR 240.12b–2.

[20] *See, e.g.,* Leverage PR Letter; StartEngine Letter 1; StartEngine Letter 2; Wilson Letter.

[21] *See, e.g.,* Advanced Hydro Letter; Bushroe Letter; Cole D. Letter; Concerned Capital Letter; Hamman Letter; Harrison Letter; Hillside Letter; Jazz Letter; Kickstarter Coaching Letter; McCulley Letter; McGladrey Letter; Meling Letter; Miami Nation Enterprises Letter; Multistate Tax Service Letter; Peers Letter; Pioneer Realty Letter; Public Startup Letter 2; Qizilbash Letter; Rosenthal O. Letter; Sarles Letter; SBM Letter; Taylor R. Letter; Taylor T. Letter; Wales Capital Letter 1; Wales Capital Letter 3; WealthForge Letter; Wear Letter; Wilhelm Letter; Winters Letter; Yudek Letter.

[22] *See, e.g.,* Benjamin Letter; FundHub Letter 1; Hackers/Founders Letter; Joinvestor Letter; Odhner Letter; Omara Letter; Public Startup Letter 2; RFPIA Letter; RoC Letter; RocketHub Letter; Seed&Spark Letter; Thomas Letter 1; Wales Capital Letter 1; Whitaker Chalk Letter; Wilson Letter.

[23] *See, e.g.,* Arctic Island Letter 4; ASSOB Letter; Commonwealth of Massachusetts Letter; MCS Letter; PeoplePowerFund Letter.

[24] *See, e.g.,* AngelList Letter; Arctic Island Letter 4; Campbell R. Letter; CFA Institute Letter; CFIRA Letter 11; EarlyShares Letter; EMKF Letter; Farnkoff Letter; Feinstein Letter; Growthfountain Letter; Hackers/Founders Letter; Heritage Letter; NSBA Letter; Parsont Letter; Perfect Circle Solutions Letter; Public Startup Letter 2; RoC Letter; RocketHub Letter; Wales Capital Letter 1; Wefunder Letter; Whitaker Chalk Letter; Wilson Letter.

[25] *See, e.g.,* AFL–CIO Letter (not integrating other exempt offerings will make crowdfunding available to larger companies and ''crowd out'' smaller companies that lack other options for raising capital); AFR Letter; Brown J. Letter; Consumer Federation Letter (not integrating other exempt offerings will allow issuers to evade regulatory requirements); Fund Democracy Letter (not integrating other exempt offerings will give issuers an incentive to engage in advertising in concurrent private offerings to indirectly publicly advertise their crowdfunding offering); IAC Recommendation; MCS Letter; NASAA Letter.

[26] *See* Rule 100(a)(1) of Regulation Crowdfunding. There is a technical change to the rule text (''offer and sell securities'' is changed to ''offer or sell securities'') to clarify that an issuer does not have to complete a sale in order to rely on the Section 4(a)(6) exemption for an offering.

[27] *See, e.g.,* Benjamin Letter; FundHub Letter 1; Hackers/Founders Letter; Joinvestor Letter; Odhner Letter; Omara Letter; Public Startup Letter 2; RFPIA Letter; RoC Letter; RocketHub Letter; Seed&Spark Letter; Thomas Letter 1; Wales Capital Letter 1; Whitaker Chalk Letter; Wilson Letter.

Title III provides that the $1 million limit applies to the ''aggregate amount sold to all investors by the issuer, including any amount sold in reliance on the exemption provided under [Section 4(a)(6)].'' Securities Act Section 4A(g), however, provides that ''[n]othing in the exemption shall be construed as preventing an issuer from raising capital through means other than [S]ection 4[(a)](6).'' Considered together, these two provisions create statutory ambiguity because the first provision could be read to provide for the aggregation of amounts raised in all exempt transactions, even those that do not involve crowdfunding, while the second provision could be read to provide that nothing in the Section 4(a)(6) exemption should limit an issuer's capital raising through other methods. We believe that the overall intent of providing the exemption under Section 4(a)(6) was to provide an additional mechanism for capital raising for startup and small businesses and not to affect the amount an issuer could raise outside of that exemption. Thus, we believe that only the capital raised in reliance on the exemption provided by Section 4(a)(6) should be counted toward the limit. Capital raised through other means should not be counted in determining the aggregate amount sold in reliance on Section 4(a)(6). The opposite approach—requiring aggregation of amounts raised in any exempt transaction—would be inconsistent with the goal of alleviating the funding gap for startups and small businesses because, by electing crowdfunding, such issuers would be placing a cap on the amount of capital they could raise. An issuer that already sold $1 million in reliance on the exemption provided under Section 4(a)(6), for example, would be prevented from raising capital through other exempt methods and, conversely, an issuer that sold $1 million through other exempt methods would be prevented from raising capital under Section 4(a)(6).

In determining the amount that may be sold in reliance on Section 4(a)(6), an issuer should aggregate amounts it sold (including amounts sold by entities controlled by, or under common control with, the issuer, as well as any amounts sold by any predecessor of the issuer) in reliance on Section 4(a)(6) during the 12-month period preceding the expected date of sale and the amount the issuer intends to raise in reliance on the exemption. An issuer should not include amounts sold in other exempt offerings during the preceding 12-month period.

Further, in light of Section 4A(g) and for the reasons discussed above, we continue to believe that an offering made in reliance on Section 4(a)(6) should not be integrated with another exempt offering made by the issuer, provided that each offering complies with the requirements of the applicable exemption that is being relied upon for the particular offering. For example, an issuer conducting a concurrent exempt offering for which general solicitation is not permitted will need to be satisfied that purchasers in that offering were not solicited by means of the offering made in reliance on Section 4(a)(6).[28] As another example, an issuer conducting a concurrent exempt offering for which general solicitation is permitted, for example, under Securities Act Rule 506(c), could not include in any such general solicitation an advertisement of the terms of an offering made in reliance on Section 4(a)(6), unless that advertisement otherwise complied with Section 4(a)(6) and the final rules. As such, a concurrent offering would be bound by the more restrictive solicitation requirements of Regulation Crowdfunding, unless the issuer can conclude that the purchasers in the Regulation Crowdfunding offering were not solicited by means of the offering made in reliance on Rule 506(c).

The amount of securities sold in reliance on Section 4(a)(6) by entities controlled by or under common control with the issuer must be aggregated with the amount to be sold by the issuer in the current offering to determine the aggregate amount sold in reliance on Section 4(a)(6) during the preceding 12-month period. The statute does not define the term ''controlled by or under common control with'' the issuer; however, the term ''control'' is defined in Securities Act Rule 405.[29] Under the final rules, for purposes of determining whether an entity is ''controlled by or under common control with'' the issuer, an issuer will be required to consider whether it possesses, directly or indirectly, the power to direct or cause the direction of the management and policies of the entity, whether through the ownership of voting securities, by contract or otherwise, consistent with the definition of ''control'' in Securities Act Rule 405.[30]

Under the final rules, the amount of securities sold in reliance on Section 4(a)(6) also includes securities sold by any predecessor of the issuer in reliance on Section 4(a)(6) during the preceding 12-month period.[31] We believe this approach is necessary to prevent an issuer from exceeding the $1 million limit by reorganizing into a new entity that would otherwise not be limited by previous sales made by its predecessor.

2. Investment Limits

a. Proposed Rules

Under the exemption from registration set forth in Securities Act Section 4(a)(6)(B), the aggregate amount of securities sold to any investor by an issuer, including any amount sold in reliance on the exemption during the 12-month period preceding the date of such transaction, cannot exceed: ''(i) the greater of $2,000 or 5 percent of the annual income or net worth of such investor, as applicable, if either the annual income or the net worth of the investor is less than $100,000; and (ii) 10 percent of the annual income or net worth of such investor, as applicable, not to exceed a maximum aggregate amount sold of $100,000, if either the annual income or net worth of the investor is equal to or more than $100,000.''

In the Proposing Release, we noted that this statutory language may present ambiguity in some cases about which of the two investment limits governs, because paragraph (i) applies if ''either'' annual income or net worth is less than $100,000 and paragraph (ii) applies if ''either'' annual income or net worth is equal to or more than $100,000. Accordingly, in a situation in which annual income is less than $100,000 and net worth is equal to or more than $100,000 (or vice versa), the language of the statute may be read to cause both paragraphs to apply. Paragraph (i) also fixes the maximum annual investment by an investor at 5 percent of ''the annual income or net worth of such investor, as applicable'' and paragraph (ii) fixes the maximum annual investment by an investor at 10 percent of ''the annual income or net worth of such investor, as applicable,'' but neither states when that percentage should be applied against the investor's

[28] For a concurrent offering under Rule 506(b), an issuer will have to conclude that purchasers in the Rule 506(b) offering were not solicited by means of the offering made in reliance on Section 4(a)(6). For example, the issuer may have had a preexisting substantive relationship with such purchasers. Otherwise, the solicitation conducted in connection with the crowdfunding offering may preclude reliance on Rule 506(b). *See also* Rel. No. 33–8828 (Aug. 3, 2007) [72 FR 45116].

[29] *See* note 19.

[30] *See* Instruction to paragraph (c) of Rule 100 of Regulation Crowdfunding.

[31] *See* Rule 100(c) of Regulation Crowdfunding (defining issuer, in certain circumstances, to include all entities controlled by or under common control with the issuer and any predecessor of the issuer).

annual income and when it should be applied against the investor's net worth.

Under proposed Rule 100(a) of Regulation Crowdfunding, the aggregate amount of securities sold to any investor by any issuer in reliance on Section 4(a)(6) during the 12-month period preceding the date of such transaction, including the securities sold to such investor in such transaction, could not exceed the greater of: (i) $2,000 or 5 percent of the annual income or net worth of the investor, whichever is greater, if both annual income and net worth are less than $100,000; or (ii) 10 percent of the annual income or net worth of the investor, whichever is greater, not to exceed an amount sold of $100,000, if either annual income or net worth is equal to or more than $100,000.

We did not propose to alter these investment limits for any particular type of investor or create a different exemption based on different investment limits. Under the proposal, the annual income and net worth of a natural person would be calculated in accordance with the Commission's rules for the calculation of annual income and net worth of an accredited investor, and an investor's annual income or net worth could be calculated jointly with the annual income or net worth of the investor's spouse. An issuer would be able to rely on the efforts of an intermediary to determine that the aggregate amount of securities purchased by an investor will not cause the investor to exceed the investment limits, provided the issuer does not have knowledge to the contrary.

b. Comments on the Proposed Rules

Commenters were divided on the proposed investment limits. Many commenters supported some type of investment limit without necessarily expressing a specific opinion on the proposed investment limits,[32] while many others generally opposed any type of investment limit.[33] A number of commenters recommended changes to the proposed limits.[34]

While some commenters supported the proposal to apply the higher investment limit (10 percent, as set forth in Section 4(a)(6)(B)(ii)) if only one of the annual income or net worth of the investor is equal to or more than $100,000,[35] some commenters also supported the lower investment limit ($2,000 or 5 percent, as set forth in Section 4(a)(6)(B)(i)) unless both the annual income and net worth of the investor are equal to or more than $100,000.[36]

A number of commenters supported the proposal that within each of the two levels of investment limits, the limits would be calculated based on the ''greater of'' an investor's annual income or net worth,[37] while a number of other commenters preferred a ''lesser of'' approach.[38] A few commenters suggested a combination of the approaches (*e.g.,* if either annual income or net worth is below $100,000, the lower investment limit level ($2,000 or 5 percent) would apply, but within that level, the limit would be based on the greater of annual income or net worth).[39]

Many commenters supported the proposal that an issuer may rely on the efforts of an intermediary to determine that the aggregate amount of securities purchased by an investor will not cause the investor to exceed the investment limits, provided that the issuer does not have knowledge that the investor had exceeded, or would exceed, the investment limits as a result of purchasing securities in the issuer's offering.[40] A few commenters recommended that an issuer be required to obtain a written representation from the investor that the investor has not and will not exceed the limits by purchasing from the issuer.[41]

Commenters were divided about the joint calculation of annual income and net worth with the investor's spouse. Several commenters supported the proposal that an investor's annual income and net worth be calculated jointly with that of the investor's spouse,[42] while other commenters generally opposed that aspect of the proposal.[43] Several commenters recommended that if an investor's annual income and net worth are to be calculated jointly, the Commission should establish higher thresholds or an aggregate investment limit applicable to both spouses.[44]

A number of commenters favored different or no investment limits for accredited and institutional investors. Many commenters supported exempting accredited and institutional investors from the investment limits,[45] although a number of other commenters opposed such an exemption.[46] A few commenters recommended allowing higher investment limits for accredited and institutional investors.[47] One commenter stated that applying the investment limits to accredited and institutional investors would deter those investors from participating, but noted that allowing concurrent offerings under Securities Act Rule 506(c)[48] may mitigate this problem.[49]

c. Final Rules

Consistent with the statute, we are adopting investment limits for securities-based crowdfunding transactions, but with some modifications from the proposed rules. We have modified the final rules from the proposal to clarify that the investment limit reflects the aggregate amount an investor may invest in all offerings under Section 4(a)(6) in a 12-month period across all issuers. In addition, as noted above, some commenters supported a ''greater of'' approach to implementing the two statutory investment limits, while others supported a ''lesser of'' approach. After

[32] *See, e.g.,* Accredify Letter; Ahmad Letter; Crowley Letter; Farnkoff Letter; Merkley Letter; Milken Institute Letter; Patel Letter; Saunders Letter; StartEngine Letter 1; Wales Capital Letter 1.

[33] *See, e.g.,* ASSOB Letter; Crowdstockz Letter; Hamman Letter; Holland Letter; McCulley Letter; Meling Letter; Qizilbash Letter; Ramsey Letter; SBM Letter; Taylor R Letter.

[34] *See, e.g.,* Crowdstockz Letter; Gill Letter; Johnston Letter; Morse Letter; Qizilbash Letter; Vossberg Letter; Winters Letter.

[35] *See, e.g.,* ABA Letter; CFA Institute Letter; CFIRA Letter 12; Craw Letter; Finkelstein Letter; RocketHub Letter; Wilson Letter.

[36] *See, e.g.,* AFL–CIO Letter; BetterInvesting Letter; Consumer Federation Letter; Fund Democracy Letter; IAC Recommendation; Jacobson Letter; NASAA Letter; Schwartz Letter.

[37] *See, e.g.,* ABA Letter; Anonymous Letter 6; CFIRA Letter 12; Craw Letter; EarlyShares Letter; Jacobson Letter; Omara Letter; RocketHub Letter; Wilson Letter.

[38] *See, e.g.,* AFR Letter; BetterInvesting Letter; Consumer Federation Letter; Fund Democracy Letter; Fryer Letter; Growthfountain Letter; IAC Recommendation (stating that the ''greater of'' approach would be appropriate for accredited investors); Merkley Letter; NASAA Letter; Schwartz Letter; Zhang Letter (recommending that net worth not be used to calculate the investment limit).

[39] *See, e.g.,* Consumer Federation Letter; Fund Democracy Letter; Jacobson Letter.

[40] *See, e.g.,* Arctic Island Letter 4; CFA Institute Letter; Consumer Federation Letter; CrowdBouncer Letter; EarlyShares Letter; EMKF Letter; Finkelstein Letter; Fund Democracy Letter; Heritage Letter; Joinvestor Letter; Public Startup Letter 2; RoC Letter; RocketHub Letter; Vann Letter; Wefunder Letter; Whitaker Chalk Letter.

[41] *See, e.g.,* FundHub Letter 1; Public Startup Letter 2; RocketHub Letter.

[42] *See, e.g.,* Arctic Island Letter 4; Heritage Letter; Joinvestor Letter; NSBA Letter; Omara Letter; RocketHub Letter; Wilson Letter.

[43] *See, e.g.,* Brown J. Letter; Consumer Federation Letter; Fund Democracy Letter; Jacobson Letter; Projectheureka Letter; Public Startup Letter 2.

[44] *See, e.g.,* Brown, J. Letter; Consumer Federation Letter; Fund Democracy Letter; Jacobson Letter.

[45] *See, e.g.,* ASSOB Letter; Crowdstockz Letter; Crowley Letter; EMKF Letter; FundHub Letter 1; Gibb Letter; Heritage Letter; Joinvestor Letter; Public Startup Letter 2; RoC Letter; RocketHub Letter; Vann Letter; Wales Capital Letter 1; WealthForge Letter; Wefunder Letter.

[46] *See, e.g.,* CFA Institute Letter; FundDemocracy Letter; Hackers/Founders Letter; Jacobson Letter; PeoplePowerFund Letter; Projectheureka Letter; Whitaker Chalk Letter; Wilson Letter.

[47] *See, e.g.,* Growthfountain Letter; RFPIA Letter; WealthForge Letter.

[48] 17 CFR 230.506.

[49] *See* Arctic Island Letter 4.

considering the comments received, we have decided to adopt a ''lesser of'' approach. Thus, under the final rules, an investor will be limited to investing: (1) The greater of: $2,000 or 5 percent of the lesser of the investor's annual income or net worth if either annual income or net worth is less than $100,000; or (2) 10 percent of the lesser of the investor's annual income or net worth, not to exceed an amount sold of $100,000, if both annual income and net worth are $100,000 or more.[50]

Under this approach, an investor with annual income of $50,000 a year and $105,000 in net worth would be subject to an investment limit of $2,500, in contrast to the proposed rules in which that same investor would have been eligible for an investment limit of $10,500.[51] We recognize that this change from the proposed rules could place constraints on capital formation. Nevertheless, we believe that the investment limits in the final rules appropriately take into consideration the need to give issuers access to capital while minimizing an investor's exposure to risk in a crowdfunding transaction.

The chart below illustrates a few examples:

Investor annual income	Investor net worth	Calculation	Investment limit [52]
$30,000	$105,000	Greater of $2,000 or 5% of $30,000 ($1,500)	$2,000
150,000	80,000	Greater of $2,000 or 5% of $80,000 ($4,000)	4,000
150,000	100,000	10% of $100,000 ($10,000)	10,000
200,000	900,000	10% of $200,000 ($20,000)	20,000
1,200,000	2,000,000	10% of $1,200,000 ($120,000), subject to $100,000 cap	100,000

A number of commenters expressed concerns about investors potentially incurring unaffordable losses under the proposed rule,[53] and we find these comments persuasive given the risks involved. The startups and small businesses that we expect will rely on the crowdfunding exemption are likely to experience a higher failure rate than more seasoned companies.[54] Applying the lower limit ($2,000 or 5%, rather than 10%) for investors whose annual income or net worth is below $100,000 and applying that formula to the lesser of annual income or net worth will potentially limit investment losses in crowdfunding offerings for investors who may be less able to bear the risk of loss. We are concerned about the number of households where there is a sizeable gap between net worth and annual income, and the ability of these households to withstand the risk of loss. According to Commission staff analysis of the data in the 2013 Survey of Consumer Finances, approximately 20% of U.S. households with net worth over $100,000 have annual income under $50,000.

Consistent with the proposed rules, the final rules allow an issuer to rely on efforts that an intermediary is required to undertake in order to determine that the aggregate amount of securities purchased by an investor does not cause the investor to exceed the investment limits, provided that the issuer does not have knowledge that the investor had exceeded, or would exceed, the investment limits as a result of purchasing securities in the issuer's offering.[55]

We are adopting, as proposed, final rules that allow an investor's annual income and net worth to be calculated as those values are calculated for purposes of determining accredited investor status.[56] Securities Act Rule 501 specifies the manner in which annual income and net worth are calculated for purposes of determining accredited investor status.[57] As in the proposal, the final rules allow spouses to calculate their net worth or annual income jointly. Although some commenters opposed permitting net worth or annual income to be calculated jointly, we believe this approach is appropriate in light of the stricter investment limits being adopted in the final rules. Several commenters recommended that, if the final rules permit net worth and annual income to be calculated jointly, we should establish an aggregate investment limit applicable to both spouses.[58] Consistent with this recommendation, the final rules add an instruction to explain that when such a joint calculation is used, the aggregate investment of the spouses may not exceed the limit that would apply to an individual investor at that income and net worth level.[59] We believe this approach is necessary to preserve the intended protections of the investment limits.

While a number of commenters supported the creation of a different investment limit for accredited or institutional investors, or exempting them altogether, we are not making such a change. As noted above, crowdfunding is an innovative approach to raising capital in which the entity or individual raising capital typically seeks small individual contributions from a large number of people. As such, we believe that crowdfunding transactions were intended under Section 4(a)(6) to be available equally to all types of investors.[60] The statute provides specific investment limits, and the only reference in the statute to changing those investment limits is the requirement that we update the investment limits not less frequently than every five years based on the Consumer Price Index. Further, issuers can rely on other exemptions to offer

[50] *See* paragraph (a)(2) of Rule 100 of Regulation Crowdfunding.

[51] *See* Instruction 2 to paragraph (a)(2) of Rule 100 of Regulation Crowdfunding.

[52] This ''Investment Limit'' column reflects the aggregate investment limit across all offerings under Section 4(a)(6) within a 12-month period.

[53] *See, e.g.,* AFL–CIO Letter; BetterInvesting Letter; Consumer Federation Letter; Fund Democracy Letter; IAC Recommendation; Jacobson Letter; Merkley Letter; NASAA Letter; Schwartz Letter.

[54] For a more detailed discussion of survival rates for startups and small businesses see Section III.A, below.

[55] *See* Instruction 3 to paragraph (a)(2) of Rule 100 of Regulation Crowdfunding.

[56] *See* Instruction 1 to paragraph (a)(2) of Rule 100 of Regulation Crowdfunding.

[57] 17 CFR 230.501. Thus, for example, a natural person's primary residence shall not be included as an asset in the calculation of net worth. 17 CFR 230.501(a)(5)(i)(A).

[58] *See* Brown J. Letter; Consumer Federation Letter; Fund Democracy Letter; Jacobs Letter.

[59] For example, if each spouse's annual income is $30,000, the spouses jointly may invest up to an aggregate of 5% of their joint income of $60,000. If one spouse's annual income is $120,000 and the other's is $30,000, the spouses jointly may invest up to an aggregate of 10% of their joint income of $150,000, the same investment limit that would apply for an individual investor with income of $150,000. *See* Instruction 2 to paragraph (a)(2) of Rule 100 of Regulation Crowdfunding.

[60] *See* 158 CONG. REC. S1689 (daily ed. Mar. 15, 2012) (statement of Sen. Mark Warner (''There is now the ability to use the Internet as a way for small investors to get the same kind of deals that up to this point only select investors have gotten that have been customers of some of the best known investment banking firms, where we can now use the power of the Internet, through a term called crowdfunding.'').

and sell securities to accredited investors and institutional investors. As discussed above, concurrent offerings to these types of investors are possible if the conditions of each applicable exemption are met.[61] Therefore, we are not altering the investment limits for any particular type of investor or to create a different exemption based on different investment limits. Thus, as proposed, the investment limits will apply equally to all investors, including retail, institutional and accredited investors.

3. Transaction Conducted Through an Intermediary

a. Proposed Rules

Section 4(a)(6)(C) requires that a transaction in reliance on Section 4(a)(6) be conducted through a broker or funding portal that complies with the requirements of Securities Act Section 4A(a). To implement this provision, we proposed in Rule 100(a)(3) of Regulation Crowdfunding that for any transaction conducted in reliance on Section 4(a)(6), an issuer use only one intermediary (that complies with the requirements of Section 4A(a) and the related requirements in Regulation Crowdfunding) and that the transaction be conducted exclusively on the intermediary's platform. We also proposed to permit the intermediary to engage in back office [62] or other administrative functions other than on the intermediary's platform, and to define ''platform'' as ''an Internet Web site or other similar electronic medium through which a registered broker or a registered funding portal acts as an intermediary in a transaction involving the offer or sale of securities in reliance on Section 4(a)(6).''

b. Comments on the Proposed Rules

Commenters were divided about the proposed prohibition on an issuer using more than one intermediary for any transaction conducted pursuant to Section 4(a)(6). Supporters of the proposed prohibition expressed the view that the prohibition would benefit communication between issuers and investors.[63] One commenter stated that the prohibition also would assist in assessing whether investors are within their investment limits.[64] Commenters who opposed the proposed prohibition noted that increasing the number of platforms used per transaction would both increase the likelihood of investors becoming informed that a transaction is taking place, as well as elicit information from a more diverse crowd.[65]

Commenters were generally divided about the proposed requirement that transactions made in reliance on Section 4(a)(6) be conducted exclusively through the intermediary's platform. Commenters who supported [66] the proposed requirement cited concerns that allowing the transactions to be effected through means other than the intermediary's platform could increase the potential for fraudulent activity [67] and prevent the leveraging of information sharing and crowdsourced review that are intended through crowdfunding.[68] Commenters who opposed [69] the proposed requirement expressed their view that permitting other means would allow persons who lack Internet access to invest through crowdfunding,[70] and also would foster different types of in-person communication that are not possible to achieve online.[71] One commenter expressed a preference for issuers to be able to host their own offerings subject to certain conditions.[72] One commenter also suggested that intermediaries should be able to engage in certain activities other than on their platforms, such as physically meeting with representatives of issuers and investors, and hosting launch parties. [73]

A few commenters supported, but suggested technical revisions to, our proposed definition of ''platform.'' [74] One commenter suggested deleting the phrase ''an Internet Web site or other similar electronic medium'' and replacing the phrase with ''a software program accessible via TCP/IP enabled applications'' or to more commonly define ''platform'' as ''a software program accessible via the Internet.'' [75]

c. Final Rules

After considering the comments, we are adopting as proposed Rule 100(a)(3). We also are adopting the definition of ''platform'' with one clarifying amendment and with a change in location to Rule 300(c).

As stated in the Proposing Release, we believe that requiring an issuer to use only one intermediary to conduct an offering or concurrent offerings in reliance on Section 4(a)(6) would help foster the creation of a ''crowd'' and better accomplish the purpose of the statute. In order for a crowd to effectively share information, we believe it would be most beneficial to have one meeting place for the crowd to obtain and share information, thus avoiding dilution or dispersement of the ''crowd.'' We also believe that limiting a crowdfunding transaction to a single intermediary's online platform helps to minimize the risk that issuers and intermediaries would circumvent the requirements of Regulation Crowdfunding. For example, allowing an issuer to conduct an offering using more than one intermediary would make it more difficult for intermediaries to determine whether an issuer is exceeding the $1 million aggregate offering limit.

We continue to believe that crowdfunding transactions made in reliance on Section 4(a)(6) and activities associated with these transactions should occur over the Internet or other similar electronic medium that is accessible to the public. Such an ''online-only'' requirement enables the public to access offering information and share information publicly in a way that will allow members of the crowd to share their views on whether to participate in the offering and fund the business or idea. While we acknowledge, as one commenter observed, that there are forms of communication that cannot be achieved

[61] For a discussion of integration, see Section II.A.1.c.

[62] Back office personnel typically perform functions such as, but not limited to, recordkeeping, trade confirmations, internal accounting, and account maintenance.

[63] *See, e.g.,* CFA Institute Letter; Rockethub Letter.

[64] *See* CFA Institute Letter.

[65] *See, e.g.,* Graves Letter.

[66] *See, e.g.,* Joinvestor Letter; RoC Letter; RocketHub Letter; Wilson Letter.

[67] *See, e.g.,* StartupValley Letter.

[68] *See, e.g.,* RocketHub Letter.

[69] *See, e.g.,* Benjamin Letter; Omara Letter; Public Startup Letter 2.

[70] *See, e.g.,* Projecteureka Letter.

[71] *See, e.g.,* Benjamin Letter (''Without doubt, the web fosters a crowd and a convenient forum to express ideas and learn about the Issuer. However, small community gatherings provide similar feedback loops and often times serve the community and some investors better by fostering nuanced forms of communication that can never be achieved. Further, some SEC concerns can be assuaged regarding the loss of creating a 'crowd' online because some investors that may rely on the Web site to educate themselves may not be inclined to contribute to the 'crowd intelligence' online, yet would be vocal in a community gathering.'').

[72] *See* Public Startup Letter 2. We note that Section 4(a)(6) of the Securities Act requires that, as a condition of the exemption, the transaction be ''conducted through a broker or funding portal that complies with the requirements of section 4A(b).'' 15 U.S.C. 77d(a)(6).

[73] *See* Wilson Letter.

[74] *See, e.g.,* Arctic Island Letter 1, Arctic Island Letter 3; Arctic Island Letter 4; and Startup Valley Letter (explaining that Web sites, application programmable interfaces (APIs) and other electronic media are generally only the means to access a platform, which itself is an Internet-accessible software program).

[75] *See* Arctic Island Letter 1; Arctic Island Letter 4 (noting that a ''platform'' is actually a software program that is accessible via the Internet and that a ''Web site or other electronic medium'' is merely a way to access the platform, not the platform itself).

online,[76] we nevertheless believe that the requirement that the transaction be conducted exclusively through the intermediary's platform will help to ensure transparency, provide for ready availability of information in one place to all investors, and promote greater uniformity in the distribution of information among investors. We also do not believe that funding portals should be permitted to physically meet with investors to solicit investments and offerings on its platform, or host launch parties, as one commenter recommended, because these activities likely violate the statutory prohibition on funding portals soliciting and providing investment advice and recommendations. However, we continue to believe that intermediaries should be able to engage in back office and other administrative functions other than on their platforms.

In a change from the proposed rules, and consistent with the suggestions of commenters, the final rules define ''platform'' as ''*a program or application accessible via the Internet or other similar electronic communication medium* through which a registered broker or a registered funding portal acts as an intermediary in a transaction involving the offer or sale of securities in reliance on Section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6))'' [emphasis added].[77] We believe that this definition is more technically accurate and also will accommodate innovation in the event of technological advancements. We are moving the definition of ''platform'' from Rule 100 to Rule 300(c) so that it will be located alongside the other Regulation Crowdfunding definitions related to intermediaries. Also, in a change from the proposed rule, we are moving to the definition of platform an instruction stating that an intermediary through which a crowdfunding transaction is conducted may engage in back office or other administrative functions other than on the intermediary's platform.[78]

4. Exclusion of Certain Issuers From Eligibility Under Section 4(a)(6)

Securities Act Section 4A(f) excludes certain categories of issuers from eligibility to rely on Section 4(a)(6) to engage in crowdfunding transactions. These are: (1) Issuers that are not organized under the laws of a state or territory of the United States or the District of Columbia; (2) issuers that are subject to Exchange Act reporting requirements;[79] (3) investment companies as defined in the Investment Company Act of 1940 (the ''Investment Company Act'')[80] or companies that are excluded from the definition of investment company under Section 3(b) or 3(c) of the Investment Company Act;[81] and (4) any other issuer that the Commission, by rule or regulation, determines appropriate.

a. Proposed Rules

Rule 100(b) of Regulation Crowdfunding, as proposed, would exclude the categories of issuers specifically identified in Section 4A(f). In addition, the proposed rules would exclude: (1) Issuers that are disqualified from relying on Section 4(a)(6) pursuant to the disqualification provision in Rule 503(a) of Regulation Crowdfunding; (2) issuers that have sold securities in reliance on Section 4(a)(6) if they have not filed with the Commission and provided to investors, to the extent required, the ongoing annual reports required by Regulation Crowdfunding during the two years immediately preceding the filing of the required new offering statement; and (3) issuers that have no specific business plan or that have indicated that their business plan is to engage in a merger or acquisition with an unidentified company or companies.

b. Comments on the Proposed Rules

Foreign Issuers, Exchange Act Reporting Companies, and Investment Companies. Several commenters opposed the exclusion of foreign issuers, Exchange Act reporting companies, and investment companies.[82] Other commenters, however, supported the exclusion of investment companies or companies that are excluded from the definition of investment company under Section 3(b) or 3(c) of the Investment Company Act.[83] Some commenters recommended that, despite the exclusion of investment companies, the Commission allow a single purpose fund, including LLCs and LPs, to conduct an offering in reliance on Section 4(a)(6) if such fund were organized to invest in, or lend money to, a single company.[84]

Delinquent in Ongoing Reporting. A number of commenters supported the exclusion of issuers that are delinquent in their reporting obligations,[85] although others opposed the exclusion of delinquent issuers.[86] Some commenters suggested options such as disclosure of the issuer's reporting delinquency in its offering documents or on its Web site or a cure provision.[87]

We also received comments about whether the exclusion should extend to issuers that are delinquent in other reporting requirements (*e.g.,* updates on the progress of the issuer in meeting the target offering amount, issuers whose affiliates have failed to comply with the ongoing reporting requirements, and issuers with an officer, director, or controlling shareholder who served in a similar capacity with another issuer that failed to file its ongoing reports). Commenters generally opposed extending the exclusion beyond issuers delinquent in their ongoing annual reports during the two years immediately preceding the filing of the required new offering statement.[88]

[76] *See* Benjamin Letter (in-person gatherings may foster more ''nuanced forms of communication'').

[77] Rule 300(c) of Regulation Crowdfunding.

[78] In the final rule, this is an instruction to Rule 300(c)(4). The instruction was proposed under proposed Rule 100(a)(3), but we believe it is more appropriate under the definition of platform because the instruction explains that back office activities can happen off the platform.

[79] These are issuers who are required to file reports with the Commission pursuant to Exchange Act Sections 13(a) (15 U.S.C. 78m(a)) or 15(d) (15 U.S.C. 78*o*(d)).

[80] 15 U.S.C 80a–1 *et seq.*

[81] 15 U.S.C. 80a–3(b) or (c).

[82] *See, e.g.,* M.A.V. Letter (opposing the exclusion of public companies from eligibility to rely on Section 4(a)(6)); Ritter Letter (asking for clarification regarding companies that are excluded from the definition of investment company pursuant to 3(b) of the Investment Company Act); TAN Letter (opposing the exclusion of foreign issuers over concerns that investors would not have Title III protections when investing in foreign issuers and that investors' ability to invest in early opportunities would be reduced).

[83] *See, e.g.,* Commonwealth of Massachusetts Letter; PeoplePowerFund Letter.

[84] *See, e.g.,* EMKF Letter (stating that having hundreds of direct shareholders can give startups ''messy cap tables'' that deter follow-on financing and alternatively recommending the Commission permit an intermediary, including a funding portal, to act as a holder of record); Fryer Letter; Growthfountain Letter; Martin Letter (recommending that crowdfunding be operated through a trust fund mechanism that would own shares of the entity seeking capital); Propellr Letter 2; Ritter Letter; Wefunder Letter.

[85] *See, e.g.,* ASSOB Letter; Commonwealth of Massachusetts Letter; Consumer Federation Letter; Fund Democracy Letter; Grassi Letter; Joinvestor Letter; NASAA Letter; Wefunder Letter.

[86] *See, e.g.,* ABA Letter; Parsont Letter; Projectheureka Letter; Public Startup Letter 2; RocketHub Letter.

[87] *See, e.g.,* ABA Letter (suggesting a reasonable cure period and limiting the ''look-back'' period to one year); Grassi Letter (recommending that a delinquent issuer be required to file a form with the Commission and publish on its Web site and the relevant intermediary's platform a notice to potential investors that it has not met its reporting obligations); Parsont Letter (recommending the Commission treat the ongoing reporting requirements as a condition to the Section 4(a)(6) exemption and create a notice and cure provision in the proposed insignificant deviation safe harbor); RocketHub Letter (suggesting delinquent issuers be required to disclose their delinquent status in their offering documents); Vann Letter (recommending a grace period for curing the deficiency).

[88] *See, e.g.,* Grassi Letter (stating that further exclusions would impose a more onerous burden on issuers under Section 4(a)(6) than that placed on

Further, two commenters opposed the idea of excluding an issuer whose officer, director, or controlling shareholder served in a similar capacity with another issuer that failed to file its annual reports.[89]

Business Plans. Commenters were divided on excluding issuers that have no specific business plan from eligibility to rely on Section 4(a)(6).[90] Commenters, however, supported the exclusion of issuers that have business plans to engage in a merger or acquisition with an unidentified company.[91]

c. Final Rules

We are adopting the issuer eligibility requirements as proposed, with the addition of two clarifications. As noted above, Section 4A(f) expressly excludes foreign issuers, Exchange Act reporting companies and companies that are investment companies as defined in the Investment Company Act or companies that are excluded from the definition of investment company under Section 3(b) or 3(c) of the Investment Company Act from the exemption for crowdfunding transactions provided by Section 4(a)(6). Although some commenters expressed concerns about these statutory exclusions, including that such exclusions could limit the investment choices of crowdfunding investors, we are not creating additional exemptions for these categories of issuers. In reaching this determination, we have considered that the primary purpose of Section 4(a)(6), as we understand it, is to facilitate capital formation by early stage companies that might not otherwise have access to capital.[92] As a general matter, we do not believe that Exchange Act reporting companies, investment companies and foreign issuers accessing the U.S. capital markets constitute the types of issuers that Section 4(a)(6) and Regulation Crowdfunding are intended to benefit. Moreover, we believe that certain of these issuers, such as foreign issuers or investment companies, may present unique risks that would make them unsuitable for the scaled regulatory regime associated with securities-based crowdfunding transactions. Accordingly, the final rules exclude these categories of issuers from Regulation Crowdfunding.[93]

We are not creating, as suggested by some commenters,[94] an exception to this exclusion for a single purpose fund organized to invest in, or lend money to, a single company. The statute specifically excludes investment funds from eligibility to rely on Section 4(a)(6) and investment fund issuers present considerations different from those for non-fund issuers.

In addition to these statutorily excluded categories of issuers, the final rules also exclude, as proposed, several additional categories of issuers. Below we discuss each of these additional categories:

Disqualification Provisions. As discussed further in Section II.E.6 below, the final rules also exclude issuers that are disqualified from relying on Section 4(a)(6).[95]

Delinquent in Ongoing Reporting. Consistent with the proposed rules and the views of a number of commenters,[96] the final rules exclude an issuer that has sold securities in reliance on Section 4(a)(6) if the issuer has not filed with the Commission and provided to investors, to the extent required, the ongoing annual reports required by Regulation Crowdfunding[97] during the two years immediately preceding the filing of the required new offering statement.[98] As discussed further in Section II.B.2 below, we believe that the annual ongoing reporting requirement will benefit investors by enabling them to consider updated information about the issuer, thereby allowing them to make more informed investment decisions. If issuers fail to comply with this requirement, we do not believe that they should have the benefit of relying on the exemption under Section 4(a)(6) again until they file, to the extent required, the two most recent annual reports.[99] In addition, as discussed further in Section II.B.1 below, in a modification to the proposed rules, the final rules require an issuer to disclose in its offering statement and annual report if it, or any of its predecessors, previously failed to comply with the ongoing reporting requirements of Regulation Crowdfunding.

We note that some commenters read the provision requiring issuers to have filed their two most recent annual reports to mean that the disqualification would be triggered only after the issuer was delinquent for two consecutive years or that an issuer would be disqualified for two years.[100] Instead, the final rule requires that any ongoing annual report that was due during the two years immediately preceding the currently contemplated offering must be filed before an issuer may rely on the Section 4(a)(6) exemption. For example, if more than 120 days have passed since the issuer's fiscal year end and the issuer has not filed the required annual report for that most recently ended fiscal year, the issuer will not be able to conduct a new offering of securities in reliance on the Section 4(a)(6) exemption until the delinquent annual report has been filed. Similarly, if an issuer did file an annual report for the most recently ended fiscal year but did not file an annual report for the fiscal year prior to that, the issuer will not be able to rely on the Section 4(a)(6) exemption until the missing report has been filed. In both cases, as soon as the issuer has filed with the Commission and provided to investors both of the annual reports required during the two years immediately preceding the filing

current registrants filing under Exchange Act Sections 13(a) or 15(d) or emerging growth companies); Projectheureka Letter.

[89] *See* Grassi Letter (stating that these persons may not have the authority or responsibility to file an annual report); Whitaker Chalk Letter.

[90] For commenters who expressed support, *see, e.g.,* Anonymous Letter 2; CFA Institute Letter; CFIRA Letter 7; Commonwealth of Massachusetts Letter; Consumer Federation Letter; Hackers/Founders Letter; NASAA Letter; ODS Letter; Traklight Letter; Whitaker Chalk Letter. For commenters who expressed opposition, *see, e.g.,* ABA Letter (expressing concern that a particular business idea disclosed by a crowdfunding issuer might be deemed after-the-fact to be too non-specific to have permitted reliance on Section 4(a)(6), thus exposing that issuer to a potential Section 5 violation); FundHub Letter 1; Projectheureka Letter; Public Startup Letter 2; RoC Letter; RocketHub Letter; SBM Letter; Wilson Letter.

[91] *See, e.g.,* ABA Letter; CFA Institute Letter; Commonwealth of Massachusetts Letter; Consumer Federation Letter; Grassi Letter; ODS Letter; RFPIA Letter.

[92] *See, e.g.,* 158 Cong. Rec. S1765 (daily ed. Mar. 29, 2012) (statement of Sen. Jack Reed) (''[Crowdfunding] is the place where we envision the smallest entrepreneurs could obtain much needed seed capital for their good ideas.''); 158 Cong. Rec. H1581 (daily ed. Mar. 27, 2012) (statement of Rep. Patrick McHenry (''Crowdfunding is the best of microfinancing and crowdsourcing. You use a wide network of individuals and you can raise capital for your new business, your start-up, or your small business.'').

[93] See Rule 100(b) of Regulation Crowdfunding.

[94] *See, e.g.,* EMKF Letter; Fryer Letter; Growthfountain Letter; Martin Letter; Propellr Letter 2; Wefunder Letter.

[95] *See* Rule 100(b)(4) of Regulation Crowdfunding. *See also* Rule 503 of Regulation Crowdfunding and Section II.E.6 for a discussion of the disqualification provisions.

[96] *See, e.g.,* ASSOB Letter; Commonwealth of Massachusetts Letter; Consumer Federation Letter; Fund Democracy Letter; Grassi Letter; Joinvestor Letter; NASAA Letter; Wefunder Letter.

[97] *See* Rules 202 and 203(b) of Regulation Crowdfunding and Section II.B.2 for a discussion of the ongoing reporting requirements.

[98] *See* Rule 100(b)(5) of Regulation Crowdfunding.

[99] We note that even if an issuer has regained eligibility to rely on Regulation Crowdfunding, the Commission could still bring an enforcement action under the federal securities laws based on the issuer's failure to make the required filings. In addition, as discussed in Section II.E.4., new Rule 12g–6 provides an exemption from Section 12(g) conditioned, among other things, on the issuer's compliance with the annual reporting requirements of Rule 202 of Regulation Crowdfunding.

[100] *See, e.g.,* Consumer Federation Letter; Fund Democracy Letter; NASAA Letter.

of the required offering statement, the issuer will be able to rely on the Section 4(a)(6) exemption. The final rule text includes an instruction to clarify this requirement.[101]

Consistent with the proposal and the recommendations of commenters,[102] we are not extending the exclusion to issuers that are delinquent in the progress update or termination of reporting requirements, nor are we excluding issuers whose officer, director, or controlling shareholder served in a similar capacity with another issuer that failed to file its annual reports. Extending the exclusion to those issuers would impose more stringent requirements than those faced by current reporting companies and issuers under Regulation A.

Business Plans. The final rules also exclude an issuer that has no specific business plan or has indicated that its business plan is to engage in a merger or acquisition with an unidentified company or companies.[103] We believe that the exemption under Section 4(a)(6) is intended to provide an issuer with an early stage project, idea or business an opportunity to share it publicly with a wider range of investors. Those investors may then share information with each other about the opportunity and use that information to decide whether or not to invest. Thus, we believe that an issuer engaging in crowdfunding under the exemption should give the public sufficient information about a particular proposed project or business to allow investors to make an informed investment decision.[104]

As discussed in the proposal, we are cognizant of the challenges noted by some commenters [105] in distinguishing between early-stage proposals that have information sufficient to support the crowdfunding mechanism and those that cannot by their terms do so. After considering the comments received,[106] we continue to believe that the rules should exclude issuers that have no specific business plan or whose business plan is to engage in a merger or acquisition with an unidentified company or companies. We understand that issuers engaging in crowdfunding transactions may have businesses at various stages of development in differing industries, and therefore, we believe that a specific ''business plan'' for such issuers could encompass a wide range of project descriptions, articulated ideas, and business models.

Overall, we believe that the exclusions in the final rules appropriately consider the need to limit the potential risks to investors that could result from extending issuer eligibility to certain types of entities without unduly limiting the benefits of the exemption as a tool for capital formation.

B. Issuer Requirements

1. Disclosure Requirements

Securities Act Section 4A(b)(1) sets forth specific disclosures that an issuer offering or selling securities in reliance on Section 4(a)(6) must ''file with the Commission and provide to investors and the relevant broker or funding portal, and make available to potential investors''. These disclosures include:

- The name, legal status, physical address and Web site address of the issuer; [107]
- the names of the directors and officers (and any persons occupying a similar status or performing a similar function), and each person holding more than 20 percent of the shares of the issuer; [108]
- a description of the business of the issuer and the anticipated business plan of the issuer; [109]
- a description of the financial condition of the issuer; [110]
- a description of the stated purpose and intended use of the proceeds of the offering sought by the issuer with respect to the target offering amount; [111]
- the target offering amount, the deadline to reach the target offering amount and regular updates about the progress of the issuer in meeting the target offering amount; [112]
- the price to the public of the securities or the method for determining the price; [113] and
- a description of the ownership and capital structure of the issuer.[114]

In addition, Section 4A(b)(1)(I) specifies that the Commission may require additional disclosures for the protection of investors and in the public interest.

As discussed further in Section II.B.3 below, we are requiring issuers to file these disclosures with the Commission on Form C.[115] Unless otherwise indicated in the form, Form C must be filed in the standard format of eXtensible Markup Language (XML). The XML-based fillable portion of Form C will enable issuers to provide information in a convenient medium without requiring the issuer to purchase or maintain additional software or technology. This will provide the Commission and the public with readily available data about offerings made in reliance on Section 4(a)(6). Other required disclosure that is not required to be provided in the XML-based text boxes will be filed as attachments to Form C. We are not mandating a specific presentation format for the attachments to Form C; however, the final Form C does include an optional Q&A format that crowdfunding issuers may use to provide disclosures that are not required to be filed in XML format.[116] We believe that this optional format should help reduce the burden on crowdfunding issuers of preparing disclosures.

By filing Form C with the Commission and providing it to the relevant intermediary, issuers will satisfy the requirement of Securities Act Section 4A(b) that issuers relying on Section 4(a)(6) must ''file with the Commission and provide to investors and the relevant broker of funding portal, and make available to potential investors'' certain information. In a clarifying change from the proposal, we have moved the definition of ''investor'' from proposed Rule 300(c)(4) to Rule

[101] *See* instruction to paragraph (b)(5) of Rule 100 of Regulation Crowdfunding.

[102] *See, e.g.*, Grassi Letter; Projectheureka Letter; Whitaker Chalk Letter.

[103] *See* Rule 101(b)(6) of Regulation Crowdfunding.

[104] *See, e.g.*, Section 4A(b)(1)(C) (requiring a description of the business of the issuer and the anticipated business plan of the issuer).

[105] S*ee, e.g.*, ABA Letter; FundHub Letter 1; Projectheureka Letter; Public Startup Letter 2; RoC Letter; RocketHub Letter; SBM Letter; Wilson Letter.

[106] *See, e.g.*, ABA Letter; Anonymous Letter 2; CFA Institute Letter; CFIRA Letter 7; Commonwealth of Massachusetts Letter; Consumer Federation Letter; FundHub Letter 1; Grassi Letter; Hackers/Founders Letter; NASAA Letter; ODS Letter; Projectheureka Letter; Public Startup Letter 2; RFPIA Letter; RoC Letter; RocketHub Letter; SBM Letter; Traklight Letter; Whitaker Chalk Letter; Wilson Letter.

[107] Section 4A(b)(1)(A).

[108] Section 4A(b)(1)(B).

[109] Section 4A(b)(1)(C).

[110] Section 4A(b)(1)(D).

[111] Section 4A(b)(1)(E).

[112] Section 4A(b)(1)(F).

[113] Section 4A(b)(1)(G).

[114] Section 4A(b)(1)(H). Specifically, Section 4A(b)(1)(H) requires a description of: ''(i) terms of the securities of the issuer being offered and each other class of security of the issuer . . .; (ii) a description of how the exercise of the rights held by the principal shareholders of the issuer could negatively impact the purchasers of the securities being offered; (iii) the name and ownership level of each existing shareholder who owns more than 20 percent of any class of the securities of the issuer; (iv) how the securities being offered are being valued . . .; and (v) the risks to purchasers of the securities relating to minority ownership in the issuer, the risks associated with corporate actions, including additional issuances of shares, a sale of the issuer or of assets of the issuer, or transactions with related parties.''

[115] Issuers will use Form C to provide the required disclosures about the crowdfunding transaction and the information required to be filed annually. *See* Section II.B.3.

[116] *See* Item 1 of General Instruction III to Form C of Regulation Crowdfunding.

100(d) to clarify that for purposes of all of Regulation Crowdfunding, ''investor'' includes any investor or any potential investor, as the context requires.[117] In connection with this clarifying move we have deleted the phrase ''and make available to potential investors'' each time it appeared in the proposed Rules 201 and 203 to avoid redundancy.[118]

Additionally, as we clarify in the final rules, to the extent that some of the required disclosures overlap, issuers are not required to duplicate disclosures.

a. Offering Statement Disclosure Requirements

(1) Information About the Issuer and the Offering

(a) General Information About the Issuer, Officers and Directors, and Certain Shareholders

(i) Proposed Rules

To implement Sections 4A(b)(1)(A) and (B), we proposed in Rule 201 of Regulation Crowdfunding to require an issuer to disclose information about its legal status, directors, officers and certain shareholders and how interested parties may contact the issuer. Specifically, we proposed to require that an issuer disclose:

- Its name and legal status, including its form of organization, jurisdiction in which it is organized and date of organization;
- its physical address and its Web site address; and
- the names of the directors and officers, including any persons occupying a similar status or performing a similar function, all positions and offices with the issuer held by such persons, the period of time in which such persons served in the positions or offices and their business experience during the past three years, including:
  - Each person's principal occupation and employment, including whether any officer is employed by another employer; and
  - the name and principal business of any corporation or other organization in which such occupation and employment took place.

We proposed to define ''officer'' consistent with the definition in Securities Act Rule 405 and in Exchange Act Rule 3b–2. We further proposed to require disclosure of the business experience of directors and officers of the issuer during the past three years.

Section 4A(b)(1)(B) requires disclosure of ''the names of . . . each person holding more than 20 percent of the shares of the issuer.'' In contrast, Section 4A(b)(1)(H)(iii) requires disclosure of the ''name and ownership level of each existing shareholder who owns more than 20 percent *of any class* of the securities of the issuer'' (emphasis added). We proposed in Rule 201(c) to require disclosure of the names of persons, as of the most recent practicable date, who are the beneficial owners of 20 percent or more of the issuer's outstanding voting equity securities, calculated on the basis of voting power (''20 Percent Beneficial Owners''). Neither Section 4A(b)(1)(B) nor Section 4A(b)(1)(H)(iii) states as of what date the beneficial ownership should be calculated. We proposed in Rule 201(c) to require issuers to calculate beneficial ownership as of the most recent practicable date.

(ii) Comments on the Proposed Rules

Of the commenters that addressed the proposed issuer, officer and director disclosure rules, some generally supported them,[119] while others opposed specific disclosure requirements. For example, one commenter opposed requiring issuers to disclose a Web site address.[120] Other commenters opposed requiring issuers to disclose the business experience of their officers and directors,[121] while one commenter suggested narrowing the definition of the term ''officer.''[122] Some commenters expressed opposition to any revision to the proposed rules that would require disclosure of any court orders, judgments or civil litigation involving any directors and officers.[123]

Some commenters supported the proposed three-year time period to be covered by the officer and director disclosure rules,[124] while others recommended that officer and director disclosure cover the previous five years.[125] Some commenters recommended we require additional disclosures about an issuer's officers, directors and persons occupying a similar status or performing a similar function.[126]

A few commenters commented on the proposed 20 Percent Beneficial Owner rules. One commenter supported the requirement to disclose the names of persons who are the 20 Percent Beneficial Owners,[127] while one commenter opposed the requirement.[128] One commenter recommended that, to provide greater certainty for investors and more guidance for issuers, the beneficial ownership be calculated as of a specific date, rather than the most recent practicable date, and that the disclosure be updated when there are significant changes in beneficial ownership.[129] Finally, one commenter recommended that the Commission keep the requirement as simple as possible.[130]

(iii) Final Rules

We are adopting the issuer, officer and director, and 20 Percent Beneficial Owners disclosure requirements largely as proposed.[131] An issuer will be required to disclose information about its president, vice president, secretary, treasurer or principal financial officer, comptroller or principal accounting officer and any person routinely performing similar functions. As noted by at least one commenter,[132] an issuer may not have officers serving in each of these roles. Accordingly, the final rules require the disclosure only to the extent an issuer has individuals serving in these capacities or performing similar functions.[133] The required information includes all positions and offices held with the issuer, the period of time in which such persons served in the position or office and their prior business experience.[134] Contrary to the views of some commenters,[135] we

[117] *See* Rule 100(d) of Regulation Crowdfunding.

[118] *See* Rules 201 and 203(a) of Regulation Crowdfunding.

[119] *See, e.g.,* Angel Letter 1; CCI Letter; Denlinger Letter 1; Mollick Letter; Wefunder Letter; Wilson Letter.

[120] *See* Vann Letter (recommending that the disclosure requirement be optional or only required for businesses that have a Web site).

[121] *See, e.g.,* Public Startup Letter 2; RocketHub Letter; Schwartz Letter; Zhang Letter.

[122] *See* RocketHub Letter (stating that only relevant officers for most companies using Regulation Crowdfunding would be the principal executive officer and the principal financial officer, which may be the same person.)

[123] *See, e.g.,* FundHub Letter 1; RocketHub Letter; Wefunder Letter.

[124] *See, e.g.,* Denlinger Letter 1; Joinvestor Letter; Wefunder Letter.

[125] *See, e.g.,* Commonwealth of Massachusetts Letter; NASAA Letter.

[126] *See, e.g.,* Angel Letter 1 (qualifications of candidates for the board of directors); Denlinger Letter 1(educational background of the officers and directors); Mollick Letter (online identities of the officers and directors); ODS Letter (educational background of the officers and directors); Wilson Letter (technical and business skills of the officers and directors); Zeman Letter (any officer and director positions held by the officers and directors or their family members, as well as any 10 percent beneficial holdings they may have with other SEC registrants; and disputes the officers and directors had with other employers).

[127] *See* RocketHub Letter.

[128] *See* Public Startup Letter 2.

[129] *See* NASAA Letter.

[130] *See* RocketHub Letter.

[131] *See* Rule 201(a)–(c) of Regulation Crowdfunding.

[132] *See* RocketHub Letter.

[133] *See* Instruction to paragraph (b) of Rule 201 of Regulation Crowdfunding.

[134] *See* Rule 201(b) of Regulation Crowdfunding.

[135] *See, e.g.,* Denlinger 1 Letter (educational background of officers); ODS Letter (educational

Continued

believe that additional disclosures about an issuer's officers, directors and persons occupying a similar status or performing a similar function would be unduly burdensome and generally not necessary for investors to be in a position to make an informed investment decision. Given the diverse nature of the startups and small businesses that we anticipate will seek to raise capital in reliance on Section 4(a)(6), additional disclosures such as those recommended by some commenters may not be relevant in all instances.

The required disclosure about the business experience of the directors and officers (and any persons occupying a similar status or performing a similar function) must cover the past three years,[136] which, as some commenters noted,[137] is shorter than the five-year period that applies to issuers conducting registered offerings [138] or exempt offerings pursuant to Regulation A.[139] We believe that startups and small businesses that may seek to raise capital in reliance on Section 4(a)(6) generally will be smaller than the issuers conducting registered offerings or exempt offerings pursuant to Regulation A, and generally are likely to have a more limited operating history.[140] Therefore, in comparison to registered offerings and Regulation A, we believe the three-year period is more relevant given the stage of development of these issuers and should help to reduce compliance costs for issuers conducting offerings pursuant to Section 4(a)(6) while still providing investors with sufficient information about the business experience of directors and officers of the issuer to make an informed investment decision.

Notwithstanding the suggestion of one commenter, and consistent with the statute, the final rules require disclosure of an issuer's Web site.[141] Given the Internet-based nature of Crowdfunding, we anticipate that every issuer will have a Web site or be able to create one at a minimal cost.

We also are adopting the 20 Percent Beneficial Owner disclosure requirement as proposed with one modification.[142] Instead of requiring issuers to disclose the name of each 20 Percent Beneficial Owner as of the most recent practicable date, we are requiring such disclosure as of the most recent practicable date, but no earlier than 120 days prior to the date the offering statement or report is filed. We believe that this change should address commenter concerns [143] about the discretion afforded by the proposed ''most recent practicable date.'' While we are not adding to Rule 201(c) a specific requirement that the disclosure be updated when there are significant changes in beneficial ownership, as requested by one commenter,[144] to the extent a material change in beneficial ownership takes place during the offering, an issuer would be required to file an amended offering statement on Form C/A: Amendment.

As stated in the Proposing Release, we believe that the universe of 20 Percent Beneficial Owners should be the same for the disclosure requirements and the disqualification provisions [145] because this would ease the burden on issuers by requiring them to identify only one set of persons who would be the subject of these rules. We continue to believe that assessing beneficial ownership based on total outstanding voting securities is consistent with Section 4A(b)(1)(B). Section 4A(b)(1)(B) is not limited to voting equity securities, but we believe the limitation is necessary to clarify how beneficial ownership should be calculated since issuers could potentially have multiple classes of securities with different voting powers.

(b) Description of the Business

(i) Proposed Rules

Consistent with Section 4A(b)(1)(C), we proposed in Rule 201(d) of Regulation Crowdfunding to require an issuer to disclose information about its business and business plan. The proposed rules did not specify the disclosures that an issuer would need to include in the description of the business and the business plan.

(ii) Comments on the Proposed Rules

While several commenters expressed concerns about requiring an issuer to disclose a description of its business and business plan,[146] most commenters supported this proposed requirement.[147] Some commenters recommended that the disclosure include specific items, such as disclosure of any material contracts of the issuer, any material litigation or any outstanding court order or judgment affecting the issuer or its property; [148] the issuer's business value proposition, revenue model, team, regulatory issues and executive compensation; [149] how the issuer will build value for the shareholders; [150] and plans for implementation, concrete next steps, outside recommendations about the validity of the business, backgrounds of the individuals involved and prototypes or concept drawings.[151] One commenter recommended that the disclosure requirement be scaled to match the size of the offering.[152]

Some commenters recommended that the Commission provide a non-exclusive list of the types of information an issuer should consider disclosing, templates, examples or other guidance to assist the issuer in complying with this disclosure requirement.[153] One commenter recommended that the Commission not specify the information to be included in the description of the business or the business plan.[154] Commenters also opposed revising the proposed business description requirement to require the description to include the information requirements of Items 101(a)(2) and 101(h) [155] of Regulation S–K.[156]

(iii) Final Rules

Consistent with the proposal, Rule 201(d) requires an issuer to disclose information about its business and business plan. We are not modifying the proposed rule, as some commenters

background of officers, directors and similar persons); Zeman Letter (proposing that officers and directors of an issuer be required to disclose their (or family members) officer and director positions with other SEC registrants, and disclose material holdings of more than 10% with other SEC registrants).

[136] *See* Rule 201(b) of Regulation Crowdfunding.

[137] *See, e.g.,* Commonwealth of Massachusetts Letter; NASAA Letter.

[138] *See* Item 401(e) of Regulation S–K [17 CFR 229.401(e)].

[139] *See* Item 8(c) of Form 1–A [17 CFR 239.90].

[140] There is no limit on the amount of proceeds that may be raised in a registered offering, and Regulation A permits offerings of up to $50 million of securities annually.

[141] *See* Rule 201(a) of Regulation Crowdfunding.

[142] *See* Rule 201(c) of Regulation Crowdfunding.

[143] *See* NASAA Letter.

[144] *Id.*

[145] *See* Rule 503 of Regulation Crowdfunding and Section II.E.6 for a discussion of the disqualification provisions.

[146] *See, e.g.,* ABA Letter; ASSOB Letter; Public Startup Letter 2; Traklight Letter.

[147] *See, e.g.,* Anonymous Letter 2; Arctic Island Letter 5; Benjamin Letter; CFIRA Letter 7; Consumer Federation Letter; EMKF Letter; Hackers/Founders Letter; Mollick Letter; NFIB Letter; RocketHub Letter; Saunders Letter; Wefunder Letter.

[148] *See, e.g.,* Arctic Island Letter 4 (referencing only pending litigation); Arctic Island Letter 5 (referencing only threatened or pending litigation); FundHub Letter 1; Wilson Letter.

[149] *See, e.g.,* Arctic Island Letter 5.

[150] *See, e.g.,* Hackers/Founders Letter.

[151] *See, e.g.,* Mollick Letter.

[152] *See* Consumer Federation Letter.

[153] *See, e.g.,* ABA Letter; Benjamin Letter; CFIRA Letter 7; Commonwealth of Massachusetts Letter; FundHub Letter 1 (recommending a safe harbor list of requirements); Traklight Letter; Wilson Letter (recommending a checklist or prescribed list of questions).

[154] *See* RocketHub Letter.

[155] 17 CFR 229.101.

[156] *See, e.g.,* Hamilton Letter; Public Startup Letter 2; RocketHub Letter.

recommended,[157] to specify the disclosures that an issuer must include in the description of the business and the business plan or to provide a non-exclusive list of the types of information an issuer should consider disclosing. We anticipate that issuers engaging in crowdfunding transactions may have businesses at various stages of development in different industries, and therefore, we believe that the rules should provide flexibility for these issuers regarding what information they disclose about their businesses. This flexible approach is consistent with the suggestion of one commenter that the business plan requirements be scaled to match the size of the offering.[158] We also are concerned that a non-exclusive list of the types of information an issuer should consider providing would be viewed as a *de facto* disclosure requirement that all issuers would feel compelled to meet and would, therefore, undermine the intended flexibility of the final rules.

(c) Use of Proceeds

(i) Proposed Rules

Consistent with Section 4A(b)(1)(E), we proposed in Rule 201(i) of Regulation Crowdfunding to require an issuer to provide a description of the purpose of the offering and intended use of the offering proceeds. We expected that such disclosure would provide a sufficiently detailed description of the intended use of proceeds to permit investors to evaluate the investment. Under the proposed rules, if an issuer did not have definitive plans for the proceeds, but instead had identified a range of possible uses, then the issuer would be required to identify and describe each probable use and factors affecting the selection of each particular use. In addition, if an issuer indicated that it would accept proceeds in excess of the target offering amount,[159] the issuer would be required to provide a separate, reasonably detailed description of the purpose and intended use of any excess proceeds with similar specificity.

(ii) Comments on the Proposed Rules

Most commenters supported the requirement that issuers disclose the intended use of the offering proceeds.[160] One commenter recommended that we prescribe the use of proceeds disclosure or provide a list of examples that issuers should consider when providing such disclosures.[161] Others recommended a variety of circumstances under which an issuer should be required to update the use of proceeds disclosure.[162]

(iii) Final Rules

We are adopting the use of proceeds disclosure requirement substantially as proposed in Rule 201(i). An issuer will be required to provide a reasonably detailed description of the purpose of the offering, such that investors are provided with enough information to understand how the offering proceeds will be used.[163] While one commenter[164] recommended that we prescribe this disclosure or provide a list of examples, we believe a more prescriptive rule would not best accommodate a diverse range of issuers. Instead, below we provide several examples of the disclosures issuers should consider making with respect to various uses of proceeds.

The disclosure requirement is designed to provide investors with sufficient information to evaluate the investment. For example, an issuer may intend to use the proceeds of an offering to acquire assets or businesses, compensate the intermediary or its own employees or repurchase outstanding securities of the issuer. In providing its description, an issuer would need to consider the appropriate level of detail to provide investors about the assets or businesses that the issuer anticipates acquiring, based on its particular facts and circumstances, so that the investors could make informed decisions. If the proceeds will be used to compensate existing employees or to hire new employees, the issuer should consider disclosing whether the proceeds will be used for salaries or bonuses and how many employees it plans to hire, as applicable. If the issuer will repurchase outstanding issuer securities, it should consider disclosing its plans, terms and purpose for repurchasing the securities. An issuer also should consider disclosing how long the proceeds will satisfy the operational needs of the business. If an issuer does not have definitive plans for the proceeds, but instead has identified a range of possible uses, then the issuer should identify and describe each probable use and the factors the issuer may consider in allocating proceeds among the potential uses.[165] If an issuer indicates that it will accept proceeds in excess of the target offering amount, the issuer must provide a reasonably detailed description of the purpose, method for allocating oversubscriptions, and intended use of any excess proceeds with similar specificity.[166]

(d) Target Offering Amount and Deadline

(i) Proposed Rules

Consistent with Section 4A(b)(1)(F), we proposed in Rule 201(g) of Regulation Crowdfunding to require issuers to disclose the target offering amount and the deadline to reach the target offering amount. In addition, we proposed in Rule 201(h) to require an issuer to disclose whether it would accept investments in excess of the target offering amount, and, if it would, we proposed to require the issuer to disclose, at the commencement of the offering, the maximum amount it would accept. The issuer also, under proposed Rule 201(h), would be required to disclose, at the commencement of the offering, how shares in oversubscribed offerings would be allocated. We further proposed in Rule 201(j) to require issuers to describe the process to cancel an investment commitment or to complete the transaction once the target amount is met, including a statement that:

- Investors may cancel an investment commitment until 48 hours prior to the deadline identified in the issuer's offering materials; [167]
- the intermediary will notify investors when the target offering amount has been met;
- if an issuer reaches the target offering amount prior to the deadline identified in its offering materials, it may close the offering early if it provides at least five business days'

[157] *See, e.g.,* ABA Letter; Arctic Island Letter 4; Arctic Island Letter 5; Benjamin Letter; CFIRA Letter 7; Commonwealth of Massachusetts Letter; FundHub Letter 1; Hackers/Founders Letter; Mollick Letter; Traklight Letter; Wilson Letter.

[158] *See* Consumer Federation Letter.

[159] *See* Section II.B(1)(d) below for a description of the final rule's disclosure requirements with respect to target amounts.

[160] *See, e.g.,* ABA Letter; ASSOB Letter; Consumer Federation Letter; Joinvestor Letter; Saunders Letter; Traklight Letter; Whitaker Chalk Letter; Wilson Letter. *But see,* Public Startup Letter 2.

[161] *See* Commonwealth of Massachusetts Letter.

[162] *See, e.g.,* ASSOB Letter (five percent change); CFIRA Letter 7 (material deviations in the offering statement and any deviations in the annual report); Commonwealth of Massachusetts Letter (material change); Joinvestor Letter (substantial change); RocketHub Letter (significant change); Traklight Letter (material deviations); Whitaker Chalk Letter (material change); Wilson Letter (any deviation). *See* also Section II.B.3 for discussion of when an amendment to the offering statement may be required.

[163] *See* Instruction to paragraph (i) of Rule 201 of Regulation Crowdfunding.

[164] *See* Commonwealth of Massachusetts Letter.

[165] *See* Instruction to paragraph (i) of Rule 201 of Regulation Crowdfunding.

[166] *See* Instruction to paragraph (i) of Rule 201 of Regulation Crowdfunding.

[167] Section II.C.6 further discusses the cancellation provisions.

notice prior to that new deadline (absent a material change that would require an extension of the offering and reconfirmation of the investment commitment);[168] and

• if an investor does not cancel an investment commitment before the 48-hour period prior to the offering deadline, the funds will be released to the issuer upon closing of the offering and the investor will receive securities in exchange for his or her investment.

In addition, proposed Rule 201(k) would require issuers to disclose that if an investor does not reconfirm his or her investment commitment after a material change is made to the offering, the investor's investment commitment will be cancelled and committed funds will be returned. Proposed Rule 201(g) also would require issuers to disclose that if the sum of the investment commitments does not equal or exceed the target offering amount at the time of the offering deadline, no securities will be sold in the offering, investment commitments will be cancelled and committed funds will be returned.[169]

(ii) Final Rules

Commenters were supportive of the proposed rules, and we are adopting the target offering amount and deadline disclosure rules as proposed.[170] As an example of how the final rules will apply, if an issuer sets a target offering amount of $80,000 but is willing to accept up to $650,000, the issuer will be required to disclose both the $80,000 target offering amount and the $650,000 maximum offering amount that it will accept.[171] In an instance where an issuer reaches the target offering amount prior to the deadline identified in its offering materials, it may close the offering early if it provides at least five business days' notice about the new offering deadline as set forth in Rules 201(j) and 302(d) of Regulation Crowdfunding. Accelerating the deadline would not require an extension of the offering and reconfirmation of the investment commitment; however, issuers would need to consider whether any material change occurred that would require an extension and reconfirmation from investors.[172]

We do not believe it is necessary for us to prescribe how oversubscribed offerings must be allocated if the issuer is required to disclose, at the commencement of the offering, how shares in oversubscribed offerings will be allocated. Commenters were supportive of this approach,[173] and we believe this disclosure should provide investors with important information while maintaining flexibility for issuers to structure the offering as they believe appropriate.

We believe that investors in a crowdfunding transaction will benefit from clear disclosure about their right to cancel, the circumstances under which an issuer may close an offering early and the need to reconfirm the investment commitment under certain circumstances, as they will be more aware of their rights to rescind an investment commitment. Therefore, we are adopting disclosure requirements covering these points, as proposed.

(e) Offering Price

Consistent with Section 4A(b)(1)(G), we proposed in Rule 201(l) of Regulation Crowdfunding to require an issuer to disclose the offering price of the securities or, in the alternative, the method for determining the price, so long as before the sale each investor is provided in writing the final price and all required disclosures.

Commenters were supportive of the proposed disclosure[174] and we are adopting the offering price disclosure rules as proposed.[175] We believe that disclosure of the price or the methods used for determining the price, coupled with investors' rights to cancel their investment upon determination of the final price, provide sufficient opportunity for investors to evaluate the price.

(f) Ownership and Capital Structure

(i) Proposed Rules

Consistent with Section 4A(b)(1)(H), we proposed in Rule 201(m) of Regulation Crowdfunding to require an issuer to provide a description of its ownership and capital structure. This disclosure would include:

• The terms of the securities being offered and each other class of security of the issuer, including the number of securities being offered and those outstanding, whether or not such securities have voting rights, any limitations on such voting rights, how the terms of the securities being offered may be modified and a summary of the differences between such securities and each other class of security of the issuer, and how the rights of the securities being offered may be materially limited, diluted or qualified by the rights of any other class of security of the issuer;

• a description of how the exercise of the rights held by the principal shareholders of the issuer could affect the purchasers of the securities;

• the name and ownership level of persons who are 20 Percent Beneficial Owners;

• how the securities being offered are being valued, and examples of methods for how such securities may be valued by the issuer in the future, including during subsequent corporate actions;

• the risks to purchasers of the securities relating to minority ownership in the issuer and the risks associated with corporate actions including additional issuances of securities, issuer repurchases of securities, a sale of the issuer or of assets of the issuer or transactions with related parties; and

• a description of the restrictions on the transfer of the securities.

As proposed, the rules would require disclosure of the number of securities being offered and those outstanding, whether or not such securities have voting rights, any limitations on such voting rights and a description of the restrictions on the transfer of the securities.

(ii) Comments on the Proposed Rules

A number of commenters supported the proposed ownership and capital structure disclosure rules,[176] while two commenters opposed them as burdensome.[177] One of these

[168] *Id.*

[169] *See* Section 4A(a)(7) (requiring intermediaries to ''ensure that all offering proceeds are only provided to the issuer when the aggregate capital raised from all investors is equal to or greater than a target offering amount. . . .'') and discussion in Section II.C.6.

[170] *See* Rules 201(g), 201(h), 201(j) and 201(k) of Regulation Crowdfunding.

[171] The issuer in this case also will need to disclose the intended use of the additional proceeds. *See* Instruction to paragraph (i) of Rule 201 of Regulation Crowdfunding. *See also* Section II.B.1.a.i(c) above. In addition, the issuer in this case will be required to provide financial statements reviewed by an independent public accountant (rather than certain tax return information for the most recently completed fiscal year and financial statements certified by the principal executive officer). *See* Section II.B.1.a.ii for a discussion of the financial statement requirements.

[172] Section II.B.1.c discusses the amendment and reconfirmation requirements.

[173] *See, e.g.,* CFA Institute Letter; RoC Letter; RocketHub Letter; Wilson Letter.

[174] *See, e.g.,* CFA Institute Letter; Wilson Letter. As discussed below, however, a few commenters recommended that the Commission require a fixed price at the commencement of an offering. *See, e.g.,* Joinvestor Letter; RocketHub Letter. We address those comments in Section II.B.6.

[175] *See* Rule 201(l) of Regulation Crowdfunding.

[176] *See, e.g.,* CFA Institute Letter; Commonwealth of Massachusetts Letter; Hackers/Founders Letter; Joinvestor Letter; NASAA Letter; RocketHub (supporting only to the extent that such disclosures do not require additional form submission or accountant or legal work); Saunders Letter; Wilson Letter.

[177] *See* Campbell R. Letter; Schatz Letter.

commenters suggested that issuers should only be required to disclose the price of a share and the percentage ownership represented by a share, and noted that the principals of an issuer conducting a crowdfunding offering may not consider the issuer's capital structure or whether its shareholders will have voting rights.[178]

(iii) Final Rules

We are adopting the ownership and capital structure disclosure rules as proposed, with the addition of language specifying that beneficial ownership must be calculated no earlier than 120 days prior to the date of the filing of the offering statement or report,[179] consistent with the treatment of beneficial ownership elsewhere in the rule.[180] Investors in crowdfunding transactions will benefit from clear disclosure about the terms of the securities being offered and each other class of security of the issuer. The final rules require disclosure of the number of securities being offered and those outstanding, whether or not such securities have voting rights, any limitations on such voting rights [181] and a description of the restrictions on the transfer of securities.[182] Although Section 4A(b)(1)(H) does not specifically call for all aspects of this disclosure, we believe that such disclosure is necessary to provide investors with a more complete picture of the issuer's capital structure than would be obtained solely pursuant to the statutory requirements. This should help investors better evaluate the terms of the offer before making an investment decision.

(g) Additional Disclosure Requirements

(i) Proposed Rules

We also proposed to require the following additional disclosures: [183]

- Disclosure of the name, SEC file number and Central Registration Depository number (''CRD number'') (as applicable) [184] of the intermediary through which the offering is being conducted;
- disclosure of the amount of compensation paid to the intermediary for conducting the offering, including the amount of any referral or other fees associated with the offering;
- certain legends in the offering statement;
- disclosure of the current number of employees of the issuer;
- a discussion of the material factors that make an investment in the issuer speculative or risky;
- a description of the material terms of any indebtedness of the issuer, including the amount, interest rate, maturity date and any other material terms;
- disclosure of any exempt offerings conducted within the past three years; and
- disclosure of related-party transactions since the beginning of the issuer's last fiscal year in excess of five percent of the aggregate amount of capital raised by the issuer in reliance on Section 4(a)(6) during the preceding 12-month period, inclusive of the amount the issuer seeks to raise in the current offering.

(ii) Comments on the Proposed Rules

Identity of the Intermediary. Several commenters supported the proposed requirement that issuers identify the intermediary through which the offering is being conducted.[185] Two commenters opposed such a requirement as unnecessary.[186]

Compensation Paid to the Intermediary. Some commenters supported the proposed requirement that issuers disclose the amount of compensation paid to the intermediary for conducting the offering, including the amount of any referral or other fees associated with the offering.[187] One commenter noted that to the extent components of the intermediary's fee are percentage based, the exact amount of the compensation may not be calculable at the onset of an offering.[188] A few commenters recommended that issuers also should disclose all payments and fees, if any, they make to the intermediary.[189]

Legends. Comments were mixed as to the proposed requirement that issuers include specified legends in the offering statement about the risks of investing in a crowdfunding transaction and the required ongoing reports. Some commenters supported such a requirement,[190] while others opposed the requirement.[191]

Current Number of Employees. While several commenters supported the proposed requirement that issuers disclose their current number of employees,[192] two commenters opposed such a requirement.[193] One commenter opposed this requirement, noting that the number of employees is not useful for investors in evaluating early-stage startups, and is likely to increase during the course of a crowdfunding offering conducted concurrently with an offering pursuant to Rule 506(c).[194] This commenter also noted that many early-stage startups spend the majority of their initial funds on consultants.[195] Another commenter noted that it may be unreasonably costly, relative to the benefit gained, to accurately count the number of employees in instances where businesses engage many contract workers, or have workers on arrangements such as ''flex-time'' or ''half-time.'' [196]

Risk Factors. Commenters were divided as to the proposed requirement that issuers discuss the material factors that make an investment in the issuer speculative or risky. A number of commenters supported this proposed requirement,[197] while a number of others opposed it.[198] Some commenters

[178] Schatz Letter.

[179] *See* Rule 201(m) of Regulation Crowdfunding.

[180] *See* Rule 201(c) of Regulation Crowdfunding.

[181] *Id.*

[182] *See* Rule 501 of Regulation Crowdfunding and Section II.E.2 for a discussion of restrictions on resales.

[183] Section 4A(b)(1)(I) provides us with discretion to require crowdfunding issuers to provide additional information for the protection of investors and in the public interest.

[184] The Financial Industry Regulatory Authority, Inc. (''FINRA'') issues CRD numbers to registered broker-dealers.

[185] *See, e.g.,* Commonwealth of Massachusetts Letter; Joinvestor Letter; Schwartz Letter; Wilson Letter (recommending that issuers also disclose whether the intermediary specializes in offerings based on criteria such as industry size or type).

[186] *See* Public Startup Letter 2; RocketHub.

[187] *See, e.g.,* ASSOB Letter; Commonwealth of Massachusetts Letter; RocketHub Letter; Startup Valley Letter; Wilson Letter. *But see, e.g.,* Grassi Letter (opposing the requirement unless offering proceeds will be used to compensate the intermediary); Public Startup Letter 2; Schwartz Letter.

[188] *See* RocketHub Letter.

[189] *See, e.g.,* ASSOB Letter (recommending disclosure of all payments); RocketHub Letter (recommending disclosure of fees paid for compliance and overhead to enhance transparency for investors).

[190] *See, e.g.,* ABA Letter; CFA Institute Letter; Commonwealth of Massachusetts Letter; Jacobson Letter; Schwartz Letter; Wilson Letter.

[191] *See, e.g.,* Grassi Letter (recommending that general risks be disclosed on the intermediaries' platforms rather than in each issuer's offering statement); Hackers/Founders Letter (noting that crowdfunding issuers will tend to be smaller and lack the resources of large companies, and intermediaries should be required to provide examples of risks associated with crowdfunding offerings); Public Startup Letter 2; Startup Valley Letter (stating that a legend by the issuer about the risks of investing in a crowdfunding transaction is not needed because it is the responsibility of the intermediary to educate the public about this information).

[192] *See, e.g.,* NASAA Letter; Wilson Letter; Zhang Letter.

[193] *See* Schwartz Letter; Wefunder Letter.

[194] *See* Wefunder Letter.

[195] *Id.*

[196] *See* Schwartz Letter.

[197] *See, e.g.,* ASSOB Letter; CFA Institute Letter; Commonwealth of Massachusetts Letter; Consumer Federation Letter; EMKF Letter; Jacobson Letter; McGladrey Letter; STA Letter; StartupValley Letter; Wilson Letter.

[198] *See, e.g.,* ABA Letter; Campbell R. Letter; Cole A. Letter; Grassi Letter; Hackers/Founders Letter; RocketHub Letter (recommending that a generic

Continued

recommended that we provide examples of, or develop standard disclosures for, issuer risk factor discussions.[199]

Indebtedness. Commenters supported the proposed requirement that issuers describe the material terms of any indebtedness of the issuer.[200] Two commenters recommended that we clarify that this disclosure requirement could be satisfied if the issuer includes such disclosure in its financial statements.[201] Another recommended that we require issuers to disclose the identities of their creditors.[202]

Prior Exempt Offerings. Commenters supported the proposed requirement that issuers disclose their prior exempt offerings.[203] One commenter recommended that we require additional disclosure to help non-accredited investors understand how well aligned their interests are with earlier accredited investors,[204] while other commenters suggested scaling back this disclosure in order to contain costs.[205]

Related-Party Transactions. Commenters generally supported our proposal to require disclosure of certain related-party transactions between the issuer and any director or officer of the issuer, any person who is a 20 Percent Beneficial Owner, any promoter of the issuer (if the issuer was incorporated or organized within the past three years) or immediate family members of the foregoing persons.[206] Rather than using the definition of ''immediate family member'' contained in Item 404 of Regulation S–K,[207] one commenter recommended that we use a common definition for ''immediate family member'' in the related-party transactions context and ''member of the family of the purchaser or the equivalent'' in the resale restrictions context.[208]

One commenter supported the proposal to limit the disclosure of related-party transactions to transactions since the beginning of the issuer's last fiscal year.[209] Other commenters recommended that the related-party transaction disclosure cover the period for which financial statements are required.[210] In addition, one commenter supported the proposal to limit disclosure of related-party transactions based on the size of the offering,[211] while a few commenters suggested alternatives to such proposal.[212]

Other Disclosures. Several commenters specifically recommended that we not require any additional disclosures.[213] One commenter pointed out that there was no ''catch-all'' clause requiring any other material information not specifically enumerated in Rule 201 of Regulation Crowdfunding.[214]

Other commenters recommended that we require issuers to disclose general information; [215] executive compensation; [216] zoning issues and issues with the Environmental Protection Agency or Food and Drug Administration; [217] a copy of their articles of incorporation; [218] the extent to which they are affected by market risk, material contracts, business backlogs and the names of, and number of shares being sold by, existing shareholders; [219] and the credit history of the business and the business owners.[220]

As discussed in Section II.B.2 below in connection with ongoing annual reports, a number of commenters recommended ways to make it easier for investors to locate an issuer's annual reports.[221]

(iii) Final Rules

We are adopting the additional disclosure requirements as proposed in Rule 201 with several modifications. As discussed below, we have added a requirement to disclose any material information necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.[222] We also have modified the rule to require disclosure of the compensation to be paid to the intermediary so that it could be disclosed either as a dollar amount or percentage of the offering amount or as a good faith estimate if the exact amount is not available at the time of the filing.[223] We also have added a requirement to disclose the location on the issuer's Web site where investors will be able to find the issuer's annual report and the date by which such report will be available on the issuer's Web site.[224] In addition, we have added a requirement to disclose whether the issuer or any of its predecessors previously has failed to comply with the ongoing reporting requirements of Regulation Crowdfunding.[225]

We agree with the suggestion by some commenters that issuers should not be required to disclose in multiple places the information required to be provided

500-word statement suffice); Schwartz Letter; Scruggs Letter.

[199] *See, e.g.,* Commonwealth of Massachusetts Letter; EMKF Letter; Heritage Letter (recommending also that the Commission define ''material''); Jacobson Letter; SBA Office of Advocacy Letter. *But see,* StartupValley Letter (opposing such a recommendation).

[200] *See, e.g.,* Consumer Federation Letter; ODS Letter; Schwartz Letter; Wilson Letter.

[201] *See* Grassi Letter; EY Letter.

[202] *See* ODS Letter.

[203] *See, e.g.,* CFA Institute Letter (recommending a brief statement about prior capital raising transactions); Commonwealth of Massachusetts Letter; Grassi Letter; Joinvestor Letter; ODS Letter; Parsont Letter; RoC Letter (supporting the disclosure covering the past three years); RocketHub Letter (recommending disclosure of successful prior offerings only); Whitaker Chalk Letter (recommending that the disclosure exclude the target amount of any offerings made in reliance on Section 4(a)(6) and whether such target was reached); Wilson Letter. *But see, e.g.,* Heritage Letter; Public Startup Letter 2; Schwartz Letter; Wefunder Letter.

[204] *See* Parsont Letter.

[205] *See, e.g.,* Grassi Letter (recommending disclosure of only the date, amount raised, type of securities sold and a link to a Web site where more information on such prior offerings can be found); Wefunder Letter (recommending disclosure of only the aggregate capital raised in all prior exempt transactions, as well as the date, terms, valuation of and types of securities issued in the most recent exempt offering).

[206] *See, e.g.,* AICPA Letter (recommending disclosure of transactions between the issuer and 10 percent beneficial owners); Commonwealth of Massachusetts Letter; Grassi Letter (also recommending disclosure of transactions between the issuer and employees or affiliated entities with common ownership or control); NASAA Letter; RocketHub Letter; Wilson Letter. *But see,* Public Startup Letter 2; Schwartz Letter.

[207] 17 CFR 229.404.

[208] *See* Brown J. Letter. *See also,* Section II.E.2 for a discussion of the restrictions on resales.

[209] *See* RocketHub Letter.

[210] *See* AICPA Letter; Grassi Letter.

[211] *See* AICPA Letter.

[212] *See, e.g.,* Grassi Letter (recommending disclosure of all related-party transactions not deemed *de minimis*); NASAA Letter (recommending a lower percentage threshold); RocketHub Letter (recommending a fixed threshold).

[213] *See, e.g.,* ABA Letter; Public Startup Letter 2; RocketHub Letter; Schwartz Letter.

[214] *See* CrowdCheck Letter 1.

[215] *See, e.g.,* ODS Letter; STA Letter; Tiny Cat Letter. Such general information may include the issuer's contact information; agent for service; information about the manner in which ownership interests will be evidenced; who will be providing record keeping services; where records of ownership will be maintained; and/or statements that the issuer may not provide account statements and that investors will have the responsibility of monitoring their investments, communicating with the record keeper and updating their information with the record keeper.

[216] *See, e.g.,* Arctic Island Letter 4; Denlinger Letter 1 (recommending disclosure of deferred compensation, stock options or warrants, contingent payments for services, shareholder and other related-party loans and contingent liabilities); Grassi Letter (recommending separate amounts for base salary, bonus and an ''other'' category for the three highest paid individuals and the number and type of equity instruments granted); NASAA Letter; RFPIA Letter (recommending inclusion of owners' compensation).

[217] *See, e.g.,* Arctic Island Letter 4.

[218] *See, e.g.,* Hackers/Founders Letter.

[219] *See, e.g.,* CFA Institute Letter.

[220] *See, e.g.,* SBM Letter.

[221] *See, e.g.,* Arctic Island Letter 5; CFA Institute Letter (recommending advance notice as to when and where annual reports will be available); RocketHub Letter.

[222] *See* Rule 201(y) of Regulation Crowdfunding.

[223] See Rule 201(o) of Regulation Crowdfunding.

[224] *See* Rule 201(w) of Regulation Crowdfunding.

[225] *See* Rule 201(x) of Regulation Crowdfunding.

to investors.[226] As a result, to avoid duplicative disclosure, an issuer will not be required to repeat what is already provided elsewhere in the issuer's disclosure, including the financial statements.[227] Issuers may cross-reference within the offering statement or report, including to the location of the information in the financial statements.[228]

Identity of the Intermediary. Despite the suggestion of one commenter that this disclosure is unnecessary,[229] we believe requiring an issuer to identify the name, SEC file number and CRD number (as applicable) of the intermediary through which the offering is being conducted should assist investors and regulators in obtaining information about the offering and use of the exemption.[230] It also could help investors obtain background information on the intermediary, for instance, through filings made by the intermediary with the Commission, as well as through the Financial Industry Regulatory Authority's (''FINRA'') BrokerCheck system for broker-dealers [231] or a similar system, if created, for funding portals.

Compensation Paid to the Intermediary. Requiring an issuer to disclose the amount of compensation paid to the intermediary for conducting the offering, including the amount of any referral or other fees associated with the offering, will permit investors and regulators to determine how much of the proceeds of the offering is used to compensate the intermediary. Based on a comment received,[232] we understand that in some instances the exact amount of compensation and fees to be paid to the intermediary will not be known at the time the Form C is filed, and we have modified the rule from the proposal to address this issue. Consistent with this understanding, and to avoid suggesting that only amounts certain and paid to date must be disclosed, the final rules require disclosure of all compensation paid or to be paid to the intermediary for conducting the offering, which may be disclosed as a dollar amount or as a percentage of the offering amount. If the exact amount of the compensation paid or to be paid is not available at the time of the filing, issuers are permitted to provide a good faith estimate.[233]

In addition, we are modifying the rule text from the proposal to require issuers to disclose any other direct or indirect interest in the issuer held by the intermediary, or any arrangement for the intermediary to acquire such an interest.[234] The proposed rules would have prohibited an intermediary from holding any financial interest in the issuers conducting offerings on its platforms. However, as discussed in Section II.C.2.b below, the final rules permit intermediaries to hold such interests. We believe that, similar to the amount of compensation paid to the intermediary, an intermediary's interests in an issuer and the issuer's transaction could be material to an investment decision in the issuer. Therefore, we believe that issuers should disclose such interests to investors.

Legends. We are adopting this requirement as proposed.[235] The requirement for an issuer to include in the offering statement specified legends about the risks of investing in a crowdfunding transaction is intended to help investors understand the general risks of investing in a crowdfunding transaction. We continue to believe, despite the suggestions of some commenters,[236] that requiring legends in each issuer's offering statement, regardless of any general warnings available on an intermediary's platform, will provide additional investor protection with minimal costs. For example, the requirement that an issuer include in the offering statement certain legends about the required ongoing reports, including how those reports will be made available to investors and how an issuer may terminate its ongoing reporting obligations, will help investors understand an issuer's ongoing reporting obligations and how they will be able to access those reports.

Current Number of Employees. Consistent with the proposal and the recommendation of several commenters,[237] the final rules require disclosure of the current number of employees.[238] We believe this disclosure is important to investors in evaluating a crowdfunding transaction because it will give investors a sense of the size of the issuers using the exemption. We expect that the early-stage issuers who are likely to use securities-based crowdfunding will not have many employees, so we do not believe this requirement will be unreasonably burdensome.

Risk Factors. We are adopting this disclosure requirement as proposed.[239] While some commenters expressed concerns about potential expenses or confusion associated with risk disclosure,[240] we agree with those commenters who indicated that disclosure of the material factors that make an investment in the issuer speculative or risky is important to help investors understand the risks of investing in a specific issuer's offering.[241] To help investors to better understand these risks, we believe that risk factor disclosure should be tailored to the issuer's business and the offering and should not repeat the factors addressed in the required legends.[242] For similar reasons, we are not providing examples of, or developing standard disclosure for, issuer risk factor discussions, as we believe issuers will be in the best positions to articulate the risks associated with their business and offerings in light of their particular facts and circumstances.

Indebtedness. Consistent with the proposal, we are adopting the requirement to provide a description of the material terms of any indebtedness of the issuer.[243] We believe disclosure of the material terms of any indebtedness of the issuer, including, among other items, the amount, interest rate and maturity date of the indebtedness, is important to investors because servicing debt could place additional pressures on an issuer in the early stages of development. We expect that for many issuers this information will be included in the financial statements, which will satisfy this reporting requirement.[244]

While one commenter recommended that we require issuers to disclose the

[226] *See, e.g.*, EY Letter (noting that certain required disclosure would be included in an issuer's financial statements); Grassi Letter (same).

[227] *See* Instruction to Item 201 of Regulation Crowdfunding.

[228] *Id.*

[229] *See* RocketHub Letter.

[230] *See* Rule 201(n) of Regulation Crowdfunding.

[231] *See* FINRA, FINRA BrokerCheck, *available at http://www.finra.org/Investors/ToolsCalculators/BrokerCheck/P015175*.

[232] *See* RocketHub Letter.

[233] *See* Rule 201(o)(1) of Regulation Crowdfunding.

[234] *See* Rule 201(o)(2) of Regulation Crowdfunding.

[235] *See* Item 2 of General Instruction III to Form C.

[236] *See, e.g.*, Grassi Letter; Hackers/Founders Letter; Public Startup Letter 2; Startup Valley Letter.

[237] *See, e.g.*, NASAA Letter; Wilson Letter; Zhang Letter.

[238] *See* Rule 201(e) of Regulation Crowdfunding.

[239] *See* Rule 201(f) of Regulation Crowdfunding.

[240] *See, e.g.*, Campbell R. Letter; Cole A. Letter; Grassi Letter; Hackers/Founders Letter; RocketHub Letter; Schwartz Letter; Scruggs Letter.

[241] *See, e.g.*, ASSOB Letter; CFA Institute Letter; Commonwealth of Massachusetts Letter; Consumer Federation Letter; EMKF Letter; Jacobson Letter; McGladrey Letter; STA Letter; StartupValley Letter; Wilson Letter.

[242] *See* Item 2 of General Instruction III to Form C.

[243] *See* Rule 201(p) of Regulation Crowdfunding.

[244] *See* Instruction to Rule 201 of Regulation Crowdfunding; Items 1 and 3 of General Instruction III to Form C.

identities of their creditors,[245] we do not believe, as a general matter, that such disclosure would provide meaningful information to investors. Accordingly, under the final rules, such disclosure is required only to the extent the creditor's identity is a material aspect of the indebtedness.[246]

Prior Exempt Offerings. Consistent with the proposal and with commenters' recommendations, we are requiring issuers to provide disclosure about the exempt offerings that they conducted within the past three years.[247] For each exempt offering within the past three years, issuers must describe the date of the offering, the offering exemption relied upon, the type of securities offered and the amount of securities sold and the use of proceeds.[248] We believe that information about prior offerings will better inform investors about the capital structure of the issuer and will provide information about how prior offerings were valued.

Related-Party Transactions. We are adopting this disclosure requirement substantially as proposed.[249] Related-party transactions create potential conflicts of interest that may result in actions that benefit the related parties at the expense of the issuer or the investors. After considering the comments received, we continue to believe the related-party transactions disclosure will assist investors in obtaining a more complete picture of the financial relationships between certain related parties and the issuer and provide additional insight as to potential uses of the issuer's resources, including the proceeds of the offering. The final rule differs from the proposal in that an issuer is required to disclose transactions with any person who is, as of the most recent practicable date but no earlier than 120 days prior to the date the offering statement or report is filed, the beneficial owner of 20 percent or more of the issuer's outstanding voting equity securities. Limiting the relevant period to 120 days prior to the date of the offering statement or report is consistent with the treatment of beneficial ownership elsewhere in Regulation Crowdfunding.[250] We also believe this limitation and the consistency it provides will help limit compliance costs for issuers.

The final rule also includes an instruction to clarify that, for purposes of Rule 201(r), a transaction includes, but is not limited to, any financial transaction, arrangement or relationship (including any indebtedness or guarantee of indebtedness) or any series of similar transactions, arrangements or relationships.[251] This instruction is consistent with Item 404 of Regulation S–K.[252]

Given the early stage of development of the small businesses and startups that we expect will seek to raise capital pursuant to Section 4(a)(6), as well as the investment limits prescribed by the rules, we believe that limiting the disclosure of related-party transactions to transactions occurring since the beginning of the issuer's last fiscal year, as proposed, will help to limit compliance costs for issuers while still providing investors with sufficient information to evaluate the relationship between related parties and the issuer.[253] In addition, we are requiring issuers to disclose only related-party transactions that, in the aggregate, are in excess of five percent of the aggregate amount of capital raised by the issuer in reliance on Section 4(a)(6) during the preceding 12-month period, inclusive of the amount the issuer seeks to raise in the current offering under Section 4(a)(6). We also have added an instruction to clarify that any series of similar transactions, arrangements or relationships should be aggregated for purposes of determining whether related-party transactions should be disclosed.[254] For example, an issuer seeking to raise $1 million will be required to disclose related-party transactions that, in the aggregate, are in excess of $50,000, which is the same dollar threshold required in Form 1–A [255] for offerings of any size made pursuant to Tier 1 of Regulation A,[256] and an issuer that raises $250,000 will be required to disclose such transactions in excess of $12,500. We believe that, in light of the sizes and varieties of issuers that may make offerings in reliance on Section 4(a)(6), this approach could mitigate the potential for the requirement to be disproportionate to the size of certain offerings and issuers. While one commenter suggested we use a percentage threshold less than five percent, we believe this threshold appropriately takes into consideration the need to provide investors with relevant information about the issuer's activities involving related parties during this crucial early stage of development.

As suggested by one commenter,[257] in a change from the proposal, we are adopting a definition for ''member of the family'' in the related-party transactions context that is consistent with the definition of ''member of the family of the purchaser or the equivalent'' in the resale restrictions context.[258] The final rule defines ''member of the family'' as a ''child, stepchild, grandchild, parent, stepparent, grandparent, spouse or spousal equivalent, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law, [including] adoptive relationships'' of any of the persons identified in Rules 201(r)(1), (r)(2) or (r)(3).[259] This definition tracks the definition of ''immediate family'' in Exchange Act Rule 16a–1(e),[260] but with the addition of ''spousal equivalent,'' which the final rule defines to mean ''a cohabitant occupying a relationship generally equivalent to that of a spouse.'' [261] We believe a common definition of ''member of the family'' that is consistent with our disclosure rules in other contexts [262] will provide certainty for issuers in identifying the persons covered by the rule.

Other Disclosures. We are adopting this provision as proposed but with the addition of three issuer disclosure requirements in response to comments received.

The first is a requirement that an issuer disclose the location on its Web site where investors will be able to find the issuer's annual report and the date by which such report will be available on its Web site.[263] We believe this requirement addresses the concern expressed by commenters that investors may not know where to find an issuer's annual report. We do not believe physical delivery of the annual report is necessary due to the electronic nature of the crowdfunding marketplace, nor do we believe that email delivery of the annual report is practical because the

[245] *See* ODS Letter.

[246] *See* Rule 201(y) of Regulation Crowdfunding.

[247] *See* Rule 201(q) of Regulation Crowdfunding.

[248] *See* Instruction to paragraph (q) of Rule 201 of Regulation Crowdfunding.

[249] *See* Rule 201(r) of Regulation Crowdfunding.

[250] *See, e.g.*, Rules 201(c) and 201(m) of Regulation Crowdfunding.

[251] *See* Instruction 2 to Rule 201(r) of Regulation Crowdfunding.

[252] *See* Instruction 2 to Item 404(a) of Regulation S–K [17 CFR 229.404(a)].

[253] We note, however, that financial statements covering the two most recently completed fiscal years will include disclosure of related-party transactions, as required by U.S. GAAP, for each of the years presented.

[254] *See* Instruction 1 to Rule 201(r) of Regulation Crowdfunding.

[255] 17 CFR 239.900

[256] 17 CFR 230.251 through 230.263

[257] *See* Brown J. Letter.

[258] *See* Rule 501(a) of Regulation Crowdfunding;

[259] *See* Rule 201(r)(4) of Regulation Crowdfunding.

[260] 17 CFR 240.16a–1(e).

[261] *See* Rule 201(r)(4) of Regulation Crowdfunding.

[262] *See, e.g.*, Exchange Act Rule 16a–1(e).

[263] *See* Rule 201(w) of Regulation Crowdfunding. *See also*, Section II.B.2 for a discussion of the requirement on issuers to post their annual reports on their Web sites.

issuer may not have access to email addresses of its investors. Instead, we are requiring issuers to disclose this information in the offering statement, which will assist investors in locating the information while limiting the compliance costs for issuers.

The second additional disclosure requirement, as suggested by a commenter,[264] is a requirement that the disclosure include any material information necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.[265] This provision should help ensure that investors have all of the material information they need on which to base their investment decisions.

The third additional requirement, similar to suggestions from some commenters,[266] requires the issuer to disclose whether it or any of its predecessors previously failed to comply with the ongoing reporting requirements of Regulation Crowdfunding.[267] While we continue to believe, and the final rules provide, that only those issuers that have failed to file their two most recent annual reports should be prohibited from relying on the exemption available under Section 4A(6), we also believe that any history of non-compliance with ongoing reporting obligations would provide important information to investors about the issuer.

Although we appreciate that commenters made various suggestions for additional issuer disclosure requirements, such as those relating to executive compensation, market risk and material contracts, we are not mandating further disclosures. In adopting issuer requirements for Regulation Crowdfunding, we have been mindful of the limited resources and start-up operations of issuers likely to use security-based crowdfunding and have sought to consider the need to provide investors with relevant information to make an informed investment decision while limiting the compliance costs for issuers. We believe the issuer disclosure requirements we are adopting along with other protections, such as investment limits, achieve this goal.

(2) Financial Disclosure

Section 4A(b)(1)(D) requires ''a description of the financial condition of the issuer.'' It also establishes a framework of tiered financial disclosure requirements based on aggregate target offering amounts of the offering and all other offerings made in reliance on Section 4(a)(6) within the preceding 12-month period.

(a) Financial Condition Discussion

(i) Proposed Rules

Consistent with Section 4A(b)(1)(D), we proposed in Rule 201(s) of Regulation Crowdfunding to require an issuer to provide a narrative discussion of its financial condition.

(ii) Comments on the Proposed Rules

Commenters generally supported the proposed requirement that issuers provide a narrative discussion of their financial condition.[268] One commenter expressed concern that the requirement could be challenging for issuers at an early stage of development and result in duplicative disclosure.[269] The same commenter suggested that issuers be encouraged, rather than mandated, to discuss material historical operating results.[270]

(iii) Final Rules

We are adopting this requirement as proposed, with a few technical modifications.[271] Rule 201(s) clarifies that the description must include, to the extent material, a discussion of liquidity, capital resources and historical results of operations. Rule 201(s) also includes an instruction noting that issuers will be required to include a discussion of each period for which financial statements are provided and a discussion of any material changes or trends known to management in the financial condition and results of operations of the issuer subsequent to the period for which financial statements are provided.[272] In connection with this instruction, an issuer will need to consider whether more recent financial information is necessary to make the disclosure in the offering document not misleading. The instruction in final Rule 201(s) was included in proposed Rule 201(t) as an instruction to the financial statement requirements, but we have moved this instruction to Rule 201(s) because it elicits narrative disclosure that we believe is more appropriately presented as part of the discussion of the issuer's financial condition. In addition, another instruction clarifies that references to the issuer in Rule 201(s) refer to the issuer and its predecessors, if any.[273]

We expect that the discussion required by the final rule and instructions will inform investors about the financial condition and results of operations of the issuer by providing management's perspective on the issuer's operations and financial results, including information about the issuer's liquidity and capital resources and any known trends or uncertainties that could materially affect the company's results. Because issuers seeking to engage in crowdfunding transactions will likely be smaller, less complex and at an earlier stage of development than issuers conducting registered offerings or Exchange Act reporting companies, we expect that the discussion generally will not, contrary to the concern of at least one commenter,[274] need to be as lengthy or detailed as the management's discussion and analysis of financial condition and results of operations of those issuers. Accordingly, we are not prescribing a specific content or format for this information, but instead set forth general principles for making this disclosure.[275] The discussion should address, to the extent material, the issuer's historical results of operations in addition to its liquidity and capital resources. If an issuer does not have a prior operating history, the discussion should focus on financial milestones and operational, liquidity and other challenges. If an issuer has a prior operating history, the discussion should focus on whether historical earnings and cash flows are representative of what investors should expect in the future. An issuer's discussion of its financial condition should take into account the proceeds of the offering and any other known or pending sources of capital. Issuers also should discuss how the proceeds from the offering will affect their liquidity, whether these funds and any other additional funds are necessary to the viability of the business and how quickly the issuer anticipates using its available cash. In addition, issuers should describe the other available sources of capital to the business, such as lines of credit or required contributions by principal shareholders. To the extent these items of disclosure overlap with the issuer's discussion of its business or business plan, issuers are not required to make

[264] *See* CrowdCheck Letter 1.

[265] *See* Rule 201(y) of Regulation Crowdfunding.

[266] *See* Grassi Letter; RocketHub Letter.

[267] *See* Rule 201(x) of Regulation Crowdfunding.

[268] *See, e.g.*, ABA Letter; CFA Institute Letter; CFIRA Letter 5; Commonwealth of Massachusetts Letter; Grassi Letter; Jacobson Letter; Joinvestor Letter; Saunders Letter. *But see, e.g.*, EY Letter; Public Startup Letter 2; RocketHub Letter.

[269] *See* EY Letter.

[270] *Id.*

[271] *See* Rule 201(s) of Regulation Crowdfunding.

[272] *See* Instruction 1 to Rule 201(s) of Regulation Crowdfunding.

[273] *See* Instruction 4 to Rule 201(s) of Regulation Crowdfunding.

[274] *See* EY Letter.

[275] *See* Instructions 1 and 2 to Rule 201(s) of Regulation Crowdfunding.

duplicate disclosures.[276] While we are not mandating a specific presentation, we expect issuers to present the required disclosures, including any other information that is material to an investor, in a clear and understandable manner.

(b) Financial Disclosures

(i) Proposed Rules

Proposed Rule 201(t) of Regulation Crowdfunding would have established financial statement disclosure requirements that are based on aggregate target offering amounts within the preceding 12-month period:

- Issuers offering $100,000 or less would be required to file with the Commission and provide to investors and the relevant intermediary income tax returns filed by the issuer for the most recently completed year (if any) and financial statements that are certified by the principal executive officer to be true and complete in all material respects;
- issuers offering more than $100,000, but not more than $500,000, would be required to file with the Commission and provide to investors and the relevant intermediary financial statements reviewed by a public accountant that is independent of the issuer; and
- issuers offering more than $500,000 would be required to file with the Commission and provide to investors and the relevant intermediary financial statements audited by a public accountant that is independent of the issuer.

Under proposed Rule 201(t), issuers would be permitted to voluntarily provide financial statements that meet the requirements for a higher aggregate target offering amount.

The proposed rules also would have set forth the following requirements for the financial statements:

- *Basis of Accounting.* All issuers would be required to file with the Commission and provide to investors and the relevant intermediary a complete set of their financial statements (balance sheets, income statements, statements of cash flows and statements of changes in owners' equity), prepared in accordance with U.S. generally accepted accounting principles (''U.S. GAAP'').
- *Public Accountant Requirements.* To qualify as independent of the issuer, a public accountant would be required to comply with the Commission's independence rules, which are set forth in Rule 2–01 of Regulation S–X.[277]
- *Periods Covered in the Financial Statements.* The financial statements would be required to cover the shorter of the two most recently completed fiscal years or the period since inception of the business.
- *Age of Financial Statements.* During the first 120 days of the issuer's fiscal year, an issuer would be able to conduct an offering in reliance on Section 4(a)(6) and the related rules using financial statements for the fiscal year prior to the most recently completed fiscal year if the financial statements for the most recently completed fiscal year are not otherwise available or required to be filed.
- *Review and Audit Standards.* Reviewed financial statements would be required to be reviewed in accordance with the Statements on Standards for Accounting and Review Services (''SSARS'') issued by the American Institute of Certified Public Accountants (''AICPA''). Audited financial statements would be required to be audited in accordance with the auditing standards issued by either the AICPA or the Public Company Accounting Oversight Board (''PCAOB'').
- *Review and Audit Reports.* Issuers would be required to file with the Commission and provide to investors and the relevant intermediary a copy of the public accountant's review or audit report. An issuer that received an adverse opinion or disclaimer of opinion in its audit report would not be in compliance with the audited financial statement requirements.
- *Exemptions from the Financial Statement Requirements.* The proposed rules would not exempt any issuers from the financial statement requirements.

(ii) Comments on the Proposed Rules

Commenters were divided on the proposed financial statement requirements,[278] although commenters generally supported allowing issuers to voluntarily provide financial statements that meet the requirements for a higher aggregate target offering amount.[279]

Offerings of $100,000 or less. In general, commenters supported requiring issuers to provide financial statements certified by the principal executive officer to be true and complete in all material respects.[280] Further, several recommended that all issuers relying on the Section 4(a)(6) exemption be required to provide such certification.[281]

Commenters were divided on the requirement that issuers offering $100,000 or less file and provide to investors their federal income tax returns. Supporters of the tax return requirement noted that income tax returns would be a source of credible information for investors that should be readily available without requiring issuers to bear significant additional preparation expenses.[282] On the other hand, opponents of the tax return requirement raised concerns about privacy,[283] identity theft and tax fraud.[284] One commenter expressed concern that small issuers may not be adequately prepared to consider the patchwork of state and federal privacy laws that might apply to the disclosure of tax returns.[285]

Several commenters suggested approaches to allow access by investors to the information available from a tax return,[286] including permitting issuers to digitally submit the data from their

[276] *See* Instruction to Rule 201 of Regulation Crowdfunding.

[277] 17 CFR 210.2–01.

[278] For an example of those who generally supported the proposed financial disclosure requirements, *see, e.g.,* ABA Letter (recommending some modifications); CFA Institute Letter; Commonwealth of Massachusetts Letter; Consumer Federation Letter (the financial information is critical to an informed evaluation of the investment opportunity); Denlinger Letter 1; Funderbuddies Letter; NASAA Letter.

For an example of those who generally opposed, *see, e.g.,* AEO Letter; Joinvestor Letter (recommending that only issuer-generated documents produced in good faith be required); Marsala Letter; RocketHub (stating that ''requirements are excessive in cost and misguided in intent''); Traklight Letter (recommending that instead of pre-raise and ongoing financial statement reviews or audits, issuers only be required to have a limited review engagement on the use of proceeds after the raise); Zhang Letter.

[279] *See, e.g.,* AICPA Letter; Denlinger Letter 1; Grassi Letter; Heritage Letter; RocketHub Letter; Wilson Letter. *But see* Public Startup Letter 2.

[280] *See, e.g.,* AICPA Letter; Zeman Letter.

[281] *See, e.g.,* AICPA Letter; Denlinger Letter 1; Grassi Letter; Jacobson Letter. *But see* Public Startup Letter 2.

[282] *See, e.g.,* Angel Letter 1 (''tax returns are even more credible than audited financial statements, as companies are highly unlikely to exaggerate profitability to the IRS.''); Fund Democracy Letter; NPCM Letter; Zeman Letter (''the small risk for these investors does not meet the consideration of audited financial statements.'').

[283] *See, e.g.,* AICPA Letter (disclosing an issuer's tax return ''. . . has the potential to cause serious problems. Tax returns are intended to be confidential and should remain so.''); Public Startup Letter 2; RocketHub Letter; SBM Letter; Wilson Letter (personal income tax information should be on a voluntary basis only); Zhang Letter.

[284] *See* AICPA Letter.

[285] *See* AICPA Letter.

[286] *See, e.g.,* Arctic Island Letter 5 (recommending that only the two primary pages and not the schedules be made public); CrowdBouncer Letter (recommending the Commission allow issuers to disclose electronic transcripts of filed tax returns to investors through the intermediary platforms); NPCM (expressing concern that unless tax returns are filed as a PDF stamped by the IRS, there is no way to know if the posted document is a true reflection of the tax return); RocketHub Letter.

tax return in a standardized format.[287] Supporters of digital submission suggested that approach would provide a standardized format and protect issuers from accidental disclosure of confidential information. Commenters generally supported the proposal to require issuers to redact personally identifiable information from their tax returns,[288] although some requested clarifications.[289]

Two commenters recommended that the timing of financial statement disclosures correspond to any extended tax filing deadlines,[290] while two other commenters opposed such application.[291] Further, a few commenters supported the proposal to permit an issuer that has not yet filed its tax return for the most recently completed fiscal year to use the tax return filed for the prior year and update the information after filing the tax return for the most recently completed fiscal year.[292] One commenter recommended that at least one tax return be available,[293] and another recommended that the Commission provide guidance for issuers who have not filed a U.S. tax return.[294] One commenter supported requiring issuers to describe any material changes that are expected in the tax returns for the most recently completed fiscal year,[295] while another recommended that such disclosure be permitted, but not required.[296]

A number of commenters recommended raising the maximum offering amount for issuers that provide this level of financial information.[297]

Offerings of more than $100,000 but not more than $500,000. Some commenters supported the requirement in the proposed rules that offerings of more than $100,000 but not more than $500,000 include financial statements reviewed by an independent public accountant,[298] while other commenters opposed such requirement.[299] A number of commenters recommended a different range of offering amounts or methods for determining when an issuer is required to file and provide reviewed financial statements.[300]

Offerings of more than $500,000. We received extensive comments on our proposal that issuers offering more than $500,000 be required to file with the Commission and provide to investors and the relevant intermediary financial statements audited by an independent public accountant. A significant number of those commenters opposed the proposed requirement,[301] although some commenters expressed support.[302] Some commenters recommended the elimination of the audit requirement,[303] and others recommended that we consider additional criteria for determining when an issuer would be required to provide audited financial statements.[304] A number of commenters opposed the proposed $500,000 threshold as being too low,[305] and a number recommended alternative thresholds.[306] A number of commenters stated that funding the upfront cost of an audit would be particularly difficult for issuers raising capital for the first time.[307]

[287] *See, e.g.,* RocketHub Letter (suggesting digital submission ''will protect the issuers from accidental disclosure of confidential information, and will allow investors to view the information in a structured and consistent manner. For example, if each issuer were to upload their version of a financial statement, the responsibility of learning to understand each format would fall to the investor. Standardized formats for financial projections, financial statements, and business plans will allow investors to quickly compare issuances and more readily evaluate investment opportunities.''); Zhang Letter.

[288] *See, e.g.,* ABA Letter; AICPA Letter; Fund Democracy Letter; Whitaker Chalk Letter.

[289] *See, e.g.,* ABA Letter (recommending the Commission provide a non-exhaustive list of the specific types of information that may be redacted); AICPA Letter (recommending that if the tax return requirement is adopted, the Commission define ''personally identifiable information'' and clarify that the redaction includes third-party information).

[290] *See* EY Letter; Grassi Letter.

[291] *See, e.g.,* ASSOB Letter (recommending that issuers should provide their tax accounts within three months of the end of the reporting period); Fund Democracy Letter.

[292] *See, e.g.,* Grassi Letter; RocketHub Letter.

[293] *See* Fund Democracy Letter.

[294] *See* AICPA Letter.

[295] *See* Grassi Letter.

[296] *See* RocketHub Letter (also recommending that the Commission define what qualifies as a material change).

[297] *See, e.g.,* Hackers/Founders Letter ($500,000); Kickstarter Coaching Letter ($250,000); RocketHub Letter ($500,000); Zeman Letter (recommending that offerings under $500,000 require two years of tax returns and unaudited balance sheets).

[298] *See, e.g.,* Denlinger Letter 1; Leverage PR Letter (stating that the industry will evolve to provide lower cost reviews); StartEngine Letter 1 (stating that the industry will evolve to provide lower cost reviews, such as in the $1,500–$10,000 range for smaller, newer companies).

[299] *See, e.g.,* Angel Letter 1 (recommending requiring audited financial statements if they are available and tax returns if they are not); Arctic Island Letter 5 (recommending only for issuers that have greater than $15 million in annual revenue); Johnston Letter; McGladrey Letter (recommending only after the issuer meets certain revenue and operational thresholds); NACVA Letter; Public Startup Letter 2; Zeman Letter.

[300] *See, e.g.,* ABA Letter; CIFRA Letter 5 (noting the financial disclosure standards of the SBA's Section 8(a) program require reviewed financial statements for companies with gross annual receipts for $2 million to $10 million); Grassi Letter ($300,000 to $700,000); Kickstarter Coaching Letter ($250,000 to $1 million).

[301] *See, e.g.,* AEO Letter; Angel Letter 1; AWBC Letter; CFIRA Letter 5; CfPA Letter; CrowdFundConnect Letter; EarlyShares Letter; EMKF Letter; EY Letter; Finkelstein Letter; FundHub Letter 1; Generation Enterprise Letter; Fryer Letter; Grassi Letter; Graves Letter; Guzik Letter 1; Hakanson Letter; Holland Letter; Johnston Letter; Kickstarter Coaching Letter; McGladrey Letter; Milken Institute Letter; NACVA Letter; NFIB Letter; NPCM Letter; NSBA Letter; PBA Letter; Reed Letter; RocketHub Letter; Saunders Letter; SBA Office of Advocacy Letter; SBEC Letter; SBM Letter; Seyfarth Letter; WealthForge Letter; Wefunder Letter; Woods Letter; Zeman Letter.

[302] *See, e.g.,* AICPA Letter; Consumer Federation Letter; CSTTC Letter; Denlinger Letter 2; FundDemocracy Letter; Leverage PR; NASAA Letter; StartEngine Letter 1.

[303] *See, e.g.,* CrowdFundConnect Letter; FundHub Letter 1; Johnston Letter; SBEC Letter; StartupValley Letter (for issuers less than two years old); Woods Letter.

[304] *See, e.g.,* Angel Letter 1 (only if such financial statements are available); Arctic Island Letter 5 (only apply to issuers that have greater than $15 million in revenue); EY Letter (only if issuer has raised $5 million in equity securities in crowdfunding transactions unless audited financial statements are otherwise available); McGladrey Letter (eliminate the audit requirements until the issuer meets certain revenue and operational thresholds); Reed Letter (if an audit is required, the requirement only apply to issuers that reach a certain size in investment or investors); RocketHub Letter ($5 million offering amount and the issuer has been in operation for more than two years). *But see* AICPA Letter (additional criteria would add complexity without any additional benefit).

[305] *See, e.g.,* ABA Letter; CCA Letter; CFIRA Letter 5; CfPA Letter; CrowdFundConnect Letter; EarlyShares Letter; EMKF Letter; EY Letter; FundHub Letter 1; Generation Enterprise Letter; Grassi Letter; Graves Letter; Guzik Letter 1; Kickstarter Coaching Letter; Milken Institute Letter; NFIB Letter; PBA Letter; RocketHub Letter; SBA Office of Advocacy Letter; SBM Letter; Seyfarth Letter; WealthForge Letter; Wefunder Letter; Woods Letter. *But see* AICPA Letter; Denlinger Letter 1; Fund Democracy Letter; Zeman Letter.

[306] *See, e.g.,* ABA Letter ($750,000); EarlyShares Letter ($1 million); EMKF Letter ($800,000); EY Letter ($5 million, unless audited financial statements are otherwise available); Grassi Letter ($700,000); Graves Letter ($900,000); Guzik Letter 1 ($700,000); Kickstarter Coaching Letter ($1 million); PBA Letter ($1 million); RocketHub Letter ($5 million and the issuer has been in operation for more than two years); Seyfarth Letter ($1 million); WealthForge Letter ($1 million).

[307] *See, e.g.,* AEO Letter (expressing concern that start-up businesses with no revenue to date, and raising capital for the first time, would find it difficult or impossible to fund the cost of an audit); AWBC Letter; CFIRA Letter 5 (stating that the proposed level of financial disclosure for capital raises over $500,000 would be an impediment for small business when many will have limited financial resources to absorb the expense prior to raising capital using crowdfunding); CfPA Letter (suggesting the Commission determine an alternate audit threshold because ''the costs of an audit must necessarily be incurred prior to an offering, and in the numerous expected cases of unsuccessful offerings, would lead to substantial net losses to the businesses that Crowdfunding is supposed to help''); EMKF Letter (stating that many of the issuers looking to raise capital through crowdfunding will be startups with little or no revenue to afford audited financial statements); Generation Enterprise Letter; Grassi Letter; Graves Letter; Holland Letter; McGladrey Letter; NSBA Letter; Reed Letter (noting that few start-ups could afford auditing fees); RocketHub Letter (stating that the filing and audit requirements establish an upfront cost that is too high for small businesses to accept); SBM Letter (noting that many startups do not have the resources to obtain audited financials);

Continued

We received a number of comments expressing concern about the anticipated costs associated with audited financial statements.[308] Other commenters noted that costs would be lower than those estimated in the Proposing Release or in other comment letters.[309]

Basis of Accounting. Commenters generally were divided on whether issuers relying on Section 4(a)(6) should be required to prepare financial statements in accordance with U.S. GAAP.[310] Commenters in support of requiring U.S. GAAP noted the benefit to investors of having a single standard to facilitate comparison of different issuers,[311] and also that U.S. GAAP would be more likely to provide investors with a fair representation of an issuer's financial position and results of operations than financial statements using a comprehensive basis of accounting other than U.S. GAAP.[312]

A number of commenters recommended that, as a less expensive alternative to requiring U.S. GAAP, the Commission allow financial statements prepared in accordance with a comprehensive basis of accounting other than U.S. GAAP.[313] Other commenters recommended that if financial statements prepared in accordance with U.S. GAAP are required, they only be required in certain circumstances.[314]

A few commenters recommended that issuers relying on Section 4(a)(6) be permitted to take advantage of the extended transition period applicable to private companies for complying with new or revised accounting standards.[315] A few commenters expressed concern that Section 4(a)(6) issuers may be viewed as ''public business entities'' by FASB.[316] One commenter recommended that the Commission provide an exemption from this definition for such issuers.[317]

Periods Covered in the Financial Statements. While two commenters generally supported requiring two years of financial statements,[318] a number of commenters generally opposed the proposal, recommending one year of financial statements instead.[319] Many commenters opposed requiring interim financial statements,[320] while several supported such a requirement.[321] Several commenters recommended that if interim financial statements are required, they not be subject to audit or review,[322] while another commenter recommended that they not be filed with the Commission, but only be provided to investors.[323]

Age of Financial Statements. Several commenters opposed our proposal that financial statements be dated within 120 days of the start of the offering,[324] while one commenter supported it.[325] Some commenters opposed our proposal to permit an issuer, during the first 120 days of the issuer's fiscal year, to conduct an offering in reliance on Section 4(a)(6) using financial statements for the fiscal year prior to the

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Seyfarth Letter (stating that the audit requirement will deny access to issuers who do not have the necessary upfront capital); WealthForge Letter; Wefunder Letter.

[308] *See, e.g.*, AEO Letter; CfPA Letter; CFIRA Letter 5; CrowdCheck Letter 4; ErrandRunner Letter; Finkelstein Letter; FundHub Letter 1 (stating that the difference in cost for reviewed versus audited financial statements could easily run into tens of thousands of dollars); Graves Letter (stating that a partner from a leading accounting firm predicted the cost to small businesses of providing audited financial statements could be upwards of $18,000 to $25,000); Grassi Letter (stating that audits take more time than companies seeking capital may have); NFIB Letter; RocketHub Letter; SBA Office of Advocacy Letter; SBEC Letter; SBM Letter; Seyfarth Letter; StartupValley Letter (stating that audits for small startups with no financials can cost $10,000 and that GAAP audits typically cost 25–50% more than other comprehensive basis of accounting audits); Stephenson Letter; Traklight Letter (stating that audit costs have been cited as low as $5,000 and as high as $20,000 for a startup; also stating that review costs are estimated at about 60% of the cost of an audit); WealthForge Letter.

[309] *See, e.g.*, CCA Letter (analyzing regulatory costs borne by Title II issuers); CrowdFranchise Letter 1; CrowdFunding Network (stating that projected costs are already decreasing through market forces); D'Amore Letter; ddb*mckennon* Letter (noting that the majority of issuers will be newly formed with limited historical operations and that an audit for such companies may range from $4,000–$9,000 in year one); Denlinger Letter 1 (citing a study that found that about half of the cost of an audit is made up for in interest rate savings on bank loans); Denlinger Letter 2 (the market will evolve for small issuers such that audit costs may be in the range of $2,000–$4,000); FundHub Letter 2 (noting the emergence of CPA firms willing to do a complete audit for a startup business for $2,500 or less); Holm Letter (stating that new providers are offering compliance services at much lower costs than anticipated); JumperCard Letter; Kemp Letter; Leverage PR Letter; Sfinarolakis Letter; StartEngine Letter 1 (noting that reviews and audits will be in the range of $1,500–$10,000 for smaller, newer companies); StartEngine Letter 2 (noting the emergence of third-party service providers); tempCFO Letter; Upchurch Letter (stating that the market will adjust for costs).

[310] For supporters, *see, e.g.*, AICPA Letter (for offerings over $100,000); CFA Institute Letter; EY Letter (for offerings over $100,000 for only the most recent year); Hackers/Founders Letter; Heritage Letter (recommending for issuers with assets over $100,000, that if financial statements are not prepared in accordance with U.S. GAAP, the issuer be required to note any variance from U.S. GAAP and state the reason for such variance); NASAA Letter; RocketHub Letter; Whitaker Chalk Letter (for offerings over $500,000 until such time as the Commission accepts IFRS for U.S. domestic issuers).

For opponents, *see, e.g.*, ABA Letter (noting that the benefits associated with GAAP-compliant financial statements do not outweigh the burdens that mandatory application of GAAP would impose); CrowdCheck Letter 4; EarlyShares Letter; Graves Letter (recommending that U.S. GAAP only be required for issuers with $5 million in revenue); Milken Institute Letter (recommending that U.S. GAAP only be required for issuers with $5 million in revenue, the threshold at which the IRS requires a switch to accrual accounting); Public Startup Letter 2; SBEC Letter (noting the AICPA's release of new guidelines in June 2013 for small and mid-size businesses); Tiny Cat Letter; U.S. Chamber of Commerce Letter; Wilson Letter (recommending that the Commission consider the stage of the business in determining whether to require compliance with U.S. GAAP); Zhang Letter.

[311] *See, e.g.*, NASAA Letter.

[312] *See, e.g.*, EY Letter.

[313] *See, e.g.*, ABA Letter (for offerings of $100,000 or less, but stating that the Commission could require providing U.S. GAAP financial statements if available); AICPA Letter; CFIRA Letter 5; CFIRA Letter 7; CrowdCheck Letter 4; EarlyShares Letter; EY Letter (for offerings of $100,000 or less, unless U.S. GAAP financial statements are available); Grassi Letter; Graves Letter (for issuers with less than $5 million in revenue); Mahurin Letter (stating that simple Excel spreadsheets accompanied by bank records should meet the financial statement requirements); Milken Institute Letter (for early-stage issuers); NFIB Letter; SBEC Letter; StartupValley Letter; Tiny Cat Letter (for offerings of less than $500,000); Whitaker Chalk Letter (for offerings of less than $500,000 if the issuer has an asset or income level below a certain level).

[314] *See, e.g.*, ABA Letter (suggesting that: (i) In offerings of $100,000 or less, the certifying principal executive officer could be required to represent that the issuer is unable to prepare financial statements in accordance with U.S. GAAP without unreasonable effort or expense; (ii) in offerings of more than $100,000, but not more than $500,000, the exception could also require the principal executive officer representation and be limited to issuers that have not prepared U.S. GAAP-compliant financial statements for any other purpose and who have no operating history, no revenues and/or a minimal amount of assets (*e.g.*, $500,000); and (iii) in offerings of more than $500,000, the exception could require the principal executive officer representation, including a representation that the other comprehensive basis of accounting methodology selected is acceptable under AICPA standards, and be limited to issuers with no operating history or revenue and minimal assets).

[315] *See, e.g.*, EY Letter; U.S. Chamber of Commerce Letter.

[316] *See, e.g.*, ABA Letter; EY Letter (noting also the definition of ''public entity'' under the Accounting Standards Codification).

[317] *See* EY Letter.

[318] *See* ASSOB Letter; Zeman Letter.

[319] *See, e.g.*, Denlinger Letter 1; EY Letter; Grassi Letter; Joinvestor Letter; Public Startup Letter 2; RFPIA Letter (as it relates to audited financial statements); RocketHub Letter; Verrill Dana Letter.

[320] *See, e.g.*, CFIRA Letter 7; EMKF Letter; EY Letter; FundHub Letter 1; Grassi Letter; Public Startup Letter 2; RocketHub Letter; Traklight Letter; Wefunder Letter; Whitaker Chalk Letter.

[321] *See, e.g.*, AICPA Letter; Consumer Federation Letter (recommending supplementing the proposed financial statement requirements with unaudited CEO-certified financial statements through the end of the month ending no more than two months before the offering begins); Denlinger Letter 1 (recommending quarterly basic financial reporting, including a balance sheet, income statement and statement of cash flows); Fund Democracy Letter.

[322] *See, e.g.*, CFIRA Letter 7; Consumer Federation Letter; Denlinger Letter 1; Fund Democracy Letter; Traklight Letter.

[323] *See,* RocketHub Letter.

[324] *See, e.g.*, Grassi Letter; Public Startup Letter 2; RocketHub Letter.

[325] *See* Denlinger Letter 1.

most recently completed fiscal year,[326] while two others supported such accommodation.[327] One commenter recommended that, to provide ''truly current financials'' for large offerings, the Commission could require unaudited financial statements through the end of the month that ends no more than two months before the month in which the offering begins (*e.g.*, an offering any day in March would require financials up to January 31); for smaller offerings, the commenter indicated a modified standard for providing current information might be appropriate.[328]

Public Accountant Requirements. We received several comments on standards for audit firms.[329] Commenters supported not requiring audits to be conducted by a PCAOB-registered firm.[330] Some commenters supported our proposal to require the public accountant reviewing or auditing an issuer's financial statements to comply with the independence requirements set forth in Rule 2–01 of Regulation S–X,[331] while other commenters recommended allowing the public accountant to comply by meeting the independence requirements of the AICPA.[332] Some commenters noted that many startups and early-stage small businesses require assistance in the preparation of financial statements, and that complying with the independence standards of Regulation S–X would require such issuers to engage two external accountants—one to assist in preparing the financial statements and another to audit or review them.[333] One commenter asked the Commission not to create new independence standards.[334]

Review and Audit Standards. With respect to review standards, commenters supported requiring reviewed financial statements to be reviewed in accordance with the SSARS issued by the AICPA.[335] Commenters also opposed creating a new set of review standards.[336]

With respect to audit standards, several commenters supported our proposal to require that financial statements be audited in accordance with the auditing standards issued by either the AICPA or the PCAOB,[337] while several others opposed it.[338] Two commenters recommended that audits be required to be conducted in accordance with the auditing standards issued by the PCAOB.[339] Commenters generally opposed creating a new set of audit standards,[340] although one commenter recommended that if the Commission were to create a new set of audit standards, it ''should be designed as an ultra-low-cost procedure.'' [341]

Review and Audit Reports. With respect to review reports, two commenters supported our proposal that a review report that includes modifications would satisfy the reviewed financial statement requirement,[342] while one commenter opposed it.[343] With respect to audit reports, commenters supported our proposal that a qualified audit opinion would satisfy the audited financial statement requirements,[344] although one commenter opposed it.[345] One commenter requested clarification as to the requirements that may be applicable to the issuer and the public accountant when an issuer intends to include a previously issued audit or review report in an offering statement.[346]

Exemptions from Financial Statement Requirements. While the proposed rules did not exempt any issuers from the financial statement requirements, a number of commenters recommended exempting issuers with no operating history or issuers that have been in existence for fewer than 12 months from the requirement to provide financial statements,[347] although a few commenters opposed such a concept.[348] A number of commenters recommended that if an exemption for such issuers is allowed, the exempted issuers should provide certain basic disclosures,[349] and two commenters specifically recommended that if an exemption for such issuers is allowed, the exempted issuers should still provide a balance sheet.[350]

(iii) Final Rules

We are adopting financial disclosure requirements for Title III issuers in Rule

[326] *See, e.g.*, Consumer Federation Letter (stating that the proposal allows for the provision of stale and limited financial information because it ''would allow issuers to submit financial statements that are more than a year out of date and that cover only a very limited portion of the issuer's existence.''); EY Letter (recommending this time period be extended to 180 days if an issuer presents interim financial statements certified by the principal executive officer that cover the first six months of the issuer's most recently completed fiscal year); Fund Democracy Letter (noting that financial statements could be 16-months stale); Merkley Letter (recommending that the Commission not permit financial statements ''to be so thoroughly out of date''); Public Startup Letter 2.

[327] *See, e.g.*, Grassi Letter (noting that the material change disclosure requirements should be sufficient to keep investors updated); RocketHub Letter.

[328] *See* Fund Democracy Letter.

[329] *See, e.g.*, Grassi Letter (recommending no audit be accepted that has been performed by a firm that is not subject to, or that has received a fail report under, the AICPA peer review standards); ASSOB Letter (recommending the rules not place restrictions on the type of accountant an issuer is required to use to review or audit its financial statements); Multistate Tax Letter (an issuer should not be required to obtain accounting services).

[330] *See, e.g.*, AICPA Letter; ASSOB Letter (recommending the rules not place restrictions on the type of accountant an issuer is required to use to review or audit its financial statements); Denlinger Letter 1; Funderbuddies Letter; EY Letter; Grassi Letter; Heritage Letter; Multistate Tax Letter (an issuer should not be required to obtain accounting services); Public Startup Letter 2; RocketHub Letter; Traklight Letter. *See also* RFPIA Letter (recommending the public accountants conducting an audit be required to be members of the AICPA or the PCAOB for one year.).

[331] *See, e.g.*, ABA Letter; Commonwealth of Massachusetts Letter; RocketHub Letter.

[332] *See, e.g.*, AICPA Letter; Denlinger Letter 1; EY Letter; Grassi Letter; McGladrey Letter.

[333] *See, e.g.*, AICPA Letter; EY Letter; Grassi Letter.

[334] *See* AICPA Letter (recommending that the Commission not create new independence, review, or auditing standards or that the definition of ''a complete set of financial statements'' be different than under U.S. GAAP because doing so would result in confusion, further complexity and increased costs).

[335] *See, e.g.*, ABA Letter; AICPA Letter; Denlinger Letter 1; EY Letter; Fund Democracy Letter; Grassi Letter. *But see* Public Startup Letter 2.

[336] *See, e.g.*, AICPA Letter; Denlinger Letter 1; Grassi Letter; Traklight Letter.

[337] *See, e.g.* AICPA Letter; Denlinger Letter 1; EY Letter; Grassi Letter.

[338] *See, e.g.*, Consumer Federation Letter; Fund Democracy Letter; Public Startup Letter 2; RocketHub Letter; Rucker Letter (stating that GAAS fit poorly with the kinds of businesses Title III is intended to accommodate).

[339] *See* Consumer Federation Letter; Fund Democracy Letter.

[340] *See, e.g.*, AICPA Letter; Grassi Letter (recommending that the Commission require issuers to use the same standards used in the offering or higher standards, with the PCAOB standards deemed to be the higher standard, when complying with the ongoing reporting requirements); Heritage Letter; Traklight Letter.

[341] RocketHub Letter.

[342] *See* AICPA Letter; Heritage Letter (for going concern opinions).

[343] *See* Grassi Letter.

[344] *See, e.g.*, AICPA Letter; Arctic Island Letter 5 (noting that most small business audit opinions are likely to include a going concern clause); Denlinger Letter 1 (noting, however, that a going concern opinion is not a qualified opinion); EY Letter; Heritage Letter (noting that a majority of crowdfunding issuers should receive going concern opinions but should not be disqualified); RocketHub Letter; Traklight Letter (recommending that going concern opinions and noncompliance with U.S. GAAP should be allowed); Whitaker Chalk Letter.

[345] *See* Grassi Letter.

[346] *See* EY Letter.

[347] *See, e.g.*, Arctic Island Letter 5 (supporting only an exemption from the audit requirement); CFIRA Letter 5; CFIRA Letter 7; CrowdFundConnect Letter; Crowdpassage Letter 2; EY Letter; Grassi Letter; Hackers/Founders Letter; Joinvestor Letter; McGladrey Letter; PBA Letter; PeoplePowerFund Letter; RocketHub Letter (recommending that the audit requirements should only apply to issuers that have been in operation for more than two years and are raising more than $5 million); StartupValley Letter (supporting an exemption from the audit requirements); Wefunder Letter; Whitaker Chalk Letter.

[348] *See, e.g.*, AICPA Letter; Denlinger Letter 1; Wilson Letter.

[349] *See, e.g.*, ASSOB Letter; CFIRA Letter 5; Denlinger Letter 1; Grassi Letter; McGladrey Letter; PBA Letter; PeoplePowerFund Letter; RocketHub Letter; Wefunder Letter; Whitaker Chalk Letter; Zhang Letter.

[350] *See* EY Letter; PBA Letter.

201(t) with a number of changes from the proposal. As described in more detail below, the final requirements are based on the amount offered and sold in reliance on Section 4(a)(6) within the preceding 12-month period, as follows:

- For issuers offering $100,000 or less: Disclosure of the amount of total income, taxable income and total tax as reflected in the issuer's federal income tax returns certified by the principal executive officer to reflect accurately the information in the issuer's federal income tax returns (in lieu of filing a copy of the tax returns), and financial statements certified by the principal executive officer to be true and complete in all material respects.[351] If, however, financial statements of the issuer are available that have either been reviewed or audited by a public accountant that is independent of the issuer, the issuer must provide those financial statements instead and need not include the information reported on the federal income tax returns or the certification of the principal executive officer.
- Issuers offering more than $100,000 but not more than $500,000: Financial statements reviewed by a public accountant that is independent of the issuer.[352] If, however, financial statements of the issuer are available that have been audited by a public accountant that is independent of the issuer, the issuer must provide those financial statements instead and need not include the reviewed financial statements.
- Issuers offering more than $500,000:
  - For issuers offering more than $500,000 but not more than $1 million of securities in reliance on Regulation Crowdfunding for the first time: Financial statements reviewed by a public accountant that is independent of the issuer. If, however, financial statements of the issuer are available that have been audited by a public accountant that is independent of the issuer, the issuer must provide those financial statements instead and need not include the reviewed financial statements.
  - For issuers that have previously sold securities in reliance on Regulation Crowdfunding: Financial statements audited by a public accountant that is independent of the issuer.[353]

Content of Financial Statements. We are adopting substantially as proposed the requirement that all issuers file with the Commission and provide to investors and the relevant intermediary a complete set of their financial statements, which includes balance sheets, statements of comprehensive income, statements of cash flows, statements of changes in stockholders' equity and notes to the financial statements.[354] In order to avoid potential confusion as to the presentation of financial statements, and consistent with Tier 1 offerings under Regulation A,[355] the final rule adds an instruction that financial statements that are not audited must be labeled as unaudited.[356] Consistent with the proposal, the final rules do not exempt any issuers from the financial statement requirements. Although some commenters expressed concerns about the costs of the financial statement requirements for issuers with no operating history or issuers that have been in existence for fewer than 12 months,[357] we believe that financial statements are important information for investors and that the changes from the proposed rules described below will help reduce the costs associated with preparing financial statements for many of those issuers.

The final rule also includes an instruction to clarify that references to the issuer in Rule 201(t) refer to the issuer and its predecessors, if any.

Offerings of $100,000 or less. Consistent with Securities Act Section 4A(b)(1)(D)(i), we are adopting as proposed the requirement in Rule 201(t)(1) that an issuer offering $100,000 or less provide financial statements of the issuer that are certified by the principal executive officer of the issuer to be true and complete in all material respects.[358] While we believe it will be beneficial for investors to have an independent accountant review financial statements in offerings over $100,000, we believe that for offerings of $100,000 or less this certification is sufficient and will contribute to the integrity of the issuer's financial reporting process. It will affirm for investors that, although the financial statements have not been reviewed or audited by an independent public accountant, there has been senior executive attention paid to the financial statements. We are not requiring this certification for reviewed or audited financial statements, as some commenters suggested, because we believe the certification is intended as an added measure of assurance that is not needed in offerings of this size when an independent accountant reviews or audits the financial statements. We also are adopting the form of the certification that must be provided by the issuer's principal executive officer as proposed with one change relating to the information from the issuer's tax return.[359]

Instead of mandating that issuers offering $100,000 or less provide copies of their federal income tax returns as proposed, the final rules require an issuer to disclose the amount of total income, taxable income and total tax, or the equivalent line items from the applicable form, exactly as reflected in its filed federal income tax returns, and to have the principal executive officer certify that those amounts reflect accurately the information in the issuer's federal income tax returns.[360] As noted by commenters,[361] requiring that issuers provide tax returns may present a significant risk of disclosure of private information. While the proposed rule would require personally identifiable information to be redacted, we are persuaded by commenters that such a requirement might not provide an adequate safeguard against inadvertent disclosure of this type of information in some instances. The consequences for an issuer and an intermediary of such disclosure, including the potential violation of applicable privacy laws, could be severe. Specifying the information from the tax return that is required without requiring submission of the tax return itself will provide standardized disclosure for investors and help protect against the accidental disclosure of personally identifiable or confidential information. Requiring that these amounts be certified by the principal executive officer will provide investors additional assurance of the accuracy of those amounts in lieu of providing the underlying tax returns.[362] At the same

[351] *See* Rule 201(t)(1) of Regulation Crowdfunding.

[352] *See* Rule 201(t)(2) of Regulation Crowdfunding.

[353] *See* Rule 201(t)(3) of Regulation Crowdfunding. *See also* discussion below under ''Offerings of more than $500,000.''

[354] *See* Instruction 3 to paragraph (t) of Rule 201 of Regulation Crowdfunding.

[355] *See* Paragraph (b) of Part F/S of Form 1–A.

[356] *See* Instruction 3 to paragraph (t) of Rule 201 of Regulation Crowdfunding.

[357] *See, e.g.*, Arctic Island Letter 5; CFIRA Letter 5; CFIRA Letter 7; CrowdFundConnect Letter; Crowdpassage Letter 2; EY Letter; Grassi Letter; Hackers/Founders Letter; Joinvestor Letter; McGladrey Letter; PBA Letter; PeoplePowerFund Letter; RocketHub Letter; StartupValley Letter; Wefunder Letter; Whitaker Chalk Letter. *But see* AICPA Letter; Denlinger Letter 1; Wilson Letter.

[358] *See* Rule 201(t)(1) of Regulation Crowdfunding.

[359] *See* Instruction 7 to paragraph (t) of Rule 201 of Regulation Crowdfunding.

[360] *See* Rule 201(t)(1) of Regulation Crowdfunding.

[361] *See, e.g.,* AICPA Letter; Public Startup Letter 2; RocketHub Letter; SBM Letter; Wilson Letter; Zhang Letter.

[362] We note that any intentional misstatements or omissions of facts may constitute federal criminal

time, because the principal executive officer will be certifying only that the amounts are as reported on the applicable income tax return, we do not expect this requirement to impose any significant new burdens on principal executive officers, who will already be certifying as to the truth and completeness of the financial statements themselves. We believe the alternative approach we are adopting provides a similar benefit to investors as the proposal while addressing the privacy concerns raised by commenters.

As we stated in the Proposing Release, it remains unclear to us to what extent all of the information presented in a tax return would be useful for an investor evaluating whether to purchase securities from the issuer. We believe, however, that certain information such as total income, taxable income and total tax could be informative and would likely be available to the issuer in tax documentation. The final rules, therefore, provide that an issuer must disclose its total income, taxable income and total tax, or the equivalent line items from its federal income tax documentation and have the principal executive officer certify that those amounts reflect accurately the information in the issuer's federal income tax returns.[363]

Under the final rules, an issuer that offers securities in reliance on Section 4(a)(6) before filing its tax return for the most recently completed fiscal year will be allowed to use information from the tax return filed for the prior year. An issuer that uses information from the prior year's tax return will be required to provide tax return information for the most recently completed fiscal year when filed with the U.S. Internal Revenue Service (if the tax return is filed during the offering period). An issuer that has requested an extension from the U.S. Internal Revenue Service would not be required to provide the information until the date when the return is filed, which is consistent with the concept of not requiring tax information until that information has been filed with the U.S. Internal Revenue Service. If an issuer has not yet filed a tax return and is not required to file a tax return before the end of the offering period, then the tax return information does not need to be provided.[364]

We are adding to Rule 201(t)(1) a requirement that if financial statements of the issuer are available that have either been reviewed or audited by a public accountant that is independent of the issuer, the issuer must provide those financial statements instead, and need not include the information reported on the federal income tax returns or the certification of the principal executive officer.[365] This approach was suggested by two commenters,[366] and we believe it will benefit investors by providing access to audited or reviewed financial statements that were already prepared for other purposes. Unlike audit reports in a registered offering,[367] we are not requiring that review or audit reports be accompanied by a formal consent or acknowledgment letter. Rather, the final rules clarify that review and audit reports must be signed and that the issuers must notify the public accountants of their intended use in an offering in reliance on Section 4(a)(6).[368]

Offerings of more than $100,000 but not more than $500,000. Consistent with Section 4A(b)(1)(D)(iii) and the proposed rules, issuers must file and provide reviewed financial statements when offering more than $100,000 but not more than $500,000.[369] Similar to the addition to Rule 201(t)(1) discussed above, we have added to Rule 201(t)(2) a requirement that if financial statements of the issuer are available that have been audited by a public accountant that is independent of the issuer, the issuer must provide those financial statements instead.[370] The approach of providing audited financial statements that are otherwise available is consistent with what the Commission adopted for issuers undertaking Tier 1 offerings under Regulation A.[371] We believe the benefits to investors of having access to these audited financial statements justify any additional burden imposed on issuers to provide these statements, which were already prepared for other purposes.

Offerings of more than $500,000. As proposed, Rule 201(t)(3) provides that issuers offering more than $500,000 are required to provide audited financial statements. In a change from the proposal, the final rule includes an accommodation for issuers offering more than $500,000 but not more than $1 million that have not previously sold securities in reliance on Section 4(a)(6).[372] Under Rule 201(t)(3), those first-time issuers are permitted to provide reviewed rather than audited financial statements, unless audited financial statements are otherwise available.

We are adding this accommodation for first-time issuers in response to commenters' concerns about the expense of obtaining audited financial statements. While some commenters expressed support for the proposed audit requirement,[373] many others noted that the proposed audit requirement would be too costly and burdensome for issuers in comparison to the size of the offering proceeds.[374] A number of commenters expressed particular concern that issuers would need to incur the expense of an audit before having proceeds or even an assurance of proceeds from the offering.[375] After considering the comments, we are persuaded that for issuers undertaking a first-time crowdfunding offering of more than $500,000 but not more than $1 million, the benefits of requiring audited financial statements are not likely to justify the costs. Accordingly, consistent with applicable standards,[376] for these first-time issuers, we are adopting instead a requirement that those selling securities in reliance on Section 4(a)(6) in these circumstances

violations by the certifying principal executive officer. *See* 18 U.S.C. 1001.

[363] *See* Rule 201(t)(1) of Regulation Crowdfunding.

[364] *See* Instruction 6 to paragraph (t) of Rule 201 of Regulation Crowdfunding.

[365] *See* Rule 201(t)(1) of Regulation Crowdfunding.

[366] *See* Angel Letter 1; EY letter.

[367] *See* Securities Act Rule 436; Item 601 of Regulation S–K.

[368] *See* Instructions 8 and 9 to paragraph (t) of Rule 201 of Regulation Crowdfunding.

[369] *See* Rule 201(t)(2) of Regulation Crowdfunding.

[370] *Id.*

[371] *See* Paragraph (b) of Part F/S of Form 1–A. While Regulation Crowdfunding incorporates a number of requirements that are consistent with Regulation A, it is important to note that Regulation Crowdfunding and Regulation A are different exemptions with distinct requirements. For example, unlike offerings under Regulation Crowdfunding, Tier 1 offerings under Regulation A are subject to state registration requirements and are required to be ''qualified'' by Commission staff.

[372] For purposes of determining whether an issuer has previously sold securities in reliance on Section 4(a)(6), ''issuer'' includes all entities controlled by or under common control with the issuer and any predecessors of the issuer. *See* Rule 100(c) of Regulation Crowdfunding.

[373] *See, e.g.,* AICPA Letter; Consumer Federation Letter; CSTTC Letter; Denlinger Letter 2; FundDemocracy Letter; Leverage PR; NASAA Letter; StartEngine Letter 1.

[374] *See, e.g.,* AEO Letter; Angel Letter 1; AWBC Letter; CFIRA Letter 5; CfPA Letter; CrowdFundConnect Letter; EarlyShares Letter; EMKF Letter; EY Letter; Finkelstein Letter; FundHub Letter 1; Generation Enterprise Letter; Grassi Letter; Graves Letter; Guzik Letter 1; Hakanson Letter; Holland Letter; Johnston Letter; Kickstarter Coaching Letter; McGladrey Letter; Milken Institute Letter; NACVA Letter; NFIB Letter; NPCM Letter; NSBA Letter; PBA Letter; Reed Letter; RocketHub Letter; Saunders Letter; SBA Office of Advocacy Letter; SBEC Letter; SBM Letter; Seyfarth Letter; Verrill Dana Letter; WealthForge Letter; Wefunder Letter; Woods Letter; Zeman Letter.

[375] *See, e.g.,* AEO Letter; AWBC Letter; CFIRA Letter 5; CfPA Letter; EMKF Letter; Generation Enterprise Letter; Grassi Letter; Graves Letter; Holland Letter; McGladrey Letter; NSBA Letter; Reed Letter; RocketHub Letter; SBM Letter; Seyfarth Letter; WealthForge Letter; Wefunder Letter.

[376] *See* Securities Act Section 28 [15 U.S.C. 77z–3].

provide reviewed financial statements. Commenters stated that reviewed financial statements would cost less than audited financial statements,[377] and one commenter noted that the cost of an accounting review is approximately 60% of the cost of an audit.[378]

Basis of Accounting. We are adopting as proposed the requirement that all issuers provide financial statements prepared in accordance with U.S. GAAP.[379] As discussed in the Proposing Release, financial statements prepared in accordance with U.S. GAAP are generally self-scaling to the size and complexity of the issuer, which we believe can reduce the costs of preparing financial statements for many early stage issuers. We would not expect that the required financial statements would be long or complicated for issuers that are recently formed and have limited operating histories. Although we acknowledge, as some commenters observed, that other bases of accounting may be less expensive than U.S. GAAP, we believe the benefit of a single standard that will facilitate comparison among issuers relying on Section 4(a)(6) justifies any incremental expenses associated with U.S. GAAP. In addition, we are concerned that it may be difficult for investors to determine whether the issuer complied with another comprehensive basis of accounting. For these reasons, we continue to believe that financial statements prepared in accordance with U.S. GAAP will be the most useful for investors in securities-based crowdfunding transactions, particularly when presented along with the required description of the issuer's financial condition.[380]

Additionally, as suggested by one commenter,[381] in order to be consistent with the treatment of emerging growth companies [382] and offerings relying on Regulation A,[383] Rule 201(t) permits issuers, where applicable, to delay the implementation of new accounting standards to the extent such standards provide for delayed implementation by non-public business entities.[384] In this regard, if the issuer chooses to take advantage of this extended transition period, the issuer:

- Must disclose such choice at the time the issuer files the offering statement; and
- May not take advantage of the extended transition period for some standards and not others, but must apply the same choice to all standards.

However, consistent with the treatment of emerging growth companies and offerings relying on Regulation A,[385] issuers electing not to use this accommodation must forgo this accommodation for all financial accounting standards and may not elect to rely on this accommodation in any future filings.[386]

On December 23, 2013, after we proposed rules for Regulation Crowdfunding, the Financial Accounting Standards Board (FASB) and Private Company Council (PCC) issued a guide for evaluating financial accounting and reporting for non-public business entities.[387] The PCC was created in 2012 by the FASB and the Financial Accounting Foundation to improve the standard-setting process, and provide for accounting and reporting alternatives, for non-public business entities under U.S. GAAP.[388] As the standards for non-public business entities are new, there are currently very few distinctions between U.S. GAAP for public and non-public business entities. Over time, however, more distinctions between non-public business entity and public company accounting standards could develop.

Issuers that offer securities pursuant to Regulation Crowdfunding will be considered ''public business entities'' as defined by the FASB [389] and, therefore, ineligible to rely on any alternative accounting or reporting standards for non-public business entities.[390] Even though issuers of securities in a Regulation Crowdfunding offering fit within the definition of ''public business entity,'' the Commission retains the authority to determine whether or not such issuers would be permitted to rely on the developing non-public business entity standards.[391] Commenters generally expressed concern about the costs associated with requiring issuers relying on Section 4(a)(6) to follow public company U.S. GAAP accounting standards.[392]

The final rules do not allow Regulation Crowdfunding issuers to use the alternatives available to non-public business entities under U.S. GAAP in the preparation of their financial statements. One of the significant factors considered by the FASB in developing its definition of ''public business entity'' was the number of primary users of the financial statements and their access to management.[393] As the FASB noted, ''users of private company financial statements have continuous access to management and the ability to obtain financial information throughout the year.'' [394] As the number of investors increases and their ability individually to influence management decreases, it is important that all investors receive or have timely access to comprehensive financial information. As a result, although commenters generally expressed concern about the costs associated with requiring issuers relying on Section 4(a)(6) to follow public company U.S. GAAP accounting standards,[395] because crowdfunding investors will likely not have the access to management that the FASB envisions, the Commission believes that investor protection will be enhanced by requiring Regulation Crowdfunding issuers to provide financial statements prepared in the same manner as other entities meeting the FASB's definition of ''public business entity.''

Periods Covered in the Financial Statements. We are adopting substantially as proposed the requirement that financial statements cover the shorter of the two most recently completed fiscal years or the

[377] *See, e.g.,* Crowdcheck Letter 4; CfPA Letter (noting that many offerings made in reliance on Rule 506 that involve companies further along in their business development include reviewed but not audited financial statements); Graves Letter (discussing the ''thorough'' nature of a CPA review and the cost differential between reviewed and audited financial statements); NFIB Letter; Traklight Letter.

[378] *See* Traklight Letter.

[379] *See* Instruction 3 to paragraph (t) of Rule 201 of Regulation Crowdfunding.

[380] *See* Rule 201(s) of Regulation Crowdfunding.

[381] S*ee* EY Letter.

[382] *See* Securities Act of 1933 Section 7(a)(2)(B) [15 U.S.C. 77g(a)(2)(B)].

[383] *See* paragraph (a)(3) of Part F/S of Form 1–A.

[384] *See* Instruction 5 to paragraph (t) of Rule 201 of Regulation Crowdfunding.

[385] *See* paragraph (a)(3) of Part F/S of Form 1–A. *See* also JOBS Act, Section 107(b)(1) and (3).

[386] *See* Instruction 5 to paragraph (t) of Rule 201 of Regulation Crowdfunding.

[387] The Private Company Decision-Making Framework: A Guide for Evaluating Financial Accounting and Reporting for Private Companies (the ''PCC Guide''), *available at: http://www.fasb.org/cs/ContentServer?c=Document_C&pagename=FASB%2FDocument_C%2FDocumentPage&cid=1176163703583.*

[388] For a brief history behind the creation of the PCC, *see: http://www.fasb.org/cs/ContentServer?c=Page&pagename=FASB%2FPage%2FSectionPage&cid=1351027243391.*

[389] Criterion (a) of FASB's Accounting Standards Update 2013–12, *Definition of a Public Business Entity,* states that an entity that ''is required by the U.S. Securities and Exchange Commission (SEC) to file or furnish financial statements, or does file or furnish financial statements (including voluntary filers), with the SEC (including other entities whose financial statements or financial information are required to be or are included in a filing)'' is a Public Business Entity.

[390] *See* numbered paragraph 12 of the PCC Guide, p. 3.

[391] *Id.*

[392] *See, e.g.,* ABA Letter; CFIRA Letter 5; Grassi; EY Letter; U.S. Chamber of Commerce Letter.

[393] *See* PCC Guide, p. 6.

[394] *Id.*

[395] *See, e.g.,* ABA Letter; CFIRA Letter 5; Grassi; EY Letter; U.S. Chamber of Commerce Letter.

period since the issuer's inception.[396] While a number of commenters recommended only one year of financial statements,[397] we believe that requiring a second year will provide investors with a basis for comparison against the most recently completed period, without substantially increasing the costs for the issuer.

In addition, consistent with the proposal and with the views of many commenters,[398] the final rules do not require interim financial statements. While we recognize the needs of investors for current financial information, we are also cognizant of the anticipated costs of obtaining interim financial statements. We believe that the required discussion of any material changes or trends known to management in the financial condition and results of operations of the issuer since the period for which financial statements are provided will help provide investors with the necessary information.[399]

Age of Financial Statements. We are adopting substantially as proposed rules providing that during the first 120 days of the issuer's fiscal year, an issuer may conduct an offering in reliance on Section 4(a)(6) using financial statements for the fiscal year prior to the most recently completed fiscal year if the financial statements for the most recently completed fiscal year are not otherwise available.[400] For example, if an issuer that has a calendar fiscal year end conducts an offering in April 2016, it would be permitted to include financial statements for the fiscal year ended December 31, 2014 if the financial statements for the fiscal year ended December 31, 2015 are not yet available. Once more than 120 days have passed since the end of the issuer's most recently completed fiscal year, the issuer would be required to include financial statements for its most recently completed fiscal year.[401] Regardless of the age of the financial statements, an issuer would be required to include in the narrative discussion of its financial condition a discussion of any material changes or trends known to management in the financial condition and results of operations of the issuer during any time period subsequent to the period for which financial statements are provided to inform investors of more recent developments.[402]

While some commenters expressed concern that this accommodation would not provide investors with sufficiently current financial information,[403] we believe that this risk will be mitigated by the requirement that the issuer include a narrative discussion of any material changes or trends known to management in the financial condition and results of operations during any time period subsequent to the period for which financial statements are provided.[404] Further, we believe this accommodation is needed because otherwise issuers would not be able to conduct offerings for a period of time between the end of their fiscal year and the date when the financial statements for that period are available.

We are not adopting the alternative proposed by one commenter to require unaudited financial statements through the end of the month that ends no more than two months before the month in which the offering began.[405] Such a requirement would require an issuer to prepare a set of financial statements at a time when it would not otherwise be doing so and would be a more onerous requirement than applies to registered or Regulation A offerings.[406]

Public Accountant Requirements. In a change from proposed Rule 201(t), in response to commenters' suggestions, the final rules provide that to qualify as independent of the issuer, a public accountant would be required to either: (1) Comply with the Commission's independence rules, which are set forth in Rule 2–01 of Regulation S–X,[407] or (2) comply with the independence standards of the AICPA.[408] Allowing the AICPA independence standards as an alternative to the Commission's independence standards is consistent with the recommendations of a number of commenters [409] and the treatment of Tier 1 issuers under Regulation A.[410] We believe that providing issuers with this flexibility is appropriate in light of the potential costs to issuers that would otherwise be required to engage an accountant who was independent under Rule 2–01 of Regulation S–X.

Consistent with the recommendation of one commenter,[411] in addition to meeting the independence standards of Rule 2–01 of Regulation S–X or the AICPA, we are requiring that a public accountant that audits or reviews the financial statements provided by an issuer must meet the standards for public accountants of Rule 2–01(a) of Regulation S–X. The Commission will not recognize as a public accountant any person who: (1) Is not duly registered and in good standing as a certified public accountant under the laws of the place of his residence or principal office; or (2) is not in good standing and entitled to practice as a public accountant under the laws of the place of his residence or principal office.[412] We believe these standards will promote the use of qualified accountants that are in compliance with the requirements for their profession for the review or audit of the financial statements with respect to all offerings, including offerings in reliance on Section 4(a)(6).

Consistent with the proposal and recommendations in response to our request for comments, we are not requiring audits to be conducted by a PCAOB-registered firm. We believe the final rules will result in a greater number of public accountants being eligible to audit the issuers' financial statements, which may reduce issuers' costs.

Review and Audit Standards. In line with the general support received from commenters,[413] we are adopting as proposed the requirement that reviewed financial statements be reviewed in accordance with the SSARS issued by

[396] *See* Instruction 3 to paragraph (t) of Rule 201 of Regulation Crowdfunding.

[397] *See, e.g.,* Denlinger Letter 1; EY Letter; Fryer Letter; Grassi Letter; Joinvestor Letter; Public Startup Letter 2; RFPIA Letter; RocketHub Letter. *But see, e.g.,* ASSOB Letter; Zeman Letter.

[398] *See, e.g.,* CFIRA Letter 7; EMKF Letter; EY Letter; FundHub Letter 1; Grassi Letter; Public Startup Letter 2; RocketHub Letter; Traklight Letter; Wefunder Letter; Whitaker Chalk Letter.

[399] *See* Instruction 1 to paragraph (s) of Rule 201 of Regulation Crowdfunding.

[400] *See* Instruction 4 to paragraph (t) of Rule 201 of Regulation Crowdfunding. The final rule incorporates instructions consistent with other SEC rules explaining that if the 120th day falls on a Saturday, Sunday, or holiday, the next business day shall be considered the 120th day.

[401] *Id.*

[402] *See* Rule 201(s) of Regulation Crowdfunding and Instruction 1 to paragraph (s) of Rule 201.

[403] *See, e.g.,* Consumer Federation Letter; Fund Democracy Letter; Merkley Letter.

[404] *See* Rule 201(s) of Regulation Crowdfunding and instruction 1 to paragraph(s) of Rule 201.

[405] *See* Fund Democracy Letter.

[406] *See* Rule 3–12(a) of Regulation S–X [17 CFR 210.3–12(a)] (requires that the latest balance sheet be as of a date no more than 134 days for non-accelerated filers (or 129 days for accelerated and large accelerated filers) before the effective date of a registration statement (or date a proxy statement is mailed)); Paragraph (b) of Part F/S of Form 1–A (Tier 1 and Tier 2 issuers are required to include financial statements in Form 1–A that are dated not more than nine months before the date of non-public submission, filing, or qualification, with the most recent annual or interim balance sheet not older than nine months).

[407] 17 CFR 210.2–01.

[408] *See* Instruction 9 to paragraph (t) of Rule 201 of Regulation Crowdfunding.

[409] *See, e.g.,* AICPA Letter; Denlinger Letter 1; EY Letter; Grassi Letter; McGladrey Letter.

[410] *See* Paragraph (b)(2) of Part F/S of Form 1–A. *See also, supra,* note 371.

[411] *See* AICPA Letter.

[412] *See* 17 CFR 210.2–01(a).

[413] *See, e.g.,* ABA Letter; AICPA Letter; Denlinger Letter 1; EY Letter; Fund Democracy Letter; Grassi Letter.

the AICPA.[414] We also are adopting as proposed the requirement that audited financial statements, to the extent they are otherwise available, be audited in accordance with either the auditing standards of the AICPA (referred to as U.S. Generally Accepted Auditing Standards or GAAS) or the standards of the PCAOB.[415] We expect that this provision will provide issuers with more flexibility to file audited financial statements that may have been prepared for other purposes.

We believe that audits conducted in accordance with U.S. GAAS will provide sufficient protection for investors in these offerings, especially in light of the requirement that auditors must be independent under Rule 2–01 of Regulation S–X or AICPA independence standards. Moreover, we believe that the flexibility adopted in the final rules is appropriately tailored for the different types of issuers that are likely to conduct offerings under Regulation Crowdfunding.

Because issuers under Regulation Crowdfunding are not ''issuers'' as defined by Section 2(a)(7) of the Sarbanes-Oxley Act of 2002 nor broker-dealers registered with the Commission under Section 15(b) of the Securities Exchange Act of 1934, AICPA rules would require the audit to be compliant with U.S. GAAS even if the auditor has conducted the audit in accordance with PCAOB standards. Staff of the Commission consulted with the AICPA on this issue and has been advised that an audit performed by its members of an issuer conducting an offering under Regulation Crowdfunding would be required to comply with U.S. GAAS in accordance with the AICPA's Code of Professional Conduct.[416] As a result, an auditor for such an issuer who is conducting its audit in accordance with PCAOB standards also will be required to comply with U.S. GAAS, and the auditor will be required to comply with the reporting requirements of both the AICPA standards and the PCAOB standards. Commission staff also consulted with the AICPA on whether an auditor can currently comply with both sets of standards when issuing its auditor's report. In August 2015, the Auditing Standards Board of the AICPA proposed an amendment[417] to its auditing standards for situations when the auditor plans to refer to the standards of the PCAOB in addition to U.S. GAAS in the auditor's report. To comply with the reporting requirements of both sets of standards in those situations, the proposed amendment would require the auditor to use the report layout and wording specified by the auditing standards of the PCAOB, amended to indicate that the audit was also conducted in accordance with U.S. GAAS.

Review and Audit Reports. We are adopting, with changes from the proposal, the requirement that issuers file with the Commission and provide to investors and the relevant intermediary a signed review or audit report on the issuer's financial statements by an independent public accountant.[418] The issuer must notify the public accountant of the issuer's intended use of the report in the offering.[419]

We are adopting as proposed the provision that an audit report that includes an adverse opinion or disclaimer of opinion will not be in compliance with the audited financial statement requirements.[420] In a change from the proposal, as suggested by one commenter,[421] the final rules do not permit a qualified audit report.[422] As noted above, under the final rules an issuer is not required to provide audited financial statements for first-time crowdfunding offerings of more than $500,000 but not more than $1 million unless otherwise available. We believe that this change reduces the cost and burden for issuers generally of providing audited financial statements, and that an accommodation to permit qualified audit reports is not necessary.

The final rules also provide that a review report that includes modifications will not satisfy the requirement for reviewed financial statements.[423] Although two commenters expressed that a review report with modifications should be sufficient to satisfy the reviewed financial statement requirement,[424] one commenter opposed permitting modifications to review reports, noting that it considers certain departures from U.S. GAAP to be ''unacceptable'' and that it would not be feasible to develop a model of all allowable and disallowable modifications.[425] After considering the comments, we are persuaded that permitting modifications could result in financial statements that depart materially from U.S. GAAP, and, therefore, are not permitting modifications to review reports under the final rules. In response to concerns expressed by some commenters, however, we note that a review report or audit opinion that includes explanatory language pertaining to the entity's ability to continue as a going concern is not, under current auditing standards, a modified report or a qualified opinion.[426]

Exemptions from Financial Statement Requirements. Consistent with the proposal, the final rules do not exempt any issuers from the financial statement requirements. While we appreciate the concerns identified by commenters about the costs of the financial statement requirements for issuers with no operating history or issuers that have been in existence for fewer than 12 months,[427] we believe that financial statements are important information for all issuers and that other changes from the proposed rules such as raising the threshold at which audited financial statements are required will help reduce those costs.

b. Progress Updates

(1) Proposed Rules

Consistent with Securities Act Section 4A(b)(1)(F), proposed Rule 201(v) and Rule 203(a)(3) of Regulation Crowdfunding would require an issuer to file with the Commission and provide investors and the relevant intermediary regular updates on the issuer's progress in meeting the target offering amount no later than five business days after each of the dates that the issuer reaches particular intervals—*i.e.,* 50 percent and 100 percent—of the target offering

[414] *See* Instruction 8 to paragraph (t) of Rule 201 of Regulation Crowdfunding.

[415] *See* Instruction 9 to paragraph (t) of Rule 201 of Regulation Crowdfunding.

[416] The AICPA Code of Professional Conduct is available at: *http://pub.aicpa.org/codeofconduct/ethicsresources/et-cod.pdf.*

[417] Proposed Statement on Auditing Standards, *Amendment to Statement on Auditing Standards No. 122,* Statement on Auditing Standards: Clarification and Recodification, *section 700,* Forming an Opinion and Reporting on Financial Statements. The proposed amendment would be effective for audits of financial statements for periods ending on or after December 15, 2015.

[418] *See* Instructions 8 and 9 to paragraph (t) of Rule 201 of Regulation Crowdfunding.

[419] *Id.*

[420] *See* Instruction 9 to paragraph (t) of Rule 201 of Regulation Crowdfunding.

[421] *See* Grassi Letter.

[422] *See* Instruction 9 to paragraph (t) of Rule 201 of Regulation Crowdfunding. Accordingly, a qualified audit opinion would not be considered an audit opinion that is ''available'' for purposes of Rule 201(t) and 202(a).

[423] *See* Instruction 8 to paragraph (t) of Rule 201 of Regulation Crowdfunding. Accordingly, a modified review report would not be considered an audit opinion that is ''available'' for purposes of Rule 201(t) and 202(a).

[424] *See* AICPA Letter; Heritage Letter.

[425] *See* Grassi Letter.

[426] *See, e.g.,* Public Company Accounting Oversight Board AU sec. 508, *Reports on Audited Financial Statements.*

[427] *See, e.g.,* Arctic Island Letter 5; CFIRA Letter 5; CFIRA Letter 7; CrowdFundConnect Letter; Crowdpassage Letter 2; EY Letter; Grassi Letter; Hackers/Founders Letter; Joinvestor Letter; McGladrey Letter; PBA Letter; PeoplePowerFund Letter; RocketHub Letter; StartupValley Letter; Wefunder Letter; Whitaker Chalk Letter.

amount. If the issuer will accept proceeds in excess of the target offering amount, the issuer also would be required to file with the Commission and provide investors and the relevant intermediary a final progress update, no later than five business days after the offering deadline, disclosing the total amount of securities sold in the offering. If, however, multiple progress updates are triggered within the same five business-day period (*e.g.,* the issuer reaches 50 percent of the target offering amount on November 5, 100 percent of the target offering amount on November 7, and the maximum amount of proceeds it will accept in excess of the target offering amount on November 9), the issuer could consolidate such progress updates into one Form C–U, so long as the Form C–U discloses the most recent threshold that was met and the Form C–U is filed with the Commission and provided to investors and the relevant intermediary by the day on which the first progress update would be due. The proposed rules also would require the intermediary to make these updates available to investors through the intermediary's platform.

(2) Comments on the Proposed Rules

Commenters were generally opposed to the progress update requirements, noting that progress updates filed with the Commission would be duplicative of what is available from the intermediary's Web site and generate unnecessary costs.[428] Based on that same rationale, a number of commenters supported the concept of exempting issuers from the requirement to file progress updates with the Commission so long as the intermediary publicly displays the progress of the issuer in meeting the target offering amount.[429]

(3) Final Rules

The final rules maintain the proposed progress update requirements, with a significant modification. Based on concerns expressed by commenters, the final rules permit issuers to satisfy the progress update requirement by relying on the relevant intermediary to make publicly available on the intermediary's platform frequent updates about the issuer's progress toward meeting the target offering amount.[430] However, if the intermediary does not provide such an update, the issuer would be required to file the interim progress updates. In addition, as described in more detail below, an issuer relying on the intermediary's reports of progress must still file a Form C–U at the end of the offering to disclose the total amount of securities sold in the offering.[431]

As stated in the proposal, we continue to believe that the information available in progress updates will be important to investors by allowing them to gauge whether interest in the offer has increased gradually or whether it was concentrated at the beginning or at the end of the offering period. We believe that these same benefits can be achieved through information available on the intermediary's platform about the progress toward the target offering amount. Whether an issuer provides the required progress update report or relies on the intermediary's reporting, we believe investors will benefit by being able to stay informed during the offering of an issuer's progress.

Under the final rules, all issuers must file a Form C–U to report the total amount of securities sold in the offering. For issuers that are offering only up to a certain target offering amount, this requirement will be triggered five business days from the date they reach the target offering amount.[432] For issuers accepting proceeds in excess of the target offering amount, this requirement will be triggered five days after the offering deadline.[433] We believe that requiring a report of the total amount of securities sold in the offering is necessary to inform investors about the ultimate size of the offering, especially in cases where an issuer may have sold more than the target offering amount. Further, this requirement will result in a central repository of this information at the Commission—information that otherwise might no longer be available on the intermediary's platform after the offering terminated. Finally, we note that requiring a final report will make data available to the Commission and the general public that could be used to evaluate the effects of the Section 4(a)(6) exemption on capital formation.

c. Amendments to the Offering Statement

(1) Proposed Rules

Proposed Rule 203(a)(2) of Regulation Crowdfunding would require that an issuer amend its disclosure for any material change in the offer terms or disclosure previously provided to investors. The amended disclosure would be filed with the Commission on Form C–A: Amendment and provided to investors and the relevant intermediary. Material changes would require reconfirmation by investors of their investment commitments within five business days. In addition, an issuer would be permitted, but not required, to file amendments for changes that are not material.

(2) Comments Received on Proposed Rules

Commenters were mixed on the proposed rules relating to amendments to the offering statement, with those opposed citing the burden on issuers.[434] Some commenters recommended that the Commission specify a filing deadline for amendments reflecting a material change,[435] and some recommended we require that investors be notified of the amendment.[436] Two commenters supported our view that the establishment of the final price should be considered a material change that would always require an amendment to Form C,[437] while one commenter opposed such an approach.[438] One commenter recommended that the Commission define ''material change'' in this context.[439]

(3) Final Rules

We are adopting requirements for the amendment to the offering statement as

[428] *See, e.g.,* ASSOB Letter; EarlyShares Letter; Public Startup Letter 2; RFPIA Letter; RocketHub Letter. *But see* CFIRA Letter 7.

[429] *See, e.g.,* Arctic Island Letter 5 (stating that intermediaries can display both text (*e.g.* ''$125,000 of $500,000 raised thus far'') and graphics (*e.g.* a status bar graph) of the offering progress); ASSOB Letter; PeoplePowerFund Letter; RFPIA Letter; RocketHub Letter (noting that portals already list progress for perks-based crowdfunding); Wefunder Letter. *But see* CFIRA Letter 7 (stating that the issuer should file progress updates with the Commission on a regular basis to allow for consistency across all issuers and intermediaries.).

[430] *See* Rules 201(v) and 203(a)(3) of Regulation Crowdfunding.

[431] *See* Rule 203(a)(3)(iii) of Regulation Crowdfunding.

[432] *See* Rule 203(a)(3)(i) of Regulation Crowdfunding.

[433] *See* Rule 203(a)(3)(ii) of Regulation Crowdfunding.

[434] For commenters generally in support, *see, e.g.,* CFA Institute Letter; CrowdCheck Letter 1 (recommending that only a final amendment prior to the offering deadline be required, provided there is a five day reconfirmation period between filing and the sale of securities); EMKF Letter; Wefunder Letter.

For commenters generally opposed, *see, e.g.,* ASSOB Letter (suggesting a supplement could suffice in certain instances); Public Startup Letter 2; RocketHub Letter (suggesting that not all amendments be filed with the Commission so long as the information was made available through the intermediary).

[435] *See, e.g.,* Commonwealth of Massachusetts Letter; Grassi Letter; Hackers/Founders Letter; RocketHub Letter.

[436] *See, e.g.,* Arctic Island Letter 5; CFA Institute Letter; Grassi Letter; Joinvestor Letter; RoC Letter; RocketHub Letter. *But see* Public Startup Letter 2.

[437] *See* Grassi Letter (recommending that reconfirmation not be required if the initial price is established in the offering documents and does not vary more than within a reasonable range established in such documents); Joinvestor Letter.

[438] *See* Public Startup Letter 2.

[439] *See* ODS Letter.

proposed. The final rules require that an issuer amend its disclosure for any material change in the offer terms or disclosure previously provided to investors.[440] While we recognize commenters' concerns about the costs that requiring one or more additional filings may impose on issuers, we note that an amendment will be required only in instances in which there was a material change. In such circumstances, we believe the additional efforts required of an issuer to file an amendment will be justified in order to provide investors with the information they need to make an informed investment decision.

The amended disclosure must be filed with the Commission on Form C and provided to investors and the relevant intermediary. Under the final rules, the issuer is required to check the box for ''Form C/A: Amendment'' on the cover of the Form C and explain, in summary manner, the nature of the changes, additions or updates in the space provided.[441]

With respect to what constitutes a ''material change,'' as we stated in the Proposing Release, information is material if there is a substantial likelihood that a reasonable investor would consider it important in deciding whether or not to purchase the securities.[442] For example, we believe that a material change in the financial condition or the intended use of proceeds requires an amendment to an issuer's disclosure. Also, in those instances in which an issuer has previously disclosed only the method for determining the price, and not the final price, of the securities offered, we believe that determination of the final price is a material change to the terms of the offer and must be disclosed. These are not, however, the only possible material changes that require amended disclosure. We are not providing additional guidance on what constitutes a ''material change,'' as requested by one commenter,[443] because, consistent with our historical approach to materiality determinations, we believe that an issuer should determine whether changes in the offer terms or disclosure are material based on the facts and circumstances.

In addition, as discussed further in Section II.C.6 below, if any change, addition or update constitutes a material change to information previously disclosed, the issuer must check the box on the cover of Form C indicating that investors must reconfirm their investment commitments.

A number of commenters recommended that we specify a filing deadline for amendments reflecting a material change,[444] and that we require investors be notified in some manner of the amendment.[445] We are not, however, amending the requirement as suggested by those commenters. We appreciate the need for investors to know this information in a timely fashion, but we believe that with the requirement that investors reconfirm their commitments, it will be in an issuer's interest to file an amendment as soon as practicable and to notify investors so that it will be in a position to close the offering. Therefore, we do not believe further procedural requirements are necessary.

Issuers will be permitted, but not required, to amend the Form C to provide information with respect to other changes that are made to the information presented on the intermediary's platform and provided to investors.[446] If an issuer amends the Form C to provide such information, it is not required to check the box indicating that investors must reconfirm their investment commitments.

2. Ongoing Reporting Requirements

a. Proposed Rules

Securities Act Section 4A(b)(4) requires, ''not less than annually, [the issuer to] file with the Commission and provide to investors reports of the results of operations and financial statements of the issuer, as the Commission shall, by rule, determine appropriate, subject to such exceptions and termination dates as the Commission may establish, by rule.''

To implement the ongoing reporting requirement in Section 4A(b)(4), we proposed in Rules 202 and 203 of Regulation Crowdfunding to require an issuer that sold securities in reliance on Section 4(a)(6) to file a report annually, no later than 120 days after the end of the most recently completed fiscal year covered by the report. To implement the requirement that issuers provide the report to investors, we proposed in Rule 202(a) to require issuers to post the annual report on their Web sites. Under proposed Rule 202(a), the issuer would be required to disclose information similar to that required in the offering statement, including disclosure about its financial condition that meets the highest financial statement requirements that were applicable to its offering statement.

We also proposed in Rule 202(b) to require issuers to file the annual report until one of the following events occurs: (1) The issuer becomes a reporting company required to file reports under Exchange Act Sections 13(a) or 15(d); (2) the issuer or another party purchases or repurchases all of the securities issued pursuant to Section 4(a)(6), including any payment in full of debt securities or any complete redemption of redeemable securities; or (3) the issuer liquidates or dissolves in accordance with state law.

b. Comments on the Proposed Rules

Commenters expressed a range of views on the proposed ongoing reporting requirements.[447]

Frequency. With respect to frequency, a number of commenters supported the proposed requirement of annual reporting,[448] while a few recommended quarterly reporting.[449] Some commenters supported requiring issuers to file reports to disclose the occurrence of material events on an ongoing basis,[450] and several recommended that the Commission provide a list of events that would trigger such disclosure.[451]

[440] *See* Rule 203(a)(2) of Regulation Crowdfunding. *See also* Section II.C.6 for discussion of the requirement that investors reconfirm their investment commitments following a material change.

[441] *See* Form C.

[442] See *Basic Inc.* v. *Levinson,* 485 U.S. 224 (1988) (quoting *TSC Indus., Inc.* v. *Northway, Inc.,* 426 U.S. 438 (1976)).

[443] *See* ODS Letter.

[444] *See, e.g.,* Commonwealth of Massachusetts Letter; Grassi Letter; Hackers/Founders Letter; RocketHub Letter.

[445] *See, e.g.,* Arctic Island Letter 5; CFA Institute Letter; Grassi Letter; Joinvestor Letter; RoC Letter; RocketHub Letter. *But see* Public Startup Letter 2.

[446] *See* Instruction to paragraph (a)(2) of Rule 203 of Regulation Crowdfunding.

[447] For commenters generally supporting the proposed ongoing reporting requirements, *see, e.g.,* CfPA Letter; Commonwealth of Massachusetts Letter; Grassi Letter; Jacobson Letter; Leverage PR Letter; StartEngine Letter 1.

For commenters generally opposing the proposed ongoing reporting requirements, *see, e.g.,* ABA Letter; Campbell R. Letter; EMKF Letter; Guzik Letter 1; NFIB Letter; Public Startup Letter 2; RocketHub Letter; SeedInvest Letter 1; Stephenson, *et al.* Letter.; Traklight Letter; WealthForge Letter; Winters Letter.

[448] *See, e.g.,* AICPA Letter; CFIRA Letter 7; EY Letter; Grassi Letter; RoC Letter; RocketHub Letter; Traklight Letter.

[449] *See, e.g.,* ASSOB Letter; CCI Letter; Denlinger Letter 1 (recommending quarterly reporting to provide investors and the secondary market timely information).

[450] *See, e.g.,* ABA Letter (recommending amending Form C–AR within 15 calendar days of the material event); Angel Letter 1 (recommending prompt disclosure through postings on the issuer's Web site or social media); Denlinger Letter 1; EY Letter (recommending disclosure within 30 days of the end of the month in which the material event occurred, with such disclosure scaled for different tiers of issuers); Hackers/Founders Letter (recommending quarterly updates); RocketHub Letter (recommending quarterly updates).

[451] *See, e.g.,* Denlinger Letter 1; EY Letter; Grassi Letter; RocketHub Letter.

Two other commenters opposed such a requirement.[452]

Provision of Reports. Generally, commenters supported requiring issuers to post the annual report on their Web sites,[453] although some commenters favored a more limited distribution.[454] Similarly, a number of commenters supported requiring issuers to file the annual report on EDGAR,[455] while two commenters opposed such requirement.[456] In addition, most commenters opposed requiring physical delivery of the report directly to investors,[457] although some commenters supported requiring direct delivery in some form[458] or directly notifying investors of the availability of the annual report.[459]

Financial Statements. Commenters expressed differing views about the proposed ongoing financial statements requirements, particularly the level of public accountant involvement required. While a few supported requiring certain issuers to provide audited or reviewed financial statements on an ongoing basis,[460] a substantial number opposed an ongoing audit or review requirement.[461] Further, a number of commenters recommended that if ongoing financial statements are to be required for some issuers, the level of review be based on a higher offering amount threshold than the threshold used to determine the level of involvement of the accountant in the offering.[462]

Other Content. A number of commenters recommended that the ongoing annual reports require a more limited set of disclosure than the information required in the offering statement.[463]

Exceptions/Termination of Ongoing Reporting Requirement. A number of commenters recommended that there be exceptions to the ongoing reporting requirements for certain issuers,[464] expressing concern that the ongoing reporting obligations were too costly and could potentially extend indefinitely.[465] Others were opposed to such exceptions.[466]

We also received a range of comments about when the ongoing reporting requirements should terminate, with two supporting requiring issuers to file an annual report until one of the enumerated events occurs,[467] and others suggesting alternatives to such requirement.[468]

Some commenters recommended that the ongoing reporting requirements be a condition to the Section 4(a)(6) exemption[469] while several others generally opposed such concept.[470]

c. Final Rules

After considering the comments received, we are adopting the ongoing reporting requirements generally as proposed, with a substantial modification to the level of public accountant involvement required and another modification to provide for termination of the ongoing reporting obligation in two additional circumstances.

Frequency. The final rules require an issuer that sold securities in reliance on Section 4(a)(6) to file an annual report with the Commission, no later than 120 days after the end of the fiscal year covered by the report.[471] We believe that this ongoing reporting requirement should benefit investors by enabling them to consider updated information about the issuer, thereby allowing them to make more informed investment decisions.

We recognize the view of some commenters[472] that there may be major events that occur between annual reports about which investors would want to be updated, and we note that some commenters also recommended quarterly reporting.[473] However, we agree with those commenters[474] who said an annual requirement is sufficient. We believe a more frequent filing requirement would require an allocation of resources to the reporting function of Regulation Crowdfunding issuers that we do not believe is justified in light of the smaller amounts that will be raised pursuant to the exemption. We note that under Tier 1 of Regulation A, issuers can raise significantly more money—up to $20 million—without any ongoing reporting requirement other than to file a Form 1–Z exit report upon completion or termination of the offering. While not required, nothing in the rules prevents an issuer from updating investors when

[452] *See* Heritage Letter; Public Startup Letter 2.

[453] *See, e.g.,* ABA Letter; Angel Letter 1; CFA Institute Letter; Commonwealth of Massachusetts Letter; Grassi Letter; Jacobson Letter; Joinvestor Letter; RFPIA Letter; Traklight Letter.

[454] *See, e.g.,* Crowdpassage Letter 3 (opposing the public availability of ongoing financial statements and recommending they be distributed through a password protected Web site accessible to investors); Frutkin Letter (recommending the annual report be provided to investors via email, on a password-protected Web site accessible to investors or by mailing the report first-class to investors); Public Startup Letter 2.

[455] *See, e.g.,* Commonwealth of Massachusetts Letter; Frutkin Letter; Grassi Letter; RocketHub Letter; Traklight Letter.

[456] *See* Crowdpassage Letter 3 (opposing public availability of ongoing financial statements); Public Startup Letter 2.

[457] *See, e.g.,* CFIRA Letter 7; CFIRA Letter 8; CfPA Letter; Crowdpassage Letter 3; Grassi Letter; Jacobson Letter; Public Startup Letter 2; Traklight Letter.

[458] *See, e.g.,* Arctic Island Letter 5; CCI Letter; RocketHub Letter.

[459] *See, e.g.,* Arctic Island Letter 5; CFA Institute Letter (recommending advance notice as to when and where annual reports will be available); RocketHub Letter.

[460] *See, e.g.,* ABA Letter; Denlinger Letter 1; Grassi Letter.

[461] *See, e.g.,* AEO Letter; Arctic Island Letter 5; AWBC Letter; CrowdCheck Letter 4; EarlyShares Letter; EMKF Letter; Frutkin Letter; Graves Letter; Guzik Letter 1; iCrowd Letter; McGladrey Letter; Milken Institute Letter; NFIB Letter; PBA Letter; Peers Letter; RocketHub Letter; SeedInvest Letter 1; Seyfarth Letter; StartupValley Letter; Stephenson, *et al.* Letter; Traklight Letter; WealthForge Letter.

[462] *See, e.g.,* Arctic Island Letter 5; CrowdCheck Letter 4; EarlyShares Letter; EY Letter; Grassi Letter; Graves Letter; iCrowd Letter; Milken Institute Letter; PBA Letter; Seyfarth Letter; Traklight Letter.

[463] *See, e.g.,* EarlyShares Letter; EMKF Letter; McGladrey Letter; Milken Institute Letter; PBA Letter; RocketHub Letter.

[464] *See, e.g.,* Heritage Letter (issuers raising $100,000 or less); RocketHub Letter (issuers raising $250,000 or less, although recommending that intermediaries be permitted to require ongoing reports on their platform even if exempted by the Commission); SeedInvest Letter 1 (recommending excepting issuers from ongoing reporting when: (1) Raising less than $350,000; (2) securities are structured such that there can be no investment decisions; (3) an institutional investor, venture capitalist, or angel investor is leading the deal for investors; or (4) all investors have contractually waived the right to receive ongoing reports with informed consent); SeedInvest Letter 4. *See also* form letters designated as Type A (supporting SeedInvest Letter 1).

[465] *See* SeedInvest Letter 1 (noting that the ongoing reporting obligations were an ''obstacle to making crowdfunding a viable option for startups and small businesses'' as the cost structure would be ''out of proportion with the amounts proposed to be raised.'')

[466] *See, e.g.,* Commonwealth of Massachusetts Letter; Denlinger Letter 1; Grassi Letter; Public Startup Letter 2.

[467] *See, e.g.,* Grassi Letter; Whitaker Chalk Letter.

[468] *See, e.g.,* ABA Letter; EY Letter (recommending the ongoing reporting obligations terminate after a certain amount of time if the issuer has 300 or fewer security holders); Grassi Letter; PBA Letter (recommending the reporting obligations terminate after three consecutive annual reports or after an issuer repurchases two-thirds of the outstanding securities issued in reliance on Section 4(a)(6), so long as the issuer made a bona fide offer to repurchase all of such securities); Public Startup Letter 2; RocketHub Letter (recommending the reporting obligations terminate after three annual reports).

[469] *See, e.g.,* Parsont Letter (with a notice and cure provision); RocketHub Letter (recommending the ongoing reporting requirements be a condition for a minimum of three years).

[470] *See, e.g.,* Public Startup Letter 2; Wefunder Letter; Whitaker Chalk Letter (recommending that (i) a condition, if any, apply only to the first annual report; (ii) that the failure to file the annual report restrict an issuer's ability to raise capital in the future; or (iii) issuers, certain officers, directors and shareholders have the option to escrow their shares for up to 24 months, with certain penalties for failure to file the annual report).

[471] *See* Rule 202(a) of Regulation Crowdfunding.

[472] *See, e.g.,* ABA Letter; Angel Letter 1; Denlinger Letter 1; EY Letter; Grassi Letter; Hackers/Founders Letter; RocketHub Letter.

[473] *See, e.g.,* ASSOB Letter; CCI Letter; Denlinger Letter 1.

[474] *See, e.g.,* AICPA Letter; CFIRA Letter 7; EY Letter; Grassi Letter; RoC Letter; RocketHub Letter; Traklight Letter.

major events occur. Nor do our rules prevent intermediaries from requiring more frequent reporting. However, we do not believe that it is necessary in the final rules to require reporting on a more frequent basis than the annual ongoing reporting directly contemplated by the statute.

Provision of Reports. We also are adopting as proposed the requirement that an issuer post the annual report on its Web site.[475] Consistent with the proposal, the final rules do not require delivery of a physical copy of the annual report. As discussed in the Proposing Release and as supported by a number of commenters, we believe that investors in this type of Internet-based offering will be familiar with obtaining information on the Internet and that providing information in this manner will be cost efficient. While some commenters [476] suggested that limiting distribution of the annual report to investors through use of a password-protected Web site would help protect an issuer's commercially-sensitive information, we believe such a requirement would add complexity for issuers and investors without providing significant protection of commercially-sensitive information since the reports could still be accessed by the public on EDGAR.

Consistent with the proposal, the final rule does not require an issuer to provide direct notification via email or otherwise of the posting of the report, as was suggested by some commenters.[477] As discussed above in Section II.B.1.a.(i)(g), however, we are revising the final rules to require an issuer to disclose in the offering statement where on the issuer's Web site investors will be able to find the issuer's annual report and the date by which the annual report will be available on the issuer's Web site.[478] We believe these changes will help investors to locate the annual report. As discussed in the Proposing Release, we believe that many issuers may not have email addresses for investors, especially after the shares issued pursuant to Section 4(a)(6) are traded by the original purchasers. Nonetheless, to the extent email addresses for investors are available, an issuer could refer investors to the posted report via email.

Financial Statements. After considering the comments, we are persuaded by the commenters that opposed requiring that an audit or review of the financial statements be included in the annual report.[479] Therefore, instead of requiring financial statements in the annual report that meet the highest standard previously provided, the final rules require financial statements of the issuer certified by the principal executive officer of the issuer to be true and complete in all material respects.[480] However, issuers that have available financial statements that have been reviewed or audited by an independent certified public accountant because they prepare them for other purposes must provide them and will not be required to have the principal executive officer certification.[481]

Many commenters expressed concerns with the costs associated with preparing reviewed and audited financial statements on an ongoing basis. Commenters also noted the absence of comparable ongoing reporting requirements under Tier 1 of Regulation A and other offering exemptions.[482] While we recognize that Regulation Crowdfunding is different in many respects from Regulation A, we believe that crowdfunding issuers should not have more onerous ongoing reporting compliance costs than issuers that use another public offering exemption that permits higher maximum offering amounts. The changes to the ongoing reporting requirements in the rules we are adopting today will alleviate some of the costs on crowdfunding issuers. At the same time, we also believe, consistent with the views of at least one commenter,[483] that investors still will be provided with sufficient ongoing financial information about the issuer under the final rules.

Other Content. With the exception of the financial statement requirement described above, the final rule adopts as proposed the requirement that the annual report include the information required in the offering statement. Although an issuer will not be required to provide the offering-specific information that it filed at the time of the offering (because the issuer will not be offering or selling securities),[484] it will be required to disclose information about the company and its financial condition, as required in connection with the offer and sale of the securities.[485] While we appreciate the recommendations of commenters for a more limited set of disclosure in the annual report, we believe that the disclosure costs of ongoing reporting for issuers will be less than in the initial offering statement, because they will be able to use the offering materials as a basis to prepare the annual reports. We believe investors will benefit from the availability of annual updates to the information they received when making the decision to invest in the issuer's securities, since these updates will allow them to be informed about issuer developments as they decide whether to continue to hold or sell, or how to vote, the securities. Under the statute and the final rules, the securities will be freely tradable after one year. Therefore, this information also will benefit potential future holders of the issuer's securities and help them to make more informed investment decisions.

Exceptions/Termination of Ongoing Reporting Requirement. After considering the comments, we are providing for termination of the ongoing reporting obligation in the three

[475] *See* Rule 202(a) of Regulation Crowdfunding.

[476] *See, e.g.,* Crowdpassage Letter 3; Frutkin Letter.

[477] *See, e.g.,* Arctic Island Letter 5 (intermediary should notify); Frutkin Letter; RocketHub Letter.

[478] *See* Rule 201(w) of Regulation Crowdfunding.

[479] *See, e.g.,* AEO Letter; Arctic Island Letter 5; AWBC Letter; CrowdCheck Letter 4 (''ongoing audit requirement will create an unpredictable on-going burden''); EarlyShares Letter; EMKF Letter (''audited financial statements, particularly for ongoing reporting requirements, are so cost-prohibitive for startups that they make absolutely no sense as an appropriate use of funds.''); Frutkin Letter; Graves Letter; Guzik Letter 1; iCrowd Letter; McGladrey Letter; Milken Institute Letter; NFIB Letter; PBA Letter; Peers Letter; RocketHub Letter; SeedInvest Letter 1; Seyfarth Letter; StartupValley Letter; Stephenson, *et al.* Letter; Traklight Letter; WealthForge Letter.

[480] *See* Rule 202(a) of Regulation Crowdfunding.

[481] *Id.*

[482] *See, e.g.,* CrowdCheck Letter 4; EMKF Letter; EY Letter.

[483] *See* CrowdCheck Letter 4 (''While the on-going audit requirement is designed to provide investors and potential secondary purchasers of the company's securities with updated information about the company, it is unnecessary given the other, less burdensome, on-going disclosure requirements contained in the statute and proposed regulation.'').

[484] *See* Rule 202(a) of Regulation Crowdfunding. An issuer will not be required to provide information about: (1) The stated purpose and intended use of the proceeds of the offering; (2) the target offering amount and the deadline to reach the target offering amount; (3) whether the issuer will accept investments in excess of the target offering amount; (4) whether, in the event that the offer is oversubscribed, shares will be allocated on a pro-rata basis, first come-first served basis, or other basis; (5) the process to complete the transaction or cancel an investment commitment once the target amount is met; (6) the price to the public of the securities being offered; (7) the terms of the securities being offered; (8) the name, SEC file number and CRD number (as applicable) of the intermediary through which the offering is being conducted; and (9) the amount of compensation paid to the intermediary.

[485] *See* Rule 202(a) of Regulation Crowdfunding. Issuers will be required to provide disclosure about its directors and officers, business, current number of employees, financial condition (including financial statements), capital structure, significant factors that make an investment in the issuer speculative or risky, material indebtedness and certain related-party transactions.

circumstances that we proposed as well as the following two additional circumstances: (1) When the issuer has filed at least one annual report and has fewer than 300 holders of record; and (2) when the issuer has filed at least three annual reports and has total assets that do not exceed $10 million. Accordingly, under Rule 202(b), issuers will be required to file the annual report until the earliest of the following events occurs:

(1) The issuer is required to file reports under Exchange Act Sections 13(a) or 15(d);

(2) the issuer has filed at least one annual report and has fewer than 300 holders of record;

(3) the issuer has filed at least three annual reports and has total assets that do not exceed $10 million;

(4) the issuer or another party purchases or repurchases all of the securities issued pursuant to Section 4(a)(6), including any payment in full of debt securities or any complete redemption of redeemable securities; or

(5) the issuer liquidates or dissolves in accordance with state law.

We believe the addition of the two termination events, which are generally consistent with the suggestions of commenters,[486] should help alleviate commenters' concerns about related costs for certain issuers that may not have achieved a level of financial success that would sustain an ongoing reporting obligation. The 300 shareholder threshold reflected in Rule 202(b)(2) is consistent with the threshold used to determine whether an Exchange Act reporting company is eligible to suspend its Section 15(d)[487] or terminate its Section 13[488] reporting obligations. The option for an issuer to conclude ongoing reporting after three annual reports as reflected in Rule 202(b)(3) should help address concerns raised by some commenters that the reporting obligation could potentially extend indefinitely, while still requiring larger issuers with more than $10 million in total assets to continue reporting. We chose the $10 million threshold in order to be consistent with the total asset threshold in Section 12(g)(1) of the Exchange Act.[489] Under that provision, a company that has total assets exceeding $10 million and a class of securities held of record by a certain number of persons must register that class of securities with the Commission.

As proposed, Rule 203(b)(3) provides that any issuer terminating its annual reporting obligations will be required to file with the Commission, within five business days from the date on which the issuer becomes eligible to terminate its reporting obligation, a notice that it will no longer file and provide annual reports pursuant to the requirements of Regulation Crowdfunding. The issuer also must check the box for ''Form C–TR: Termination of Reporting'' on the cover of Form C.[490]

We are not persuaded by the suggestion of one commenter[491] that ongoing reports should be a condition to the Section 4(a)(6) exemption. As two commenters noted at the pre-proposal stage, under such an approach, compliance with the exemption would not be known at the time of the transaction.[492] This, in turn, would create substantial uncertainty for issuers because there would be an indefinite possibility of a potential future violation of the exemption. We have modified the final rules from the proposal to clarify that the availability of the crowdfunding exemption is not conditioned on compliance with the annual reporting, progress update or termination of reporting obligations.[493] Nevertheless, issuers offering and selling securities in reliance on Section 4(a)(6) remain obligated to comply with these reporting requirements. Moreover, as discussed in Section II.A.4 above, the final rules deny issuers the benefit of relying on the exemption under Section 4(a)(6) for future offerings until they file, to the extent required, the two most recently required annual reports.[494] In addition, the final rules require the issuer to disclose in its offering statement and annual report if it, or any of its predecessors, previously failed to comply with the ongoing reporting requirements of Regulation Crowdfunding.

3. Form C and Filing Requirements

a. Proposed Rules

Securities Act Section 4A(b)(1) requires issuers who offer or sell securities in reliance on Section 4(a)(6) to ''file with the Commission and provide to investors and the relevant broker or funding portal, and make available to potential investors'' certain disclosures. The statute does not specify a format that issuers must use to present the required disclosures and file these disclosures with the Commission. We proposed in Rule 203 of Regulation Crowdfunding to require issuers to file the mandated disclosure using new Form C, which would require certain disclosures to be presented in a specified format, while allowing the issuer to customize the presentation of other disclosures required by Section 4A(b)(1) and the related rules.

We proposed to require issuers to use an XML-based fillable form to input certain information. Information not required to be provided in text boxes in the XML-based fillable form would be filed as attachments to Form C.

Under the proposed rules, Form C would be used for all of an issuer's filings with the Commission related to the offering made in reliance on Section 4(a)(6). The issuer would check one of the following boxes on the cover of the Form C to indicate the purpose of the Form C filing:

- ''Form C: Offering Statement'' for issuers filing the initial disclosures required for an offering made in reliance on Section 4(a)(6);
- ''Form C–A: Amendment'' for issuers seeking to amend a previously-filed Form C for an offering;
- ''Form C–U: Progress Update'' for issuers filing a progress update required by Section 4A(b)(1)(H) and the related rules;
- ''Form C–AR: Annual Report'' for issuers filing the annual report required by Section 4A(b)(4) and the related rules; and
- ''Form C–TR: Termination of Reporting'' for issuers terminating their reporting obligations pursuant to Section 4A(b)(4) and the related rules.

EDGAR would automatically provide each filing with an appropriate tag depending on which box the issuer checks so that investors could distinguish among the different filings.[495]

Section 4A(b)(1) requires issuers to file the offering information with the Commission, provide it to investors and the relevant intermediary and make it available to potential investors.[496]

[486] *See, e.g.,* ABA Letter; EY Letter (recommending the reporting obligations terminate after a certain amount of time if the issuer has 300 or fewer security holders); PBA Letter; RocketHub Letter (recommending the reporting obligations terminate after three consecutive annual reports).

[487] *See* 17 CFR 240.12h–3.

[488] 15 U.S.C. 78m.

[489] 15 U.S.C. 78*l*(g)(1).

[490] *See* cover page of Form C.

[491] *See* Parsont Letter.

[492] *See* Letter from Andrea L. Seidt, Comm'r, Ohio Div. of Sec. *available at http://www.sec.gov/comments/jobs-title-iii/jobstitleiii-199.pdf*; Letter from John R. Fahy, Partner, Whitaker Chalk Swindle Schwartz, *available at http://www.sec.gov/comments/jobs-title-iii/jobstitleiii-175.htm.*

[493] *See* Rule 100(b)(4) of Regulation Crowdfunding.

[494] *See* Rule 100(b)(5) of Regulation Crowdfunding.

[495] EDGAR would tag the offering statement as ''Form C,'' any amendments to the offering statement as ''Form C–A,'' progress updates as ''Form C–U,'' annual reports as ''Form C–AR'' and termination reports as ''Form C–TR.''

[496] Section 4A(b)(4) requires issuers to file with the Commission and provide to investors, not less

Continued

Under the proposed rules, issuers would satisfy the requirement to file the information with the Commission by filing the Form C: Offering Statement, including any amendments and progress updates, on EDGAR. To satisfy the requirement to provide the disclosures to the relevant intermediary, we proposed that issuers provide to the relevant intermediary a copy of the disclosures filed with the Commission. To satisfy the requirement to provide the disclosures, or make them available, as applicable, to investors, we proposed that issuers provide the information to investors electronically by referring investors, such as through a posting on the issuer's Web site or by email, to the information on the intermediary's platform. The proposed rules would not require issuers to provide physical copies of the information to investors.

b. Comments on the Proposed Rules

Commenters generally supported the proposed Form C requirement.[497] Two commenters supported the proposal to use one form with different EDGAR tags for each type of filing,[498] while another commenter recommended creating multiple forms in order to minimize the length of the form.[499] Two commenters recommended that the Commission modify Form C and its variants to require an issuer to indicate the jurisdictions in which the securities will be or are sold, with one of those commenters recommending ongoing disclosure of the amount sold in each state.[500]

Commenters were divided on the EDGAR filing requirement. Some commenters supported the filing requirement, with a few of those specifically supporting the proposal that issuers file the Form C in electronic format only.[501] Some commenters generally opposed the filing requirements or opposed specific aspects of the requirements.[502]

A few commenters requested clarification whether all offering material made available on the intermediary's platform must be filed on Form C.[503] Two commenters recommended that not all materials be required to be filed as exhibits.[504] A number of commenters noted that issuers would likely use various types of media for their offerings, some of which cannot be filed on EDGAR.[505] A number of commenters recommended that the Commission adopt other disclosure formats, such as a question-and-answer format.[506]

A number of commenters generally supported the proposal to refer investors to information on the intermediary's platform.[507] With respect to the proposed methods (Web site posting or email), one commenter stated that issuers would not have investors' email addresses,[508] and another commenter noted that maintaining investors' email addresses would require significant resources.[509]

c. Final Rules

We are adopting Form C and the related filing requirements[510] with a few modifications from the proposed rules.[511]

First, the final rules will amend Regulation S–T to permit an issuer to submit exhibits to Form C in Portable Document Format (''PDF'') as official filings.[512] We appreciate the views of commenters that issuers would likely use various types of media for their offerings,[513] and believe that permitting these materials to be filed in PDF format will allow for more diverse presentations of information to be reasonably available to investors through a standardized, commonly available media. Under the final rules, issuers may customize the presentation

than annually, reports of the results of operations and financial statements of the issuer. As discussed above in Section II.B.2, to satisfy this requirement, the rules require an issuer to post the annual report on its Web site and file it with the Commission.

[497] *See, e.g.,* Angel Letter 1 (specifically supporting the XML requirements); CFIRA Letter 7; Consumer Federation Letter; Grassi Letter; Hackers/Founders Letter; Traklight Letter; RocketHub Letter.

[498] *See* Grassi Letter; RocketHub Letter.

[499] *See* CFIRA Letter 7.

[500] *See,* Commonwealth of Massachusetts Letter (recommending Form C require an issuer to check boxes indicating the jurisdictions in which securities will be sold); NASAA Letter (recommending Form C–U (offering update form) and Form C–AR (annual report form) require disclosure of the states where interests in the offering have been sold and the amount sold in each state).

[501] For commenters supporting the EDGAR filings requirement generally, *see, e.g.,* CFIRA Letter 7; Traklight Letter. For those specifically supporting the electronic filing proposal, *see, e.g.,* Arctic Island Letter 5; CFIRA Letter 7; RocketHub Letter; Wilson Letter.

[502] *See, e.g.,* Angel Letter 1; CFIRA Letter 1; CrowdCheck Letter 1; Mollick Letter; Public Startup Letter 2; RocketHub Letter; WealthForge Letter (recommending that the Commission require the filing of a Form C within 15 days of the offering first receiving an investment and at the completion of the offering).

[503] *See, e.g.,* CrowdCheck Letter 1; Grassi Letter; Stephenson Letter.

[504] *See, e.g.,* CFIRA Letter 1 (recommending that only ''those documents most suited to police against fraud'' be filed with the Commission because the intermediary serves as the primary repository of the offering materials); CrowdCheck Letter 1 (recommending the Commission permit issuers to use ''free writing'' disclosure materials in certain circumstances without having to file them with the Commission).

[505] *See, e.g.,* CFIRA Letter 6; CFIRA Letter 7; CrowdCheck Letter 1; Grassi Letter; Hackers/Founders Letter; RocketHub Letter; Wefunder Letter; Wilson Letter.

[506] *See, e.g.,* Guzik Letter 1; Guzik Letter 2; Guzik Letter 3 (encouraging the Commission to provide an optional simplified disclosure format, perhaps in a question and answer format); Hackers/Founders Letter (encouraging the Commission to require a standard format and to allow issuers to provide additional information); Hamilton Letter (suggesting the Commission provide prototypes of Form C and sample disclosures); RocketHub (seeking a simple, standardized general form other than U–7 or A–1 to provide legal certainty); Saunders Letter (proposing that Form C be completed by selecting from a database of stock responses); SBA Office of Advocacy Letter (describing recommendations from its roundtable attendees to adopt a simple question and answer format similar to that previously used in Regulation A or to provide ''standard boilerplate disclosures for some of the more complicated nonfinancial disclosures, such as risk factors,'' that are not required by the JOBS Act).

We also received several comments prior to the Proposing Release on whether the Commission should require a specific format for the required disclosure. Several commenters recommended that the Commission require the disclosure on a form modeled after, or require the use of NASAA's Small Company Offering Registration Form (U–7). *See, e.g.,* Coan Letter; Liles Letter 1; Vim Funding Letter; NASAA Letter. One commenter suggested modeling the required disclosure format after then-current Form 1–A, which is used for securities offerings made pursuant to Regulation A, but which has since been modified as a result of recently adopted amendments to Regulation A. *See* 17 CFR 230.251 *et seq.; Amendments to Regulation A,* Release No. 33–9741 (March 25, 2015) [80 FR 21805 (April 20, 2015)] Regulation A Adopting Release''); Commonwealth of Massachusetts Letter.

[507] *See, e.g.,* Grassi Letter; Joinvestor Letter; PeoplePowerFund Letter; Public Startup Letter 2; Wefunder Letter; Wilson Letter.

[508] *See* Wefunder Letter.

[509] *See* Grassi Letter.

[510] An issuer that does not already have EDGAR filing codes, and to which the Commission has not previously assigned a user identification number, which we call a ''Central Index Key (CIK)'' code, will need to obtain the codes by filing electronically a Form ID [17 CFR 239.63; 249.446; 269.7 and 274.402] at *https://www.filermanagement.edgarfiling.sec.gov.* The applicant also will be required to submit a notarized authenticating document as a Portable Document Format (PDF) attachment to the electronic filing. The authenticating document will need to be manually signed by the applicant over the applicant's typed signature, to include the information contained in the Form ID and to confirm the authenticity of the Form ID. *See* 17 CFR 232.10(b)(2).

[511] *See* Rule 203 of Regulation Crowdfunding. We have made some technical changes in the final rules that do not affect their substantive requirements. To maintain consistency with other Commission rules and to keep electronic filing requirements consolidated in Regulation S–T, we have deleted from proposed Rules 201, 202 and 203 the phrase ''on EDGAR'' where it appeared after ''file with the Commission.'' We also have deleted the instruction to proposed Rule 203(a)(1) as the list of information set forth in that instruction was duplicative of the XML-based portion of Form C itself.

[512] *See* Rule 101(a)(1)(xvii) of Regulation S–T. Regulation S–T generally allows PDF documents to be filed only as unofficial copies. *See* Rule 104 of Regulation S–T. However, Rule 101 provides for certain exceptions to this restriction. *See, e.g.,* Rule 101(ix) (allowing a PDF attachment to Form ID); Rule 101(a)(xiv) (requiring the filing of Form NRSRO and related exhibits in PDF as official filings).

[513] *See, e.g.,* CFIRA Letter 6; CFIRA Letter 7; CrowdCheck Letter 1; Grassi Letter; Hackers/Founders Letter; RocketHub Letter; Wefunder Letter; Wilson Letter.

of their non-XML disclosures and file those disclosures as exhibits to the Form C. For example, an issuer may provide the required disclosures by uploading to EDGAR, as an exhibit to Form C, a PDF version of the relevant information presented on the intermediary's platform, including charts, graphs, and a transcript or description of any video presentation or any other media not reflected in the PDF. This approach should provide key offering information in a standardized format and give issuers flexibility in the presentation of other required disclosures. We believe this flexibility is important given that we expect that issuers engaged in offerings in reliance on Section 4(a)(6) would encompass a wide variety of industries at different stages of business development.

We are adopting the XML-based fillable form as proposed with a few modifications.[514] As suggested by some commenters,[515] the XML-based portion of Form C will require issuers to indicate by checkbox the jurisdictions in which securities are intended to be offered. We also are changing the name of proposed Form C–A to Form C/A to be consistent with the naming convention of our other amendment forms and adding Form C–AR/A to allow, and facilitate identification of, the amendment of an issuer's Form C–AR annual report. In addition, we are adding an instruction to clarify that the issuer should mark the appropriate box on the cover of Form C to indicate which form it is filing. We also are splitting the ''Form, jurisdiction and date of organization'' field into three fields to facilitate more accurate tracking of this data. We also inserted the statement required by paragraph (g) of Rule 201 immediately following the data required by that paragraph, so that statement appears together with the relevant data. Finally, we are modifying certain other field names and the General Instructions to Form C to clarify them or to reflect applicable changes to the disclosure requirements discussed above.

We believe that requiring certain information to be submitted in XML format will support the assembly and transmission of those required disclosures to EDGAR on Form C.[516] It also will make certain key information about each offering available to investors and market observers in electronic format and allow the Commission to observe the implementation of the crowdfunding exemption under Section 4(a)(6). Information will be available about the types of issuers using the exemption, including the issuers' size, location, securities offered and offering amounts and the intermediaries through which the offerings are taking place. We believe the addition of the requirement to indicate the jurisdictions in which the issuer intends to offer the securities, as suggested by several commenters, will facilitate oversight by state regulators, who retain antifraud authority over crowdfunding transactions, while imposing only minimal costs on issuers.

In addition, in a change from the proposed rules, the final Form C includes an optional Question and Answer (''Q&A'') format that issuers may elect to use to provide the disclosures that are not required to be filed in XML format.[517] Issuers opting to use this format would prepare their disclosures by answering the questions provided and filing that disclosure as an exhibit to the Form C. A number of commenters noted that an optional format such as this would be less burdensome for small issuers while still providing the Commission and investors with the required information.[518] We believe that this option may help to facilitate compliance and ease burdens on by providing a mechanism by which issuers can easily confirm that they have provided all required information.

Consistent with the proposal, we are adopting a single Form C for all filings under Regulation Crowdfunding.[519] We believe that the use of one form will be more efficient than requiring multiple forms, will not result in unduly lengthy forms, and will simplify the filing process for issuers and their preparers. EDGAR will automatically provide each filing with an appropriate tag depending on which box the issuer checks so that investors can distinguish among the different filings.

We also are adopting, largely as proposed, the requirements to provide the offering information to investors and the relevant intermediary and make it available to potential investors under Section 4A(b)(1).[520] In addition, as discussed above in Section II.B., we moved the definition of ''investor'' from proposed Rule 300(c)(4) to Rule 100(d) to clarify that for purposes of all of Regulation Crowdfunding, ''investor'' includes any investor or any potential investor, as the context requires.[521] In connection with this clarifying change, we have deleted the phrase ''and make available to potential investors'' each time it appeared in the rule text to avoid redundancy.[522]

The final rules provide that issuers will satisfy the requirement to file the offering information with the Commission and provide it to the relevant intermediary by filing the Form C: Offering Statement and any amendments and progress updates and providing to the relevant intermediary a copy of the disclosures filed with the Commission.[523] The initial offering statement should include all of the information that is provided on the intermediary's Web site.[524] We also are adopting as proposed the requirements to file with the Commission and provide, or make available, as applicable, to investors and the relevant intermediary an amendment to the offering statement to disclose any material changes, additions or updates to information provided to investors through the intermediary's platform.[525] Issuers may, but are not required to, file an amendment to reflect other changes, additions or updates to information provided to investors through the

[514] As discussed in Section II.B.1, issuers will input in the proposed XML-based filing the following information: Name, legal status and contact information of the issuer; name, SEC file number and CRD number (as applicable) of the intermediary through which the offering will be conducted; the amount of compensation paid to the intermediary to conduct the offering, including the amount of referral and other fees associated with the offering; any other direct or indirect interest in the issuer held by the intermediary, or any arrangement for the intermediary to acquire such an interest; number of securities offered; offering price; target offering amount; whether oversubscriptions will be accepted and, if so, how they will be allocated; maximum offering amount (if different from the target offering amount); deadline to reach the target offering amount; current number of employees of the issuer; selected financial data for the prior two fiscal years; and the jurisdictions in which the issuer intends to offer the securities.

[515] *See, e.g.,* Commonwealth of Massachusetts Letter; NASAA Letter.

[516] The Commission will make the information available via EDGAR both in a traditional text-based format for reading and as downloadable XML-tagged data for analysis.

[517] *See* Item 1 of General Instruction III to Form C of Regulation Crowdfunding.

[518] *See, e.g.,* Guzik Letter 1; Guzik Letter 2; Guzik Letter 3; Hackers/Founders Letter; Hamilton Letter; RocketHub Letter; Saunders Letter; SBA Office of Advocacy Letter.

[519] *See* Rule 203 of Regulation Crowdfunding.

[520] *See* Rule 203(a) of Regulation Crowdfunding.

[521] *See* Rule 100(d) of Regulation Crowdfunding.

[522] *See* Rule 203(a) of Regulation Crowdfunding.

[523] *See* Instructions 1 and 2 to paragraph (a) of Rule 203 of Regulation Crowdfunding. We anticipate that issuers seeking to engage in an offering in reliance on Section 4(a)(6) may likely work with an intermediary to prepare the disclosure that would be provided on the intermediary's platform and filed with the Commission. In some cases, intermediaries may offer, as part of their service, to file the disclosure with the Commission on behalf of the issuer.

[524] *See* Rule 203(a)(1) of Regulation Crowdfunding.

[525] *See* Rule 203(a)(2) of Regulation Crowdfunding.

intermediary's platform that it considers not material.

To satisfy the requirement to provide the disclosures, or make them available, as applicable, to investors, the final rules allow issuers to provide the information to investors electronically by referring investors to the information on the intermediary's platform through a posting on the issuer's Web site or by email.[526] As discussed in the proposal and noted by commenters, many issuers may not have email addresses for investors. Accordingly, the final rules permit issuers to provide this information to investors through a Web site posting.[527] However, to the extent email addresses for investors are available to issuers, issuers may contact investors via email to direct them to the posted information. We continue to believe that investors in this type of Internet-based offering will be familiar with obtaining information on the Internet and that providing the information in this manner will be cost-effective for issuers. As discussed in the Proposing Release, we believe Congress contemplated that crowdfunding would, by its very nature, occur over the Internet or other similar electronic media that is accessible to the public.[528] Therefore, consistent with the proposed rules, the final rules do not require issuers to provide physical copies of the information to investors.

4. Prohibition on Advertising Terms of the Offering

a. Proposed Rules

Securities Act Section 4A(b)(2) provides that an issuer shall ''not advertise the terms of the offering, except for notices which direct investors to the funding portal or broker.'' Consistent with the statute, proposed Rule 204 of Regulation Crowdfunding would allow an issuer to publish a notice advertising the terms of an offering in reliance on Section 4(a)(6) so long as the notice includes the address of the intermediary's platform on which additional information about the issuer and the offering may be found. The proposal did not impose limitations on how the issuer distributes the notices. As proposed, the notice could include no more than: (1) A statement that the issuer is conducting an offering, the name of the intermediary through which the offering is being conducted and a link directing the investor to the intermediary's platform; (2) the terms of the offering; and (3) factual information about the legal identity and business location of the issuer, limited to the name of the issuer of the security, the address, phone number and Web site of the issuer, the email address of a representative of the issuer and a brief description of the business of the issuer. Under the proposed rules, ''terms of the offering'' would include: (1) The amount of securities offered; (2) the nature of the securities; (3) the price of the securities; and (4) the closing date of the offering period. The proposed rules would not, however, restrict an issuer's ability to communicate other information that does not refer to the terms of the offering.

The proposed rules also would allow an issuer to communicate with investors about the terms of the offering through communication channels provided by the intermediary on the intermediary's platform, so long as the issuer identifies itself as the issuer in all communications.

b. Comments Received

Commenters were mostly supportive of these provisions. Several commenters expressed support for the proposed content of advertising notices[529] and the definition of ''terms of the offering.''[530] A number of commenters also supported the proposal's absence of a restriction on an issuer's ability to communicate information that does not refer to the terms of the offering.[531] Several commenters requested clarification on various aspects of the proposal.[532]

Several commenters recommended that, consistent with the proposal, the Commission not restrict the media or format that may be used for advertising notices,[533] with some pointing to the changing nature of social media and potential new user interfaces.[534] Two commenters, however, stated that communications about the offering should always be conducted through the intermediary.[535] A number of commenters also supported allowing an issuer to communicate with investors about the terms of the offering through communication channels provided by the intermediary on the intermediary's platform, so long as the issuer identifies itself in all communications.[536]

Some commenters opposed the proposed advertising rules, with some stating that the advertising restrictions are unnecessary because sales must occur through an intermediary's platform, which would contain all of the relevant disclosures and investor acknowledgments.[537] One commenter asked that an issuer be given broader leeway to publicize its business or offering on its own Web site or social media platform so long as the specific terms of the offering can be found only through the intermediary's platform.[538] One commenter recommended allowing advertising notices to have a section for supplemental information highlighting certain intangible purposes such as a particular social cause.[539]

Two other commenters recommended that any advertising notices be filed with the Commission and/or the relevant intermediary.[540] Several other commenters supported the proposed approach of not having advertising notices filed with the Commission or the intermediary, citing concerns about various formats of the communications, inability to capture all third-party communications, and the costs

[526] *See* Instruction 2 to Rule 203(a) of Regulation Crowdfunding.

[527] *See, e.g.,* Grassi Letter; Wefunder Letter.

[528] We note that Section 301 of the JOBS Act states that ''[Title III] may be cited as the 'Capital Raising Online While Deterring Fraud and Unethical Non-Disclosure Act of 2012'.'' *See* Section 301 of the JOBS Act. *See also* 158 Cong. Rec. S1689 (daily ed. March 15, 2012) (statement of Sen. Mark Warner) (''There is now the ability to use the Internet as a way for small investors to get the same kind of deals that up to this point only select investors have gotten . . . , where we can now use the power of the Internet, through a term called crowdfunding.''); *id.* at S–1717 (Statement of Sen. Mary Landrieu) (''this crowdfunding bill—which is, in essence, a way for the Internet to be used to raise capital . . .'').

[529] *See, e.g.,* CFIRA Letter 6; Commonwealth of Massachusetts Letter; RocketHub Letter.

[530] *See, e.g.,* Arctic Island Letter 5; CFIRA Letter 6; Heritage Letter; Joinvestor Letter; RocketHub Letter.

[531] *See, e.g.,* ABA Letter; CFIRA Letter 6; Consumer Federation Letter; Hackers/Founders Letter; Public Startup Letter 2; RocketHub Letter.

[532] *See, e.g.,* ABA Letter (recommending the rule text include a safe harbor for regularly released factual business information so long as it does not refer to the terms of the offering); CIFRA Letter 6 (requesting more guidance on advertising formats and content and the definition of ''terms of the offering'').

[533] *See, e.g.,* Arctic Island Letter 5; Joinvestor Letter; Public Startup Letter 2; RoC Letter; RocketHub Letter.

[534] *See, e.g.,* Arctic Island Letter 5; Public Startup Letter 2; RocketHub Letter.

[535] *See* Hackers/Founders Letter (supporting the issuer being able to repost the communications elsewhere so long as it first appeared through the intermediary); Joinvestor Letter.

[536] *See, e.g.,* ASSOB Letter; CFIRA Letter 6; Commonwealth of Massachusetts Letter; Consumer Federation Letter; Hackers/Founders Letter; Odhner Letter; Public Startup Letter 2; RoC Letter; RocketHub Letter; Wefunder Letter. Some of these commenters also recommended that all interested persons, such as officers, directors and other agents, should identify themselves in all communications on the intermediary's platform. *See* CIFRA Letter 6; Hackers/Founders Letter.

[537] *See, e.g.,* FundHub Letter 1; Seed&Spark Letter (noting the proposed advertising restrictions will restrict the ability of filmmakers to market and raise money for their films); Arctic Island Letter 5; PeoplePowerFund Letter.

[538] *See* Fryer Letter.

[539] *See* RocketHub Letter.

[540] *See, e.g.,* Commonwealth of Massachusetts Letter; CFIRA Letter 6.

associated with trying to capture the data.[541]

c. Final Rules

We are adopting the prohibition on advertising terms of the offering substantially as proposed, with minor changes to the rule text for clarity.[542] Under the final rules, an advertising notice that includes the terms of the offering can include no more than: (1) A statement that the issuer is conducting an offering, the name of the intermediary through which the offering is being conducted and a link directing the investor to the intermediary's platform; (2) the terms of the offering; and (3) factual information about the legal identity and business location of the issuer, limited to the name of the issuer of the security, the address, phone number and Web site of the issuer, the email address of a representative of the issuer and a brief description of the business of the issuer. Consistent with the proposal, the final rules define ''terms of the offering'' to include: (1) The amount of securities offered; (2) the nature of the securities; (3) the price of the securities; and (4) the closing date of the offering period.[543]

The permitted notices will be similar to ''tombstone ads'' under Securities Act Rule 134,[544] except that the notices will be required to direct an investor to the intermediary's platform through which the offering is being conducted, such as through a link directing the investor to the platform.

Although at least one commenter recommended allowing advertising notices to have a section for supplemental information highlighting certain intangible purposes such as a particular social cause,[545] we do not believe a separate section is necessary. Instead, this type of information may be included as part of the ''brief description of the business.''

Two commenters[546] expressed concern that the proposed rule would not allow enough flexibility for brief, informal social media communications, but we disagree. A notice cannot include more than the enumerated matters, but an issuer has the flexibility not to include each of the enumerated matters in the notice, which may facilitate certain types of social media communications. For example, an issuer would be able to note on its own Web site or on social media that it is conducting an offering and direct readers to the materials on the intermediary's platform. There is no requirement for legends on these notices because the issuer will be directing investors to the materials on the intermediary's platform that will include those required legends.

We believe that this approach will provide flexibility for issuers while protecting investors by limiting the advertising of the terms of the offering to the information permitted in the notice and directing them to the intermediary's platform where they can access the disclosures necessary for them to make informed investment decisions.

Consistent with the recommendation of several commenters,[547] the final rules do not impose limitations on how the issuer distributes the notices. For example, an issuer could place notices in newspapers or post notices on social media sites or the issuer's own Web site. We believe the final rules will allow issuers to leverage social media to attract investors, while at the same time protecting investors by limiting the ability of issuers to advertise the terms of the offering without directing them to the required disclosure. We are not adopting a requirement that all notices be filed with the Commission or relevant intermediary, as requested by some commenters.[548] Other commenters expressed concerns about the costs that would be associated with such a requirement, and given that investors will be directed to the required disclosure on the intermediary's platform, we believe the final rules appropriately take these factors into account.[549]

Further, the final rules allow an issuer to communicate with investors about the terms of the offering through communication channels provided by the intermediary on the intermediary's platform, so long as the issuer identifies itself as the issuer in all communications. We believe that one of the central tenets of the concept of crowdfunding is that the members of the crowd decide whether or not to fund an idea or business after sharing information with each other. As part of those communications, we believe it is important for the issuer to be able to respond to questions about the terms of the offering or even challenge or refute statements made through the communication channels provided by the intermediary. Therefore, the final rules do not restrict issuers from participating in those communications so long as the issuer identifies itself as the issuer in all communications.

Based on the suggestion of a few commenters,[550] we are clarifying in the final rules that the prohibition on advertising the terms of the offering and related requirements apply to persons acting on behalf of the issuer.[551] For example, persons acting on behalf of the issuer are required under Rule 204(c) to identify their affiliation with the issuer in all communications on the intermediary's platform.[552]

In addition, the final rules do not restrict an issuer's ability to communicate other information that might occur in the ordinary course of its operations and that does not refer to the terms of the offering. As stated in the Proposing Release, we believe that this is consistent with the statute because Section 4A(b)(2) restricts the advertising of the terms of the offer. The Commission has interpreted the term ''offer'' broadly, however, and has explained that ''the publication of information and publicity efforts, made in advance of a proposed financing which have the effect of conditioning the public mind or arousing public interest in the issuer or in its securities constitutes an offer. . .''[553] In this regard, we also note that Securities Act Rule 169[554] permits non-Exchange Act reporting issuers engaged in an initial public offering to continue to publish, subject to certain exclusions and conditions, regularly released factual business information that is intended for use by persons other than in their capacity as investors.

While one commenter requested a safe harbor for regularly released factual business information so long as it does not refer to the terms of the offering,[555] we do not believe that a safe harbor is necessary. Ultimately, whether or not a communication is limited to factual business information depends on the facts and circumstances of that particular communication. However,

[541] *See, e.g.,* Arctic Island Letter 5; ASSOB Letter; Public Startup Letter 2; RocketHub Letter.

[542] *See* Rule 204 of Regulation Crowdfunding.

[543] *See* Instruction to Rule 204 of Regulation Crowdfunding.

[544] 17 CFR 230.134.

[545] *See* RocketHub Letter.

[546] *See* FundHub Letter 1; Fryer Letter (''a rigid tombstone approach is inconsistent with the structure and informality of modern social media communication tools.'')

[547] *See, e.g.,* Arctic Island Letter 5; Joinvestor Letter; Public Startup Letter 2; RoC Letter; RocketHub Letter.

[548] *See, e.g.,* Hackers/Founders Letter; Joinvestor Letter.

[549] *See, e.g.,* ASSOB Letter; RocketHub Letter.

[550] *See, e.g.,* CIFRA Letter 6; Hackers/Founders Letter.

[551] *See* Rule 204 of Regulation Crowdfunding.

[552] *See also* Section II.B.5 for disclosures required by persons promoting the offering.

[553] *Securities Offering Reform,* Release No. 33–8591 (July 19, 2005) [70 FR 44722 (Aug. 3, 2005)] at 44731. The term ''offer'' has been interpreted broadly and goes beyond the common law concept of an offer. *See, e.g., Diskin* v. *Lomasney & Co.,* 452 F.2d 871 (2d. Cir. 1971).

[554] 17 CFR 230.169.

[555] *See* ABA Letter.

issuers may generally look to the provisions of Rule 169 for guidance in making this determination in the Regulation Crowdfunding context.

5. Compensation of Persons Promoting the Offering

a. Proposed Rules

Consistent with Securities Act Section 4A(b)(3), proposed Rule 205 of Regulation Crowdfunding would prohibit an issuer from compensating, or committing to compensate, directly or indirectly, any person to promote the issuer's offering through communication channels provided by the intermediary, unless the issuer takes reasonable steps to ensure that the person clearly discloses the receipt (both past and prospective) of compensation each time the person makes a promotional communication. Further, a founder or an employee of the issuer that engages in promotional activities on behalf of the issuer through the communication channels provided by the intermediary would be required to disclose, with each posting, that he or she is engaging in those activities on behalf of the issuer.

Under the proposed rules, an issuer would not be able to compensate or commit to compensate, directly or indirectly, any person to promote its offerings outside of the communication channels provided by the intermediary, unless the promotion is limited to notices that comply with the proposed advertising rules.

b. Comments Received

Commenters were generally supportive of promoter disclosure and the proposed rule.[556] A number of commenters supported the broad applicability of the proposed rules to persons acting on behalf of the issuer.[557] Some commenters recommended that the issuer or intermediary bear more responsibility for ensuring that the identity of the promoters be prominently disclosed.[558]

A number of commenters also supported the requirement in the proposal that an issuer not compensate or commit to compensate, directly or indirectly, any person to promote its offerings outside of the communication channels provided by the intermediary, unless the promotion is limited to notices that comply with the proposed advertising rules.[559]

c. Final Rules

We are adopting, as proposed, final rules about the compensation of persons promoting the offering, with one clarifying change.[560] We anticipate that communication channels provided by the intermediary will provide a forum through which investors could share information to help the members of the crowd decide whether or not to fund the issuer. We believe that it will be important for investors to know whether persons using those communication channels are persons acting on behalf of the issuer or persons receiving compensation from the issuer (or from persons acting on behalf of the issuer), to promote the issuer's offering because of the potential for self-interest or bias in communications by these persons.

A number of commenters supported the broad applicability of the proposed rules to persons acting on behalf of the issuer.[561] The text of the proposed rule included a sentence stating that the disclosure obligation would apply to ''a founder or an employee of the issuer that engages in promotional activities on behalf of the issuer through the communication channels.'' Based on comments received, we are removing that sentence and adding an instruction to clarify that the requirement applies broadly to all persons acting on behalf of the issuer, regardless of whether or not the compensation they receive is specifically for the promotional activities. The change is intended to clarify that the disclosure requirement applies to persons hired specifically to promote the offering as well as to persons (including, but not limited to, founders, employees and directors) who are otherwise employed by the issuer or who undertake promotional activities on behalf of the issuer.

While we appreciate the views of commenters who suggested that we impose additional requirements on issuers or intermediaries to ensure that the identity of promoters is prominently disclosed, we believe the requirement that the issuer take reasonable steps to ensure that promoters clearly disclose the receipt of compensation for communications is sufficient to achieve the objectives of this provision without being overly prescriptive. There are a number of reasonable steps the issuer can take to ensure compliance. An issuer could, for example, contractually require any promoter to include the required statement about receipt of compensation, confirm that the promoter is adhering to the intermediary's terms of use that require promoters to affirm whether or not they are compensated by the issuer, monitor communications made by such persons and take the necessary steps to have any communications that do not have the required statement removed promptly from the communication channels, or retain a person specifically identified by the intermediary to promote all issuers on its platform.

As proposed, the final rules also specify that the issuer shall not compensate or commit to compensate, directly or indirectly, any person to promote its offerings outside of the communication channels provided by the intermediary, unless the promotion is limited to notices that comply with the advertising rules discussed above in Section II.B.4.[562] This prohibition should prevent issuers from circumventing the restrictions on advertising by compensating a third party to do what the issuer cannot do directly.

6. Other Issuer Requirements

a. Oversubscriptions

The proposed rules would not limit an issuer's ability to accept investments in excess of the target offering amount, subject to the $1 million annual limit.[563] Issuers would be required to disclose how much they would be willing to accept in oversubscriptions, how the oversubscriptions would be allocated, and the intended purpose of those additional funds.

Commenters were generally supportive of this approach to oversubscriptions.[564] Some commenters supported the proposed flexibility to allow issuers to determine how to allocate oversubscribed offerings,[565] while other commenters recommended that the Commission require issuers to allocate oversubscriptions using a prescribed method.[566] Two commenters

[556] *See, e.g.,* CFA Institute Letter; Consumer Federation Letter (supporting proposal but generally questioning the wisdom of allowing paid promoters to participate in the communication channels at all); NASAA Letter; NFIB Letter; Public Startup Letter 2.

[557] *See, e.g.,* CFA Institute Letter; CFIRA Letter 6; Commonwealth of Massachusetts Letter; Consumer Federation Letter; Hackers/Founders Letter; Joinvestor Letter; RocketHub Letter; MCS Letter.

[558] *See, e.g.,* ASSOB Letter; Commonwealth of Massachusetts Letter; Joinvestor Letter; MCS Letter; RoC Letter; RocketHub Letter.

[559] *See, e.g.,* ASSOB Letter; Consumer Federation Letter; Joinvestor Letter; Public Startup Letter 2; RoC Letter; RocketHub Letter.

[560] *See* Rule 205 of Regulation Crowdfunding.

[561] *See, e.g.,* CFA Institute Letter; CFIRA Letter 6; Commonwealth of Massachusetts Letter; Consumer Federation Letter; Hackers/Founders Letter; Joinvestor Letter; RocketHub Letter; MCS Letter.

[562] *See* Rule 205(b) of Regulation Crowdfunding.

[563] *See* proposed Rule 201(h) and Instruction to paragraph (i) of Rule 201 of Regulation Crowdfunding, and cover page of Form C.

[564] *See, e.g.,* CFA Institute letter; EMKF letter; Jacobson letter; Wefunder letter.

[565] *See, e.g.,* ASSOB Letter; CFA Institute Letter; EMKF Letter; Public Startup Letter 2; RocketHub Letter; Wefunder letter.

[566] *See, e.g.,* Fund Democracy Letter (pro-rata); Consumer Federation Letter (same as Fund

recommended that the Commission limit the maximum oversubscription amount to a certain percentage of the target offering amount,[567] while two other commenters opposed such a limit.[568] One commenter recommended that the Commission revise the proposed rules to clarify that issuers would be required to disclose the ''other'' basis upon which oversubscriptions would be allocated.[569]

We are adopting the rule relating to oversubscriptions as proposed, with one clarifying change.[570] We do not believe, as some commenters suggested, that it is necessary to limit the maximum oversubscription amount. Nor do we believe it is necessary to prescribe how to allocate oversubscribed offerings so long as the issuer discloses, at the commencement of the offering, how securities in such offerings will be allocated, and the intended purpose of those additional funds. This disclosure should provide investors with information they need to make informed investment decisions while providing issuers flexibility to structure the offering as they believe appropriate. In response to a comment received,[571] we are clarifying in the final rules that, regardless of the structure, the issuer must describe how securities in oversubscribed offerings will be allocated.

b. Offering Price

As discussed above in Section II.B.1.a.i.(e), proposed Rule 201(l) would require an issuer to disclose the offering price of the securities or, in the alternative, the method for determining the price, provided that prior to any sale of securities, each investor is provided in writing the final price and all required disclosure. The proposed rules would not require issuers to set a fixed price or prohibit dynamic pricing.

We received a few comments supporting the proposed approach or expressing opposition to requiring a fixed price,[572] while another commenter suggested the Commission require issuers to set a fixed price.[573]

We are adopting the final rules as proposed.[574] While we appreciate the view of at least one commenter[575] that a fixed price may be simpler for investors to understand, we believe that the statute contemplated flexible pricing by providing that issuers may disclose the method for determining the price, provided that the final price and required disclosures are provided to each investor prior to any sales. We also believe the cancellation rights in the final rules[576] will provide investors a reasonable opportunity to cancel their investment commitment if they wish to do so after the price is fixed.

c. Types of Securities Offered and Valuation

The proposed rules would not limit the type of securities that may be offered in reliance on Section 4(a)(6) nor prescribe a method for valuing the securities. Issuers would be required to describe the terms of the securities and the valuation method in their offering materials.

A number of commenters generally supported not limiting the types of securities that may be offered and sold in reliance of Section 4(a)(6).[577] Comments were more varied on valuation methodology. Some commenters recommended that the Commission neither require nor prohibit a specific valuation methodology,[578] while others recommended that the Commission prescribe a set of valuation standards that have universal application for startups.[579] Two commenters recommended that the Commission require issuers to base the valuation of their securities on the price at which the issuer previously sold securities,[580] and another commenter recommended that the Commission consider whether additional standards are needed to ensure that securities are fairly valued and that approaches to valuation that put investors at a disadvantage be prohibited.[581] One commenter generally supported requiring issuers to describe how securities being offered are being valued,[582] while another commenter generally opposed such requirement.[583]

We are adopting, as proposed, final rules that neither limit the type of securities that may be offered in reliance on Section 4(a)(6) nor prescribe a method for valuing the securities.[584] We noted in the proposal that the statute refers to ''securities'' and does not limit the type of securities that could be offered pursuant to the exemption. Issuers are required to describe the terms of the securities and the valuation method in their offering materials.[585] We believe this approach is consistent with the statute and will provide flexibility to issuers to determine the types of securities that they offer to investors and how those securities are valued, while providing investors with the information they need to make an informed investment decision.

While some commenters suggested that the Commission should provide specific valuation methods or standards for securities-based crowdfunding transactions, we are not persuaded that there would be sufficient benefits to being prescriptive in this regard. Methods and valuations of early stage companies vary significantly, and any attempt to choose a particular valuation methodology could limit flexibility and have the result of endorsing one approach over another without necessarily having a sound basis for doing so. We believe the requirement that issuers describe the methods they use to value their securities in their offering materials, including the requirement that they describe examples of methods for how such securities may be valued by the issuer in the future, will provide investors with the information they need to make an informed investment decision.

The final rules do not limit the types of securities that may be offered in reliance on Section 4(a)(6), and thus debt securities may be offered and sold in crowdfunding transactions. As we stated in the Proposing Release, in general, the issuance of a debt security

Democracy); Joinvestor letter (first-come, first-served or algorithmic random selection); PeoplePowerFund Letter (first-come, first-served).

[567] *See* Joinvestor Letter (10%); RFPIA Letter (20%).

[568] *See* Jacobson Letter; Public Startup Letter 2.

[569] *See* Fund Democracy Letter.

[570] *See* Rule 201(h) to Regulation Crowdfunding.

[571] *See* Fund Democracy Letter.

[572] *See, e.g.,* CFA Institute Letter (stating that disclosure of changes and methods used to determine share prices, along with investors' rights to cancel their investment commitments, provide reasonable safeguards); Wilson Letter; Public Startup Letter 2.

[573] *See* RocketHub Letter.

[574] *See* Rule 201(l) of Regulation Crowdfunding. *See also* Section II.C.6 for a discussion of cancellation provisions.

[575] *See* RocketHub Letter.

[576] *See* Rules 201(j) and 201(k) of Regulation Crowdfunding.

[577] *See, e.g.,* CFA Institute Letter; Concerned Capital Letter; Crowdstockz Letter; Hackers/Founders Letter; Joinvestor Letter; Public Startup Letter 2; RocketHub Letter; Tiny Cat Letter; Wilson Letter.

[578] *See, e.g.,* Hackers/Founders Letter; Heritage Letter; PeoplePowerFund Letter; Public Startup Letter 2; RocketHub Letter; Wilson Letter.

[579] *See, e.g.,* 11 Wells Letter; Active Agenda Letter; Borrell Letter; Ellenbogen Letter; Greer Letter; Mountain Hardwear Letter; Moyer Letter; NaviGantt Letter; Vidal Letter.

[580] *See, e.g.,* Public Startup Letter 3; Wefunder Letter.

[581] *See* Consumer Federation Letter.

[582] *See* CFIRA Letter 7.

[583] *See* Thomas Letter 2 (recommending that if issuers are required to describe the valuation method in their offering materials, the rule should provide ''safe harbor'' language that issuers can use in providing such description.)

[584] *See* Rule 201(m) of Regulation Crowdfunding.

[585] *See* Rule 201(m)(1) and (4) of Regulation Crowdfunding.

raises questions about the applicability of the Trust Indenture Act of 1939 (''Trust Indenture Act'').[586] Although the Trust Indenture Act applies to any debt security sold through the use of the mails or interstate commerce, including debt securities sold in transactions that are exempt from Securities Act registration, Trust Indenture Act Section 304(b) provides an exemption for any transaction that is exempted by Securities Act Section 4 from the provisions of Section 5 of the Act.[587] An issuer offering debt securities in reliance on Section 4(a)(6), therefore, would be able to rely on this exemption.[588] Based on the availability of this exemption, we are not adopting a specific exemption from the requirements of the Trust Indenture Act for offerings of debt securities made in reliance on Section 4(a)(6).

C. Intermediary Requirements

1. Definitions of Funding Portals and Associated Persons

a. Proposed Rules

Securities Act Section 4(a)(6)(C) requires a crowdfunding transaction to be conducted through a broker or funding portal that complies with the requirements of Securities Act Section 4A(a). The term ''broker'' is generally defined in Exchange Act Section 3(a)(4) as any person that effects transactions in securities for the account of others. Exchange Act Section 3(a)(80) defines the term ''funding portal'' as any person acting as an intermediary in a transaction involving the offer or sale of securities for the account of others, solely pursuant to Securities Act Section 4(a)(6), that does not: (1) Offer investment advice or recommendations; (2) solicit purchases, sales or offers to buy the securities offered or displayed on its Web site or portal; (3) compensate employees, agents or other persons for such solicitation or based on the sale of securities displayed or referenced on its Web site or portal; (4) hold, manage, possess or otherwise handle investor funds or securities; or (5) engage in such other activities as the Commission, by rule, determines appropriate.[589]

In the Proposing Release, we explained that because a funding portal would be engaged in the business of effecting securities transactions for the accounts of others through crowdfunding, it would be a ''broker'' within the meaning of Section 3(a)(4) of the Exchange Act.[590] Accordingly, proposed Rule 300(c)(2) of Regulation Crowdfunding would define ''funding portal'' consistent with the statutory definition of ''funding portal,'' with the substitution of the word ''broker'' for the word ''person.''

We also stated in the Proposing Release that the proposed rules would apply not only to funding portals, but also to their associated persons in many instances. The terms ''person associated with a broker or dealer'' and ''associated person of a broker or dealer'' are defined in Exchange Act Section 3(a)(18).[591] Proposed Rule 300(c)(1) of Regulation Crowdfunding would similarly define the term ''person associated with a funding portal or associated person of a funding portal'' to mean any partner, officer, director or manager of a funding portal (or any person occupying a similar status or performing similar functions), any person directly or indirectly controlling or controlled by a funding portal, or any employee of a funding portal, other than persons whose functions are solely clerical or ministerial. The proposed rules would provide, however, that persons who are excluded from the definition of associated person of a funding portal because their functions are solely clerical or ministerial would remain subject to our sanctioning authority under Exchange Act Sections 15(b)(4) and 15(b)(6).[592] This definition is consistent with, and modeled on, the language of Exchange Act Section 3(a)(18).[593]

In proposed Rule 300(c)(4), we also defined ''investor'' as any investor or any potential investor, as the context requires.

b. Comments on the Proposed Rules

The Proposing Release requested comments on whether there were funding portal activities, other than those in Exchange Act Section 3(a)(80), that we should prohibit, and whether any prohibitions should be modified or removed. We also requested comments about whether further guidance was necessary on the provisions of the Exchange Act and the rules and regulations thereunder that would apply to funding portals.

Some commenters stated that the Commission should not provide any further guidance or prohibitions on funding portal activity in addition to those required by statute.[594] One of these commenters stated that the proposed regulations for funding portal activities are ''sufficient for investor protection and proper regulatory oversight.'' [595] Another commenter opposed removing or modifying the statutory limitations on funding portal activities, stating that if funding portals wish to engage in the prohibited activities, they could do so by registering, and being appropriately regulated as, broker-dealers.[596]

c. Final Rules

After considering the comments, we are adopting, as proposed, the definitions of ''associated person of a funding portal or person associated with a funding portal'' and ''funding portal'' in Rules 300(c)(1) and(2), respectively. In particular, we believe that, at the present time, the statutory prohibitions on a funding portal in Exchange Act Section 3(a)(80), as reflected in the final rule definition of a funding portal, provide appropriate investor protections.

We also are adopting the definition of ''investor'' from the proposed rules but have moved the definition to Rule 100(d), and made a modification to clarify that the definition applies to all of Regulation Crowdfunding.[597] Although commenters did not address

[586] 15 U.S.C. 77aaa *et seq.*

[587] 15 U.S.C. 77ddd(b).

[588] Trust Indenture Act Section 304(a)(8) [15 U.S.C. 77ddd(a)(8)] and Rule 4a–1 [17 CFR 260.4a–1] also provide an exemption to issue up to $5 million of debt securities without an indenture in any 12-month period.

[589] Congress in the JOBS Act inadvertently created two Sections 3(a)(80) in the Exchange Act, the other being the definition of ''emerging growth company'' (added by Section 101(b) of Title I of the JOBS Act).

[590] *See* Proposing Release at 78 FR 66458. *See also* discussion in Section II.D.2.

[591] 15 U.S.C. 78c(a)(18).

[592] Section 15(b)(4) (15 U.S.C. 78*o*(b)(4)) authorizes the Commission to bring administrative proceedings for the imposition of sanctions, up to and including the revocation of a broker's registration, when the broker violates the federal securities laws (and for other misconduct). Section 15(b)(6) (15 U.S.C. 78*o*(b)(6)) provides similar sanctioning authority with respect to persons associated with a broker, including the ability to bar such persons from associating with any Commission registrant.

[593] We note, however, that the definition in proposed Rule 300(c)(1) does not include persons under common control with the funding portal, unlike the definition in Exchange Act Section 3(a)(18) which includes such persons as associated persons of broker-dealers.

[594] *See, e.g.,* RocketHub Letter; Tiny Cat Letter (stating that the proposed regulations provide a ''healthy level of investor protection, but are not overly burdensome and we wholeheartedly appreciate the [C]ommission's general attitude of restraint''). Another commenter also opposed additional prohibitions, stating that ''to add prohibitions would be an illegal Rule not authorized by the JOBS Act legislation.'' *See* Public Startup Letter 2. This commenter made a similar argument with respect to various aspects of the rule. We note, however, that the JOBS Act provides the Commission the authority to provide other requirements for the protection of investors and in the public interest. *See, e.g.,* Securities Act Section 4A(a)(12); 4A(b)(5).

[595] *See* Tiny Cat Letter.

[596] *See* Consumer Federation Letter.

[597] *See* Section II.B.1.

the definition of ''investor,'' we are making this change to address any potential confusion about whether the definition is applicable to all of Regulation Crowdfunding.

2. General Requirements for Intermediaries

a. Registration and SRO Membership

(1) Proposed Rules

Securities Act Section 4A(a)(1) requires that a person acting as an intermediary in a crowdfunding transaction register with the Commission as a broker or as a funding portal.[598] Proposed Rule 300(a)(1) of Regulation Crowdfunding would implement this requirement by providing that a person acting as an intermediary in a transaction involving the offer or sale of securities made in reliance on Section 4(a)(6) must be registered with the Commission as a broker under Exchange Act Section 15(b), or as a funding portal pursuant to Section 4A(a)(1) and proposed Rule 400 of Regulation Crowdfunding. As discussed below, we also proposed to make the information that a funding portal provides on the proposed registration form (*i.e.,* Form Funding Portal), other than personally identifiable information or other information with a significant potential for misuse, accessible to the public.[599]

Securities Act Section 4A(a)(2) requires an intermediary to register with any applicable self-regulatory organization (''SRO''), as defined in Exchange Act Section 3(a)(26).[600] Exchange Act Section 3(h)(1)(B) separately requires, as a condition of the exemption from broker registration, that a funding portal be a member of a national securities association that is registered with the Commission under Exchange Act Section 15A. Proposed Rule 300(a)(2) would implement these provisions by requiring an intermediary in a transaction involving the offer or sale of securities made in reliance on Section 4(a)(6) to be a member of FINRA or any other national securities association registered under Exchange Act Section 15A. Currently, FINRA is the only registered national securities association.

We also proposed definitions for the terms ''intermediary'' and ''SRO'' in proposed Rules 300(c)(3) and 300(c)(5) of Regulation Crowdfunding, respectively. As proposed, intermediary would mean a broker registered under Section 15(b) of the Exchange Act or a funding portal registered under proposed Rule 400 of Regulation Crowdfunding and would include, where relevant, an associated person of the registered broker or registered funding portal. SRO was proposed to have the same meaning as in Section 3(a)(26) of the Exchange Act.

(2) Comments on the Proposed Rules

Commenters generally supported FINRA being the appropriate SRO and national securities association for intermediaries.[601] In the Proposing Release, we asked if we were to approve the registration of another national securities association under Exchange Act Section 15A in the future, in addition to FINRA, whether it would it be appropriate for us to require membership in both the existing and new association. Commenters urged that intermediaries be required to register with only one such national securities association.[602]

Certain commenters expressed concern about potential competitive advantages of registered broker-dealers over funding portals, suggesting that the Commission should prohibit brokers from engaging in transactions conducted pursuant to Section 4(a)(6) until funding portals can become registered,[603] or provide funding portals a grace period so they may be able to operate before their registration becomes effective.[604] Another commenter, however, suggested that licensed broker-dealers should be immediately authorized to provide services associated with a ''registered crowdfunding portal'' to any issuer looking to self-host or to an issuer that has ''an offline mechanism available for crowdfunding.'' [605]

In response to our requests for comment in the Proposing Release, commenters were also divided on whether the Commission should require minimum qualification, testing and licensure requirements for funding portals and their associated persons.[606]

(3) Final Rules

After considering the comments, we are adopting Rule 300(a) generally as proposed but deleting specific references to FINRA in the final rule, as well as the rest of Regulation Crowdfunding and Form Funding Portal, when referring to a registered national securities association. Although we recognize that FINRA is currently the only registered national securities, we believe it is redundant to specifically include its name when referring to registered national securities associations in the rule text and Form Funding Portal.

We are cognizant of the fact that funding portals must register with the Commission and become compliant with an entirely new set of rules. The effective date for the final rules (which is 180 days after publication in the **Federal Register**, except for § 227.400, Form Funding Portal, and the amendments to Form ID, which are effective January 29, 2016) is designed to provide a sufficient amount of time for funding portals to register and establish the necessary infrastructure to comply with other requirements being imposed in Regulation Crowdfunding before any intermediaries—either broker-dealers or funding portals—may engage in crowdfunding activities. We believe this should address commenters' concerns that broker-dealers otherwise may gain a competitive advantage if they were able to engage in crowdfunding activities before funding portals are able to comply with the requirements needed to begin operation.[607]

While FINRA is the only registered national securities association at present, we recognize that a new national securities association or associations could register with us in the future. At that time, a funding portal could choose to become a member of the new association(s) instead of, or in

[598] As we noted in the Proposing Release, facilitating crowdfunded transactions (which involve the offer or sale of securities by an issuer and not secondary market activity) alone would not require an intermediary to register as an exchange or as an alternative trading system (*i.e.,* registration as a broker-dealer subject to Regulation ATS). *See* Proposing Release at 78 FR 66459 (discussing secondary market activity and exchange or ATS registration).

[599] *See* Section II.D.1 (discussing registration requirements).

[600] 15 U.S.C. 78c(a)(26). Exchange Act Section 3(a)(26) defines an ''SRO'' to include, among other things, a ''registered securities association.'' *Id.*

[601] *See, e.g.,* Joinvestor Letter; RocketHub Letter. One commenter stated that funding portals should not be required to register with the Commission or become FINRA members because, unlike brokers, they serve only as an ''information delivery service.'' *See* Perfect Circle Letter. We note, however, that registration is a statutory requirement under Securities Act Section 4A(a)(1).

[602] *See, e.g.,* Joinvestor Letter; Public Startup Letter 2; RocketHub Letter; Vann Letter.

[603] *See, e.g.,* RocketHub Letter.

[604] *See, e.g.,* Joinvestor Letter.

[605] Public Startup Letter 2.

[606] Comments in support included Hakanson Letter; Reichman Letter; RocketHub Letter. *See also* CrowdCorp Letter (stating that the Commission should establish a separate licensing scheme for persons who help prepare issuer disclosure documents and advise issuers, but who are not brokers or funding portals). Comments opposed included Public Startup Letter 2; Startup Valley Letter.

[607] We note that broker-dealers may nonetheless have a competitive advantage to the extent that they are able to provide a wider range of services than those permitted funding portals under the statute. However, we believe this competitive advantage is balanced to a significant degree by a strong regulatory regime tailored to that wider range of services.

addition to, its FINRA membership. As we noted above, we requested comment on whether we should require membership in both the existing national securities association (FINRA) and a new national securities association, if we were to approve another national securities association in the future. We have considered commenters' views and have determined not to require that funding portals be members of multiple securities associations (should new associations be registered in the future). Because all registered national securities associations must satisfy the same statutory standards set forth in Exchange Act Section 15A, we do not believe at this time that requiring membership in additional associations would add significant investor protections.

After considering comments, we have determined not to impose any licensing, testing or qualification requirements for associated persons of funding portals. We believe that a registered national securities association is well-positioned, given the requirements for registration as a national securities association, as well as the statutory and regulatory requirements that apply to such a registered entity, to determine whether to propose additional requirements such as licensing, testing or qualification requirements for associated persons of funding portals.[608]

We also are adopting as proposed the definitions for the terms ''intermediary'' in Rule 300(c)(3). However, we are removing the definition of ''self-regulatory organization'' and ''SRO'' from the final rules because the term is already defined in Exchange Act Section 3(a)(26).

b. Financial Interests

(1) Proposed Rules

Securities Act Section 4A(a)(11) requires an intermediary to prohibit its directors, officers or partners (or any person occupying a similar status or performing a similar function) from having any financial interest in an issuer using its services. In the Proposing Release, we proposed to use our discretion to extend the prohibition to the intermediary itself. Thus, proposed Rule 300(b) of Regulation Crowdfunding would prohibit the intermediary, as well as its directors, officers or partners (or any person occupying a similar status or performing a similar function), from having: (1) A financial interest in an issuer using its services; and (2) from receiving a financial interest in the issuer as compensation for services provided to, or for the benefit of, the issuer, in connection with the offer and sale of its securities. Proposed Rule 300(b) defined ''a financial interest in an issuer'' to mean a direct or indirect ownership of, or economic interest in, any class of the issuer's securities.

(2) Comments on the Proposed Rules

In general, commenters supported the Commission's proposed financial interest prohibition as it applies to an intermediary's directors, officers or partners (or any person occupying a similar status or performing a similar function),[609] as well as the proposed definition of financial interest.[610] In contrast, however, many commenters opposed the Commission's proposed prohibition on an intermediary itself having or receiving a financial interest in the issuer,[611] while some supported this proposed prohibition.[612]

Commenters who supported our proposal to extend the prohibition on financial interests to the intermediary suggested that such prohibitions may help to mitigate conflicts of interests.[613] One commenter stated that an intermediary having a financial interest in the issuer would skew the incentives of the intermediary toward its own interests rather than the integrity of the transaction, and also stated its view that disclosure of this interest could not cure this problem.[614]

Several commenters who opposed the prohibition on an intermediary having a financial interest in the issuer suggested that the prohibition would reduce the number and types of intermediaries that might otherwise participate in crowdfunding activities.[615] These commenters asserted that allowing an intermediary to take this financial interest would provide an option through which issuers could provide payment to the intermediary for its services, and also permit co-investments, which would ultimately benefit investors.[616] These commenters also asserted that such a financial interest could align the interests of intermediaries with those of investors.[617] One commenter suggested that ''by removing an upfront cost and incentivizing an ongoing relationship between the intermediary and the issuer, equity compensation for intermediaries fulfils the Commission's twin aims of efficient capital markets and investor protection.'' [618] Another commenter noted that permitting the intermediary to take a financial interest in the issuer would encourage the development of funding portals that are sponsored by or affiliated with Community Development Financial Institutions (''CDFIs'').[619] Yet another

[608] All SROs are required to file proposed rules and rule changes with us under Exchange Act Section 19(b) and Rule 19b–4. In general, the Commission reviews proposed SRO rules and rule changes and publishes them for comment. The Commission then approves or disapproves them, or the rules become effective immediately or by operation of law.

[609] *See, e.g.,* CFA Institute Letter; Consumer Federation Letter; Jacobson Letter.

[610] *See, e.g.,* Hackers/Founders Letter; Joinvestor Letter; Tiny Cat Letter. *See also* Consumer Federation Letter (stating that the Commission should ''monitor practices in this area once rules are adopted to ensure that the intended limits appropriate to intermediaries' gatekeeper functions are not being circumvented through the use of other types of payments or financial arrangements'').

[611] *See, e.g.,* AngelList Letter; Anonymous Letter 3; Arctic Island Letter 6; EMKF Letter; Growthfountain Letter; Guzik Letter 1; Hackers/Founders Letter; Heritage Letter; Milken Institute Letter; Propellr Letter 1; Public Startup Letter 2; RoC Letter; RocketHub Letter; Seyfarth Letter; Thomas Letter 1.

[612] *See, e.g.,* CFA Institute Letter; Clapman Letter; Consumer Federation Letter; Jacobson Letter; Joinvestor Letter.

[613] *See, e.g.,* CFA Institute Letter; Consumer Federation Letter (''An intermediary that is compensated through receipt of a financial interest in an issuer may have an incentive to take steps to ensure that the issuer reaches its funding target so that the offering can move forward or engage in other practices designed to artificially inflate the value of its securities.''); Jacobson Letter.

[614] *See* Jacobson Letter.

[615] *See, e.g.,* Hackers/Founders Letter (''Furthermore, rules that preclude the [i]ntermediary from holding any financial interest would overly restrict the [i]ntermediary environment; for example, such restrictions might prevent a diverse set of platforms from developing that serve the specific needs of different communities. The impact of which might disproportionately impact certain communities, such as the not-for-profit community.'').

[616] *See, e.g.,* EMKF Letter (''The current proposed rules with a fee-based system is a recipe for disaster. No credible startups that have viable alternatives would choose to pay 5–15% of their fundraising round in cash to an intermediary.'').

[617] *See, e.g.,* AngelList Letter (''So long as the program was consistently applied without judgment by the intermediary, the net effect would purely be to align the interests of the intermediary with the investor.''). *See also* EMKF Letter; Hackers/Founders Letter; Heritage Letter; Milken Institute Letter; RoC Letter; Thomas Letter 1.

[618] Seyfarth Letter.

[619] *See* Concerned Capital Letter (suggesting the Commission broaden the definition of intermediaries to encourage portals sponsored by and/or affiliated with U.S. Treasury-recognized CDFIs and exempt such portals from the prohibitions against having a financial interest in issuers). *See also* City First Letter (suggesting that the Commission allow CDFIs to act as co-lenders).

The Community Development Financial Institutions Fund, which was established by the Riegle Community Development and Regulatory Improvement Act of 1994, is a government program that promoted access to capital and local economic growth by, among other things, investing in, supporting and training CDFIs that provide loans, investments, financial services and technical assistance to underserved populations and communities. *See generally http://www.cdfifund.gov/what_we_do/programs_id.asp?programID=9.* A

commenter suggested that permitting the intermediary to take a financial interest in the issuer would incentivize intermediaries to screen potential issuers for possible fraud or wrongdoing.[620] Other commenters supported permitting the intermediary to take a financial interest in the issuer so long as the terms of the financial interests taken by the intermediary are the same as or not more favorable than those taken by investors in the offering.[621] Commenters suggested additional measures, such as adequate disclosure,[622] a five percent interest limitation,[623] and restrictions on the ability of an intermediary to transfer its interests in the issuer, could help to address any conflicts of interest concerns.[624]

(3) Final Rules

After considering the comments, we are adopting Rule 300(b), as proposed, with respect to an intermediary's directors, officers or partners (or any person occupying a similar status or performing a similar function). Rule 300(b), as adopted, prohibits an intermediary's directors, officers or partners (or any person occupying a similar status or performing a similar function) from having any financial interest in an issuer using its services. Rule 300(b) also specifically prohibits these persons from receiving a financial interest in the issuer as compensation for services provided to, or for the benefit of, the issuer, in connection with the offer and sale of its securities. Consistent with the proposal, Rule 300(b), as adopted, defines ''a financial interest in an issuer'' to mean a direct or indirect ownership of, or economic interest in, any class of the issuer's securities.[625]

We are not adopting, however, the proposed complete prohibition on the intermediary itself having or receiving a financial interest in an issuer using its services. Although intermediaries are generally prohibited under the rule as adopted from having such a financial interest, as discussed below, in response to comments, we have amended the rule to permit an intermediary to have a financial interest in an issuer that is offering or selling securities in reliance on Section 4(a)(6) through the intermediary's platform, provided that: (1) The intermediary receives the financial interest from the issuer as compensation for the services provided to, or for the benefit of, the issuer in connection with the offer or sale of such securities being offered or sold in reliance on Section 4(a)(6) through the intermediary's platform; and (2) the financial interest consists of securities of the same class and having the same terms, conditions and rights as the securities being offered or sold in reliance on Section 4(a)(6) through the intermediary's platform.

We are mindful of concerns raised by commenters that a prohibition could have a chilling effect on the ability of small issuers to use the crowdfunding exemption. These issuers may be small businesses or neighborhood establishments that may not have the liquid capital to compensate intermediaries for services. As commenters noted, allowing an intermediary to have or receive a financial interest in the issuer could provide a method for the issuer to pay an intermediary for its services, which may facilitate capital formation. This may, in turn, encourage the development of funding portals that are, for example, affiliated with CDFIs, as one commenter suggested.[626] As commenters further noted, permitting such a financial interest may also help to align the interests of intermediaries and investors, and provide an additional incentive to screen for fraud. We believe at this time the interest of promoting capital formation for small businesses, and developing a workable framework for securities-based crowdfunding, counsels against extending the prohibition on financial interests to the intermediary itself.

However, we are cognizant of the potential conflicts of interest that may arise, and therefore we are placing certain conditions on the ability of intermediaries to have a financial interest in an issuer that is offering or selling securities in reliance on Section 4(a)(6) through the intermediary's platform.[627] First, the intermediary must receive the financial interest from the issuer as compensation for the services provided to, or for the benefit of, the issuer in connection with the offer or sale of such securities being offered or sold in reliance on Section 4(a)(6).[628] We believe that this limitation, which will allow intermediaries to receive securities as payment for services but not otherwise permit them to invest in the offering, addresses commenters' concerns that a prohibition could have a ''chilling effect'' on the ability of small issuers to use the crowdfunding exemption, while serving to mitigate concerns relating to intermediaries taking steps to ''artificially inflate'' the value of securities in the offerings.[629] Second, we have considered the comments in support of limiting an intermediary's financial interest by requiring that such interest be the same as or not more favorable than those taken by investors in the offering,[630] and have determined to prohibit intermediaries from receiving a financial interest unless it is in securities that are of the same class, and that have the same terms, conditions and rights as the securities in the offering. We believe that this limitation will further serve to mitigate any potential conflicts by helping to align

certified Community Development Financial Institution (''CDFI'') is a specialized financial institution that works in market niches that are underserved by traditional financial institutions. CDFIs provide a unique range of financial products and services in economically distressed target markets, such as mortgage financing for low-income and first-time homebuyers and not-for-profit developers, flexible underwriting and risk capital for needed community facilities, and technical assistance, commercial loans and investments to small start-up or expanding businesses in low-income areas. CDFIs include regulated institutions such as community development banks and credit unions, and non-regulated institutions such as loan and venture capital funds.

[620] *See* Anonymous Letter 3.

[621] *See, e.g.,* Hackers/Founders Letter; Propellr 1 Letter; Public Startup Letter 2; RocketHub Letter.

[622] *See, e.g.,* Growthfountain Letter; Hackers/Founders Letter; Propellr Letter 1; RoC Letter; RocketHub Letter.

[623] *See* RocketHub Letter.

[624] *See* Hackers/Founders Letter.

[625] As we explained in the Proposing Release, the prohibition is intended to protect investors from the conflicts of interest that may arise when the persons facilitating a crowdfunding transaction have a financial stake in the outcome. 78 FR at 66461. The prohibition extends to ''any person occupying a similar status or performing a similar function,'' and applies with respect to both direct or indirect ownership of, or economic interest in, any class of the issuer's securities. In addition, we note that Section 15(b) of the Securities Act creates liability for persons who aid and abet violations of the Securities Act or the rules and regulations thereunder, such as would occur if a third person knowingly or recklessly provided substantial assistance to a director, officer or partner (or any person occupying a similar status or position), for example, by accepting and holding, on the officer's behalf, a financial interest in the issuer in circumvention of the prohibition.

[626] *See* Concerned Capital Letter.

[627] *See* notes 613–614 and accompanying text.

[628] As noted above in Section II.C.2, an intermediary must be either a registered funding portal or a registered broker-dealer, and must be a member of a registered national securities association. FINRA rules currently require that its broker-dealer members charge reasonable fees for their services and observe just and equitable principles of trade in the conduct of their business. FINRA has also filed a proposed rule change with the Commission to apply certain rules to funding portals, including requiring them to observe high standards of commercial honor and just and equitable principles of trade in the conduct of their businesses. *See* Proposed Rule Change to Adopt the Funding Portal Rules and Related Forms and FINRA Rule 4518, SR–FINRA–2015–040 (Oct. 9, 2015).

[629] *See* Consumer Federation Letter.

[630] *See* note 621.

the interests of the intermediary with those of the investors in the offering.[631]

We are persuaded that the disclosures otherwise required by Regulation Crowdfunding also will help to address any potential conflicts of interest arising from an intermediary having or receiving a financial interest in an issuer. Among other things, Rule 302(d) requires an intermediary to clearly disclose the manner in which it will be compensated in connection with offerings and sales of securities made in reliance on Section 4(a)(6) at account opening and Rule 303(f) requires disclosure of remuneration received by an intermediary (including securities received as remuneration) on confirmations.[632] We believe that these disclosures will provide investors with relevant information concerning any intermediary's financial interests (including whether such interest was acquired on the same terms that are available to investors), which, in turn, will help investors to make better informed investment decisions. In addition, the intermediary must comply with all other applicable requirements of Regulation Crowdfunding, including the statutory limitations on a funding portal's activities.[633]

Commission staff expects to review the compensation structure of intermediaries during the study of the federal crowdfunding exemption it plans to undertake no later than three years following the effective date of Regulation Crowdfunding.[634]

3. Measures To Reduce Risk of Fraud

Securities Act Section 4A(a)(5) requires an intermediary to ''take such measures to reduce the risk of fraud with respect to [transactions made in reliance on Section 4(a)(6)], as established by the Commission, by rule, including obtaining a background and securities enforcement regulatory history check on each officer, director, and person holding more than 20 percent of the outstanding equity of every issuer whose securities are offered by such person.'' As discussed below, after considering the comments, we are adopting Rule 301 of Regulation Crowdfunding substantially as proposed, with a few changes to Rule 301(c)(2).

a. Issuer Compliance

(1) Proposed Rule

We proposed in Rule 301(a) of Regulation Crowdfunding to require that an intermediary have a reasonable basis for believing that an issuer seeking to offer or sell securities though the intermediary's platform complies with the requirements of Section 4(a)(6) and the related requirements of Regulation Crowdfunding. For this requirement, we proposed that an intermediary may reasonably rely on an issuer's representations about compliance unless the intermediary has reason to question the reliability of those representations.

(2) Comments on Proposed Rule

Commenters generally agreed that intermediaries play a significant role in preventing and detecting fraud and should take measures to reduce potential fraud. Some commenters, however, expressed concerns about the proposed ''reasonable basis'' standard for an intermediary's belief about an issuer's compliance with applicable laws stating that the standard should be higher.[635] Others commenters supported the standard.[636]

A number of commenters expressed concern about the proposed reliance on issuer representations.[637] Some commenters suggested an intermediary should be required to conduct some type of due diligence on the issuer, as opposed to relying on issuer representations.[638] Another commenter went further by suggesting that an intermediary should also have an ongoing obligation to monitor communications by issuers during the course of the offering to detect and prevent violations of the securities laws and the regulations thereunder.[639] Another commenter stated that an issuer's representation should not suffice unless it is detailed enough to evidence a reasonable awareness by the issuer of its key obligations and the ability to comply with those obligations.[640]

One commenter argued that the language of the proposed rule was contradictory because relying on representations made by the issuer is not the same as establishing a reasonable basis for believing the issuer is in compliance.[641]

One commenter recommended that the Commission ''consider a tiered approach to compliance obligations'' where, as the size of the offering or other risk factors increased, intermediaries would be required to conduct more rigorous compliance reviews.[642] Under such an approach, this commenter stated that for small offerings that cap investments at a low level, $500 for example, and where there is no participation by individuals with a history of security law violations, the intermediary would be permitted to

[631] The rule does not preclude an intermediary from receiving securities as compensation for services from the same issuer for a subsequent offering conducted by the issuer in reliance on Section 4(a)(6) as long as the securities received are compensation for services provided during the subsequent offering and are of the same class and have the same terms, conditions and rights as the securities being offered in the subsequent offering.

[632] *See* Sections II.C.4.d and II.C.5.f. *See also* Rule 302(c) of Regulation Crowdfunding (requiring intermediaries to inform investors, at the time of account opening, that promoters must clearly disclose in all communications on the platform the receipt of compensation and the fact that he or she is engaging in promotional activities on behalf of the issuer).

[633] *See* Exchange Act Section 3(a)(80) (defining ''funding portal'' and establishing certain limitations on their activities consistent with the statute, such as prohibiting a funding portal from offering investment advice or recommendation; soliciting purchases, sales or offers to buy securities offered or displayed on its Web site or portal; or holding, managing, possessing, or otherwise handling investor funds or securities). In this regard, compliance with disclosures required by Regulation Crowdfunding generally would not cause a funding portal to provide investment advice or recommendations. Nonetheless, a funding portal should seek to ensure that disclosure of its financial interest(s) in an issuer is not inconsistent with the statutory prohibition on providing investment advice or recommendations. For example, a funding portal must not present its financial interest in an issuer as a recommendation or endorsement of that issuer. *See* Section II.D.3. We also note that if a funding portal holds, owns or proposes to acquire securities issued by an issuer, or multiple issuers, that individually or in aggregate exceed more than 40% of the value of the funding portal's total assets (excluding government securities and cash items) on an unconsolidated basis, the funding portal may fall within the definition of investment company under Section 3(a)(1)(C) of the Investment Company Act. We generally would expect, however, that such funding portal would seek to rely on the exclusion from the definition of investment company in Section 3(c)(2) of the Investment Company Act for (among other things) a person primarily engaged in the business of acting as a broker.

[634] *See* Section II.

[635] *See, e.g.,* AFR Letter; ASTTC Letter; Computershare Letter; Consumer Federation Letter; CSTTC Letter; Grassi Letter; Merkley Letter; NYSSCPA Letter.

[636] *See, e.g.,* RocketHub Letter; STA Letter.

[637] *See, e.g.,* AFR Letter; Computershare Letter; Consumer Federation Letter; Merkley Letter.

[638] *See, e.g.,* CSTTC Letter; Grassi Letter; NYSSCPA Letter; Consumer Federation Letter (stating that an intermediary's responsibility is rendered meaningless without establishing specific standards that require due diligence in order to reasonably conclude the issuer is in compliance).

[639] *See* AFR Letter (''[T]he Commission's proposal to allow intermediaries to rely on self-certification by issuers makes a mockery of its proposed requirement that intermediaries have 'a reasonable basis for believing that an issuer seeking to offer and sell securities in reliance on Section 4(a)(6), through the intermediary's platform, complies with the requirements in Securities Act Section 4A(b) and the related requirements in Regulation Crowdfunding.' '').

[640] *See* STA Letter.

[641] *See* ABA Letter.

[642] *See* IAC Recommendation; *see also* BetterInvesting Letter.

rely on representations by issuers to satisfy its obligation to ensure compliance. As the size of the offering, the size of permitted investments, or other risk factors increase, the commenter stated that the Commission should consider requiring intermediaries to conduct more rigorous compliance reviews.

(3) Final Rule

Rule 301(a), as adopted, requires that an intermediary have a reasonable basis for believing that an issuer seeking to offer and sell securities in reliance on Section 4(a)(6) through the intermediary's platform complies with the requirements in Securities Act Section 4A(b) and the related requirements in Regulation Crowdfunding. While some commenters argued for higher or different standards, such as requiring intermediaries to conduct due diligence on issuers or monitor communications by issuers during the course of the offering, we believe that a reasonable basis standard is appropriate, particularly in view of the issuer's own obligation to comply with the requirements in Section 4A(b) and the related requirements in Regulation Crowdfunding. We are mindful as well of the associated costs of a potentially higher standard. Consistent with the proposal, Rule 301(a) also permits intermediaries to reasonably rely on representations of the issuer, unless the intermediary has reason to question the reliability of those representations.

In satisfying the requirements of Rule 301(a), we emphasize that an intermediary has a responsibility to assess whether it may reasonably rely on an issuer's representation of compliance through the course of its interactions with potential issuers.[643] We agree with comments that an intermediary seeking to rely on an issuer representation should consider whether the representation is detailed enough to evidence a reasonable awareness by the issuer of its obligations and its ability to comply with those obligations. The specific steps an intermediary should take to determine whether it can rely on an issuer representation may vary, but should be influenced by and tailored according to the intermediary's knowledge and comfort with each particular issuer. We believe this approach is generally consistent with the view of one commenter that suggested a tiered approach to compliance obligations where intermediaries should conduct more rigorous compliance reviews and background checks as risk factors increase.[644]

b. Records of Securities Holders

(1) Proposed Rule

We proposed in Rule 301(b) of Regulation Crowdfunding a requirement that an intermediary have a reasonable basis for believing that an issuer has established means to keep accurate records of the holders of the securities it would offer and sell through the intermediary's platform. We proposed that an intermediary may reasonably rely on an issuer's representations about compliance unless the intermediary has reason to question the reliability of those representations. We did not propose a particular form or method of recordkeeping of securities, nor did we propose to require that an issuer use a transfer agent or other third party.[645] We noted, however, that requiring a registered transfer agent to be involved after the offering could introduce a regulated entity with experience in maintaining accurate shareholder records,[646] and we asked in the Proposing Release whether we should require an issuer to use a regulated transfer agent to keep such records and whether there were less costly means by which an issuer could rely on a third party to assist with the recordkeeping.[647]

(2) Comments on Proposed Rule

Commenters agreed that an intermediary should have a basis for believing that an issuer has established a means to keep accurate records.[648] Commenters were divided, however, between those who supported[649] and those who opposed[650] any requirement mandating the use of a registered transfer agent. Commenters supporting the required use of registered transfer agents cited potential benefits, including reducing internal costs and providing corporate transparency;[651] having the transfer agent serve as the issuer's paying agent, proxy agent, exchange agent, tender agent and mailing agent for ongoing reports;[652] providing a back-up and recovery system for records;[653] and conducting internal audits to protect against theft.[654] Some commenters also highlighted potential problems when non-registered transfer agents or the issuer maintains records, including improper registration of multiple owners, duplicate records, missing certificate numbers, inability to trace ownership, and inability to maintain records;[655] and incorrect handling of corporate actions, failure to observe restrictions on transfers, and failure to follow abandoned property reporting requirements.[656] One commenter suggested that the Commission should identify specific areas for an intermediary to consider about an issuer's recordkeeping capabilities when determining whether or not to provide access to that issuer.[657] This commenter also urged the Commission to create a safe harbor whereby an intermediary would be deemed to have met the recordkeeping requirement if the issuer has retained a registered transfer agent or registered broker-dealer.[658]

Commenters that opposed the mandatory use of a registered transfer

[643] In addition, an intermediary's potential liability under Securities Act Section 4A(c), as added by the JOBS Act, may encourage intermediaries to develop adequate procedures to fully assess whether reliance on an issuer's representation is reasonable. We also note that Congress provided a defense to any such liability if an intermediary did not know, and in the exercise of reasonable care could not have known, of the untruth or omission. Therefore, and as identified in the Proposing Release, we continue to believe that there are appropriate steps that intermediaries might take in exercising reasonable care in light of this liability provision. *See* Section II.E.5 (discussing scope of statutory liability).

[644] We also emphasize that when an intermediary seeks to rely on the representations of others to form a reasonable basis, the intermediary should have policies and procedures regarding under what circumstances it can reasonably rely on such representations and when additional investigative steps may be appropriate. *See* Section II.D.4.

[645] Proposing Release, 78 FR at 66462.

[646] *Id.*

[647] *Id.* at 66464.

[648] *See, e.g.,* Arctic Island Letter 5; ASTTC Letter; CFIRA Letter 8; Computershare Letter; CST Letter; CSTTC Letter; FAST Letter; Grassi Letter; Joinvestor Letter; Public Startup Letter 2; RocketHub Letter; STA Letter; Tiny Cat Letter.

[649] *See, e.g.,* ASTTC Letter; ClearTrust Letter; CST Letter; CSTTC Letter; Empire Stock Letter; Equity Stock Letter; FAST Letter; Sharewave Letter; Stalt Letter.

[650] *See, e.g.,* Arctic Island Letter 5; CapSchedule Letter; CFIRA Letter 8; Computershare Letter; Grassi Letter; Joinvestor Letter; NYSSCPA Letter; Public Startup Letter 2; RocketHub Letter; Tiny Cat Letter.

[651] *See* CST Letter.

[652] *See* Empire Stock Letter.

[653] *See* FAST Letter.

[654] *Id.*

[655] *See, e.g.,* ClearTrust Letter; STA Letter; Stalt Letter.

[656] *See* STA Letter.

[657] *Id.*

[658] *Id.* The commenter also stated that such a safe harbor would encourage third-party recordkeepers to register as transfer agents and thereby enhance protection to investors. The commenter further stated that the safe harbor should not apply if a community bank is utilized because it would not have similar recordkeeping experience. *See also* Computershare Letter (stating that a safe harbor should apply if another regulated entity, such as a broker-dealer or a bank, is engaged to perform the services, which in turn may encourage the use of professional regulated recordkeepers, thus enhancing overall protection in the crowdfunding market).

agent pointed to cost concerns.[659] Some of these commenters stated that alternatives to transfer agents will develop, including CPA firms,[660] registered broker-dealers[661] and software applications or other potential low-cost alternatives.[662] Some commenters stated that intermediaries should be permitted to provide the relevant recording services to issuers.[663] One commenter suggested funding portals should only be permitted to do so with respect to securities purchased on their platform or transferred among platforms, such that they would not be permitted to act as ''full-fledged [b]rokerage firms or transfer agents.''[664]

(3) Final Rules

After considering the comments, we are adopting Rule 301(b), as proposed, with one modification. Rule 301(b) as adopted requires an intermediary to have a reasonable basis for believing that an issuer has established means to keep accurate records of the holders of the securities it would offer and sell through the intermediary's platform, and provides that in satisfying this requirement, an intermediary may rely on the representations of the issuer concerning its means of recordkeeping unless the intermediary has reason to question the reliability of those representations. We also are adding a provision to Rule 301(b) as adopted stating that an intermediary will be deemed to have satisfied this requirement if the issuer has engaged the services of a transfer agent that is registered under Section 17A of the Exchange Act.[665] As we noted in the Proposing Release, we believe that the recordkeeping function may be provided by the issuer, a broker, a transfer agent or some other (registered or unregistered) person. We recognize that, as a commenter explained, recordkeeping functions can be extensive and could include, for example, the ability to (1) monitor the issuance of the securities the issuer offers and sells through the intermediary's platform, (2) maintain a master security holder list reflecting the owners of those securities, (3) maintain a transfer journal or other such log recording any transfer of ownership, (4) effect the exchange or conversion of any applicable securities, (5) maintain a control book demonstrating the historical registration of those securities, and (6) countersign or legend physical certificates of those securities. While the use of a registered transfer agent could introduce a regulated entity with experience in maintaining accurate shareholder records, as noted in the Proposing Release, we believe the issuer should have flexibility in establishing such means, and that such flexibility may allow for competition among service providers that could reduce operating costs for funding portals. We continue to believe that accurate recordkeeping can be accomplished by diligent issuers or through a variety of third parties. We note also that, for investors to have confidence in crowdfunding, issuers and intermediaries must have a shared interest in ensuring stability and accuracy of records. Therefore, intermediaries should consider the numerous obligations required of a record holder when determining whether an issuer has established a reasonable means to keep accurate records of the security holders being offered and sold securities through the intermediary's platform.

At the same time, mindful of the role that may be played by registered transfer agents in maintaining accurate shareholder records, we are providing a safe harbor for compliance with Rule 301(b) for those issuers that use a registered transfer agent. While we do not intend to provide regulated entities with a competitive advantage over other recordkeeping options that comply with the rule's requirements, we believe it is appropriate to provide certainty as to Rule 301(b) compliance in instances in which an issuer has engaged the services of a transfer agent that is registered under Section 17A of the Exchange Act.

c. Denial of Platform Access

(1) Proposed Rule

We also proposed in Rule 301(c)(1) of Regulation Crowdfunding a requirement that an intermediary deny access by an issuer to its platform if it has a reasonable basis for believing that an issuer, or any of its officers, directors or any person occupying a similar status or performing a similar function, or any 20 Percent Beneficial Owner is subject to a disqualification under proposed Rule 503.[666] In satisfying this requirement, we proposed to require an intermediary to, at a minimum, conduct a background and securities enforcement regulatory history check on each issuer whose securities are to be offered by the intermediary and on each officer, director or 20 Percent Beneficial Owner.

We further proposed in Rule 301(c)(2) to require an intermediary to deny access to its platform if the intermediary believes the issuer or offering presents the potential for fraud or otherwise raises concerns about investor protection. In satisfying this requirement, the proposed rule would require that an intermediary deny access if it believes that it is unable to adequately or effectively assess the risk of fraud of the issuer or its potential offering. In addition, we proposed in Rule 301(c)(2) that if an intermediary becomes aware of information after it has granted access that causes it to believe the issuer or the offering presents the potential for fraud or otherwise raises concerns about investor protection, the intermediary would be required to promptly remove the offering from its platform, cancel the offering, and return (or, for funding portals, direct the return of) any funds that have been committed by investors in the offering.

(2) Comments on Proposed Rule

Commenters generally supported proposed Rule 301(c).[667] Commenters noted with approval the discretion the proposed rules would provide intermediaries.[668] The ''reasonable basis'' standard in proposed Rule 301(c)(1) also garnered comments. One commenter suggested that the reasonable basis standard was not strong enough.[669] One commenter stated that having a reasonable basis standard in the disqualification determination would be ''difficult to imagine'' unless the Commission maintains a database for intermediaries to search.[670]

Commenters had varied views on the proposed requirement in Rule 301(c)(1) for an intermediary to perform a background check on the issuer and certain of its affiliated persons. Several commenters supported the requirement,

[659] *See, e.g.,* AICPA Letter; Arctic Island Letter 5; CapSchedule Letter; CFIRA Letter 8; Computershare Letter; Grassi Letter; Joinvestor Letter; RocketHub Letter; STA Letter; Tiny Cat Letter.

[660] *See, e.g.,* Grassi Letter; NYSSCPA Letter.

[661] *See* Public Startup Letter 2.

[662] *See* Arctic Island Letter 5.

[663] *See, e.g.,* Joinvestor Letter; RocketHub Letter.

[664] *See* RocketHub Letter.

[665] 15 U.S.C. 78q–1(c). We also note that an issuer's exemption from Section 12(g) is conditioned on, among other things, that issuer engaging a registered transfer agent. *See* Section II.E.4.

[666] *See* Section II.E.6 (discussing Rule 503 of Regulation Crowdfunding, which describes disqualification).

[667] *See, e.g.,* CFA Institute Letter; StartupValley Letter.

[668] *Id.*

[669] *See* NYSSCPA Letter (opposing the use of two different standards within Rule 301(c) as it could lead to confusion and presents vulnerability for fraud to occur through the ''weakest link,'' and suggesting instead that a ''prudent care'' standard should be used for both requirements).

[670] *See* Public Startup Letter 2.

but a few commenters suggested ways to decrease costs.[671] One commenter stated that only low-cost, minimum requirements should be implemented,[672] while another commenter suggested that the background checks be required only after an issuer has met its target offering amount so as to prevent unnecessary expense to the intermediary.[673] Representing a different view, one commenter opposed a requirement for background checks to be conducted on all persons related to an issuer.[674] Another commenter noted that the checks would be appropriate, but did not support the requirement.[675]

Commenters were divided as to whether we should set specific requirements for background checks. One commenter stated that the proposal ''fails to set even the most general of standards for these checks'' and ''instead relies on intermediaries to use their experience and judgment to reduce the risk of fraud.'' [676] The same commenter stated that the proposed approach is flawed and as such the checks are likely to be ineffective, especially because many intermediaries are likely to be inexperienced.[677] Several commenters requested further clarification and specification about required checks.[678] However, other commenters stated that the Commission should not specify steps for an intermediary to take in conducting checks.[679]

With respect to our request for comment on whether intermediaries should be required to make the results of background checks public, several commenters opposed the requirement,[680] while some supported it.[681] Another commenter stated its view that the results should not be made public unless a regulator called them into question.[682] Another commenter explained that issuers should be able to publish the results if they choose, but no such requirement should be placed on intermediaries.[683] One commenter urged us to ''require that a summary of the sources consulted as part of the background check be posted on the [portal's] Web site.'' [684]

As to proposed Rule 301(c)(2) requiring a funding portal to deny access if the intermediary believes the issuer or offering presents the potential for fraud or otherwise raises concerns regarding investor protection, one commenter stated that the proposed requirement conflicts with the restrictions on a funding portal's ability to limit the offerings on its platform in proposed Rule 402(b)(1).[685]

Regarding the standard for denial based on potential fraud or investor protection concerns in the proposed rule, one commenter suggested a stronger standard,[686] while another suggested a weaker standard.[687] Other commenters suggested that the standard for an intermediary to deny access to its platform is unclear.[688] One commenter urged the Commission to require that a funding portal post on its Web site a description of its standards for determining which offerings present a risk of fraud.'' [689]

One commenter stated the intermediaries should be required to report denied issuers, noting that it would not only help prevent fraud but also assist other intermediaries in excluding issuers already discovered to be disqualified.[690] Other commenters disagreed with this suggestion,[691] while one commenter stated that reporting should be required only if the Commission or another agency created a database for such information.[692] One of these commenters suggested that intermediaries should be required to notify a potential issuer when the intermediary uses information from a third party to deny the issuer.[693]

(3) Final Rules

After considering the comments, we are adopting Rule 301(c)(1) as proposed. Rule 301(c)(1) requires an intermediary to deny access to its platform if the intermediary has a reasonable basis for believing that an issuer, or any of its officers, directors (or any person occupying a similar status or performing a similar function), or any 20 Percent Beneficial Owner is subject to a disqualification under Rule 503 of Regulation Crowdfunding. We believe that a ''reasonable basis'' standard for denying access is an appropriate standard for Rule 301(c)(1), in part because this requirement on an intermediary is buttressed by the fact that an issuer independently is subject to the disqualification provisions under Rule 503, as discussed below.[694] In addition, Rule 301(c)(1) implements the requirement of Section 4A(a)(5) that an intermediary conduct a background and securities enforcement regulatory history check on each issuer whose securities are to be offered by the intermediary, as well as on each of its officers, directors (or any person occupying a similar status or performing a similar function) and 20 Percent Beneficial Owners.

While we understand commenters' concerns about the cost of the requirement that intermediaries conduct background checks on issuers and certain affiliated persons, we are not eliminating or limiting the requirement as suggested by commenters because we believe the requirement is an important tool for intermediaries to employ when determining whether or not they have a reasonable basis to allow issuers on their platforms. Even though a number of commenters requested that the

[671] *See, e.g.,* AFR Letter; CFA Institute Letter; Grassi Letter; Joinvestor Letter; NYSSCPA Letter.

[672] *See* RocketHub Letter.

[673] *See* Anonymous Letter 4.

[674] *See* Zhang Letter.

[675] *See* Public Startup Letter 2.

[676] *See* Consumer Federation Letter.

[677] *Id.*

[678] *See, e.g.,* BetterInvesting Letter; Heritage Letter; IAC Recommendation; Jacobson Letter; NSBA Letter. *See also* RocketHub Letter (stating that intermediaries ''should be allowed to satisfy their obligations by checking commonly used databases for criminal background, bankruptcy filings, and tax liens, as well as cross check against the Office of Foreign Assets Control (OFAC) sanctions lists, and Specially Designated Nationals (SDN) and Blocked Persons lists''); Bullock Letter (recommending fingerprinting for key issuer personnel and noting that most sheriff's departments in most U.S. counties can take fingerprints for a small fee).

[679] *See, e.g.,* StartupValley Letter; Vann Letter.

[680] *See, e.g.,* Grassi Letter; Joinvestor Letter; NYSSCPA Letter; Public Startup Letter 2; StartupValley Letter.

[681] *See, e.g.,* AFR Letter; Consumer Federation Letter.

[682] *See* Joinvestor Letter.

[683] *See* Public Startup Letter 2.

[684] IAC Recommendation (suggesting that ''[r]equiring posting of information about the sources consulted in compiling the reports would better enable investors to evaluate the thoroughness of the background check, thus creating an incentive for intermediaries to conduct thorough reviews in the absence of clear Commission guidelines''); *see also* BetterInvesting Letter.

[685] *See* Guzik Letter 1 (noting that under the proposed rules, an intermediary which is not a broker-dealer is prohibited from, at least in that commenter's view, ''curating,'' that is, ''excluding companies from its platform based upon qualitative factors, such as quality of management, valuation of the company, market size, need for additional capital, pending litigation, or other qualitative factors which increase the risk to an investor'').

[686] *See* note 669 (discussing the NYSSCPA Letter, which suggested a ''prudent care'' standard for denying issuers under Rule 301(c)).

[687] *See* Grassi Letter (stating that an intermediary ''should not be required to vet issuers for potential fraud other than would be done through the normal course of assessing whether they wish to do business with a particular issuer'').

[688] *See, e.g.,* BetterInvesting Letter; Heritage Letter; IAC Recommendation; Jacobson Letter; NSBA Letter.

[689] *See* IAC Recommendation; *see also* BetterInvesting Letter.

[690] *See* Joinvestor Letter. *See also* ASSOB Letter and Vann Letter.

[691] *See, e.g.,* Public Startup Letter 2 (opposing the requirement but suggesting that the Commission maintain a database of known bad actors).

[692] *See* StartupValley Letter.

[693] *See* Vann Letter.

[694] *See* Section II.E.6 (discussing issuer disqualification).

Commission provide specific requirements for background and securities enforcement regulatory history checks, we are not establishing specific procedures in the final rules. As we indicated in the Proposing Release, we believe that the better approach is to allow an intermediary to be guided by its experience and judgment to design systems and processes to help reduce the risk of fraud in securities-based crowdfunding.[695] We also believe that such flexibility could mitigate cost concerns related to conducting the background and securities enforcement regulatory history checks.

We are not developing a database of denied issuers as suggested by some commenters because we do not believe it would significantly increase investor protection. The requirement to deny an issuer access to a crowdfunding platform under the final rules based on fraud or other investor protection concerns is important to the viability of crowdfunding, and the legitimacy of the intermediary. This obligation is the responsibility of each intermediary, which must make a determination about whether to deny access to an issuer. While a third party may decide to create a database of denied issuers at some point and an intermediary could use such a database to help make its determination as to whether it was required to deny access to an issuer, such a database could not be used as a substitute for an intermediary making its own determination.

We also are not requiring an intermediary to make publicly available the results of the background checks or the sources consulted. We believe that the goal of the background check is sufficiently served by the exclusion of an issuer from the intermediary's platform. We do not believe that making the results or sources publicly available adds a significant degree of investor protection under these circumstances, given the potential problems that could arise from such public disclosure of the results, such as the risk of disclosing personally identifiable information or other information with significant potential for misuse. In addition, we are concerned that such requirements could add to the cost of administration and could expose the individuals at the issuer that are subject to a background check to harm, for example, if there were errors in the information made publicly available.

We are adopting Rule 301(c)(2) substantially as proposed, but with certain revisions. As adopted, Rule 301(c)(2) now contains a ''reasonable basis'' standard as opposed to the initially proposed ''believes'' standard. Rule 301(c)(2) requires denial of access to its platform when the intermediary has a reasonable basis for believing that the issuer or offering presents the potential for fraud or otherwise raises concerns about investor protection.[696] In a conforming change, Rule 301(c)(2) also requires (i) an intermediary deny access to an issuer if it reasonably believes that it is unable to adequately or effectively assess the risk of fraud of the issuer or its potential offering, and (ii) if the intermediary becomes aware of information after it has granted the issuer access to its platform that causes it to reasonably believe that the issuer or the offering presents the potential for fraud or otherwise raises concerns regarding investor protection, the intermediary must promptly remove the offering from its platform, cancel the offering and return to investors any funds they may have committed.

We believe that a ''reasonable basis'' standard is appropriate for Rule 301(c)(2) because it is a more objective standard.[697] Under this standard, an intermediary may not ignore facts about an issuer that indicate fraud or investor protection concerns such that a reasonable person would have denied access to the platform or cancelled the offering. Rule 301(c)(2) is intended to give an intermediary an objective standard regarding the circumstances in which it must act to protect its investors from potentially fraudulent issuers or ones that otherwise present red flags concerning investor protection. This objective standard also will make it easier for an intermediary to assess whether it would be compliant with Rule 301(c)(2) when deciding if it should deny an issuer access or cancel its offering.[698] Thus, we believe these measures likely will promote compliance and help to reduce the risk of fraud with respect to crowdfunding transactions, as required by Section 4A(a)(5). This standard also will provide the Commission with a clear basis to review whether an intermediary's decision not to deny access to its platform or cancel an offering was reasonable given the facts and circumstances.

We are not requiring that an intermediary report the issuers that have been denied access to its platforms, as some commenters suggested, or that the intermediary post a summary of the sources consulted as part of the background check on its platform along with a description of the intermediary's standards for determining which offerings present a risk of fraud. We also are not adopting a requirement, as suggested by a commenter, that an intermediary notify a potential issuer when the intermediary utilizes third-party information to deny access to the issuer. As with background checks, discussed above, we believe that the investor protection goal is sufficiently served by the exclusion of an issuer from the intermediary's platform. In addition, we are concerned that such requirements could add to the cost of administration and could expose the issuers in question to harm, for example, if there were errors in the information made publicly available. Likewise, we do not believe that requiring an intermediary to post to its Web site a summary of the sources consulted as part of the background check and a description of the intermediary's standards for determining which offerings present a risk of fraud would sufficiently increase investor protection to justify the burdens, such as those outlined above, that would be associated with imposing such requirements. We also note that providing this information on an intermediary's Web site may give potentially fraudulent issuers or those that otherwise present investor protection concerns a roadmap to an intermediary's proprietary procedures for screening for fraud that could assist such issuers with impeding or obstructing intermediaries from detecting offerings that present a risk of fraud.

[695] We disagree with the commenter that suggested that this method is ineffective because intermediaries lack experience. *See* Consumer Federation Letter. Crowdfunding is a new form of capital formation. We believe broker-dealers and funding portals will gain the relevant experience that will appropriately position them to develop requirements for conducting background checks required by the rule. In addition, we believe that an intermediary's interest in developing a successful platform will motivate it to conduct rigorous background checks.

[696] *See* Section II.D.2. (discussing modified Rule 402(b)(1), which relates to a funding portal's ability to deny access to an issuer).

[697] Adding the reasonable basis standard to Rule 301(c)(2) also provides a consistent standard across Rule 301, including Rules 301(a), (b) and (c)(1).

[698] Aside from the requirement to deny access to issuers under Rule 302(c)(2), it is important to note that intermediaries are permitted to determine whether and under what terms to allow an issuer to offer and sell securities in reliance on Section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) through their platforms. *See* Rule 402(b)(1) and Section II.D.3. The objective standard under Rule 301(c)(2) also helps to clarify that a funding portal would not be providing investment advice or recommendations, if it denies access to or cancels an offering because it has a reasonable basis for believing that there is a potential for fraud or other investor protection concerns. *See* Rule 402(b)(10) of Regulation Crowdfunding and Section II.D.3.i.

4. Account Opening

a. Accounts and Electronic Delivery

(1) Proposed Rule

Proposed Rule 302(a)(1) of Regulation Crowdfunding would prohibit an intermediary or its associated persons from accepting an investment commitment in a transaction involving the offer or sale of securities in reliance on Section 4(a)(6) unless the investor has opened an account with the intermediary, and the intermediary has obtained from the investor consent to electronic delivery of materials. Proposed Rule 302(a)(2) would require an intermediary to provide all information required by Subpart C of Regulation Crowdfunding, including, but not limited to, educational materials, notices and confirmations, through electronic means.

Proposed Rule 302(a)(2) also would require an intermediary to provide such information through an electronic message that either contains the information, includes a specific link to the information as posted on the intermediary's platform, or provides notice of what the information is and that it is located on the intermediary's platform or the issuer's Web site. As proposed, Rule 302(a)(2) stated that electronic messages would include, but not be limited to, messages sent via email.

(2) Comments on the Proposed Rule

One commenter suggested that intermediaries who are brokers should not be required to open new accounts for persons who are existing customers of the broker.[699] In response to our request for comments on whether an intermediary should be required to obtain specific information from investors, and if so what type of information should be required, some commenters generally supported requiring an intermediary to gather specific information from investors, particularly identifying information that could help prevent duplicate or fraudulent accounts and information about other intermediary accounts and investments.[700] A few of these commenters supported the Commission requiring intermediaries to collect investors' social security numbers.[701] One commenter opposed the Commission requiring intermediaries to obtain particular information from investors.[702]

With respect to electronic delivery, some commenters urged that it should be sufficient for the intermediary simply to make Subpart C materials, such as educational materials, notices and confirmations, available on the intermediary's platform for investors to access.[703] Other commenters broadly opposed permitting intermediaries to satisfy their information delivery requirement by providing an electronic message that informs an investor that information can be found on the intermediary's platform or an issuer's Web site.[704] One commenter suggested that investors may not actually receive required disclosures because they will not spend the time to find the information.[705] Another commenter suggested that the Commission should ''continue to rely instead on the strong and effective policy for electronic delivery of disclosure adopted by the Commission in the mid-1990s.'' [706] The same commenter noted that it would be ''a simple matter to require that any electronic message through which disclosures are delivered include, at a minimum, the specific URL where the required disclosures can be found.'' [707]

One commenter stated it was concerned that earlier Commission policies on electronic delivery might be read as implying that paper delivery might be permitted in certain circumstances.[708] This commenter did agree, however, that any electronic message through which disclosures are delivered include, at a minimum, the specific URL where the required disclosures can be found.[709]

In response to our request for comments on whether exceptions to the consent to electronic delivery should be allowed, one commenter stated that account creation and delivery of communication should be completed digitally and that there should be no exemption to allow paper delivery as a substitute.[710] Another commenter stated that investors should be allowed to waive these delivery requirements entirely.[711]

(3) Final Rules

After considering the comments, we are adopting as proposed the account opening and electronic delivery requirements in Rule 302(a). We are not prescribing particular requirements for account opening. Rather, we believe that the final rule provides flexibility to intermediaries given that intermediaries are better positioned than the Commission to determine what information and processes it will require, both as a business decision and to ensure compliance with all applicable regulatory requirements. Therefore, for example, an intermediary can decide whether or not to open a new account for an existing customer. We also are not prescribing under the final rule, as a commenter suggested, that an intermediary be required to collect identifying information that could help prevent duplicative or fraudulent accounts. We believe that even without prescribing particular account opening requirements intermediaries should be able to identify, by collecting basic account opening information, those accounts that appear to be duplicative or present red flags of potential fraud.

However, the final rules do not permit investors to waive the electronic delivery requirements entirely, as one commenter suggested.[712] We believe that electronic delivery of materials in connection with crowdfunding offerings serves an important and basic investor protection function by conveying information, such as offering materials, that will help investors to make better informed investment decisions and by a method that is appropriately suited to the electronic and Internet-based nature of crowdfunding transactions.

As explained in Section II.A.3, Rule 100(a)(3) of Regulation Crowdfunding requires that crowdfunding transactions be conducted exclusively through an intermediary's platform. Rule 302(a) implements this requirement by requiring that investors consent to electronic delivery of materials in connection with crowdfunding offerings.[713] This requirement applies to

[699] *See* Arctic Island Letter 2.

[700] *See, e.g.,* Consumer Federation Letter; Jacobson Letter; RocketHub Letter.

[701] *See, e.g.,* Consumer Federation Letter; RocketHub Letter.

[702] *See* Public Startup Letter 3.

[703] *See, e.g.,* ASSOB Letter; CrowdCheck Letter 1; RocketHub Letter; Wefunder Letter; Vann Letter.

[704] *See, e.g.,* BetterInvesting Letter; AFR Letter; IAC Recommendation; Consumer Federation Letter (''The definition of electronic delivery must be revised to ensure the disclosures themselves, and not just notices of the availability of disclosures, are delivered to investors.'').

[705] *See* Consumer Federation Letter. *See also* Clapman Letter (suggesting that all issuers and their materials must be ''publicly accessible for all investors to have the same opportunity to invest'' and stating that ''no clubs, or paid to view investment style platforms would therefore be allowed'').

[706] IAC Recommendation; *see also* BetterInvesting Letter.

[707] IAC Recommendation; *see also* BetterInvesting Letter.

[708] *See* CFIRA Letter 12.

[709] *Id.*

[710] *See* RocketHub Letter.

[711] *See* Public Startup Letter 3.

[712] *Id.*

[713] Certain requirements of Regulation Crowdfunding that require timely actions by issuers and investors will be facilitated by requiring

Continued

all investors, including an existing customer of a registered broker that has not already consented to electronic delivery of materials. Therefore, this requirement will prohibit intermediaries from accepting an investment commitment in a Section 4(a)(6) offering from any investor that has not consented to electronic delivery.

We are adopting substantially as proposed Rule 302(a)(2), which requires that all information required to be provided by an intermediary under Subpart C be provided through electronic means. We have considered the comments but do not believe that it would be sufficient—or consistent with our previous statements about electronic media—for the intermediary simply to make Subpart C materials, such as educational materials, notices and confirmations, available on the intermediary's platform for investors to access.[714] Rather, unless otherwise indicated in the relevant rules of Subpart C,[715] the intermediary must provide the information either through (1) an electronic message that contains the information, (2) an electronic message that includes a specific link to the information as posted on the intermediary's platform, or (3) an electronic message that provides notice of what the information is and notifies investors that this information is located on the intermediary's platform or on the issuer's Web site.[716] We have added to the rule text other examples of electronic messages that are permissible in addition to email messages—specifically text, instant messages, and messages sent using social media.

b. Educational Materials

(1) Proposed Rules

Securities Act Section 4A(a)(3) states that an intermediary must ''provide such disclosures, including disclosures related to risks and other investor education materials, as the Commission shall, by rule, determine appropriate,'' but it does not elaborate on the scope of this requirement. As described in further detail below, proposed Rule 302(b)(1) of Regulation Crowdfunding would require intermediaries to deliver to investors, at account opening, educational materials that are in plain language and otherwise designed to communicate effectively and accurately certain specified information. Proposed Rules 302(b)(1)(i)–(viii) would require the materials to include:

- The process for the offer, purchase and issuance of securities through the intermediary;
- the risks associated with investing in securities offered and sold in reliance on Section 4(a)(6);
- the types of securities that may be offered on the intermediary's platform and the risks associated with each type of security, including the risk of having limited voting power as a result of dilution;
- the restrictions on the resale of securities offered and sold in reliance on Section 4(a)(6);
- the types of information that an issuer is required to provide in annual reports, the frequency of the delivery of that information, and the possibility that the issuer's obligation to file annual reports may terminate in the future;
- the limits on the amounts investors may invest, as set forth in Section 4(a)(6)(B);
- the circumstances in which the issuer may cancel an investment commitment;
- the limitations on an investor's right to cancel an investment commitment;
- the need for the investor to consider whether investing in a security offered and sold in reliance on Section 4(a)(6) is appropriate for him or her; and
- that following completion of an offering, there may or may not be any ongoing relationship between the issuer and intermediary.

Proposed Rule 302(b)(2) would further require intermediaries to make the current version of the educational materials available on their platforms, and to make revised materials available to all investors before accepting any additional investment commitments or effecting any further transactions in securities offered and sold in reliance on Section 4(a)(6).

(2) Comments on Proposed Rules

Commenters generally supported distribution of educational materials through intermediaries.[717] Some stated that intermediaries should be required to submit educational materials to the Commission or to FINRA because oversight and review is needed for materials that will be used by unsophisticated investors,[718] while others stated that intermediaries should not be required to submit educational materials to the Commission or to FINRA because it would be cumbersome and expensive.[719] One commenter stated that the proposed requirements should be modified to state that education must be done prior to an investor's first investment in a Section 4(a)(6) offering, not at account opening.[720]

Some commenters suggested that additions be made to the scope of information proposed to be required in an intermediary's educational materials,[721] to include information about exit strategies; [722] principles of investing in crowdfunding and how to evaluate investment opportunities in privately held companies; [723] the risks associated with crowdfunding investments; [724] and reasons for investors to maintain their own personal records concerning crowdfunding investments.[725] One commenter

consent to electronic delivery of documents. *See, e.g.,* Section II.C.6 (discussing the five-day periods for investor reconfirmations based on material changes and issuer cancellation notices).

[714] *See Use of Electronic Media,* Release No. 34–42728 (Apr. 28, 2000) [65 FR 25843, 25853 (May 4, 2000)] (discussing the ''access equals delivery'' concept and citing *Use of Electronic Media for Delivery Purposes,* Release No. 34–36345 (Oct. 6, 1995) [60 FR 53548, 53454 (Oct. 13, 1995)]).

[715] For example, Rule 303(a) separately requires that an intermediary must make issuer information publicly available on its platform, and so we do not believe that it is necessary to further require intermediaries to send an electronic message regarding the posting of issuer materials.

[716] As noted above, this electronic message could include a specific link to the information as posted on the intermediary's platform. However, we are not requiring intermediaries to provide a link to direct investors to the intermediary's platform or the issuer's Web site where the information is located. We believe that the final rule provides some flexibility to intermediaries when providing required information through electronic messages given that intermediaries are well-positioned to determine how best to ensure compliance with all applicable regulatory requirements. We also believe that, because of the widespread use of the Internet, as well as advances in technology that allow funding portals to send various electronic messages, our final rule requires sufficient notice to investors.

[717] *See, e.g.,* Arctic Island Letter 6; CFA Institute Letter; Cole Letter; Consumer Federation Letter; Gimpelson Letter 2; Heritage Letter; Jacobson Letter; NSBA Letter; Patel Letter; RocketHub Letter; STA Letter; StartupValley Letter; Wefunder Letter.

[718] *See, e.g.,* Consumer Federation Letter; Gimpelson Letter 2; Jacobson Letter. *See also* RocketHub Letter (stating that ''if educational materials are submitted to the Commission for approval, such approval should act to limit liability of the Portal under the Act'').

[719] *See, e.g.,* Arctic Island Letter 6; Joinvestor Letter; StartupValley Letter; Wefunder Letter.

[720] *See* Arctic Island Letter 6. The commenter also stated that the educational material requirements should only apply to unaccredited investors, but we note that the requirement under Section 4A(a)(4) runs to ''each investor.'' As discussed above, we believe that Congress intended for crowdfunding transactions under Section 4(a)(6) to be available equally to all types of investors. Consistent with that approach, we do not believe at this time it would be appropriate to tailor the educational requirements for any particular type of investor or to create an exemption for accredited investors. Further, issuers can rely on other exemptions to offer and sell securities to accredited investors or institutional investors.

[721] *See, e.g.,* Anonymous Letter 1; Gimpelson Letter 2; RocketHub Letter; STA Letter; Angel Letter 1.

[722] *See* Anonymous Letter 1.

[723] *See* Gimpelson Letter 2.

[724] *See* RocketHub Letter.

[725] *See* STA Letter.

suggested that educational materials ''should include an industry standard disclosure document on the benefits and risks of crowdfunding investments.'' [726] This commenter indicated that ''having these generic risk factors in the industry standard educational materials will help focus the company specific disclosure on the factors that are most important.'' [727]

Some commenters suggested that intermediaries should be required to design questionnaires to increase investor knowledge and to monitor whether investors actually access materials.[728] One commenter suggested that in addition to an ''interactive questionnaire,'' the Commission should also ''require that investors reaffirm each time they invest that they understand the risks associated with crowdfunding, can afford to lose their entire investment, and do not expect to need the funds being invested in the near term.'' [729]

Some commenters stated that we should develop model educational materials for investors or specify the content for intermediaries.[730] One commenter suggested that the Commission, state securities regulators, and FINRA, together, should develop ''a sample guide'' designed to alert investors to the risks of crowdfunding including, among other things, ''the high failure rate of small startup companies, the fact that shares will not be set based on market data and may therefore be mispriced, the lack of liquidity, and the risk that, absent appropriate protections, the value of their shares could be diluted.'' [731] This commenter also suggested that the guide ''should include explicit warnings that investors should not invest in crowdfunding unless they can afford to lose the entire amount of their investment or if they expect to have an immediate need for the funds.'' [732] This commenter also stated that regulators should test the materials with investors to ensure their effectiveness.[733]

One commenter stated that we should not limit or specify the type of electronic media being used to communicate educational material.[734] Finally, one commenter opposed all the educational requirements for intermediaries, and suggested instead that the Commission itself, rather than intermediaries, should provide investor educational materials to both investors and issuers with funding portals linking to, for example, the SEC Web page or an open source Web site containing any Commission drafted educational materials.[735]

(3) Final Rules

After considering the comments, we are adopting Rule 302(b) relating to educational materials substantially as proposed, but adding one further requirement as to the content of the materials. We believe that, consistent with Section 4A(a)(3) it is appropriate that intermediaries, rather than the Commission (as a commenter suggested), be required to provide such disclosures, including disclosures related to risks and other investor education materials as the Commission determines to be appropriate. We believe that intermediaries are better equipped and positioned, as compared to the Commission, to provide educational materials to investors that are reasonably tailored to an intermediary's offerings and investors, particularly in light of their access to and interactions with investors.

We further believe that the scope of information that we are requiring to be included in an intermediary's educational materials is appropriate. In the Proposing Release we discussed our rationales for requiring the different types of disclosures in the educational materials. As we noted in the Proposing Release, we generally drew upon the statutory provisions when including disclosures required in the educational materials relating to the risks of investing in securities offered and sold in reliance on Section 4(a)(6), investors' cancellation rights, resale restrictions and issuer reporting.[736] The circumstances in which an investor can cancel an investment commitment and obtain a return of his or her funds are particularly important to an investor's understanding of the investment process and may affect an investor's decision to consider any offerings made pursuant to Section 4(a)(6). The items required to be included, pursuant to Rule 302(b)(1)(i) through (viii), in the educational materials are basic terms, relevant to transactions conducted in reliance on Section 4(a)(6), of which all investors should be aware before making an investment commitment. Furthermore, information on the various types of securities that can be available for purchase on the intermediary's platform, any applicable resale restrictions, and the risks associated with each type of security, including the risk of having limited voting power as a result of dilution can affect an investor's decision to consider any offerings made pursuant to Section 4(a)(6). In addition, we are adding Rule 302(b)(1)(ix) to require the educational materials to indicate that under certain circumstances an issuer may cease to publish annual reports and, therefore, an investor may not continually have current financial information about the issuer. We are adding this requirement because we believe that it is important for investors to be able to consider the ongoing availability of information about an issuer's financial condition when they assess whether to invest in that issuer.

The final rule provides each intermediary with sufficient flexibility to determine: (1) The content of the educational materials, outside of the minimum specified information required to be included under Rule 302(b)(1)(i)–(viii), and (2) the overall format and manner of presentation of the materials. We believe this flexibility will allow the intermediary to prepare and present educational materials in a manner reasonably tailored to the types of offerings on the intermediary's platform and the types of investors accessing its platform. While we have determined not to provide model educational materials, impose additional content (beyond those proposed) or format requirements, mandate particular language or manner of presentation, or require that an intermediary design an investor questionnaire, as suggested by commenters, the final rules do not prohibit an intermediary from providing additional educational materials if they

[726] *See* Angel Letter 1.

[727] *Id.* (suggesting an issuer-specific disclosure document).

[728] *See, e.g.,* AFR Letter; BetterInvesting Letter; Consumer Federation Letter; IAC Recommendation. One commenter also suggested requiring intermediaries to post a list of previous offerings on their Web sites with information about the offerings. *See* Angel Letter 1.

[729] IAC Recommendation; *see also* BetterInvesting Letter.

[730] *See, e.g.,* CFA Institute Letter; Guzik Letter 1; Heritage Letter; Jacobson Letter; Joinvestor Letter; NSBA Letter; STA Letter. *See also* CfPA Letter (stating that guidance on the requirements for educational materials and certification of compliance should be created and administered by an industry-related body with approval and oversight by the Commission).

[731] IAC Recommendation; *see also* BetterInvesting Letter.

[732] *Id.*

[733] *Id.* (suggesting that the Commission should take additional steps ''to strengthen requirements with regard to content and delivery of educational materials in order to increase the likelihood both that they will be read and that they will clearly convey the essential information''); *see also* CFIRA Letter 12 (agreeing with IAC's suggestion that the Commission ''could establish a set of standard educational requirements for the industry that could be adopted by intermediaries'').

[734] *See* Gimpelson Letter 2.

[735] *See* Public Startup Letter 3.

[736] *See* Securities Act Sections 4A(a)(4), 4A(a)(7), 4A(e), and 4A(b)(4).

choose. For example, because the final rules do not require an intermediary to design a questionnaire, intermediaries maintain the flexibility in meeting the rule's requirements to determine whether such a disclosure format would be cost effective and appropriate particularly in light of that intermediary's particular business model. We further note the suggestion by some commenters that we require additional information in the educational materials, including, for example, requiring an intermediary to discuss exit strategies, how to evaluate investment opportunities in privately held companies, and the reasons for investors to maintain their own personal records concerning crowdfunding investments. Although these suggestions may provide investors with some useful information, we are not persuaded that imposing such additional requirements in the final rule is necessary at this time as it is unclear that those suggestions would significantly strengthen the investor protections that will result from Rule 302(b) as adopted. We also believe that adding such requirements may overly complicate these educational materials and increase the costs associated with preparing them. Therefore, we have determined to allow intermediaries the flexibility to prepare educational materials reasonably tailored to their offerings and investors, provided the materials meet the standards and include the information required to be provided under Rule 302(b).[737]

We also recognize that FINRA or any other registered national securities association may implement additional educational materials requirements. We are not, however, as one commenter suggested,[738] requiring at this time that intermediaries submit their educational materials to the Commission or to a registered national securities association for review and approval. We note, however, that a registered national securities association could propose such a requirement as its oversight of intermediaries in this new market evolves. Any such proposed requirement would be considered by the Commission, and subject to public notice and opportunity for comment, pursuant to Exchange Act Section 19(b) and Rule 19b–4.

Rule 302(b)(2) requires an intermediary to keep its educational materials accurate. Accordingly, an intermediary must update the materials as needed to keep them current. In addition, if an intermediary makes a material revision to its educational materials, the rule requires that the intermediary make the revised educational materials available to all investors before accepting any additional investment commitments or effecting any further crowdfunding transactions. An intermediary will also be required to obtain a representation that an investor has reviewed the intermediary's most recent educational materials before accepting an investment commitment from the investor.[739]

We believe that these requirements will benefit investors by helping to ensure that they receive information about key aspects of investing through the intermediary's platform, including aspects that may have changed since the last time they received the materials, prior to making investment commitments, as that information can influence their investment decisions. We also believe that requiring intermediaries to update materials on an ongoing basis, rather than at certain specified intervals, will help to ensure that those materials are updated as circumstances warrant, which, in turn, will provide investors with more current information and increase investor protection.

c. Promoters

(1) Proposed Rule

Securities Act Section 4A(b)(3) provides that an issuer shall ''not compensate or commit to compensate, directly or indirectly, any person to promote its offerings through communication channels provided by a broker or funding portal, without taking such steps as the Commission shall, by rule, require to ensure that such person clearly discloses the receipt, past or prospective, of such compensation, upon each instance of such promotional communication.'' Under Rule 205 of Regulation Crowdfunding, as discussed above, an issuer can compensate persons to promote its offerings through communications channels provided by the intermediary on its platform, where certain conditions are met.[740]

We separately proposed in Rule 302(c) of Regulation Crowdfunding to require the intermediary to inform investors, at the account opening stage, that any person who promotes an issuer's offering for compensation, whether past or prospective, or who is a founder or an employee of an issuer that engages in promotional activities on behalf of the issuer on the intermediary's platform, must clearly disclose in all communications on the platform the receipt of the compensation and the fact that he or she is engaging in promotional activities on behalf of the issuer.

(2) Comments on Proposed Rules

Some commenters suggested that the promoter disclosures should not be made at account opening where they may be ignored.[741] One commenter proposed that the disclosures should be made ''prior to any participant on the platform being able to post comments, reviews, ratings, or other promotional activities.'' [742]

(3) Final Rules

We are adopting, as proposed, Rule 302(c) requiring intermediaries to inform investors, at the time of account opening, that promoters must clearly disclose in all communications on the platform the receipt of the compensation and the fact that he or she is engaging in promotional activities on behalf of the issuer. As noted in the Proposing Release, in addition to the information required under Rule 302(c), promoters will also be required to comply with Section 17(b) of the Securities Act, which requires promoters to fully disclose to investors the receipt, whether past or prospective, of consideration and the amount of that compensation.[743] We believe that the disclosures required by Rule 302(c) will help alert investors at the outset, rather than after the account is opened, of the fact that information about the promotional activities of issuers or representatives of issuers will be disclosed at a later time on the platform, pursuant to Rule 303(c)(4). We believe that the account opening is the appropriate time for this disclosure because it gives investors notice of potential promotional activities by issuers and their representatives prior to making investment commitments. As discussed below, Rule 303(c)(4) separately mandates that intermediaries require any person, when posting a comment in the communication channels, to clearly disclose with each

[737] We note that educational materials may be subject to examination and inspection. *See* Section II.D.5. (describing the recordkeeping obligations of funding portals).

[738] *See* RocketHub Letter (stating that ''if educational materials are submitted to the Commission for approval, such approval should act to limit liability of the Portal under the Act'').

[739] *See* Rule 303(b)(2)(i) of Regulation Crowdfunding.

[740] *See* Rule 205 of Regulation Crowdfunding and the discussion in Section II.B.5.

[741] *See, e.g.,* Arctic Island Letter 6; Wefunder Letter.

[742] *See* Arctic Island Letter 6.

[743] *See* Proposing Release at 78 FR 66467–68. *See also* Section 17(b) of the Securities Act (15 U.S.C. 77q(b)).

posting whether he or she is a founder or an employee of an issuer engaging in promotional activities on behalf of the issuer, or receives compensation, whether in the past or prospectively, to promote an issuer's offering. We believe that the disclosure requirements of Rule 302(c), when coupled with the additional disclosure requirements in Rule 303(c)(4), will promote a transparent information sharing process whereby investors are able to discern the sources of information that they are receiving and any potential conflicts of interest by those sources.

d. Compensation Disclosure

(1) Proposed Rule

Proposed Rule 302(d) of Regulation Crowdfunding would require that intermediaries, when establishing an account for an investor, clearly disclose the manner in which they will be compensated in connection with offerings and sales of securities made in reliance on Section 4(a)(6). This requirement would help to ensure investors are aware of any potential conflicts of interest that may arise from the manner in which the intermediary is compensated. Rule 201(o) of Regulation Crowdfunding, which is discussed in Section II.B.1, separately requires an issuer to disclose in its offering materials, among other things, the amount of compensation paid to the intermediary for conducting a particular offering, including the amount of referral and any other fees associated with the offering.

(2) Comments on Proposed Rule

Several commenters supported the disclosure of intermediary compensation.[744] One commenter stated that the account opening is not an appropriate time to mention compensation, asserting that the account opening stage should be dedicated to discussing the risk of startup investing.[745] One commenter suggested that the best way for an intermediary to disclose compensation is through a ''Costs and Fees'' page on its Web site.[746] Another commenter requested that the Commission define compensation as any fees or compensation collected by the intermediary in connection with a Section 4(a)(6) transaction, subject to Commission and FINRA rules.[747]

(3) Final Rules

We are adopting Rule 302(d) as proposed. We believe that requiring intermediaries to provide information to investors about the manner in which they will be compensated at account opening, rather than at a subsequent time, will provide investors with notice of how the intermediary is being compensated at a threshold stage in the relationship (*i.e.,* account opening), which, in turn, will help investors make better-informed decisions. We note that the final rules—unlike the proposed rules—allow intermediaries to receive a financial interest in the issuer as compensation, subject to certain limitations.[748] Therefore, an intermediary that receives or may receive a financial interest in an issuer in the future as compensation for its services is required to disclose that compensation at account opening. We also note that Rule 201(o), which is discussed in Section II.B.1 and separately requires an issuer to disclose in its offering materials a description of the intermediary's interests in the issuer's transaction, including the amount of compensation paid or to be paid to the intermediary for conducting a particular offering, the amount of referral and any other fees associated with the offering. We are not defining compensation as one commenter suggested, as we believe the final rule's requirement to clearly disclose the manner in which an intermediary will be compensated in connection with offerings and sales of securities made in reliance on Section 4(a)(6) is sufficiently clear, and because we are also concerned that a definition of compensation could be both under- and over-inclusive in a new and evolving crowdfunding market.

5. Requirements With Respect to Transactions

a. Issuer Information

(1) Proposed Rule

Securities Act Section 4A(a)(6) requires each intermediary to make available to the Commission and investors, not later than 21 days prior to the first day on which securities are sold to any investor (or such other period as the Commission may establish), any information provided by the issuer pursuant to Section 4A(b).[749] Accordingly, we proposed Rule 303(a) of Regulation Crowdfunding to implement this provision by requiring each intermediary in a transaction involving the offer or sale of securities in reliance on Section 4(a)(6) to make available to the Commission and to investors any information required to be provided by the issuer under Rules 201 and 203(a) of proposed Regulation Crowdfunding. As proposed, Rule 303(a) would require that this information: (1) Be publicly available on the intermediary's platform, in a manner that reasonably permits a person accessing the platform to save, download or otherwise store the information; (2) be made publicly available on the intermediary's platform for a minimum of 21 days before any securities are sold in the offering, during which time the intermediary may accept investment commitments; and (3) remain publicly available on the intermediary's platform until the offer and sale of securities is completed or cancelled (including any additional information provided by the issuer). In addition, under Proposed Rule 303(a)(4), an intermediary would be prohibited from requiring any person to establish an account with the intermediary in order to access this information.

(2) Comments on the Proposed Rule

Several commenters suggested that so long as issuer information is made available on the intermediary's platform, the rules should not mandate the delivery of this information, in addition to or in lieu of, making the information available on the intermediary's platform.[750]

One commenter stated that having information about a deal publicly available on the intermediary's Web site will increase the potential for fraud—specifically, potential fraud involving ''data scraping'' from Web sites (*i.e.,* copying data from these Web sites in order to use that data for fraudulent purposes).[751] This same commenter suggested that that there should be two levels of disclosure: The first, would be available to all and would contain certain general information about the

[744] *See, e.g.,* Arctic Island Letter 6; ASSOB Letter; CFA Institute Letter; Commonwealth of Massachusetts Letter; Joinvestor Letter; StartupValley Letter; Wefunder Letter.

[745] *See* Wefunder Letter.

[746] *See* StartupValley Letter.

[747] *See* CFIRA Letter 4.

[748] *See* Section II.C.2.b.

[749] As discussed in Section II.B, Securities Act Section 4A(b) establishes the requirements for an issuer that offers or sells securities in reliance on Section 4(a)(6).

[750] *See, e.g.,* Arctic Island Letter 6 (suggesting that an electronic copy of the signed subscription agreement and risk disclosures should be sent to the investor via email, and that ''[e]verything else can be referenced by the investor online at any time''); ASSOB Letter; CrowdCheck Letter (suggesting that the Commission remove the requirement in the proposed rules that would effectively limit the presentation of information to only formats that can be saved and downloaded by prospective investors); RocketHub Letter; Wefunder Letter; Vann Letter (stating that no particular means of delivery to investors should be required because ''technologies may change'' and intermediaries should be allowed to use whatever means ''appropriate'').

[751] *See* StartupValley Letter.

issuer and the terms of deal, and the second would be made available only after investors proceed through a membership registration process and would contain disclosure documents, financial information, legal disclosures and further information.[752]

As to the amount of time that an intermediary should display issuer materials prior to the first day on which securities are sold to any investor, some commenters supported the 21-day time frame as a sufficient minimum period that offering information should be made available through the intermediary's platform.[753]

Although one commenter objected to intermediaries displaying any issuer materials,[754] several commenters supported requiring intermediaries to continue to display issuer materials for some period of time after completion of the offering.[755] One commenter, however, stated that intermediaries should not be required to display issuer materials for closed offerings.[756] Another commenter stated that ''[o]nce an offering is complete, an issuer should have the right to limit publicly available information.'' [757]

We also requested comments as to whether an intermediary should make efforts to ensure that an investor has actually reviewed the relevant issuer information. A few commenters expressed concern with requiring intermediaries to ensure that an investor has reviewed the relevant issuer information.[758] Another commenter suggested that an investor ''should demonstrate, through a representation of acknowledgment, that they have reviewed all relevant issuer information.'' [759]

(3) Final Rules

After considering the comments, we are adopting, as proposed, Rule 303(a). As stated in the Proposing Release, we believe that the requirement in Rule 303(a) that the information must be made publicly available on the intermediary's Web site satisfies the requirement under Section 4A(d) for the Commission to ''make [available to the states], or . . . cause to be made [available] by the relevant broker or funding portal, the information'' issuers are required to provide under Section 4A(b) and the rules thereunder. Moreover, this approach should help investors, the Commission, FINRA (and any other applicable registered national securities association) and other interested parties, such as state regulators, to access information without impediment. Therefore, we believe that this rule is not only consistent with the statute but that it also enhances investor protection by having issuer information about a crowdfunding security publicly available on the intermediary's Web site. While we considered the concern expressed by one commenter that having such information available on the intermediary's Web site would increase the potential for ''data scraping,'' [760] we believe the expected benefits of the requirement to investors and other interested persons, as discussed above, justifies the risk of potential harm from such potential activities.

We note that commenters who addressed the issue generally supported a 21-day time frame as the minimum period that offering information should be made available through the intermediary's platform prior to the first day on which securities are sold to any investor. Under the final rules, the information must remain available on the platform until the offering is completed or canceled. While some commenters suggested that the rule should require intermediaries to continue to display issuer materials for some period of time after completion of the offering, we are not prescribing such a requirement nor are we prohibiting intermediaries from doing so if they so choose. Although we appreciate that historical issuer information may provide helpful background for investors generally, we are concerned that imposing such a requirement could potentially result in persons relying on potentially stale issuer information particularly given the nature of the crowdfunding market (*i.e.,* we assume that each issuer generally will conduct only one offering per year).[761] We note that intermediaries nonetheless are required to retain the information in accordance with their obligation to make and preserve for a period of time records with respect to any written materials that are used as part of an intermediary's business, including issuer materials made available on their platforms.[762]

While the intermediary plays an important gatekeeper function, the investor has responsibility for his or her actions as well. To that end, we are not requiring that an intermediary ensure that an investor has actually reviewed the relevant issuer information. We believe that the requirements of Rule 303(a) provide an investor with the relevant issuer information and an adequate period of time in which to evaluate the investment opportunity before investing. We are not at this time imposing additional requirements on the intermediary in this regard.

b. Investor Qualification

(1) Compliance With Investment Limits

(a) Proposed Rule

Securities Act Section 4(a)(6)(B) limits the aggregate amount of securities that can be sold by an issuer to an investor in reliance on Section 4(a)(6) during a 12-month period. Securities Act Section 4A(a)(8) requires that intermediaries ''make such efforts as the Commission determines appropriate, by rule'' to ensure that no investor has made purchases in the aggregate, from all issuers, that exceed the limits in Section 4(a)(6).

Proposed Rule 303(b)(1) of Regulation Crowdfunding would implement this latter provision by requiring that, each time before accepting an investment commitment on its platform (including any additional investment commitment from the same person), an intermediary must have a reasonable basis for believing that the investor satisfies the investment limits established by Section 4(a)(6)(B). The proposed rule would allow an intermediary to rely on an investor's representations concerning

[752] *Id. See also* Early Shares Letter (suggesting a permission-based system for the disclosure of certain ''sensitive'' information about the offering).

[753] *See, e.g.,* ASSOB Letter; RocketHub Letter.

[754] *See* Public Startup Letter 3.

[755] *See, e.g.,* Arctic Island Letter 6 (stating that an issuer's offering materials should be permanently displayed so it can easily be referenced in the future); ASSOB Letter (suggesting a period of at least two years after receiving funding from the offering); Jacobson Letter (suggesting a period of at least six years after an offering closes); RocketHub Letter (recommending that issuer materials should remain displayed for an additional 30 days after completion of the offering and further suggesting that ''[i]ntermediaries should have the right, at their own discretion, to continue to display the entire offering, or parts of it, for as long as they see fit'').

[756] *See* Whitaker Chalk Letter (stating that removing such materials from the intermediary's platform would prevent the public from relying on ''stale'' information and opposing the requirement that intermediaries keep public any such ''stale'' information so long as the information remain subject to the intermediary's recordkeeping requirements).

[757] *See* RocketHub Letter.

[758] *See, e.g.,* Arctic Island Letter 6 (stating that such a requirement ''could make things incredibly messy and expensive''); Wefunder Letter.

[759] RocketHub Letter.

[760] *See* StartupValley Letter.

[761] As discussed in Section IV.B.1, we assume, for purposes of the Paperwork Reduction Act, that each issuer will conduct one offering per year.

[762] Registered brokers would have to maintain records pursuant to Exchange Act Section 17 and the rules thereunder. *See e.g.,* 15 U.S.C. 78q and 17 CFR 240a–3 and 17a–4. Funding portals would be subject to the recordkeeping requirements of proposed Rule 404 of Regulation Crowdfunding. *See* Section II.D.5 (discussing the recordkeeping requirements we are adopting for funding portals).

annual income, net worth and the amount of the investor's other investments in securities sold in reliance on Section 4(a)(6) through other intermediaries unless the intermediary has a reasonable basis to question the reliability of the representation.

(b) Comments on the Proposed Rule

A number of commenters supported the proposed requirements for enforcing investment limits and intermediary responsibility for investor compliance,[763] while a few commenters opposed the requirements.[764] Several commenters suggested ways to strengthen the requirements, such as by: Requiring that an intermediary conduct more stringent checks,[765] having the Commission maintain a registry of those who have purchased crowdfunding securities,[766] requiring that investors electronically upload financial documents for verification of income or net worth,[767] requiring notices detailing investment limits and highlighting their importance,[768] and precluding an investor who violates the investment limits from bringing a cause of action against an issuer.[769] Some commenters suggested that the Commission require intermediaries to create a tool for investors to use, such as a questionnaire, to assemble the underlying data on which investment limits are calculated and to perform those calculations electronically.[770] However, another commenter disagreed with this suggestion.[771] One commenter suggested intermediaries' platforms be required to provide to investors prior to accepting an investment commitment a detailed statement of the investment limits that are applicable to investors that also includes a penalty of perjury certification by the investor.[772] A few commenters emphasized a need to warn investors that the value of their primary residence should be excluded for purposes of the net worth calculation.[773] Commenters also suggested that the Commission adopt an approach similar to that under the capital gains tax rules that would limit benefits and loss recovery for investors who invest outside of their limits.[774]

Several commenters opposed the proposal to allow an intermediary to rely on the representations of an investor.[775] Some urged the Commission to provide for verification through either a third-party service or through the intermediaries themselves in lieu of reliance on investor representations.[776] Other commenters suggested that intermediaries should be required to take certain affirmative steps to verify investor representations.[777] One commenter stated that the strongest possible approach to a verification requirement should be imposed for investments beyond $2,000.[778] Another commenter suggested that the Commission create penalties for intermediaries who fail to meet their duties regarding investment limits.[779] One commenter suggested the Commission should require crowdfunding portals to collect enough data from investors to avoid the most likely errors in calculating the investment limit and to prevent evasion of those limits. This commenter also suggested that the Commission should require portals to collect social security numbers to help prevent individuals from evading limits by opening multiple accounts under false names.[780]

Other commenters supported the proposal to allow an intermediary to rely on the representations of an investor.[781] Some of these commenters warned against costly compliance requirements such as, for example, requiring verification of investment limits by both the issuer and the intermediary,[782] or burdening a broker-dealer with a vetting requirement for someone who may only want to invest a small amount, such as $25.[783]

Several commenters supported requiring an intermediary to confirm investment limits compliance using a centralized database, should one become established.[784] A number of these commenters suggested the database be created and managed by the Commission with mandatory intermediary participation[785] to allow intermediaries to check an investor's total year to date purchases across all platforms.[786] One commenter stated that the statute ''contemplates'' the development of a central data repository and suggested that it could be established at the relevant national

[763] *See, e.g.,* BetterInvesting Letter; CFA Institute Letter; CFIRA Letter 12; Finkelstein Letter; IAC Recommendation; Milken Institute Letter. *See also* NAAC Letter (stating that unsophisticated investors might not comply with the investment limits or be targets for fraudulent schemes, and recommending ''verified and stringent determinations as to the income and net worth qualifications of any potential investors.'').

[764] *See, e.g.,* Moskowitz Letter (stating that select investors on the secondary market could purchase shares in excess of the investment limit and suggesting that the limits be removed altogether); Phillips Letter.

[765] *See, e.g.,* Moskowitz Letter; NAAC Letter.

[766] *See* Clapman Letter. *See also* CFA Institute Letter (suggesting that the Commission require intermediaries to ''cross check each investor's information against other files on record with the Commission to ensure compliance with the law's limitations'').

[767] *See, e.g.,* Consumer Federation Letter; Finkelstein Letter.

[768] *See* Milken Institute Letter.

[769] *Id.*

[770] *See, e.g.,* CFA Institute Letter (suggesting that ''investors be required to complete online questionnaires denoting the different classes of asset holdings permitted by the law, with a specific and prominent notification that the value of one's primary residence is excluded''); IAC Recommendation (stating that the tool, such as an electronic work sheet, would assist investors in identifying categories of assets and liabilities such as bank accounts, investment accounts, and house value, for purposes of the net worth calculation, and prompt them to deduct outstanding liabilities and exclude the value of principle residence). *See also* BetterInvesting Letter.

[771] *See* CFIRA Letter 12 (disagreeing with IAC's suggestion ''that portals create a 'tool' to walk investors through the creation of what is essentially a personal balance sheet'').

[772] *See* Milken Institute Letter (''This would underscore the importance of the investor caps . . . and properly place the burden of compliance on the actor who can verify income or wealth at the lowest cost—the investor.'').

[773] *See, e.g.,* Brown J. Letter; CFA Institute Letter; Consumer Federation Letter.

[774] *See, e.g.,* Milken Institute Letter (supporting the proposed investment caps, but agreeing with precluding loss recovery); Phillips Letter.

[775] *See, e.g.,* Accredify Letter (stating that self-certifications are not an effective way to implement the investment limit requirements and suggesting that intermediaries be required to use existing services to check individuals' investment limits); AFL–CIO Letter; AFR Letter; Brown J. Letter; Commonwealth of Massachusetts Letter; Consumer Federation Letter; Farnkoff Letter; Letter Finkelstein Letter; Jacobson Letter; Merkley Letter (noting that permitting self-certification would expose investors to precisely the risks that the statute aimed to prevent, and should not be permitted for investments over $2,000); Saunders Letter; Verinvest Letter.

[776] *See, e.g.,* Accredify Letter; Commonwealth of Massachusetts Letter; Farnkoff Letter (''A third-party verification regime overseen by the SEC or FINRA would provide the safest protection from fraudsters and reduce risks of liability for funding portals.''); Saunders Letter; Verinvest Letter.

[777] *See, e.g.,* AFL–CIO Letter; Jacobson Letter.

[778] *See* Merkley Letter (suggesting that the Commission could reconsider possible options to relax any strict initial approach after the first few years of the final rules being in effect, and stating that ''it would be incredible if the verification requirements for ordinary investors in crowdfunding were permitted to be less than for accredited investors under Rule 506(c)'').

[779] *See* Commonwealth of Massachusetts Letter.

[780] *See* AFR Letter.

[781] *See, e.g.,* Arctic Island Letter 6; ASSOB Letter; CFA Institute Letter; Greenfield Letter; Heritage Letter; Joinvestor Letter; Patel Letter; Public Startup Letter 3; RocketHub Letter.

[782] *See* Heritage Letter.

[783] *See* Arctic Island Letter 6.

[784] *See, e.g.,* BetterInvesting Letter; Arctic Island Letter 6; Consumer Federation Letter; Finkelstein Letter; IAC Recommendation; Merkley Letter; Verinvest Letter. *See also* CFA Institute Letter (suggesting that ''the Commission require such intermediaries to cross check each investor's information against other files on record with the Commission to ensure compliance with the law's limitations'').

[785] *See, e.g.,* Arctic Island Letter 6; Consumer Federation Letter; Finkelstein Letter. *See also* CFA Institute Letter.

[786] *See* Finkelstein Letter.

securities association.[787] Another commenter suggested, in connection with its support for the use of a centralized database, imposing a three-to-five year time limit, after which intermediaries would no longer be permitted to rely on investor representations about their investments on other platforms.[788] One commenter suggested the Commission incentivize the private creation of a centralized database.[789] Another opposed the Commission imposing any obligation on intermediaries until after such a centralized database is established.[790] Another commenter, supporting the creation of a single, centralized database, warned that ''competing databases'' would be incomplete.[791]

Others commenters expressed concern that the proposed rule included no mechanism to prevent investors from registering with multiple platforms and investing far in excess of the statutory limits.[792] Commenters who addressed the issue supported requiring intermediaries to request information about any other intermediary accounts prior to accepting an investment commitment.[793] One of these commenters suggested requiring intermediaries to add a text box to their site that requires the investor to input the total dollar amount invested on other platforms.[794] The other commenter stated that an intermediary should only be required to request additional information if there are doubts about the investor's self-certification.[795]

(c) Final Rules

After considering the comments, we are adopting Rule 303(b)(1) as proposed. As a threshold matter, we note that a number of commenters supported the proposed approach for establishing compliance with investment limits. Although we appreciate some of the additional suggestions provided by commenters, as outlined above, we believe the approach in Rule 303(b)(1) for establishing compliance with investment limits is an appropriate means of implementing the provisions of Section 4A(a)(8), which is designed to help ensure that an investor has not made purchases, in the aggregate from all issuers, that exceed those limits during a 12-month period. We note, however, that intermediaries can, in their discretion, take additional measures for evaluating investors' compliance with investment limits, including those suggested by commenters, such as: Using a centralized data repository, to the extent that one is created; requiring verification of income or net worth electronically by uploading financial documents; or creating a tool for investors to use, such as a questionnaire, to assemble the underlying data.

While several commenters opposed permitting an intermediary to rely on the representations of an investor about investment limits and some suggested requiring intermediaries to take certain affirmative steps to verify compliance, we believe that it would be difficult for intermediaries to monitor or independently verify whether each investor remains within his or her investment limits where the investor may be participating in offerings on multiple platforms. We note, however, that reliance on investor representations must be reasonable. At a minimum, it would not be reasonable, and therefore would be a violation of the rule and potentially subject to an enforcement action by the Commission, for an intermediary to ignore investments made by an investor in other offerings on the intermediary's platform, to not obtain information and take into account investments made by an investor in other offerings (made in reliance on Section 4(a)(6)) on platforms that are controlled by or under common control with the intermediary, or to ignore other information or facts about an investor within its possession.

Under the final rules, an intermediary will be permitted to reasonably rely on a centralized data repository of investor information, should one be created in the future. We are not mandating the creation of such a database at this time, in part to help to minimize the obstacles that intermediaries may face in getting this newly formed marketplace up and running.[796] We note, in response to one commenter,[797] that it is the Commission's normal practice to review the effectiveness of all of its rules, particularly in light of market developments, and consider changes as the Commission deems appropriate. Commission staff expects to review the need for a centralized database during the study of the federal crowdfunding exemption that it plans to undertake no later than three years following the effective date of Regulation Crowdfunding.[798]

(2) Acknowledgment of Risk

(a) Proposed Rule

Securities Act Section 4A(a)(4) requires an intermediary to ensure that each investor: (1) Reviews educational materials; (2) positively affirms that the investor understands that he or she is risking the loss of the entire investment and that the investor could bear such a loss; and (3) answer questions demonstrating an understanding of the level of risk generally applicable to investments in startups, emerging businesses and small issuers, the risk of illiquidity and such other matters as the Commission determines appropriate. As discussed above, Rule 302(b) of Regulation Crowdfunding requires an intermediary to provide to investors certain educational materials in connection with the opening of an account. In addition, proposed Rule 303(b)(2) of Regulation Crowdfunding would require an intermediary, each time before accepting an investment commitment, to obtain from the investor a representation that the investor has reviewed the intermediary's educational materials, understands that the entire amount of his or her investment may be lost and is in a financial condition to bear the loss of the investment.[799] The proposed rule would also require that an intermediary obtain from the investor

[787] *See* Merkley Letter (noting that the proposal ''does not establish such a repository or set forth any path towards its establishment and thus fails to implement the plain meaning of the statutory language'' and suggesting that ''[t]esting, supervisory oversight, and other mechanisms to ensure investors are protected . . . be more fully considered'').

[788] *See* Consumer Federation Letter.

[789] *See* IAC Recommendation (suggesting the Commission create such an incentive by monitoring the effectiveness of the proposed reasonable reliance approach and to end that approach if a cost-effective and suitable cross-portal monitoring system is developed); *see also* BetterInvesting Letter.

[790] *See* Wefunder Letter.

[791] *See* CFIRA Letter 12.

[792] *See, e.g.,* Finkelstein Letter; Vann Letter (stating that intermediaries should be required to ''make it clear that the aggregate limits apply across all such platforms, not just their own'').

[793] *See, e.g.,* ASSOB Letter; Wefunder Letter.

[794] *See* Wefunder Letter.

[795] *See* ASSOB Letter.

[796] We do not believe that the statute requires the establishment of a centralized database or repository of investor information as one commenter suggested. *See* Merkley Letter. Instead, the statute calls for intermediaries to ''make such efforts as the Commission determines appropriate, by rule'' to ensure that no investor exceeds the investment limits set forth in Section 4(a)(6).

[797] *See* IAC Recommendation; *see also* BetterInvesting Letter.

[798] *See* Section II. Further, we anticipate that, because of the electronic nature of crowdfunding, many of the books and records maintained by intermediaries will be in electronic format. We expect this will enable the Commission to analyze data across the crowdfunding industry as part of its ongoing oversight. We note that Commission staff also expects to review the books and records practices of intermediaries as part of its planned three-year review.

[799] *See* Section II.C.4.b. (discussing Rule 302(b)(2) of Regulation Crowdfunding).

answers to questions demonstrating the investor's understanding that there are restrictions on the investor's ability to cancel an investment commitment and obtain a return of his or her investment, that it may be difficult for the investor to resell the securities, and that the investor should not invest any funds in a crowdfunding offering unless he or she can afford to lose the entire amount of his or her investment.

(b) Comments on the Proposed Rule

Several commenters supported the requirement that intermediaries obtain investor acknowledgments.[800] Some of these commenters, however, opposed requiring investors to re-acknowledge or to re-certify for each investment commitment.[801]

One commenter stated that investors should be required to complete and sign ''subscription forms'' that set forth, in addition to what the proposed rules would require, additional information concerning the investor's level of investment experience, the identity of any person from whom the investor acquired any information about the investment and the percentage of the investor's liquid net worth represented by the proposed investment.[802]

One commenter supported the Commission providing recommended forms of questions and representations, noting that ''any material examples provided by the Commission will be helpful to both the investor and the intermediary.'' [803] However, another commenter stated that it would be opposed to the Commission providing recommended forms of questions as a ''starting point'' because such recommended forms could be seen as a safe harbor and constrain effectiveness.[804] In contrast, a different commenter stated that Commission-provided questions and representations should serve as a safe harbor so there is an incentive for issuers to use them.[805]

(c) Final Rules

After considering the comments, we are adopting Rule 302(b)(2) as proposed. As noted in the Proposing Release, this rule is intended to help ensure that investors engaging in transactions made in reliance on Section 4(a)(6) are fully informed and reminded of the risks associated with their particular investment before making any investment commitment. While an intermediary cannot ensure that all investors understand the risks involved, the rule requires intermediaries to confirm that an investor: (1) Has reviewed the intermediary's educational materials delivered pursuant to Rule 302(b); (2) understands that the entire amount of his or her investment may be lost, and is in a financial condition to bear the loss of the investment; and (3) has completed a questionnaire demonstrating an understanding of the risks of any potential investment and other required statutory elements. In addition, the questionnaire required under the rule may help to address, at least in part, the concerns expressed by some commenters that Section 4A(a)(4) requires more than a mere self-certification.[806] We note, however, that the plain language of Section 4A(a)(4)(B) seemingly requires only that the investor positively affirms his or her understanding of the risk of loss.

Our final rule does not provide a model form of acknowledgment or questionnaire. Rather, the rule permits an intermediary to develop the representation and questionnaire in any format that is reasonably designed to demonstrate the investor's receipt of the information and compliance with the other requirements under the final rules. As with the educational material requirements, we continue to believe that rather than providing sample content or a model form of acknowledgment or questionnaire, intermediaries should be provided with sufficient flexibility to choose both the content, within the requirements of Rule 302(b), and the format used to present the required materials. Likewise, we also believe that an intermediary's familiarity with its business and likely investor base make it best able to determine the format in which to present the required materials. We note that any format used must be reasonably designed to demonstrate receipt and understanding of the information. There are many ways, especially on a Web-based system, to convey information to, and obtain effective acknowledgment from, investors. As explained in the Proposing Release, the requirements of the rule would not be satisfied if, for example, an intermediary were to pre-select answers for an investor.

Further, an intermediary in its discretion may require additional information, such as information concerning the investor's level of investment experience, the identity of any person from whom the investor acquired any information about the investment and the percentage of the investor's liquid net worth represented by the proposed investment, or impose additional requirements on prospective investors, such as imposing express acknowledgments of the investor's responsibilities with respect to compliance.

Finally, although several commenters suggested that once an account has been created on an intermediary's platform, an investor should be able to invest in multiple offerings on the same intermediary platform without having to re-certify and review the educational material, we continue to believe that, in order to realize the statute's investor protection goals, it is prudent to require an intermediary to obtain an investor representation and completed questionnaire each time an investor seeks to make an investment commitment. Accordingly, under Rule 303(b), an intermediary will be required to obtain these items each time an investor seeks to make an investment commitment.

c. Communication Channels

(1) Proposed Rule

Proposed Rule 303(c) of Regulation Crowdfunding would require an intermediary to provide, on its platform, channels through which investors can communicate with one another and with representatives of the issuer about offerings made available on the intermediary's platform. An intermediary that is a funding portal would be prohibited from participating in communications in these channels.[807] Proposed Rule 303(c) also would require the intermediary to: (1) Make the communications channels publicly available; (2) permit only those persons who have opened accounts to

[800] *See, e.g.,* Arctic Island Letter 6; CFA Institute Letter; Greenfield Letter; Joinvestor Letter; RocketHub Letter; STA Letter; Wefunder Letter.

[801] *See* Wefunder Letter; RocketHub Letter (suggesting that once an account has been created on an intermediary platform, an investor should be able to invest in multiple offerings on the same intermediary platform without having to re-certify and review the educational materials).

[802] *See* Greenfield Letter. *See also* STA Letter (stating that investors should be required to acknowledge that they are aware that ''they may need to be diligent in notifying the issuer, or its designee, of any changes that would affect their ability to receive communications from the issuer''). We note, however, that issuers are not obligated to contact investors directly.

[803] *See* Joinvestor Letter.

[804] *See* Wefunder Letter.

[805] *See* Public Startup Letter 3.

[806] *See, e.g.,* Accredify Letter; Commonwealth of Massachusetts Letter; Farnkoff Letter; Saunders Letter; Verinvest Letter.

[807] *See* Rule 303(c)(1) (an intermediary that is a funding portal cannot ''participate in these communications, other than to establish guidelines for communication and remove abusive or potentially fraudulent communications''). *See also* Exchange Act Section 3(a)(80) (defining the term ''funding portal'' as any person acting as an intermediary in a transaction involving the offer or sale of securities for the account of others, solely pursuant to Securities Act Section 4(a)(6), that does not, among other things, ''offer investment advice or recommendations'').

post comments; and (3) require any person posting a comment in the communication channels to disclose whether he or she is a founder or an employee of an issuer engaging in promotional activities on behalf of the issuer, or is otherwise compensated, whether in the past or prospectively, to promote the issuer's offering.

(2) Comments on the Proposed Rule

We received comments both supporting [808] and opposing the proposed rules on communications channels.[809] Several commenters agreed that posting in communication channels should be limited to registered investors on an intermediary's platform.[810]

Some commenters stated there should be more privacy or control in the manner in which comments are posted to the communications channels, such as submitting comments to intermediaries to review prior to posting or restricting the publicly viewable comments.[811] One commenter stated that he interprets the proposed rule to permit issuers to post videos and other promotional content (similar to marketing content used on non-securities-based crowdfunding sites like Kickstarter), and that he supported this approach as it would permit the issuer to ''communicate freely and creatively . . . while giving the crowd a forum to ask questions or offer criticism.'' [812] Another commenter encouraged the Commission ''to provide an investor 'hotline', where investors can report concerns relating to crowdfunding communications or transactions, and that intermediaries be required to provide notice on their platforms of how to access this hotline.'' [813]

Several commenters generally supported the disclosure requirement on communications by issuers or intermediaries and agreed that these communications should be made transparent to investors.[814]

One commenter generally supported the proposed rule requiring each promotional communication to be accompanied by disclosure of the receipt of past or prospective compensation.[815] Another commenter suggested that the proposed rules should be amended to require that intermediaries prominently post the online identities of the issuer's paid promoters in the communication channels.[816] One commenter, however, stated that the Commission should not mandate the exact methods by which an intermediary achieves compliance with the requirement for promoters to disclose their relationship with an issuer.[817]

In response to our request for comments, several commenters supported requiring intermediaries to keep the communication channels available to investors post-offering.[818] Another commenter, however, stated that the communication channels should be closed after stock certificates are issued and received by investors.[819] This commenter further noted that the continued maintenance of a communication channel after the end of a campaign would be an unnecessary cost. The same commenter suggested that the issuer's Web site is a better place for communication between investors and issuers.[820]

(3) Final Rule

After considering the comments, we are adopting Rule 303(c) as proposed. We considered commenters' suggestions that the issuer's Web site is a better place for communication between investors and issuers and that ongoing communication between issuers and investors should be an obligation of issuers alone. We believe, however, that communication channels on the intermediary's platform will provide a centralized and transparent means for members of the public that have opened an account with an intermediary to share their views about investment opportunities and to communicate with representatives of the issuer to better assess the issuer and investment opportunity.[821] While the JOBS Act does not impose this requirement, we believe it is consistent with the legislative intent that such a mechanism be in place for offerings made in reliance on Section 4(a)(6).[822] Also, though communications among investors may occur outside of the intermediary's platform, communications by an investor with a crowdfunding issuer or its representatives about the terms of the offering are required to occur through these channels [823] on the single platform through which the offering is conducted.[824] This requirement is expected to provide transparency and accountability, and thereby further the protection of investors.

Although one commenter stated that it interpreted the proposed rule to permit issuers to post videos and other promotional content, aside from Rule 303(c)(4) and its requirements for promotional activity, Rule 303(c) itself does not address the content or form used by issuers when communicating with investors through the channels provided on an intermediary's platform. Rather, Rule 204 of Regulation Crowdfunding sets forth the advertising requirements for issuers and, as explained above, Rule 204 allows an issuer to communicate with investors about the terms of the offering through communication channels provided by the intermediary on the intermediary's platform, so long as the issuer identifies

[808] *See, e.g.,* PeoplePowerFund Letter; RocketHub Letter; Vann Letter (stating that intermediaries should be allowed to decide who may post on the channels).

[809] *See, e.g.,* Cromwell Letter (claiming that ''[a]s [a] venture investor, you cannot judge the abilities of the management team over the Internet. Real venture capitalists do not make their investments over the Internet—they spend hours and hours interviewing the founders/management team, in person. Small investors cannot successfully invest over the Internet, either.''); Public Startup Letter 3; Moskowitz Letter (stating that the proposed rules do not prevent an accredited investor from, for example, posting a solicitation within the communication channels for more securities than he or she could purchase in the offering within his or her investment limits).

[810] *See, e.g.,* PeoplePowerFund Letter; RocketHub Letter; Wefunder Letter.

[811] *See, e.g.,* ASSOB Letter (stating that ''random unmoderated comments'' in communication channels should not be permitted, because it would allow for unacceptable solicitations or claims of return on investment); RocketHub Letter (expressing concern that certain confidential information may be disclosed between registered investors and the issuer, which would not be suitable for a public forum).

[812] *See* Odhner Letter.

[813] *See* CFA Institute Letter.

[814] *See, e.g.,* CFA Institute Letter; RocketHub Letter (suggesting that intermediaries should be able to assist posters in disclosing their relationship to issuer).

[815] *See* CFA Institute Letter.

[816] *See* MCS Letter.

[817] *See* Wefunder Letter (suggesting that the disclosures at the account opening stage are better devoted to the discussion of the risk of startup investing).

[818] *See, e.g.,* PeoplePowerFund Letter (suggesting that the posting forum should be live and accessible to all Web site members not less than 30 days after the issue has been completed); RocketHub Letter; StartupValley Letter (suggesting that intermediaries should open a private channel of communication between investors and issuers for the post offering period and not use the same public channel that was used for the pre-offering and funding periods).

[819] *See* RFPIA Letter.

[820] *Id. See also* CfPA Letter (stating that ongoing communication between issuers and investors should be an obligation of issuers alone).

[821] *See also* discussion in Section II.B.5.

[822] *See* 158 Cong. Rec. S2231 (daily ed. Mar. 29, 2012) (statement of Sen. Scott Brown) (''In addition to facilitating communication between issuers and investors, intermediaries should allow fellow investors to endorse or provide feedback about issuers and offerings, provided that these investors are not employees of the intermediary. Investors' credentials should be included with their comments to aid the collective wisdom of the crowd.'').

[823] *See* Rule 204 of Regulation Crowdfunding and discussion in Section II.B.4.

[824] *See* Rule 100(a)(3) of Regulation Crowdfunding and discussion in Section II.A.3.

itself as the issuer in all communications.[825]

We are requiring intermediaries to make the communications on the channels publicly available for viewing. We believe that this requirement is consistent with the concept of crowdfunding, as it provides for transparent crowd discussions about a potential investment opportunity. We also are requiring in Rule 303(c)(3) that intermediaries limit the posting in communication channels to those individuals who have opened an account with the intermediary on its platform. As stated in the Proposing Release, while we recognize that this requirement could narrow the range of views represented by excluding posts by anyone who has not opened an account with the intermediary, we believe that it will help to establish accountability for comments made in the communication channels. We continue to believe that, without this measure, there would be greater risk of the communications including unfounded, potentially abusive or biased statements intended to promote or discredit the issuer and improperly influence the investment decisions of members of the crowd.

With respect to one commenter's suggestion that the Commission provide an investor ''hotline'' where investors can report concerns relating to crowdfunding communications or transactions, we note that the Commission has an existing ''Tips, Complaints and Referrals Portal'' available on its Web site,[826] where the public may provide the Commission with information about potential fraud or wrongdoing involving alleged violations of the securities laws.

We are mindful of the cost associated with the communications channel, and, therefore, we are not requiring that intermediaries keep the communication channels available to investors post-offering, as suggested by some commenters.[827] However, an intermediary in its discretion can choose to maintain the communication channels post-offering.[828]

Consistent with the prohibition on a funding portal offering investment advice or recommendations,[829] the rule as adopted will prohibit an intermediary that is a funding portal from participating in any communications in these channels, apart from establishing guidelines for communication and removing abusive or potentially fraudulent communications. A funding portal can, for example, establish guidelines pertaining to the length or size of individual postings in the communication channels and can remove postings that include offensive or incendiary language. Also, although we understand the reasons for commenters' suggestions that there should be more privacy or control in the manner in which comments are posted, we believe that aside from intermediaries removing abusive or potentially fraudulent communications, investor protection is better served by providing the opportunity for uncensored and transparent crowd discussions about a potential investment opportunity.

Finally, under the rule as adopted an intermediary must require any person posting on the communication channel to clearly and prominently disclose with each posting whether he or she is a founder or an employee of an issuer engaging in promotional activities on behalf of the issuer, or is otherwise compensated, whether in the past or prospectively, to promote the issuer's offering. This disclosure will apply to officers, directors and other representatives of the issuer, and also will be required of an intermediary that is a broker and its associated persons. We continue to believe that intermediaries, as the hosts of the communication channels, are well placed to take measures to ensure that promoters clearly identify themselves in their communication channels, in accordance with Securities Act Section 4A(b)(3).

d. Notice of Investment Commitment

(1) Proposed Rule

Proposed Rule 303(d) of Regulation Crowdfunding would require an intermediary, upon receipt of an investment commitment from an investor, to promptly give or send to the investor a notification disclosing: (1) The dollar amount of the investment commitment; (2) the price of the securities, if known; (3) the name of the issuer; and (4) the date and time by which the investor may cancel the investment commitment. Pursuant to proposed Rule 302(a)(2) of Regulation Crowdfunding, this notification would be provided by email or other electronic media, and would be documented in accordance with applicable recordkeeping rules.[830]

(2) Comments on the Proposed Rule

Commenters generally supported the requirement that intermediaries send these notifications to investors.[831] One of these commenters stated that, in its view, the notice should be submitted twice: first, when an investor has made a commitment, and again when the cancellation period is over.[832] One commenter stated that, in its view, investors also should be notified of whether a campaign has been successful or not, both when the campaign is near completion and when the campaign has been closed.[833] However, one commenter opposed all notice requirements.[834]

(3) Final Rules

After considering the comments, we are adopting Rule 303(d) as proposed. As stated in the Proposing Release, the notification is intended, among other things, to provide the investor with a written record of the basic terms of the transaction, as well as a reminder of his or her ability to cancel the investment commitment. We believe that the adopted notification requirements will be useful to investors and provide transparency. We also believe that requiring that this notification be sent once—promptly upon receipt of an investment commitment from an investor—rather than multiple times as commenters suggested—will help to minimize the costs associated with providing additional notification, while still providing the investor with, among other things, an important reminder about the ability to cancel the investment commitment. Although an intermediary can decide, in its discretion, to provide additional notifications to its customers as a business decision, we believe at this time that adopting additional notification requirements could hamper flexibility in the evolving crowdfunding market and potentially impair the development of best practices that are

[825] *See* Section II.B.4 (discussing Rule 204).

[826] *See* Enforcement Tips and Complaints, *available at https://www.sec.gov/complaint/tips complaint.shtml*.

[827] *See, e.g.,* PeoplePowerFund Letter; RocketHub Letter; StartupValley Letter.

[828] It is important to note that an intermediary would still have to maintain records of such communications to satisfy the books and records requirements of the crowdfunding rules. *See* Rule 404(a)(3).

[829] *See* Rule 300(c)(2)(i). Exchange Act Section 3(a)(80) defines the term ''funding portal'' as any person acting as an intermediary in a transaction involving the offer or sale of securities for the account of others, solely pursuant to Securities Act Section 4(a)(6), that does not, among other things, ''offer investment advice or recommendations.''

[830] *See* Section II.C.4 (discussing Rule 100(a)(3)) and Section II.D.5 (discussing the recordkeeping rules applicable to funding portals). *See also* note 1114 (discussing the recordkeeping rules applicable to brokers and intermediaries).

[831] *See, e.g.,* CFA Institute Letter; Joinvestor Letter; RocketHub Letter.

[832] *See* RocketHub Letter.

[833] *See* Joinvestor Letter.

[834] *See* Public Startup Letter 3.

tailored to this unique form of raising capital.

e. Maintenance and Transmission of Funds

(1) Proposed Rule

Securities Act Section 4A(a)(7) requires that an intermediary ''ensure that all offering proceeds are only provided to the issuer when the aggregate capital raised from all investors is equal to or greater than a target offering amount, . . . as the Commission shall, by rule, determine appropriate.'' Proposed Rule 303(e)(1) of Regulation Crowdfunding would implement this provision and address the maintenance and protection of investor funds, pending completion of a transaction made in reliance on Section 4(a)(6), by requiring an intermediary that is a registered broker to comply with established requirements in Exchange Act Rule 15c2–4 [835] for the maintenance and transmission of investor funds.

Proposed Rule 303(e)(2) would establish separate requirements for an intermediary that is a funding portal. Because a funding portal cannot receive any funds, it would be required to direct investors to transmit money or other consideration directly to a ''qualified third party'' that has agreed in writing to hold the funds for the benefit of the investors and the issuer and to promptly transmit or return the funds to the persons entitled to such funds. Proposed Rule 303(e)(2) would define ''qualified third party'' to mean a bank [836] that has agreed in writing to either: (i) Hold the funds in escrow for the persons who have the beneficial interests in the funds and to transmit or return the funds directly to the persons entitled to them when the appropriate event or contingency has occurred; or (ii) establish a bank account (or accounts) for the exclusive benefit of investors and the issuer.

Proposed Rule 303(e)(3) would require an intermediary that is a funding portal to promptly direct transmission of funds from the qualified third party to the issuer when the aggregate amount of investment commitments from all investors is equal to or greater than the target amount of the offering and the cancellation period for each investor has expired, provided that in no event may the funding portal direct this transmission of funds earlier than 21 days after the date on which the intermediary makes publicly available on its platform the information required to be provided by the issuer under Rules 201 and 203(a) of proposed Regulation Crowdfunding.

(2) Comments on the Proposed Rule

Several commenters generally supported the proposed fund maintenance and transmission requirements.[837] One commenter suggested that intermediaries be allowed to reject an investor's investment commitment if that investor does not have a correlating balance in an account with the intermediary.[838] Another commenter suggested that the Commission require that such accounts be interest bearing and that either (1) the investors' funds be returned to them with their pro rata portion of the interest in the event the offering is canceled, or (2) the funds and the accrued interest be dispersed to the issuer upon the offering's successful closing.[839] Another commenter suggested that qualified third parties should be registered and verified for ''reputations [of] integrity''; complaints against those entities should be made public; and ''drawdown'' schedules should be submitted at the onset of projects and subsequently control issuer access to ''project funds.'' [840]

In the Proposing Release, we requested comment on various alternatives to the proposed rules. As to whether the proposed rules should prohibit any variations of a contingency offering, such as minimum-maximum, offerings, one commenter stated that the target amount of a crowdfunding campaign ''should represent the minimum to avoid investor confusion'' and that ''oversubscription should be allowed.'' [841] This commenter noted that these conditions would allow companies to ''choose to set their own minimum and maximum range.'' [842] Another commenter suggested that we permit contingency offers based on a maximum amount of funds being raised or other benchmarks if the maximum is not met or, alternatively, permit ''all-or-none'' offerings.[843]

As to whether other types of custody arrangements should be permitted, one commenter requested clarification that a carrying broker would not be deemed to accept any part of the sale price of any security for purposes of Exchange Act Rule 15c2–4 under specific circumstances.[844]

As to whether there should be a fixed deadline for transmission of funds (such as three business days), one commenter stated that ''fixed deadlines should be set to protect investor and issuer interests.'' This commenter suggested that ''one week (7 days) should be sufficient to disburse collected funds.'' [845] Another commenter suggested a three-day deadline.[846]

As to whether SRO and staff guidance on Exchange Act Rule 15c2–4 should be expressly incorporated into the rules, one commenter suggested that there was no need for incorporation of prior guidance about Rule 15c2–4 into the proposed rules.[847]

As to whether the definition of ''qualified third party'' should be expanded to include entities other than a bank, one commenter stated that the Commission should ''consider [permitting] non-bank custodians, such as internet services that specialize in escrow and payment transfer.'' [848] Another commenter suggested that ''qualified third parties'' should include credit unions, savings and loans and other institutions that offer similar protections to banks.[849] Similarly, another commenter suggested that credit unions should be included.[850] One commenter suggested that banks should not be a qualified third party.[851] One

[835] 17 CFR 240.15c2–4.

[836] *See* Exchange Act Section 3(a)(6) [15 U.S.C. 78c(a)(6)] (defining ''bank'').

[837] *See, e.g.,* Arctic Island Letter 6; ASTTC Letter; CSTTC Letter; Greenfield Letter (suggesting that the issuer should be required to certify in writing under penalty of perjury to the escrow bank that the offering has been completed pursuant to the terms in the offering statement and that there have been no material changes of circumstances that would render the representations in the offering statement false or misleading); Joinvestor Letter; STA Letter.

[838] *See* Zhang Letter.

[839] *See* MCS Letter.

[840] *See* Otherworld Letter.

[841] *See* Joinvestor Letter.

[842] *Id.*

[843] *See* PeoplePowerFund Letter (suggesting also that any oversubscribed issues be allocated on a ''first come first served'' basis in connection with ''all-or-none'' offerings).

[844] *See* FOLIOfn Letter. Although this commenter stated its belief that the proposed procedure is consistent with Rule 15c2–4 on the basis that the carrying broker would not be ''accept[ing] any part of the sale price'' until closing, at which time funds would be promptly transferred to the issuer, it stated that additional clarity would be helpful to ensure that the Proposing Release does not introduce confusion if read by some as containing an implication to the contrary.

[845] *See* Joinvestor Letter.

[846] *See* Public Startup Letter 3.

[847] *See* Arctic Island Letter 6.

[848] *See* Joinvestor Letter.

[849] *See* Growthfountain Letter.

[850] *See* Vann Letter.

[851] *See* Public Startup Letter 3 (claiming that ''[b]anks are unable to serve as the 'qualified third party' '' and that no entities other than registered broker-dealers should serve this function in connection with Regulation Crowdfunding sales.). *But see* Computershare Letter (supporting the ''inclusion of a requirement that Funding Portals use a qualified third party, which is a bank, to hold investor funds as escrow agent and transmit the funds to the issuer once the offering requirements are met''); ASTTC Letter (stating that it ''strongly supports the Proposed Rule's requirement that Funding Portals be required to utilize qualified escrow agents to hold the investor assets prior to transmittal to issuers and that ''[q]ualified escrow

commenter suggested that the definition of ''qualified third party'' be expanded to include certain broker-dealers that ''hold funds and securities on behalf of customer accounts pursuant to [Exchange Act] Rule 15c3–3 and maintain net capital pursuant to [Exchange Act] Rule 15c3–1(a)(2)(i)''.[852] The commenter also suggested that funding portals and other brokers should be able to utilize these brokers ''to the identical degree they would be able to utilize banks under Rule 15c2–4.''[853]

Commenters generally agreed with our proposed approach not to require funding portals to maintain net capital, noting among other things that imposing ''net capital requirements would increase the cost of starting a new funding portal and reduce the potential number of intermediaries, while providing little additional protection to investors and issuers.''[854]

As to whether certain methods of payment for the purchase of securities should either be required or prohibited, one commenter suggested that the types of payment methods not be limited in any way.[855] However, some commenters stated, generally, that credit cards should be prohibited as a form of payment for securities in connection with crowdfunding.[856]

agents are generally regulated banks''); STA Letter (stating that ''[it] is pleased that the Proposed Rules contain a requirement that Funding Portals transmit investor assets to qualified escrow agents, which are banks, prior to their release to the issuer.'').

[852] *See* FOLIOfn Letter. *See also* Arctic Island Letter 8 (suggesting that the rules permit a $250,000 net capital broker-dealer to act as trustee for an omnibus escrow account at an FDIC insured bank); Ex 24 Letter.

[853] *See* FOLIOfn Letter (stating also its belief that the brokers ''should be distinguished from other broker-dealers in the context of Regulation Crowdfunding and not be subject to the requirements of SEC Rule 15c2–4(b)'').

[854] *See* Tiny Cat Letter (stating that ''[f]unding portals are already prohibited from handling funds and securities, and are also subject to a fidelity bond in the proposed regulations''). *See also* Joinvestor Letter (suggesting that since funding portals will not be monetary custodians, there should be no net capital requirement instituted); Vann Letter (stating that a ''capital requirement would unnecessarily restrict competition'').

[855] *See* Public Startup Letter 3.

[856] *See, e.g.,* Arctic Island Letter 6 (suggesting that, given the chargeback periods for credit cards, broker-dealers should only be permitted to accept credit card payments from investors if the broker-dealer ''directly and unconditionally guarantees the amounts obtained thereby to both the issuer and the escrow agent''); Consumer Federation Letter (suggesting that allowing payment via credit card increases the risk that investors will make crowdfunding investments that they cannot afford); Joinvestor Letter; RocketHub Letter (stating that ''[p]ermitting debt-based payment vehicles, such as credit cards, which have their own rescission policies, (*i.e.,* charge backs) is problematic'').

(3) Final Rule

After considering the comments, we are adopting Rule 303(e) substantially as proposed, but with certain revisions in response to comments. Rule 303(e)(1), as adopted, requires an intermediary that is a registered broker-dealer to comply with established requirements in Exchange Act Rule 15c2–4 for the maintenance and transmission of investor funds. Rule 15c2–4 requires, in relevant part, that in connection with a contingency offering of a security, any money or other consideration received by a broker-dealer participating in the distribution must be promptly deposited in a separate bank account, as agent or trustee for the persons who have the beneficial interest therein, until the appropriate event or contingency has occurred, and thereafter promptly transmitted or returned to the persons entitled thereto;[857] or alternatively, that all such funds must be promptly transmitted to a bank that has agreed in writing to hold such funds in escrow for the persons who have the beneficial interests therein and to transmit or return such funds directly to the persons entitled thereto when the appropriate event or contingency has occurred.[858] When the Commission adopted Rule 15c2–4, the Commission explained that the rule was designed to prevent fraud by a broker-dealer ''either upon the person on whose behalf the distribution is being made or upon the customer to whom the payment is to be returned if the distribution is not completed.''[859] As such, consistent with Securities Act Section 4A(a)(7), the intermediary may transmit the proceeds to the issuer only if the target offering amount is met or exceeded.

Rule 303(e)(2) as adopted establishes separate requirements for an intermediary that is a funding portal (as compared to an intermediary that is a broker-dealer) because a funding portal cannot, by statute, hold, manage, possess, or otherwise handle investor funds or securities.[860] Therefore, Rule 303(e)(2) requires a funding portal to direct investors to transmit money or other consideration directly to a qualified third party that has agreed in writing[861] to hold the funds for the benefit of the investors and the issuer and to promptly transmit or return the funds to the persons entitled to such funds.[862]

We are revising the definition of a ''qualified third party'' to include for purposes of the final rule: a registered broker or dealer that carries customer or broker or dealer accounts and holds funds or securities for those persons,[863] a bank, or a credit union insured by the National Credit Union Administration (''NCUA'').[864] We had proposed to define ''qualified third party'' to mean a bank[865] because investors, as well as intermediaries and issuers, would then be afforded the protections of existing regulations that apply to banks, in particular those pertaining to the safeguarding of customer funds.[866] However, after considering the comments, we agree with those commenters who suggested that the definition of ''qualified third party'' should be expanded to include entities other than a bank and should include, as one commenter suggested, credit unions provided that these entities offer similar protections to banks.[867] We also

[857] *See* Exchange Act Rule 15c2–4(b)(1). We note, however, that any broker-dealer seeking to hold such investor funds in a separate bank account as agent or trustee for the persons who have a beneficial interest therein are still subject to net capital requirements pursuant to Exchange Act Rule 15c3–1.

[858] *See* Exchange Act Rule 15c2–4(b)(2).

[859] *Adoption of Rule 15c2–4 under the Securities Exchange Act of 1934,* Release No. 34–6737 (Feb. 21, 1962) [27 FR 2089 (Mar. 3, 1962)].

[860] *See* Exchange Act Section 3(a)(80)(D).

[861] This written agreement is required to be maintained by the funding portal pursuant to proposed Rule 404 of Regulation Crowdfunding. *See* Section II.D.5.

[862] In the crowdfunding context, we expect that the intermediary will make the determination as to whether the contingency (*i.e.,* the target offering amount) has been met. *See* Securities Act Section 4A(a)(7) (requiring that an intermediary ''ensure that all offering proceeds are only provided to the issuer when the aggregate capital raised from all investors is equal to or greater than a target offering amount, . . . as the Commission shall, by rule, determine appropriate.'').

[863] Broker-dealers that may serve as qualified third parties under Rule 303(e) include only those broker-dealers that are required to maintain minimum net capital of $250,000 or a higher minimum amount depending on their status under Appendix E of Rule 15c3–1 under the Exchange Act. *See* Exchange Act Rules 15c3–1(a)(2)(i) and 15c3–1(a)(7)(i).

[864] The NCUA was established by the Federal Credit Union Act of 1934. *See* Federal Credit Union Act of 1934, as amended, 12 U.S.C. 1752 *et seq.* The NCUA administers the National Credit Union Share Insurance Fund (''NCUSIF''), which is backed by the full faith and credit of the U.S. government. NCUSIF protection covers the deposits in federal credit unions, as well as a majority of state-chartered credit unions. *See* NCUA Share Insurance Fund Information, Reports, and Statements, Frequently Asked Questions, National Credit Union Administration, *http://www.ncua.gov/DataApps/Pages/SI–FAQs.aspx.*

[865] *See* Proposing Release, at 182–83 [78 FR 66427, at 66473]. *See also* Exchange Act Section 3(a)(6) [15 U.S.C. 78c(a)(6)] (defining ''bank'').

[866] For example, bank deposit accounts at FDIC-insured banks are protected by FDIC deposit insurance. *See* Federal Deposit Insurance Corp., Deposit Insurance FAQs, *available at http://www.fdic.gov/deposit/deposits/faq.html.*

[867] We do not believe that the definition of qualified third party should be extended to include

Continued

made a corresponding change to the language of the rule text to indicate that a qualified third party arrangement may involve either a bank or credit union account (or accounts) established for the exclusive benefit of investors and the issuer.

After considering the comments, we further believe that the definition of ''qualified third party'' should be expanded to include certain types of registered broker-dealers. We are expanding the definition to include registered broker-dealers that carry customer or broker or dealer accounts and holds funds or securities for those persons. We believe such brokers-dealers are appropriate entities to serve as qualified third parties as they are subject to various regulatory obligations, which are designed to provide enhanced protection of investor funds through the imposition of capital and other requirements.[868] We note that we are not amending the requirements of Rule 15c2–4 through this release and not distinguishing broker-dealers that participate in offerings made in reliance on Securities Act Section 4(a)(6), either as a qualified third party or an intermediary, from broker-dealers in any other contingency offerings. As such, broker-dealers participating in offerings made in reliance on Section 4(a)(6), either as an intermediary or as a qualified third party, are still subject to Rule 15c2–4.[869] Further, we believe that existing Commission and staff guidance on Rule 15c2–4 is extensive and clear and does not warrant incorporation into the final rule or clarification.

The statute does not limit or require a particular payment mechanism, and we are not imposing such a restriction because we believe that the rules should provide reasonable flexibility regarding the payment mechanisms intermediaries employ. We believe that restrictions on particular payment mechanisms would not serve to significantly increase investor protection, particularly in light of the established investment limits. We note, however that an intermediary can, in its discretion, decline to accept certain payment methods, such as credit cards, or accept them only in certain circumstances.[870]

We also are not adopting additional requirements that would, for example, (1) prohibit variations of a contingency offering, such as minimum-maximum offerings; (2) establish a fixed deadline for transmission of funds as compared to the proposed requirement to transmit funds ''promptly''; or (3) require funding portals to maintain a certain amount of net capital. We believe that additional restrictions, such as prohibiting variations of a contingency offering or establishing a fixed deadline for the transmission of funds could hamper flexibility in the nascent crowdfunding market and prohibit the development of best practices specifically tailored to this unique form of capital raising. Finally, we are not requiring in the final rule net capital standards for funding portals. As noted above, funding portals are prohibited from handling, managing or possessing investor funds or securities.[871] We continue to believe that the requirements relating, in particular, to transmission of proceeds under the final rules will help ensure that investor funds are protected, without requiring funding portals to maintain net capital.

f. Confirmation of Transactions

(1) Proposed Rule

As proposed, Rule 303(f)(1) of Regulation Crowdfunding would require that an intermediary, at or before the completion of a transaction made pursuant to Section 4(a)(6), give or send to each investor a notification disclosing: (1) The date of the transaction; (2) the type of security that the investor is purchasing; (3) the identity, price and number of securities purchased by the investor, as well as the number of securities sold by the issuer in the transaction and the price(s) at which the securities were sold; (4) certain specified terms of the security, if it is a debt or callable security; and (5) the source and amount of any remuneration received or to be received by the intermediary in connection with the transaction, whether from the issuer or from other persons. This notification would be required to be provided by email or other electronic media,[872] and to be documented in accordance with applicable recordkeeping rules.[873] Pursuant to proposed Rule 303(f)(2), an intermediary that gives or sends to each investor the notification described above would be exempt from the requirements of Exchange Act Rule 10b–10[874] for the subject transaction.

(2) Comments on the Proposed Rule

Commenters generally supported the proposed confirmation requirements.[875] One commenter, however, stated its view that permitting intermediaries to satisfy the delivery requirement for transaction confirmations through delivery of a message that contains a notice that the information is available on the intermediary's Web site would not be sufficient.[876]

(3) Final Rule

After considering the comments, we are adopting Rule 303(f), as proposed, but with one clarifying change. As proposed, Rule 303(f)(1)(vi) would have required an intermediary to give or send to each investor a notification disclosing: ''[t]he source and amount of any remuneration received or to be received by the intermediary in connection with the transaction, including the amount and form of any remuneration that is received, or will be received, by the intermediary from persons other than the issuer. We are

Internet service providers that specialize in escrow and payment transfer, as suggested by one commenter, because we do not believe that such entities are governed by a regulatory scheme designed to provide similar protections as the other entities that we are defining as qualified third parties under Rule 303(e). We note that another commenter suggested the addition of savings and loan associations. We believe that certain savings and loan associations are covered by the definition of ''bank'' under Exchange Act Section 3(a)(6), and as such, are qualified third parties under Rule 303(e). We note that the Federal Deposit Insurance Corp. extended its authority to cover savings and loan associations in 1989. *See* Financial Institutions Reform, Recovery, and Enforcement Act of 1989 (FIRREA) (creating the Savings Association Insurance Fund (SAIF)).

[868] *See, e.g.,* Exchange Act Rule 15c3–1 and Rule 15c2–4.

[869] Under existing Rule 15c2–4, the qualified third party broker-dealer will be required to promptly deposit the funds in a separate bank account, as agent or trustee for the persons who have the beneficial interest therein, until the appropriate event or contingency has occurred, and thereafter promptly transmit or return the funds to the persons entitled thereto. *See* Rule 15c2–4(b)(1).

[870] We note, for example, that an intermediary can, in its discretion, decline to accept credit cards given that, as at least one commenter suggested, an investor's use of his or her right to dispute credit card charges can inhibit the ability of an issuer to meet its target or to provide accurate disclosures to investors and the Commission regarding the progress it has made toward, and whether it has, reached the target offering amount. This potential impact will affect offerings conducted through brokers and funding portals alike. We also note that pursuant to Exchange Act Section 3(a)(80)(D) (15 U.S.C. 78c(a)(80)(D)), a funding portal is statutorily prohibited from extending credit or margin to customers.

[871] *See* Exchange Act Section 3(a)(80)(D) [15 U.S.C. 78c(a)(80)(D)] and discussion in Section II.C.1.

[872] *See* proposed Rule 302(a)(2) (requiring an intermediary to provide all information electronically). *See also* Section II.C.4.a (discussing electronic delivery requirements).

[873] Intermediaries that are brokers are subject to the recordkeeping requirements of Exchange Act Rules 17a–3 and 17a–4, and intermediaries that are funding portals are subject to recordkeeping requirements under Rule 404 of Regulation Crowdfunding. *See* note 1114 (discussing the recordkeeping rules applicable to brokers and intermediaries). *See also* Section II.D.5.

[874] *See* note 882 (discussing Exchange Act Rule 10b–10 (17 CFR 240.10b–10) generally).

[875] *See, e.g.,* CFA Institute Letter; Joinvestor Letter.

[876] *See* Consumer Federation Letter (stating that ''[w]hile most if not all intermediaries would be likely to deliver the actual confirmation to investors, the rule would not guarantee this'').

revising Rule 303(f)(1)(vi) to require disclosure as well of the form of any remuneration received or to be received by the intermediary in connection with the transaction, including any remuneration received or to be received by the intermediary from persons other than the issuer. This edit is intended to clarify the rule by placing ''source, form and amount'' together, rather than having ''form'' listed out separately as proposed.

As explained in the Proposing Release, we believe that transaction confirmations serve an important and basic investor protection function by, among other things, conveying information and providing a reference document that allows investors to verify the terms of their transactions, acting as a safeguard against fraud and providing investors a means by which to evaluate the costs of their transactions.[877] Each of the required items of information is intended to assist investors in memorializing and assessing their transactions. Furthermore, the requirement that an intermediary disclose to an investor the source, form and amount of any remuneration received or to be received is designed to help to highlight potential conflicts of interest if, for example, an intermediary has a financial interest in an issuer using its services.[878]

As for the concern raised by one commenter about the delivery requirements for transaction confirmations,[879] we note, as we did in the Proposing Release, that the confirmation is required to be provided by email or other electronic media, consistent with the Commission's long-standing policies on the use of electronic media for delivery purposes.[880] This is also consistent with the requirement for an intermediary to provide all information electronically. We believe that this delivery requirement is appropriate for crowdfunding transactions and satisfies our obligation that requirements under Securities Act Section 4A(a)(12) be for the protection of investors and in the public interest. As to the same commenter's view that the rule would not guarantee delivery of a confirmation to investors,[881] although we acknowledge that statutes and rules cannot guarantee compliance, there is a robust regulatory scheme in place that is designed to promote compliance and that is coupled with supervision and enforcement by both the Commission and the registered national securities association.

In addition, under Rule 303(f)(2) as adopted, an intermediary that gives or sends to each investor the notification described above is exempt from the requirements of Exchange Act Rule 10b–10 for the subject transaction.[882] The confirmation terms under Rule 303(f)(2) are similar to, but not as extensive as, those broker-dealers are subject to under Rule 10b–10. We believe that this difference is appropriate given the more limited scope of an intermediary's role in crowdfunding transactions. Rule 10b–10, for example, requires disclosure about such matters as payment for order flow, riskless principal transactions, payment of odd-lot differentials and asset-backed securities. These items generally would not be relevant to crowdfunding securities transactions or an intermediary's participation in such transactions, and their inclusion in a crowdfunding securities confirmation may be confusing to investors. Therefore, we believe that if an intermediary satisfies the notification requirements of the final rules, the intermediary will have provided investors with sufficient relevant information about the crowdfunding security, and so should not be required to meet the additional requirements of Rule 10b–10.

6. Completion of Offerings, Cancellations and Reconfirmations

a. Proposed Rule

Under Securities Act Section 4A(a)(7), an intermediary is required to allow investors to cancel their commitments to invest as the Commission shall, by rule, determine appropriate. Securities Act Section 4A(b)(1)(G) requires an issuer, prior to sale, to provide investors ''a reasonable opportunity to rescind the commitment to purchase the securities.'' We proposed, therefore, in Rule 304(a) of Regulation Crowdfunding, to give investors an unconditional right to cancel an investment commitment for any reason until 48 hours prior to the deadline identified in the issuer's offering materials. Under this approach, an investor could reconsider his or her investment decision with the benefit of the views of the crowd and other information, until the final 48 hours of the offering. Thereafter, an investor would not be able to cancel any investment commitments made within the final 48 hours of the offering (except in the event of a material change to the offering, as discussed below).[883]

We also proposed in Rule 304(b) that if an issuer reached the target offering amount prior to the deadline identified in its offering materials, it could close the offering once the target offering amount was reached, provided that: (1) The offering had been open for a minimum of 21 days; (2) the intermediary provided notice about the new offering deadline at least five business days prior to the new offering deadline; (3) investors would be given the opportunity to reconsider their investment decision and to cancel their investment commitment until 48 hours prior to the new offering deadline; and (4) at the time of the new offering deadline, the issuer continued to meet or exceed the target offering amount.

In addition, we proposed in Rule 304(c) that if there was a material

[877] *See* Proposing Release at 78 FR 66475. *See also Confirmation of Transactions,* Release No. 34–34962 (Nov. 10, 1994) [59 FR 59612, 59613 (Nov. 17, 1994)].

[878] Although Securities Act Section 4A(a)(11) requires an intermediary to prohibit its directors, officers or partners (or any person occupying a similar status or performing a similar function) from having any financial interest in an issuer using its services, the final rules do not include a complete prohibition on the intermediary, itself, having a financial interest in an issuer using its services. The intermediary may have a financial interest in an issuer using its services, subject to certain limitations. *See* Rule 300(b). *See also* Section II.C.2.b.

[879] *See* Consumer Federation Letter.

[880] *See* Proposing Release, at 189 [78 FR 66427, at 66475]. *See also Use of Electronic Media,* note 714 at 25853 (discussing the ''access equals delivery'' concept and citing *Use of Electronic Media for Delivery Purposes,* Release No. 34–36345 (Oct. 6, 1995) [60 FR 53548, 53454 (Oct. 13, 1995)]]).

[881] *See* Consumer Federation Letter.

[882] Exchange Act Rule 10b–10 (17 CFR 240.10b–10) generally requires a broker-dealer effecting a customer transaction in securities (other than U.S. savings bonds or municipal securities) to provide a notification to its customer, at or before completion of a securities transaction, that discloses certain information specific to the transaction. Specifically, Rule 10b–10 requires the disclosure of the date, time, identity, prices and number of securities bought or sold; the capacity in which the broker-dealer acted (*e.g.,* as agent or principal); yields on debt securities; and under specified circumstances, the amount of remuneration the broker-dealer will receive from the customer and any other parties. With regard to the specified circumstances mentioned above, the remuneration disclosures of Rule 10b–10 generally are required, but certain exclusions apply. For example, the remuneration disclosures are generally required where a broker or dealer is acting as agent for a customer or some other person. In the case where remuneration is received or to be received by the broker from such customer in connection with the transaction, the disclosures are not required where the remuneration paid by such customer is determined pursuant to written agreement with such customer, otherwise than on a transaction basis. 17 CFR 240.10b–10(a)(2)(i)(B). In contrast, the remuneration disclosure requirements of Rule 303(f)(2)(vi) are required across all crowdfunding transactions where remunerations are received or are to be received. Given the limits on the dollar amount of securities that can be offered, as well as the limits on individual investment amounts, in transactions relying on Section 4(a)(6), we do not expect investors to negotiate individualized compensation agreements.

[883] *See* proposed Rule 304(c).

change [884] to the terms of an offering or to the information provided by the issuer about the offering, the intermediary would be required to give or send to any investors who have made investment commitments notice of the material change, stating that the investor's investment commitment will be cancelled unless the investor reconfirms his or her commitment within five business days of receipt of the notice.[885] As proposed, if the investor failed to reconfirm his or her investment within those five business days, the intermediary would be required, within five business days thereafter, to: (1) Provide or send the investor a notification disclosing that the investment commitment was cancelled, the reason for the cancellation and the refund amount that the investor should expect to receive; and (2) direct the refund of investor funds.[886] This notification, like other notifications from an intermediary, would be required to be provided by email or other electronic media, and to be documented in accordance with applicable recordkeeping rules.[887]

Finally, we proposed in Rule 304(d) that if an issuer did not complete an offering, for example, because the target was not reached or the issuer decided to terminate the offering, the intermediary would be required, within five business days, to: (1) Give or send to each investor who had made an investment commitment a notification disclosing the cancellation of the offering, the reason for the cancelation, and the refund amount that the investor should expect to receive; (2) direct the refund of investor funds; and (3) prevent investors from making investment commitments with respect to that offering on its platform. This notification, like other notifications from an intermediary, would be required to be provided by email or other electronic media, and to be documented in accordance with applicable recordkeeping rules.[888]

b. Comments on the Proposed Rule

One commenter supported the unconditional right of investors to cancel an investment commitment for any reason until 48 hours prior to the close of an offering.[889] Other commenters, however, expressed concern over the potential for misconduct regarding cancellations,[890] such as scenarios where investors commit and then withdraw at the last minute.[891]

One commenter stated that the rule on early closure of an offering should be more narrowly defined.[892] This commenter requested that the Commission clarify whether, under such circumstances, an offering should be closed from accepting more funds or keep accepting commitments until the end of the five business day period, even if this puts an offering over set limits.[893]

Some commenters supported the proposal that existing disclosure materials can be modified in the event of a material change, with the original offering remaining open,[894] while one commenter also suggested that no changes should be allowed within 21 days of the close date.[895] Several commenters generally agreed that an investor should have to reconfirm the commitment to invest when a material change occurs.[896] One commenter stated that many investors would prefer not to have to re-confirm their investments and recommended allowing investors to decide how to handle material changes.[897] Another commenter opposed any reconfirmation requirement because it believed there should be a presumption that any changes made would be in the best interest of the issuer and all of its stakeholders.[898]

Some commenters supported the proposed five-day reconfirmation period for investors.[899] Some commenters, however, stated that five business days is not enough time for an investor to decide whether to reconfirm an investment commitment after a material change is made by the issuer.[900] One commenter suggested a shorter reconfirmation time period.[901] Another commenter recommended that the Commission clarify when the five-day reconfirmation period begins.[902] One commenter suggested material revisions made to the offering should restart the 21-day minimum period for the campaign, though generally agreed that a five-business day notification is sufficient in the event that an offering is cancelled.[903]

c. Final Rules

We are adopting Rule 304 as proposed, with a technical change to correct a cross-cite in the rule text. We believe that the final rule appropriately takes into consideration the needs of investors to be able to consider material

[884] In the Proposing Release, we noted that in those instances where an issuer had previously disclosed in its offering materials only the method for determining the price of the securities offered and not the final price of those securities, setting of the final price would be considered a material change. We also noted that if the change involved closing the offering once the target offering amount is reached, which would be prior to the deadline identified in the offering materials, then the procedures required under proposed Rule 304(b), and not those in Rule 304(c), would apply.

[885] The proposed rules also required that an issuer extend an offering to allow for a five business day period in instances where material changes to the offering or to the information provided by the issuer occurred within five business days of the maximum number of days that an offering was to remain open. *See* proposed Rule 304(c)(2) of Regulation Crowdfunding. *See also* Rule 302(a)(2) (requiring that notification be provided by email or through other electronic media).

[886] *See* proposed Rule 304(c)(1) of Regulation Crowdfunding.

[887] Intermediaries that are brokers would be subject to the recordkeeping requirements of Exchange Act Rules 17a–3 and 17a–4, and intermediaries that are funding portals would be subject to recordkeeping requirements under proposed Rule 404 of Regulation Crowdfunding. *See* note 1114 (discussing the recordkeeping rules applicable to brokers and intermediaries). *See also* Section II.D.5; Section II.C.4. (discussing an intermediary's electronic delivery requirements and Rule 302(a)(2)).

[888] *See* note 1114 (discussing the recordkeeping rules applicable to brokers and intermediaries).

[889] *See* CFA Institute Letter.

[890] *See, e.g.,* Joinvestor Letter (suggesting the lock-in-date should be fourteen days prior to the closing date to prevent any misconduct surrounding the approach of a target, or the limit of oversubscription, near to the close of the round); Consumer Federation Letter; RocketHub Letter.

[891] *See, e.g.,* RocketHub Letter (recommending a 24-hour cancellation period in order to protect investors from ''`pump & rescind' schemes'' and minimize an issuer's exposure to the risk of ''`short fall' situations''); Consumer Federation Letter (noting the risk that ''individuals associated with the issuer will commit money to the offering early in the process in order to stimulate interest and create a sense of urgency about investing, only to withdraw at the last minute''). The same commenter suggested that potential gamesmanship by investors associated with the issuer has the potential to discredit crowdfunding and recommended that the Commission consider more meaningful restrictions on issuer participation.

[892] *See* RFPIA Letter (stating that ''[i]f the issuer reaches the target offering amount prior to the deadline the current proposed regulation require[s] a funding portal to give a 5 day notice to investors of the new closing date. Since funding portals have no crystal balls, this process needs to be more narrowly defined'').

[893] *Id.*

[894] *See, e.g.,* Arctic Island Letter 6; Joinvestor Letter; Wales Capital Letter 2.

[895] *See* Joinvestor Letter.

[896] *See, e.g.,* CFA Institute Letter; Wales Capital 2 Letter.

[897] *See* Wefunder Letter.

[898] *See* Public Startup Letter 3.

[899] *See, e.g.,* CFA Institute Letter; Wales Capital 2 Letter.

[900] *See, e.g.,* Arctic Island Letter 6 (advocating that the time period be ''indefinite'' so as to give investors more time to consider the changes and to give issuers more time to answer questions of individual investors and provide clarifications or make subsequent changes as needed); CfPA Letter (recommending that any change in offering documents on a Web site after initial posting restart the 21-day period (or at least half of that) during which offerings cannot close and prospective or pledged investors can reconsider and rescind their commitments).

[901] *See* RFPIA Letter (suggesting eliminating the requirement or reducing it to 72 hours).

[902] *See* ODS Letter.

[903] *See* Wales Capital Letter 2.

changes to the terms of the offering and new views expressed by the crowd, while allowing issuers to have certainty about their ability to close an offering at the end of the offering period. We have considered the comments outlined above about concerns with cancellation generally and those suggesting other types of cancellation or lock-in periods. However, we continue to believe that allowing investors to cancel any investment commitments for any reason until 48 hours prior to the deadline identified in the issuer's offering materials is an appropriate cancellation period because it is consistent with the requirement of Section 4A(b)(1)(G) that investors have a ''reasonable opportunity'' to rescind investment commitments, while also providing issuers with certainty within a reasonable amount of time about whether they have indeed received investment commitments. Although we acknowledge commenters' concerns about potential misconduct in connection with cancellations of investment commitments, we note that issuers and investors, including investors associated with the issuer, are subject to the antifraud provisions of the securities laws. We also note that, as we discussed above, an intermediary is required to promptly remove an offering from its platform if it becomes aware of information that causes it to believe that the issuer or the offering presents the potential for fraud or otherwise raises concerns about investor protection.[904]

In regards to one commenter's request for clarification as to whether an intermediary may continue to receive investment commitments during the five business day period prior to an early closure of an offering (even if the commitment may be oversubscribed), we note that intermediaries are permitted to continue to receive investment commitments during that time period, provided that the intermediary informs investors about the continuation of such acceptance in accordance with Rule 304(b).[905]

In addition, we believe that when material changes arise during the course of an offering, an investor who had made a prior investment commitment should have a reasonable period during which to review the new information and to decide whether to invest by reconfirming the investment commitment. Despite some commenters' concerns outlined above, we continue to believe that a five business day period is appropriate because it reasonably reflects the need to allow an investor sufficient time to consider material changes to the terms of the offering while giving issuers certainty about their ability to close an offering. For the same reasons noted above, we also believe that five business days is a sufficient amount of time for intermediaries to notify investors about offerings that are not completed or terminated. Finally, we believe that requiring an investor to reconfirm his or her investment commitment within five business days of receipt of the notice of a material change is sufficiently clear as to when the reconfirmation period begins and provides additional investor protection and is therefore an appropriate requirement for the final rule.

7. Payments to Third Parties

a. Proposed Rule

Securities Act Section 4A(a)(10) provides that an intermediary in a transaction made in reliance on Section 4(a)(6) shall not compensate ''promoters, finders, or lead generators for providing the broker or funding portal with the personal identifying information of any potential investor.''

We proposed in Rule 305(a) of Regulation Crowdfunding to prohibit an intermediary from compensating any person for providing it with the ''personally identifiable information'' [906] of any investor. As explained in the Proposing Release, we believe that any person compensated for providing the personally identifiable information of investors would be acting as a promoter, finder or lead generator within the meaning of Securities Act Section 4A(a)(10).

Proposed Rule 305(b), however, would permit an intermediary to compensate a person for directing issuers or investors to the intermediary's platform if: (1) The person does not provide the intermediary with the personally identifiable information of any investor, and (2) the compensation, unless it is paid to a registered broker or dealer, is not based, directly or indirectly, on the purchase or sale of a security offered in reliance on Securities Act Section 4(a)(6) on or through the intermediary's platform.[907]

b. Comments on the Proposed Rule

Some commenters generally supported the portion of the proposed rule that allows intermediaries to compensate third parties for directing investors to the platform.[908] Some of these comments also agreed that intermediaries should be permitted to compensate third parties for general business advertising including, for example, web search engine direction or other standard Internet marketing techniques.[909] In response to our request for comment as to whether disclosures should be required when an intermediary compensates third parties for directing investors to its platform, one commenter suggested the Commission should not require disclosure of ''standard Internet marketing [practices]'' that ''inform investors of companies they may be interested in.'' [910] Another commenter stated that compensation should only be allowed under limited circumstances, albeit without providing examples of those limited circumstances.[911] We did not receive comments related to the definition of the term ''personally identifiable information'' as proposed in Rule 305(c).

c. Final Rules

We are adopting Rule 305 with modifications. Rule 305(a), like the proposed rule, states that an intermediary may not compensate any person for providing the intermediary with the personally identifiable information of any investor in securities offered and sold in reliance on Section 4(a)(6) of the Securities Act. However, we are not including in the final rule

[904] *See* Section II.C.3.

[905] However, the issuer will still have to comply with the rules regarding oversubscriptions. *See* Section II.B.6.a. This same commenter expressed uncertainty about how an issuer will communicate early closure to a funding portal so that the funding portal can provide appropriate notice to investors about the new offering deadline. The final rules do not prescribe the mechanics for how funding portals must communicate with issuers as we believe the better course is to provide for flexibility in this regard so that intermediaries and issuers can arrive at efficient working arrangements.

[906] As proposed, the term ''personally identifiable information'' would mean any information that can be used to distinguish or trace an individual's identity, either alone or when combined with other personal or identifying information that is linked or linkable to a specific individual. *See* proposed Rule 305(c) of Regulation Crowdfunding. As explained in the Proposing Release, personally identifiable information could include any information that can be used to identify an individual, such as name, social security number, date or place of birth, mother's maiden name or biometric records, as well as any other information that is linked directly to an individual, such as financial, employment, educational or medical information.

[907] We note that the receipt of direct or indirect transaction-based compensation would strongly indicate that the recipient is acting as a broker. As such, the party receiving the compensation in the scenario described needs to consider whether it would be required to register as a broker.

[908] *See, e.g.,* RoC Letter; RocketHub Letter; Wefunder Letter.

[909] *See, e.g.,* RocketHub Letter; Wefunder Letter. *See also* ABA Letter (discussing the practice of so-called ''passive bulletin boards'').

[910] Wefunder Letter.

[911] *See* Joinvestor Letter (''We believe such compensation should be allowed under extremely limited circumstances, as promotion will be a central issue to these campaigns.'').

what was proposed in paragraph (b), which stated that an intermediary may compensate a person for directing issuers to the intermediary's platform, provided that unless the compensation is made to a registered broker or dealer, the compensation is not based, directly or indirectly, on the purchase or sale of a security offered in reliance on Section 4(a)(6) of the Securities Act on or through the intermediary's platform. Upon further consideration, we believe this provision would be duplicative of Rule 402(b)(6), which addresses referral payments that funding portals are permitted to pay to third parties.[912] In addition, registered broker-dealers are already subject to limitations on the types of compensation that they may pay to third parties, and as we explained in the Proposing Release, are subject to an established regulatory and oversight regime that provides important safeguards for investors.

We agree with those commenters who believe intermediaries should be permitted to compensate third parties for general business advertising including, for example, web search engine direction or other standard Internet marketing techniques so long as that compensation is not based, directly or indirectly, on the purchase or sale of a security offered in reliance on Securities Act Section 4(a)(6).[913] We believe permitting compensation for these types of general business advertising does not raise the same privacy concerns as those implicated by the provision of personally identifiable information and is generally consistent with the statutory scheme for crowdfunding promotional activities. Therefore, under the rules, an intermediary may pay a person a flat fixed fee [914] to direct persons to the intermediary's platform through, for example, hyperlinks or search term results or make payments to a person to advertise its existence.[915] The intermediary, however, cannot pay to receive personally identifiable information in under any circumstances pursuant to the prohibition in Rule 305(a).

Finally, we are adopting as proposed the definition of personally identifiable information, which will be renumbered as Rule 305(b).

D. Additional Funding Portal Requirements

1. Registration Requirement

a. Generally

(1) Proposed Rules

Securities Act Section 4A(a)(1) requires that an intermediary facilitating a transaction made in reliance on Securities Act Section 4(a)(6) register with the Commission as a broker or a funding portal. The statute does not, however, prescribe the manner in which a funding portal would register with the Commission.[916] Securities Act Section 4A(a)(12) requires intermediaries to comply with requirements as the Commission may, by rule, prescribe for the protection of investors and in the public interest. Exchange Act Section 3(h)(1)(C) also permits the Commission to impose, as part of its authority to exempt funding portals from broker registration, ''such other requirements under [the Exchange Act] as the Commission determines appropriate.''

We proposed to establish a streamlined registration process under which a funding portal would register with the Commission by filing a form with information consistent with, but less extensive than, the information required for broker-dealers on the Uniform Application for Broker-Dealer Registration (''Form BD'').[917] Under proposed Rule 400(a), a funding portal would register by completing a Form Funding Portal, which would include information concerning the funding portal's principal place of business, its legal status and its disciplinary history, if any; business activities, including the types of compensation the funding portal would receive; control affiliates of the funding portal and disclosure of their disciplinary history, if any; FINRA membership or membership with any other registered national securities association; and the funding portal's Web site address(es) or other means of access.[918] Proposed Rule 400(a) also would require a funding portal to become a member of FINRA or another applicable national securities association registered under Exchange Act Section 15A. As proposed in Rule 400(a), the funding portal's registration would become effective the later of: (1) 30 calendar days after the date that the registration is received by the Commission; or (2) the date the funding portal is approved for membership in FINRA or any other registered national securities association.

Proposed Rule 400(b) would require a funding portal to file an amendment to Form Funding Portal within 30 days of any of the information previously submitted on the form becoming inaccurate for any reason.

In addition, proposed Rule 400(c)(1) would permit a funding portal that succeeds to and continues the business of a registered funding portal to also succeed to the registration of the predecessor on Form Funding Portal. As proposed in Rule 400(c)(1), the registration would remain effective as the registration of the successor if the successor, within 30 days after such succession, files a registration on Form Funding Portal and the predecessor files a withdrawal on Form Funding Portal.[919] Proposed Rule 400(c)(1), therefore, would not apply where the predecessor funding portal intends to continue to engage in funding portal activities.

In certain circumstances, proposed Rule 400(c)(2) would allow the successor to file an amendment to the predecessor's Form Funding Portal rather than requiring the successor and predecessor, respectively, to follow the registration filing and withdrawal process under Rule 400(c)(1) described above. Specifically, proposed Rule 400(c)(2) provides that, if the succession is based solely on a change of the predecessor's date or state of incorporation, form of organization or composition of a partnership, the successor may, within 30 days after the succession, amend the notice registration of the predecessor on Form Funding Portal to reflect these changes. Successions by amendment would be limited to those successions that

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[912] *See* Section II.D.3.

[913] *See, e.g.,* 158 Cong. Rec. S5474–03 (daily ed. July 26, 2012) (statement of Sen. Jeff Merkley) (''[T]he limitation on off-platform advertising is intended to prohibit issuers—including officers, directors, and 20 percent shareholders—from promoting or paying promoters to express opinions outside the platform that would go beyond pointing the public to the funding portal.'').

[914] A flat fixed fee is one that is not based on the success of the offering, and so would not be transaction-based compensation. We note that the receipt of direct or indirect transaction-based compensation would strongly indicate that the recipient is acting as a broker. As such, the party receiving this kind of compensation needs to consider whether it would be required to register as a broker.

[915] *See also* Rule 402 of Regulation Crowdfunding and discussion in Section II.D.3 (discussing advertising and marketing activities in which a funding portal may engage under the Regulation's safe harbor).

[916] *Compare* Exchange Act Section 15(b) [15 U.S.C. 78*o*(b)] (prescribing the manner of registration of broker-dealers).

[917] Brokers currently register with the Commission using Form BD. Information on that form regarding the broker's credentials, including current registrations or licenses and employment and disciplinary history, is publicly available on FINRA's BrokerCheck.

[918] We discuss in Section II.D.1.b the information required to be included in Form Funding Portal.

[919] Under the proposed rules, the registration of the predecessor funding portal would be deemed withdrawn 45 days after the notice registration on Form Funding Portal was filed by the successor. *See* proposed Rule 400(c)(1). A similar process exists for registered broker-dealers under Exchange Act Rule 15b1–3 (17 CFR 240.15b1–3).

resulted from a formal change in the structure or legal status of the funding portal but did not result in a change in control.

The instructions to the proposed Form Funding Portal would limit the term ''successor'' to an entity that assumed or acquired substantially all of the assets and liabilities of the predecessor funding portal's business.

We also proposed in Rule 400(d) to require a funding portal to promptly file a withdrawal of registration on Form Funding Portal upon ceasing to operate as a funding portal. The withdrawal would be effective on the later of 30 days after receipt by the Commission, after the funding portal was no longer operational, or within a longer period of time consented to by the funding portal or that the Commission, by order, determined as necessary or appropriate in the public interest or for the protection of investors.[920]

Proposed Rule 400(e) would provide that each application for registration, amendment thereto, successor registration or withdrawal would be considered filed when a complete Form Funding Portal was submitted with the Commission or its designee. Proposed Rule 400(e) also would require duplicate originals of the application to be filed with surveillance personnel designated by the registered national securities association of which the funding portal is a member.

(2) Comments on the Proposed Rule

We received some comments generally supporting the proposed registration method,[921] while one commenter generally opposed the proposed registration method, stating the Commission is requiring too stringent a registration process and financial overhead for funding portals.[922] One commenter encouraged the Commission to require broker-dealers to register on the same form as funding portals.[923]

In the Proposing Release, we requested comments on whether we should impose other restrictions or prohibitions on affiliations of the funding portal, such as affiliation with a registered broker-dealer or registered transfer agent. Some commenters opposed the imposition of other restrictions or prohibitions on affiliations of the funding portal.[924] One of these commenters stated that affiliations and partnerships with brokers or transfer agents should be optional.[925]

(3) Final Rules

We are adopting Rule 400(a)–(e) generally as proposed with one change. We are deleting from Rule 400(e) as proposed the language stating that Form Funding Portal may be filed with a Commission designee, as we have determined not to designate this function. Rather, these filings will be made through the EDGAR system as explained in more detail below.

Rule 400 establishes a streamlined registration process for a funding portal to register with the Commission. We have considered the general comment suggesting that the registration requirement for funding portals is too stringent and creates financial overhead. We believe, however, that the rules as adopted provide a reasonable approach to funding portal registration—they are based on broker-dealer registration requirements, which we believe have been effective in providing investor protection and allowing the Commission to perform its oversight function. At the same time, the registration requirement takes into account the more limited activities of funding portals as compared to broker-dealers. As such, the registration requirements we are imposing on funding portals are generally consistent with those imposed on broker-dealers, while not as extensive in every aspect. As we note in Section III.B.5, we have considered the costs of funding portal registration and believe that the anticipated costs to funding portals are justified in light of the expected benefits investors will receive from utilizing funding portals that are subject to registration requirements, which include public disclosure of registration information on Form Funding Portal in EDGAR, as described in more detail in Section II.D.1.b below. We believe that having such a registration system will promote investor confidence in this new and emerging market, while providing us and FINRA (and any other applicable national securities association registered pursuant to Exchange Act Section 15A) with information integral to effective oversight.

Finally, consistent with the proposal, we are not imposing additional restrictions or prohibitions on affiliations of the funding portal in the final rules. We note, however, that Form Funding Portal, which will be publicly available, requires a funding portal to disclose information about its control relationships and the disciplinary history of associated persons.[926]

b. Form Funding Portal

(1) Proposed Rules

As noted above, proposed Rule 400(a) requires a funding portal seeking to register with the Commission, through an initial application, to file a completed Form Funding Portal with the Commission. As proposed, Rule 400(b)–(d) would have also required funding portals to use proposed Form Funding Portal to amend any part of the funding portal's most recent Form Funding Portal, including certain successor registrations, or to withdraw from registration as a funding portal with the Commission.[927] We proposed to make a blank Form Funding Portal available through the Commission's Web site or such other electronic database, as determined by the Commission in the future.

As proposed, Form Funding Portal appropriately considered the need to provide efficiency in completing the

[920] A similar process exists for registered broker-dealers under Exchange Act Section 15(b)(5) (15 U.S.C. 78*o*(b)(5)) and Rule 15b6–1 (17 CFR 240.15b6–1) thereunder.

[921] *See, e.g.,* Joinvestor Letter; DreamFunded Letter (favoring the proposed rules which provide a ''high barrier to entry'' to funding portals, as it will ''stop anyone from potentially creating a funding portal over a weekend'').

[922] *See* PeoplePowerFund Letter (suggesting that the Commission should consider, ''a simple registration detailing the owners and operators of a web portal, the legal domicile and registration contact information etc. and the portals [sic] commitment to adherence of the rules of the [C]ommission'').

[923] *See* RocketHub Letter. The commenter also stated that it has ''a serious concern with [broker-dealers] having an unfair advantage in the market, by already being regulated and registered with the Commission as well as FINRA. Therefore, they may be able to service the market well ahead of [funding] [p]ortals.''

[924] *See, e.g.,* Joinvestor Letter; Tiny Cat Letter.

[925] *See* Tiny Cat Letter.

[926] *See* Item 4—Control Relationship of Form Funding Portal and Item 5—Disclosure Information of Form Funding Portal. ''Control'' is defined for the purposes of Form Funding Portal as ''[t]he power, directly or indirectly, to direct the management or policies of the *funding portal,* whether through contract, or otherwise. A *person* is presumed to *control* a *funding portal* if that *person:* (1) IS A director, general partner or officer exercising executive responsibility (or has a similar status or functions); (2) directly or indirectly has the right to vote 25 percent or more of a class of a voting security or has the power to sell or direct the sale of 25 percent or more of a class of voting securities of the *funding portal;* or (3) in the case of a partnership, has contributed, or has a right to receive, 25 percent or more of the capital of the *funding portal.*'' *See* Instructions to Form Funding Portal.

[927] As noted in Section II.D.1.a., a successor funding portal may amend the registration of its predecessor on Form Funding Portal, within 30 days after succession, if the succession is based solely on a change of the predecessor's date of incorporation, state of incorporation, form of organization, or composition of a partnership. Otherwise, a successor must file a registration statement on Form Funding portal within 30 days after succession and a predecessor must file a withdrawal on Form Funding Portal. *See* Rule 400(c).

form while requesting sufficient information from funding portals to allow for effective regulatory oversight. The proposed form would have consisted of eight sections, including items related to: Identifying information, form of organization, successions, control persons, disclosure information, non-securities related business, escrow, compensation arrangements, and withdrawal. These items would require an applicant to provide certain basic identifying and contact information concerning its business; list its direct owners and executives; identify persons that directly or indirectly control the funding portal, control the management or policies of the funding portal and persons the funding portal controls; and supply information about its litigation and disciplinary history and the litigation and disciplinary history of its associated persons.[928] Under proposed Form Funding Portal, a funding portal would be able to operate multiple Web site addresses under a single funding portal registration, provided the funding portal disclosed on Form Funding Portal all the Web sites and names under which it did business.[929] In addition, the proposed form would have required an applicant to describe any non-securities related business activities and supply information about its escrow arrangements, compensation arrangements with issuers and fidelity bond.

Upon a filing to withdraw from registration, a funding portal would be required to provide certain books and records information. In addition, as discussed in detail in Section II.D.1.d. below, applicants that are incorporated in or organized under the laws of a jurisdiction outside of the United States or its territories, or whose principal place of business is not in the United States or its territories, would have been required to complete Schedule C to Form Funding Portal, which would require information about the applicant's arrangements to have an agent for service of process in the United States, as well as a certification and an opinion of counsel addressing the ability of the applicant to provide the Commission and the national securities association of which it is a member with prompt access to its books and records and to submit to onsite inspection and examination by the Commission and the national securities association.

We also proposed that a person duly authorized to bind the funding portal be required to sign Form Funding Portal in order to execute the documents.[930] As proposed, the funding portal also would have been required to consent to service of process to its contact person on the form.[931]

Finally, we proposed to make all current Forms Funding Portal, including amendments and registration withdrawal requests, immediately accessible and searchable by the public, with the exception of certain personally identifiable information or other information with significant potential for misuse (including the contact employee's direct phone number and email address and any IRS Employer Identification Number, social security number, date of birth, or any other similar information).[932]

(2) Comments on Proposed Rules

We received one comment in support of using EDGAR for all funding portal filing and registration requirements.[933] Some commenters also generally supported allowing a funding portal to file one registration application to operate multiple Web sites.[934] One commenter, however, expressed concern about allowing funding portals to file one registration form for multiple Web sites. This commenter suggested the Commission ''clearly address Portals that register with the Commission, and then subsequently license out or sell their registration.'' [935] The same commenter stated that ''[s]ome entrepreneurs have indicated that they intend to operate a 'parent' funding [p]ortal, which allows other sites to operate under its umbrella, (leveraging the parent's systems, architecture, design, infrastructure, etc.).'' [936]

(3) Final Rules

We are adopting Form Funding Portal generally as proposed,[937] with the following changes:

- The final rules amend Regulation S–T to permit a funding portal to file PDF exhibits and attachments to Form Funding Portal on EDGAR as ''official filings.'' [938]
- The following has been added to the title of the form: ''Application or Amendment to Application for Registration or Withdrawal from Registration as Funding Portal'' to clarify that the form will be used for all funding portal registration applications, amendments and withdrawals;
- Amendments to Form Funding Portal will require a narrative explaining the amendment, which we believe will clarify to investors and potential investors the particular information being amended by the funding portal in its filing;
- Form Funding Portal will not require information about fidelity bonds since we are not adopting the fidelity bond requirement in the proposed rules; [939]
- Item 1 also will require information about Web site URL changes on the most recent Form Funding Portal, title of the contact employee and the month the applicant funding portal's fiscal year ends;
- The title of Item 4 is changed from ''Control Persons,'' as proposed, to ''Control Relationships,'' as adopted, to clarify that Item 4 may capture information not being captured in Schedules A and B;
- The language in Item 5 ''to determine whether to approve an

[928] This information would be used to determine whether to approve an application for registration, to decide whether to revoke registration, to place limitations on the applicant's activities as a funding portal and to identify potential problem areas on which to focus during examinations. If an applicant or its associated person has a disciplinary history, then the applicant could be required to complete the appropriate Disclosure Reporting Page (''DRP''), either Criminal, Regulatory, Civil Judicial, Bankruptcy, Bond or Judgment on proposed Form Funding Portal.

[929] *See* proposed Form Funding Portal, Item 1; 17 CFR 249.2000.

[930] *See* execution statement of proposed Form Funding Portal. We proposed requiring a person executing Form Funding Portal and Schedule C (if applicable) to represent that the person has executed the form on behalf of, and is duly authorized to bind, the funding portal; the information and statements contained in the form and other information filed are current, true and complete; and if the person is filing an amendment, to the extent that any information previously submitted is not amended, such information is currently accurate and complete.

[931] *See* execution statement of proposed Form Funding Portal. Specifically, we proposed requiring the funding portal to consent that service of any civil action brought by, or notice of any proceeding before, the Commission or any national securities association of which it is a member, in connection with the funding portal's investment-related business, may be given by registered or certified mail to the funding portal's contact person at the main address, or mailing address, on the form.

[932] *See* proposed Instructions to Form Funding Portal.

[933] *See* Public Startup Letter 3.

[934] *See, e.g.,* Joinvestor Letter; Tiny Cat Letter (stating that requiring new applications for each Web site would be unnecessary as it ''would not provide any new information for either the commission or the public'' so long as the expansion involves no material changes to information in the initial application).

[935] RocketHub Letter.

[936] *Id.*

[937] We also made minor non-substantive technical changes and changes to increase the clarity of the information being requested in the form.

[938] *See* Rule 101(a)(1)(xviii) of Regulation S–T. As we noted in Section II.B.3, Regulation S–T generally allows PDF documents to be filed only as unofficial copies. *See* Rule 104 of Regulation S–T. However, Rule 101 provides for certain exceptions to this restriction. The PDF documents must be in the format required by the EDGAR Filer Manual, as defined in Rule 11 of Regulation S–T.

[939] *See* Section II.D.1.c.

application for registration'' has been deleted;[940]

• Item 7, as adopted, references ''qualified third party arrangements'' rather than ''escrow arrangements,'' as proposed, to indicate that, in addition to holding the funds in escrow, a qualified third party may also hold investor funds in an account for the benefit of investors and the issuer;[941]

• ''G—Other (general partner, trustee, or elected member)'' has been added as an ownership code in Schedule A;

• Schedules A and B have been changed from the proposal to clarify that the Schedules are collecting information about whether direct owners and executive officers are ''control'' persons;

• The language to Schedule C of Form Funding Portal has been changed to track more closely the requirements of Rule 400(f) for nonresident funding portals and to add an execution section for these entities; and

• Withdrawal information for funding portals proposed to be collected under Item 8 will instead be collected in a new ''Schedule D''.[942]

We continue to believe that the information required by Form Funding Portal is important for our oversight of funding portals and to allow us to assess a funding portal's application for registration and perform examinations of funding portals. We also note that the information required by the Form will be available to investors and potential investors and will provide transparency regarding intermediaries. Although we generally modeled Form Funding Portal on Form BD, we have tailored the questions to the activities of funding portals. For example, Form Funding Portal, in contrast to Form BD, does not include any questions about holding customer funds and securities because funding portals are statutorily prohibited from holding or maintaining customer funds or securities. We also included questions in Form Funding Portal to address specific restrictions that are imposed upon funding portals but not upon broker-dealers. For example, Form Funding Portal requires specific information about a funding portal's qualified third party arrangements because a funding portal is prohibited from holding and maintaining customer funds.

In developing these requirements, we have taken into account that funding portals are limited purpose brokers that are conditionally exempt from registration as broker-dealers, and accordingly have sought to require appropriate information from these entities, while, at the same time, not making the process of completing and filing the required form inappropriately burdensome for funding portals.

As noted above, we proposed to make a blank Form Funding Portal available through our Web site or another electronic database. At the time of the Proposing Release, we had not yet determined the appropriate database through which to access and electronically file Form Funding Portal. We requested comments in the Proposing Release on the type of web-based registration that funding portals should use for accessing and filing Form Funding Portal, and as noted above, received one comment in support of using EDGAR for funding portal filing and registration requirements.[943] We have determined to require funding portals to access and file Form Funding Portal through the Commission's EDGAR system. Before a funding portal will be able to access EDGAR and electronically file Form Funding Portal, it will have to obtain EDGAR access codes and a central index key (''CIK'') by creating and submitting a Form ID with the Commission for authorization to access EDGAR. The applicant will be required to fill out general user information fields on Form ID, including filer type name, address, phone number, email address, organization name and employer identification number and file a signed, notarized version of the document. To facilitate this process, we are amending Form ID to add ''Funding Portal'' as a filer type and are also revising the instructions to the form to include the definition of ''funding portal'' (as defined by Rule 300(c)(2)). Once the application has been accepted by the Commission, the funding portal will receive an email with a CIK, which it can use (along with a passphrase that it has previously created) to generate EDGAR access codes, and access the system and Form Funding Portal.

As proposed, a funding portal will be required to check a box indicating the purpose for which the funding portal was filing the form:

• To register as a funding portal with the Commission, through an initial application;

• to amend any part of the funding portal's most recent Form Funding Portal, including a successor registration; or

• to withdraw from registration as a funding portal with the Commission.

The funding portal will receive an SEC file number after it files its Form Funding Portal initial application, and thereafter must provide us that file number when submitting an amendment or withdrawal from registration on Form Funding Portal. We will use this number to cross-reference amendments and withdrawals to the original registration.

When a funding portal's registration becomes effective, the information on Form Funding Portal will be made available to the public through EDGAR, with the exception of certain personally identifiable information or other information with significant potential for misuse (including the contact employee's direct phone number, fax number and email address and any IRS Employer Identification Number, IRS Tax Identification Number, social security number, date of birth or any other similar information). In addition to current versions of Form Funding Portal, investors and potential investors also will be able to access historical versions of a funding portal's filings on EDGAR. We believe that making these documents publicly available and searchable will provide the public with information about the registration process and the funding portal industry, thereby increasing transparency into this developing market.

The final rule permits a funding portal to operate multiple Web site addresses under a single funding portal registration. As we noted in the Proposing Release, we believe that allowing a funding portal to utilize more than one Web site address, if it chooses to do so, may allow the portal to minimize its regulatory costs while having the flexibility to customize each Web site to fit its specific needs, such as appealing to certain industries or

[940] We note, however, that failure to answer a question in Item 5 will result in an incomplete application for registration.

[941] *See* Section II.C.5.e.

[942] There have been no substantive changes to the withdrawal information to be collected on Schedule D. The instructions to Form Funding Portal have been modified from the proposal to (1) include IRS Tax Identification Number and the contact employee's fax number as information that will be redacted on Form Funding Portal by the Commission and, therefore, not disseminated to the public by the form; and (2) inform funding portals that they should manually redact certain personally identifiable information or other information with significant potential for misuse (including the contact employee's direct phone number, fax number and email address and any IRS Employer Identification Number, IRS Tax Identification Number, social security number, or any other similar information) from any PDF attachments they file as part of their Form Funding Portal submission due to privacy concerns. The instructions have also been modified to amend the definition of SRO to delete the reference to Section 3 of the Exchange Act and clarify that the phrase ''any national securities association registered with the Commission'' in the definition encompasses any national securities association registered under Section 15A of the Exchange Act, in order to alleviate any confusion by funding portals when completing the form.

[943] *See* Public Startup Letter 3.

investors. We have considered one commenter's concern about funding portals licensing or selling their registrations, and note that registrations are not transferrable among entities; rather, each funding portal is required to register with the Commission, pursuant to Rule 400(a). As explained above, an entity may succeed to and continue the business of a registered funding portal, but the successor must file a registration on Form Funding Portal within 30 days after any succession resulting in a change of control.[944]

c. Fidelity Bond

(1) Proposed Rule

Proposed Rule 400(f) would have required that funding portals, as a condition of registration, have in place, and thereafter maintain for the duration of such registration, a fidelity bond that: (1) Has a minimum coverage of $100,000; (2) covers any associated person of the funding portal unless otherwise excepted in the rules set forth by FINRA or any other registered national securities association of which it is a member; and (3) meets any other applicable requirements set forth by FINRA or any other registered national securities association of which it is a member. While fidelity bond coverage was not mandated by statute, the proposed requirement was intended to help insure against the loss of investor funds that might occur if a funding portal were to violate the express prohibition set forth in Exchange Act Section 3(a)(80) on holding, managing, possessing or otherwise handling investor funds or securities.

(2) Comments on Proposed Rule

We received comments both in support of,[945] and opposition to,[946] the proposed requirement for funding portals to maintain fidelity bonds. One commenter stated its view that a fidelity bond may be necessary as a preventative measure to protect the interests of investors and issuers.[947] Another commenter noted that although fidelity bond coverage may be ''indirect'' to customers, they are protected under such coverage because the insured entity may recover its losses due to theft or embezzlement by its employees and meet the obligations of its customers.[948] The same commenter, however, suggested that the Commission may find a surety bond more appropriate in the crowdfunding context than a fidelity bond because investors would be able to make a direct claim under it for losses due to a funding portal's violation of the rules, and the insurer would be able to seek indemnity for that amount from the funding portal.[949] One commenter stated that it is not appropriate to require that the fidelity bond cover associated persons, and that the requirement is a ''hangover from a non-transparent financial services sector,'' unlike the transparent crowdfunding model.[950] Another commenter noted that a fidelity bond would protect a funding portal from employee theft or embezzlement, and suggested that there is a low risk of this occurring since a funding portal not does hold cash or customer funds.[951] The commenter further stated that ''[o]btaining a bond is simply one more expense that the portal must incur and it is necessary to control compliance costs if crowdfunding is to be a success.'' [952]

(3) Final Rules

After taking into account the comments and upon further consideration, we have determined not to adopt a fidelity bond requirement for funding portals. We have been persuaded by the comments that such a requirement may not be appropriate. We believe that the statutory protections and prohibitions set forth in Exchange Act Section 3(a)(80) on holding, managing, possessing or otherwise handling investor funds or securities provide substantial protections to investors. We recognize, as some commenters observed, that there may be potential risks to investors if a funding portal were to violate the prohibitions in Regulation Crowdfunding, including the potential loss of investor funds. As we discussed in the Proposing Release, funding portals will not be members of the Securities Investor Protection Corporation (''SIPC'') and their customers, therefore, will not receive SIPC protection.[953] Furthermore, consistent with the proposed rules, the final rules also do not subject funding portals to minimum net capital requirements. Despite these vulnerabilities, we note that the potential burden associated with the requirement of a fidelity bond (or any bond) may not be justified by the benefits that could be derived from requiring that a funding portal obtain such a bond. In particular, we are concerned that a fidelity bond requirement could create a potential barrier to entry for some funding portals that could be detrimental to our mission of capital formation, as well as the feasibility of crowdfunding. At the same time, we are mindful of the potentially limited benefits of requiring such bonds to be obtained by funding portals, when taking into account the statutory restrictions on funding portals' permissible activities. Instead, we believe at this time that the prohibition on a funding portal from handling customer funds and securities as well as the general anti-fraud provisions of our statutes and rules provide significant investor protections that do not need to be supplemented by a fidelity bond requirement. This decision is consistent with our approach generally to the regulation of funding portals in which we have sought to structure rules tailored to the business of funding portals that address the risks posed by such activities while considering the impact that our rules may have on this emerging market.

d. Requirements for Nonresident Funding Portals

(1) Proposed Rules

Under proposed Rule 400(g), registration pursuant to Rule 400 of Regulation Crowdfunding by a ''nonresident funding portal'' [954] would be first conditioned upon there being an information sharing arrangement in place between the Commission and the competent regulator in the jurisdiction under the laws of which the nonresident funding portal is organized or where it has its principal place of business that is applicable to the nonresident funding portal. The proposed rule would further require a nonresident funding portal registered or applying for registration to: (1) Obtain a written consent and power of attorney appointing an agent for service of process in the United States (other than the Commission or a Commission member, official or employee), upon whom may be served any process, pleadings, or other papers in any action; [955] (2) furnish the Commission with the name and address of its agent for services of process on

[944] *See* Section II.D.1.a.

[945] *See, e.g.,* Joinvestor Letter; Public Startup 3 Letter; RocketHub Letter; SFAA Letter.

[946] *See, e.g.,* ASSOB Letter; Heritage Letter; PeoplePowerFund Letter; RoC Letter.

[947] *See* Joinvestor Letter.

[948] *See* SFAA Letter.

[949] *See id.*

[950] *See* ASSOB Letter.

[951] *See* Heritage Letter

[952] *Id.*

[953] *See* Proposing Release at 78 FR at 66482. Membership in SIPC applies only to persons registered as brokers or dealers under Section 15(b) of the Exchange Act. *See* 15 U.S.C. 78ccc(a)(2).

[954] *See* proposed Rule 400(g)(1) of Regulation Crowdfunding (defining ''nonresident funding portal'' as ''a funding portal incorporated in or organized under the laws of any jurisdiction outside of the United States or its territories, or having its principal place of business in any place not in the United States or its territories'').

[955] *See* proposed Rule 400(g)(2)(i) of Regulation Crowdfunding.

Schedule C of Form Funding Portal; [956] and (3) certify on Schedule C of Form Funding Portal and provide an opinion of counsel that it can, as a matter of law, provide the Commission and any national securities association of which it is a member with prompt access to its books and records and can, as a matter of law, submit to onsite inspection and examination by the Commission and such national securities association.[957]

Proposed Rule 400(g)(2)(iv) would require a registered nonresident funding portal to promptly appoint a successor agent if it discharges its identified agent for service of process or if its agent for service of process is unwilling or unable to accept service on its behalf. In addition, proposed Rule 400(g)(2)(iii) would require a registered funding portal to promptly amend Schedule C to its Form Funding Portal if its agent, or the agent's name or address, changes. Finally, proposed Rule 400(g)(2)(v) would require the registered nonresident funding portal to maintain, as part of its books and records, the agreement with the agent for service of process for at least three years after termination of the agreement.

In addition, we proposed in Rule 400(g)(3)(ii) to require a registered nonresident funding portal to re-certify, on Schedule C to Form Funding Portal, within 90 days after any changes in the legal or regulatory framework that would affect: (1) Its ability to provide (or the manner in which it provides) the Commission, or the national securities association of which it is a member, with prompt access to its books and records; or (2) the ability of the Commission or the national securities association to inspect and examine the nonresident funding portal. The re-certification would be accompanied by a revised opinion of counsel describing how, as a matter of law, the entity can continue to meet its obligations to provide the Commission and the national securities association with prompt access to its books and records and to be subject to inspection and examination.[958]

(2) Comments on the Proposed Rule

One commenter stated its view that the definition of a nonresident funding portal will create a competitive advantage for foreign intermediary platforms.[959] Another commenter stated its view that nonresident funding portals should be subject to the same rules as domestic funding portals.[960]

In the Proposing Release, we requested comments about other actions or requirements that could address our concern that the Commission and the applicable national securities association be able to have direct access to books and records and be able to adequately examine and inspect a nonresident funding portal, if it would be impossible or impractical for such funding portal to obtain the required opinion of counsel. In response, a commenter suggested an arrangement between a nonresident funding portal and a domestic funding portal in which the nonresident funding portal would be required to make and keep current books and records, but the domestic funding portal would have the ability to obtain and be responsible for the accuracy of such books and records.[961]

One commenter suggested that nonresident funding portals be required to clearly indicate on their Web sites that they are organized and operating outside of the U.S. and indicate whether a U.S. or non-U.S. bank will be used to process investors' funds.[962] One commenter suggested that a nonresident funding portal should be required to appoint a U.S. agent for all potential proceedings,[963] while another commenter suggested that a nonresident funding portal should be required to have a resident legal representative to handle any matters between issuers or investors and the portal.[964]

(3) Final Rules

We are adopting Rule 400(g) as proposed with certain minor changes, and renumbering it as Rule 400(f) due to the elimination of the fidelity bond requirement proposed as subparagraph (f).[965] We are changing the language of the rule as adopted applicable to a nonresident funding portal to:

- Add the term ''registered'' to any references to national securities association in the Rule to be more consistent with the terminology in the Exchange Act; and
- Require the nonresident funding portal also to certify that it ''will'' provide the Commission and any national securities association of which it ''becomes'' (rather than ''is'') a member with prompt access to the books and records and ''will'' submit to onsite inspection and examination by the Commission and such national securities association.[966]

As we noted in the Proposing Release, the rule aims to help ensure that we and any applicable registered national securities association can access the books and records of, conduct examinations and inspections of, and enforce U.S. laws and regulations with respect to, funding portals that are not based in the United States, or that are subject to laws other than those of the United States. We believe that these rules will further our goal of promoting the ability of the Commission and any applicable national securities association to conduct effective regulatory oversight of funding portals.

We have considered the comments and believe that the final rule appropriately takes into consideration the need to provide more choices for U.S. issuers seeking to use intermediaries or access investors outside of the United States, while meeting the challenges associated with supervising, examining, and enforcing rules regarding activities of intermediaries based outside the United States. For example, as we noted in the Proposing Release, the requirement for an information sharing arrangement is designed to provide us with greater assurance that we will be able to obtain information about a nonresident funding portal necessary for our oversight of the funding portal. The ability to obtain information and secure

[956] *See* proposed Rule 400(g)(2)(ii) of Regulation Crowdfunding.

[957] *See* proposed Rule 400(g)(3)(i) of Regulation Crowdfunding. Exchange Act Section 3(h)(1)(C) permits us to impose, as part of our authority to exempt funding portals from broker registration, ''such other requirements under [the Exchange Act] as the Commission determines appropriate.''

[958] *See* proposed Rule 400(g)(3)(ii) of Regulation Crowdfunding.

[959] *See* Public Startup Letter 3 (stating its view that the definition of nonresident funding portal is ''flawed'' because it believes these foreign entities could choose to act as intermediaries for U.S. issuers and U.S. investors in crowdfunding transactions without relying on Section 4(a)(6) and, therefore, gain a competitive advantage by not having to comply with the requirements of the rules under Regulation Crowdfunding in the same manner as domestic funding portals). *But see* Joinvestor Letter (stating its belief that ''nonresident funding portal is properly defined'').

[960] *See* Wales Capital Letter 3. The commenter also recommended using the term '' 'foreign' funding portal'' to be consistent with the treatment of corporations incorporated in another jurisdiction under various state laws. According to the commenter, a foreign corporation must file a notice of doing business in any state or nation in which it does substantial regular business, and must name an '' 'agent for acceptance of service' '' in that nation (or the Secretary of State as agent) to allow people doing business with a foreign corporation to be able bring legal actions locally.

[961] *Id.*

[962] *See* Zhang Letter.

[963] Wales Capital Letter 3.

[964] *See* Joinvestor Letter.

[965] We also added ''*Inspections and Examinations''* to the heading of Rule 400(f)(3); this modification does not change the requirements from those proposed. In addition, we changed a cross-cite in the rule text to reflect the renumbering.

[966] The language in the proposed rule required a certification that the funding portal ''can'' meet such obligations but did not require a certification that it ''will'' meet them.

the cooperation of the home country regulator according to established practices and protocols is expected to help to address the increased challenges that may arise from oversight of entities located outside of the United States. We note that nonresident funding portals are subject to the same registration requirements as other funding portals under Rule 400.[967]

We have also considered the comment submitted in response to our question about the use of books and records arrangements in situations where it would be impossible or impractical for a nonresident funding portal to obtain the required opinion of counsel.[968] We have determined not to adopt an alternative to the opinion of counsel requirement for nonresident funding portals in Regulation Crowdfunding. The opinion of counsel requirement is consistent with our approach to other nonresident registered entities and we believe it is an appropriate mechanism to use here, as well.[969] As we stated in the Proposing Release, we believe that the certification and supporting opinion of counsel requirements are important to confirm that each nonresident funding portal is in a position to provide the Commission and FINRA (or the applicable national securities association registered under Exchange Act Section 15A) with information that is necessary for us and the national securities association to effectively fulfill regulatory oversight responsibilities.[970] We do not believe that the books and records arrangement suggested by the commenter would provide assurance that we or FINRA would be able to consistently obtain such information, which could hinder our ability to fulfill our regulatory oversight responsibilities.

We have also considered the comment suggesting that a nonresident funding portal be required to clearly indicate on its Web site that it is organized and operating outside of the United States and whether it will use a U.S. or non-U.S. bank to process investors' funds.[971] However, in light of the other disclosure requirements we are adopting, we are not persuaded that such a requirement is necessary. We note that the information required to be filed on Form Funding Portal (and that will be publicly disclosed) will include information about the qualified third party for the maintenance and transmission of investors' funds under Rule 303(e), including the name and address of the qualified third party.[972] In addition, a nonresident funding portal will be required to publicly disclose information on Schedule C to Form Funding Portal. Since Schedule C is required to be completed by nonresident funding portals only, investors will be able to discern easily whether or not the entity is a nonresident funding portal and, among other things, has certified (and provided an attached opinion of counsel indicating) that it is able to provide the Commission and any national securities association prompt access to its books and records and will submit to onsite inspection and examination by the same.

Finally, we have considered the comments suggesting that a nonresident funding portal should be required to have a U.S. agent for potential proceedings,[973] or a resident legal representative to handle any matters between issuers or investors, and the portal.[974] We note that, as discussed above, we are requiring funding portals to execute a written consent and power of attorney appointing an agent in the United States. The agent will be the representative of the funding portal for service of any process, pleadings or other papers in any action to enforce the Exchange Act, Securities Act or any rule or regulation promulgated thereunder. As we noted above, we have limited the types of actions for which a nonresident funding portal will be required to have an agent for service of process, pleadings, or other papers in order to remain generally consistent with recent requirements that we have imposed on other types of nonresident entities. The funding portal will be required to disclose the name and address of its U.S. agent in Schedule C to its Form Funding Portal, and amend the Schedule promptly upon any change to the agent, agent's name or agent's address. We are not, however, requiring that nonresident funding portals have a resident legal representative to handle any matters between the portal and issuers or investors, which is consistent with our approach to other nonresident registered entities.[975]

2. Exemption From Broker-Dealer Registration

a. Proposed Rule

Exchange Act Section 3(h)(1), which was added by Section 304(a) of the JOBS Act, directs the Commission by rule to exempt, conditionally or unconditionally, a registered funding portal from the requirement to register as a broker or dealer under Exchange Act Section 15(a), provided that the funding portal: (1) Remains subject to the examination, enforcement and other rulemaking authority of the Commission; (2) is a member of a registered national securities association; and (3) is subject to other requirements that the Commission determines appropriate.

As explained earlier, the role contemplated by Title III of the JOBS Act for an entity acting as an intermediary in a crowdfunding transaction would bring that entity within the definition of ''broker'' under Exchange Act Section 3(a)(4).[976] A funding portal would be ''effecting transactions in securities for the account of others'' by, among other things, ensuring that investors comply with the conditions of Securities Act Section 4A(a)(4) and (8), making the securities available for purchase through the funding portal, and ensuring the proper transfer of funds and securities as required by Securities Act Section

[967] We have considered the commenter's view that there would be a potential competitive advantage for foreign intermediaries choosing to operate outside of the Section 4(a)(6) exemption. *See* Public Startup Letter 3. However, we note that any entities (foreign or domestic) intermediating offerings of securities between U.S. issuers and investors generally will be broker-dealers, either required to register under the Exchange Act or to be exempt from registration. *See* 15 U.S.C. 78o(a). We also note that the offer and sale of securities in the United States or to U.S. persons must be registered unless an exemption is available.

[968] *See* Wales Capital Letter 3.

[969] We note that the opinion of counsel requirement is generally consistent with the requirement for nonresident security-based swap dealers and major security-based swap participants, as well as those for nonresident municipal advisors. *See* Exchange Act Rule 15Fb2–4 and Rule 15Ba1–6.

[970] *See* Exchange Act Section 3(h)(1)(A). Failure to make this certification or re-certification or to provide an opinion of counsel or revised opinion of counsel will result in an incomplete application for registration.

[971] *See* Zhang Letter.

[972] *See* Form Funding Portal, Item 7—Qualified Third Party Arrangements; Compensation Arrangements.

[973] *See* Wales Capital Letter 3.

[974] *See* Joinvestor Letter.

[975] For example, we note that requiring a U.S. agent for service of process but not requiring a U.S. legal representative to handle any matters between a funding portal and issuers or investors is generally consistent with the requirements for nonresident security-based swap dealers and major security-based swap participants, as well as those for nonresident municipal advisors. *See* Exchange Act Rule 15Fb2–4 and Rule 15Ba1–6.

[976] *See* Exchange Act Section 3(a)(4)(A) [15 U.S.C. 78c(a)(4)(A)] (defining ''broker'' as ''any person engaged in the business of effecting transactions in securities for the account of others''). An entity acting as an intermediary in the offer and sale of securities pursuant to Section 4(a)(6), as contemplated in Title III of the JOBS Act, would not come within the meaning of ''dealer,'' which is defined in Exchange Act Section 3(a)(5)(A) (15 U.S.C. 78c(a)(4)(A)), because it would not be engaging in the business of buying and selling securities for its own account. *See also* Exchange Act Section 15(a) [15 U.S.C. 15*o*(a)].

4A(a)(7).[977] In addition, a funding portal's receipt of compensation linked to the successful completion of the offering also would be indicative of acting as a broker in connection with these transactions. Thus, absent an exemption or exception, a funding portal would be required to register as a broker under the Exchange Act.

We proposed Rule 401(a) to provide an exemption for registered funding portals from the broker registration requirements of Exchange Act Section 15(a)(1) in connection with its activities as a funding portal. Consistent with the JOBS Act, the funding portal would remain subject to the full range of our examination and enforcement authority, even though it is not registered as a broker.[978] In this regard, proposed Rule 403 would require that a funding portal permit the examination and inspection of all of its business and business operations that related to its activities as a funding portal, such as its premises, systems, platforms and records, by representatives of the Commission and of the national securities association of which it is a member.[979] Proposed Rule 404 also would impose certain recordkeeping requirements on funding portals.[980]

We had further proposed in Rule 401(b) that, notwithstanding the exemption from broker registration, for purposes of Chapter X of Title 31 of the Code of Federal Regulations, a funding portal would be a broker or dealer ''required to be registered'' with the Commission under the Exchange Act, thereby requiring funding portals to comply with Chapter X, including certain anti-money laundering (''AML'') provisions thereunder.[981]

[977] At the same time, there are statutory restrictions on the scope of services that a funding portal could provide. *See* Section II.C.1 (discussing Exchange Act Section 3(a)(80)).

[978] *See* Exchange Act Section 3(h)(1)(C). *See also* Securities Act Section 20 [15 U.S.C. 77t] and Exchange Act Sections 21 and 21C [15 U.S.C. 78u and 78u–3]. In addition, we highlighted in the Proposing Release that Exchange Act Sections 15(b)(4) and 15(b)(6) (15 U.S.C. 78*o*(b)(4) and 78*o*(b)(6)) apply to brokers (including funding portals) regardless of whether or not they are registered with the Commission as brokers. Exchange Act Section 15(b)(4) authorizes the Commission to bring administrative proceedings against a broker when the broker violates the federal securities laws (and for other misconduct) and provides for the imposition of sanctions, up to and including the revocation of a broker's registration. Exchange Act Section 15(b)(6) provides similar enforcement authority against the persons associated with a broker, including barring persons from associating with any Commission registrant.

[979] *See* Section II.D.4.

[980] *See* Section II.D.5.

[981] *See* 31 CFR 1010.100(h) and 1023.100(b) (defining broker or dealer for purposes of the applicability of AML requirements). *See* Currency and Foreign Transactions Reporting Act of 1970 (commonly referred to as the Bank Secrecy Act (''BSA'')) [12. U.S.C. 1829b, 12 U.S.C. 1951–1959, 31 U.S.C. 5311–5330].

b. Comments on the Proposed Rule

Commenters generally agreed with the funding portal exemption from registration as a broker-dealer.[982] One commenter stated that funding portals that provide no advice, make no warranties as to the suitability of an investment and do not handle share transfers or money, should not be required to register as a broker-dealer and requiring them to do so would provide no benefit to the public.[983]

One commenter stated that the exemption from broker-dealer registration actually precludes funding portals from becoming members of FINRA,[984] and asserted that funding portals should not have to comply with the same requirements as broker-dealers for purposes of Chapter X of Title 31 of the CFR.[985] Another commenter, however, stated that it ''supports the Commission's interpretation of the exemption, and believes that AML compliance is necessary.'' [986]

c. Final Rules

We are adopting, as proposed, paragraph (a) under Rule 401, but renumbering it as Rule 401 as we not adopting proposed Rule 401(b). We note, however, that the exemption from broker registration is applicable only to funding portals that are registered under Rule 400. Therefore, a funding portal that ceases to be registered under Rule 400 will no longer be exempt from broker registration under Rule 401. In response to the comment that this exemption precludes funding portals from becoming members of FINRA, as we noted above, because a funding portal will be engaged in the business of effecting securities transactions for the accounts of others through crowdfunding, it will be a ''broker'' within the meaning of Section 3(a)(4) of the Exchange Act. We also note that Exchange Act Section 3(h)(2) states that for purposes of sections 15(b)(8) and 15A, the term ''broker or dealer'' includes a funding portal and the term ''registered broker or dealer'' includes a registered funding portal. Therefore, funding portals are explicitly permitted by statute to become members of FINRA.

We are not, however, adopting proposed Rule 401(b). As described in more detail in Section II.D.4.b. below, we have determined that the imposition of AML requirements on funding portals should be addressed outside of the rules that we are adopting in this release.

3. Safe Harbor for Certain Activities

Under Exchange Act Section 3(a)(80), which was added by Section 304(b) of the JOBS Act, a funding portal is defined as an intermediary that does not: (i) Offer investment advice or make recommendations; (ii) solicit purchases, sales or offers to buy the securities offered or displayed on its platform or portal; (iii) compensate employees, agents or other persons for such solicitation or based on the sale of securities displayed or referenced on its platform or portal; (iv) hold, manage, possess or otherwise handle investor funds or securities; or (v) engage in such other activities as the Commission, by rule, determines appropriate. As noted in the Proposing Release, commenters have raised questions about the scope of permissible activities for funding portals consistent with these prohibitions.[987] To provide regulatory clarity, we proposed Rule 402, which would provide a non-exclusive conditional safe harbor for funding portals under which certain limited activities would be deemed consistent with the statutory prohibitions on funding portals. The permissible activities in the proposed safe harbor involved: (i) Limiting offerings on the platform; (ii) highlighting and displaying offerings on the platform; (iii) providing communication channels; (iv) providing search functions; (v) advising issuers; (vi) compensating others for referring persons to the funding portal; (vii) paying or offering to pay compensation to registered brokers or dealers; (viii) receiving compensation from a registered broker or dealer; (ix) advertising the funding portal and offering; (x) denying access to, or cancelling, offerings due to fraud or investor protection concerns; (xi) accepting investment commitments on behalf of the issuer; (xii) directing the transmission of investor funds; and (xiii) directing a qualified third party's transmission of investor funds.

[982] *See, e.g.,* Heritage Letter; Joinvestor Letter; PeoplePowerFund Letter; RocketHub Letter.

[983] *See, e.g.,* PeoplePowerFund Letter (stating that requiring funding portals ''to register as broker dealers thus crushing the very idea of crowd sourced funding as a people driven force for the good of the 'everyman' '').

[984] *See* Vann Letter (reasoning that, because a funding portal is ''not registered as a 'broker dealer,' '' and because ''the Securities Exchange Act of 1934 states 'A registered securities association shall deny membership to any person who is not a registered broker or dealer,' '' then funding portals cannot become members of FINRA).

[985] *Id.* (arguing that such requirements would be ''overly burdensome'' because funding portals ''do not, by law, handle any money'').

[986] *See* RocketHub Letter.

[987] *See* Proposing Release, 78 FR 66484–66485.

Proposed Rule 402(a) also stated that no presumption shall arise that a funding portal has violated the prohibitions under Section 3(a)(80) of the Exchange Act or Regulation Crowdfunding by reason of the funding portal or its associated persons engaging in activities in connection with the offer or sale of securities in reliance on Section 4(a)(6) of the Securities Act that do not meet the conditions specified in the safe harbor, and that the antifraud provisions and all other applicable provisions of the federal securities laws continue to apply to the activities described in the safe harbor.

Commenters strongly supported the idea of a safe harbor for funding portals,[988] but they also suggested additional examples for the safe harbor. We are adopting the safe harbor in Rule 402 with certain changes as discussed further below. Each activity of the safe harbor is addressed below.

a. Limiting Offerings

(1) Proposed Rule

Proposed Rule 402(b)(1) would permit a funding portal to apply objective criteria to limit the securities offered in reliance on Section 4(a)(6) of the Securities Act through the funding portal's platform where: (i) The criteria are reasonably designed to result in a broad selection of issuers offering securities through the funding portal's platform, are applied consistently to all potential issuers and offerings and are clearly displayed on the funding portal's platform; and (ii) the criteria could include, among other things, the type of securities being offered (for example, common stock, preferred stock or debt securities), the geographic location of the issuer and the industry or business segment of the issuer, *provided* that a funding portal may not deny access to an issuer based on the advisability of investing in the issuer or its offering, except to the extent described in proposed Rule 402(b)(10) for fraud and investor protection concerns.

(2) Comments on Proposed Rule

We received a significant number of comments on the ability of a funding portal to limit the offerings on its platform. Many of these comments suggested a broader standard than the standard that we proposed. Several commenters expressed concern that the proposed safe harbor placed funding portals at a competitive disadvantage to registered brokers because it did not provide funding portals with the flexibility to limit the offerings on their platforms,[989] even if they have legitimate concerns about offerings aside from fraud or investor protection.[990] For example, commenters suggested that a funding portal should be permitted to reject offerings based on whatever factors the portal deems appropriate without automatically triggering regulation as a broker-dealer,[991] especially if it deems the offering to have tangible shortcomings that could be detrimental to investors or overly risky.[992]

Commenters asserted that a funding portal's ability to limit the offerings on its platform is important for investor protection. They stated that funding portals should be permitted to screen out clearly unprepared or ill-conceived offerings,[993] and should be permitted to limit offerings on their platforms to issuers that are ''crowdfund-ready.''[994] Commenters drew a distinction between the permissibility of applying internal screening standards to limited offerings on the platform versus the prohibition on providing investment advice or recommendations.[995] Some commenters suggested that having a disclaimer that ''curation'' (or limiting offerings on a platform) does not constitute a recommendation on the advisability of any investment displayed on the platform;[996] or that the funding portal does not advertise or make statements that the offerings listed on its platform are safer or better investments than those listed on other platforms,[997] would mitigate regulatory concerns. Some commenters also suggested that the criteria used to limit offerings should be clearly displayed on a funding portal's platform.[998]

In addition, some commenters pointed to a tension in the statute under which a funding portal is potentially subject to liability for material misstatements and omissions in the issuer's offering materials but, at the same time, may be limited in its ability to deny access to its platform.[999] These commenters argued that it was not equitable for a funding portal to have such liability if it cannot determine whether and under what circumstances to permit an issuer or offering access to its platform.

(3) Final Rules

In view of the comments, and upon further consideration, we are modifying Rule 402(b)(1) to expressly provide that a funding portal may, consistent with the prohibitions under Exchange Act Section 3(a)(80) (including the prohibition against offering investment advice or recommendations in Section 3(a)(80)(A)), determine whether and under what terms to allow an issuer to offer and sell securities in reliance on Securities Act Section 4(a)(6) through its platform.[1000]

We agree with commenters that the ability of a funding portal to determine which issuers may use its platform is important for the protection of investors, as well as to the viability of the funding portal industry, and thus the crowdfunding market. We acknowledge the concerns raised by commenters that the proposed rules could otherwise have unduly restricted a funding portal's ability to limit offerings conducted on its platform, and we are modifying the safe harbor contained in Rule 402(b)(1) to address these concerns. Specifically, we are revising Rule 402(b)(1) to read that a funding portal may ''[d]etermine whether and under what terms to allow an issuer to offer and sell securities in reliance on Section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) through its platform, provided that the funding portal otherwise complies with Regulation Crowdfunding (§§ 227.100 *et se*.).'' The new language is designed to

[988] *See, e.g.,* CFIRA Letter 1; Joinvestor Letter; Merkley Letter (stating that the proposed safe harbor ''strikes the right balance''). *But see* Public Startup 3 Letter (stating that the safe harbor should cover any activity by a funding portal not directly related to the sale of securities for the account of others).

[989] *See, e.g.,* EMKF Letter; SBA Office of Advocacy Letter.

[990] *See, e.g.,* ABA Letter; CfPA Letter; CrowdCheck 2 Letter; Graves Letter; Seyfarth Letter (stating that ''even with a lower liability threshold, curation is an essential tool for investor protection'').

[991] *See, e.g.,* IAC Recommendation (suggesting that ''[o]ne of the most cost-effective ways to reduce the risk of serious compliance violations is to give crowdfunding intermediaries a free hand to reject any offering they believe could pose an undue compliance or fraud risk''); *see also* CFIRA Letter 12 (agreeing with IAC's suggestion ''that all intermediaries . . . should have greater latitude in their ability to curate offerings. . . . All intermediaries (including non-BD portals) should be allowed to use their discretion as to whether or not any particular offering is suitable for their service''). *See also* BetterInvesting Letter.

[992] *See* Graves Letter.

[993] *See* EMKF Letter.

[994] *See* SBEC Letter.

[995] *See, e.g.,* Angel 1 Letter (''Forcing portals to become the equivalent of common carriers that have to take every offering, no matter how foolish, will make crowdfunding more likely to fail.''); Consumer Federation Letter; Saunders Letter.

[996] *See, e.g.,* EarlyShares Letter; EMKF Letter; SBA Office of Advocacy Letter.

[997] *See* Milken Institute Letter.

[998] *See, e.g.,* ABA Letter; CFIRA Letter 1.

[999] *See, e.g.,* CrowdCheck 2 Letter; Milken Institute Letter; RocketHub Letter.

[1000] *See also* Rule 402(b) (limiting permissible activities to those consistent with the prohibitions under Exchange Act Section 3(a)(80)). The discretion a funding portal has to limit offerings on its platform is in addition to the requirement under Rule 301 to deny access, and cancel offerings, based on fraud and investor protection concerns.

make it clear that a funding portal may exercise its discretion, subject to the prohibition in the statute on providing investment advice or recommendations, to limit the offerings and issuers that it allows on its platform under the safe harbor, as long as it complies with all other provisions of Regulation Crowdfunding.

In making this change, we recognize that the activities in which a funding portal may engage are, by definition, far more limited than the activities in which a registered broker-dealer may engage. At the same time, we believe that the JOBS Act established an important role for intermediaries, both broker-dealers and funding portals, to play in crowdfunding offerings. While we are providing funding portals with broad discretion to determine whether and under what circumstances to allow an issuer to offer and sell securities through its platform in reliance on Section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)), a funding portal must comply with all applicable provisions of Regulation Crowdfunding, including the prohibition on providing investment advice or recommendations. In this regard and as more fully discussed below, among other things, a funding portal cannot advertise, make statements or otherwise represent that the offerings listed on its platform are safer or better investments than those listed on other platforms. Given this statutory restriction, we are not, as some commenters suggested, requiring a funding portal to provide a disclaimer stating that limiting the offerings on its platform does not constitute investment advice or a recommendation, nor are we requiring that its criteria for limiting offerings on its platform be publicly displayed. We do not believe that requiring a funding portal to display its criteria for limiting offerings on its platform will add significant investor protection. While a funding portal may decide to make such criteria public, we caution that a funding portal must avoid any appearance that it is giving investment advice or recommendations or that the funding portal believes its offerings are investment worthy.

b. Highlighting Issuers and Offerings

(1) Proposed Rule

Proposed Rule 402(b)(2) would permit a funding portal to apply objective criteria to highlight offerings on the funding portal's platform where: (i) The criteria are reasonably designed to highlight a broad selection of issuers offering securities through the funding portal's platform, are applied consistently to all issuers and offerings and are clearly displayed on the funding portal's platform; (ii) the criteria may include, among other things, the type of securities being offered (for example, common stock, preferred stock or debt securities); the geographic location of the issuer; the industry or business segment of the issuer; the number or amount of investment commitments made, progress in meeting the issuer's target offering amount or, if applicable, the maximum offering amount; and the minimum or maximum investment amount; *provided* that a funding portal may not highlight an issuer or offering based on the advisability of investing in the issuer or its offering; and (iii) the funding portal does not receive special or additional compensations for highlighting one or more issuers or offerings on its platform.

(2) Comments on Proposed Rule

Several commenters suggested additional criteria for the safe harbor, including for example: (i) How long the issuer has been operational or profitable;[1001] (ii) historical and projected revenue and earnings before interest, taxes, depreciation and amortization (EBITDA); [1002] (iii) the size of the issuer's management team; [1003] (iv) relevant experience and length of experience of the issuer's management;[1004] (v) the type of corporate structure of the issuer;[1005] (vi) the stage and operating history of the issuer; [1006] (vii) valuation methodology; [1007] (viii) results of securities and background checks;[1008] (ix) ''trending''; [1009] and (x) most money raised, soonest offering to close, most money invested, least money invested, or on a purely random basis (so long as none of the bases are value-driven—that is, which investment is a safer or better investment).[1010] Another commenter questioned whether, under the safe harbor, funding portals would be permitted to highlight offerings based on their discretion or the use of metrics, such as topic, media coverage, or momentum.[1011] However, another commenter suggested that a funding portal should not have discretion regarding which objective criteria it can use to highlight issuers or offerings because it may result in the portal implicitly recommending securities.[1012] This commenter suggested that the Commission should create a specific list of acceptable objective criteria that a funding portal may apply.[1013]

Several commenters stated that the criteria used to highlight offerings should be clearly displayed on the platform.[1014] However, one commenter stated that algorithms should not be required to be disclosed on the platform.[1015]

Several commenters suggested that the safe harbor should include the ability of a funding portal to provide mechanisms by which investors can rate an issuer or an offering, which then could be highlighted on the platform.[1016] However, one of these commenters stated that any such rating must be mathematical rather than value-driven or it would amount to ''enticement.''[1017]

(3) Final Rules

After considering the comments, we are adopting Rule 402(b)(2) as proposed. Specifically, Rule 402(b)(2) allows a funding portal to highlight particular issuers or offerings of securities made in reliance on Section 4(a)(6) on its platform based on objective criteria where the criteria are reasonably designed to highlight a broad selection of issuers offering securities through the funding portal's platform, are applied consistently to all issuers and offerings and are clearly displayed on the funding portal's platform. Consistent with the proposal, the final rule specifies in subparagraph (b)(2)(ii) that objective criteria may include, for example: The type of securities being offered (*e.g.,* common stock, preferred stock or debt securities); the geographic location of the issuer; the industry or business segment of the issuer; the number or amount of investment commitments made; the progress in meeting the target offering amount or, if applicable, the maximum offering amount; and the minimum or maximum investment amount.

It is important to note that the criteria must be reasonably designed to highlight a broad selection of issuers and offerings, so as not to recommend

[1001] *See, e.g.,* CFIRA Letter 1; CFIRA Letter 2.

[1002] *Id.*

[1003] *Id.*

[1004] *See, e.g.,* CFIRA Letter 2.

[1005] *See* RocketHub Letter.

[1006] *Id.*

[1007] *Id.*

[1008] *Id.*

[1009] *See* Seyfarth Letter.

[1010] *See* ASSOB Letter.

[1011] *See* RocketHub Letter.

[1012] *See* Commonwealth of Massachusetts Letter; *c.f.* ABA Letter (requesting Commission guidance that a portal engaging in activities covered by the safe harbor will not trigger the application of the Investment Advisers Act).

[1013] *See* Commonwealth of Massachusetts Letter. *See also* ABA Letter (requesting explicit Commission guidance as to permissible criteria).

[1014] *See, e.g.,* ABA Letter; CFIRA Letter 1.

[1015] *See* Joinvestor Letter.

[1016] *See, e.g.,* ASSOB Letter; CFIRA Letter 1; Joinvestor Letter.

[1017] *See* ASSOB Letter.

or implicitly endorse one issuer or offering over another, and must be applied consistently to all potential issuers and offerings.[1018] This highlighting of issuers or offerings that have been admitted to a funding portal's platform can, depending on relevant facts and circumstances, involve providing investment advice that violates the prohibition on a funding portal providing such advice. To that end, the rule provides a safe harbor only when a funding portal is using objective criteria and such criteria are clearly displayed on its platform to inform investors why certain issuers or offerings are being highlighted.[1019] To reiterate, a funding portal may not highlight an issuer or offering based on the advisability of investing in the issuer or offering or give the impression that the funding portal is providing an implicit (or explicit) recommendation on whether to invest in the issuer or offering.

To help prevent conflicts of interest and incentives for funding portals to favor certain issuers over others, the final rule also prohibits a funding portal from receiving any special or additional compensation for highlighting (or offering to highlight) one or more issuers or offerings on its platform.[1020]

Although some commenters suggested that we include additional criteria in subparagraph (b)(2)(ii), we emphasize that the rule does not establish an exclusive list. The listed criteria are intended as examples, and the safe harbor is non-exclusive. Crowdfunding is a new and evolving market, and we believe that providing principles in the safe harbor by which a funding portal can highlight offerings on its platform will provide it with the flexibility to adapt to the crowdfunding market as it develops while maintaining investor protection. In this regard, the examples listed in Rule 402(b)(2)(ii) are intended to provide guidance to funding portals as they develop their platform and related tools.

Although we are not including additional criteria in Rule 402(b)(2)(ii) at this time, we note that certain of the suggested highlighting criteria are covered by the criteria listed in the rule, such as the issuer's industry; the type of securities being offered; and the geographic location of the issuer's business. Others, while not listed in the final rule, we believe are based on objective criteria, such as the amount of money being raised or size of the offering; soonest offering to close; most or least money invested; how long the issuer has been operational or profitable; the size of the management team of the issuer; the stage and operating history of the issuer; valuation methodology; ''trending''; earnings before interest, taxes, depreciation and amortization (EBITDA); and highlighting on a purely random basis. However, we caution that a funding portal must be cognizant not to present highlighted issuers in a manner that, directly or implicitly, results in the provision of investment advice or recommendations.[1021]

c. Providing Search Functions

(1) Proposed Rule

Proposed Rule 402(b)(3) would permit a funding portal to provide search functions or other tools that investors can use to search, sort, or categorize the offerings available through the funding portal's platform according to objective criteria where: (i) The objective criteria may include, among other things, the type of securities being offered (for example, common stock, preferred stock or debt securities); the geographic location of the issuer; the industry or business segment of the issuer; the number or amount of investment commitments made, progress in meeting the issuer's target offering amount or, if applicable, the maximum offering amount; and the minimum or maximum investment amount; and (ii) the objective criteria may not include, among other things, the advisability of investing in the issuer or its offering, or an assessment of any characteristic of the issuer, its business plan, its key management or risks associated with an investment.

(2) Comments on Proposed Rule

Several commenters suggested that the safe harbor be broadened to include additional criteria.[1022] One commenter suggested that funding portals should be permitted to sort offerings based on an algorithmic score that takes into account any objective numerical data that is reasonably likely to correlate to successful investments, such as numeric ratings by accredited and unaccredited investors, number of investment commitments weighted by investor portfolio valuation, and number of page views.[1023] Another commenter stated that the use of the word ''assessment'' in the proposed safe harbor[1024] is inappropriately vague when applied to technology, as it could effectively prohibit the use of any computational sorting algorithm using objective searching and sorting criteria. This commenter suggested that the word ''assessment'' be substituted with the word ''opinion,'' and also that the term ''objective criteria'' be removed so that the safe harbor would prohibit the use of *subjective* criteria—such as the advisability of investing or an opinion of any characteristic of the issuer, its business plan, its key management or risks associated with an investment—''generated exclusively by the portal,'' excepting instances of peer review and feedback generated by users.[1025]

(3) Final Rules

After considering comments, we are adopting Rule 402(b)(3) substantially as proposed. The final rule permits a funding portal to provide search functions or other tools on its platform that users could use to search, sort or categorize available offerings according to objective criteria.[1026] The final rule also permits search functions that, for example, will allow an investor to sort through offerings based on a combination of different criteria, such as by the percentage of the target offering amount that has been met, geographic proximity to the investor and number of days remaining before the closing date of an offering.[1027] However, the final rule makes clear that the search criteria may not include the advisability of investing in the issuer or its offering, or an assessment of any characteristic of the issuer, its business plan, its management or risks associated with an investment. In this regard, we are

[1018] *See* Rule 402(b)(2) and (b)(2)(i).

[1019] *Id.*

[1020] *See* Rule 402(b)(2)(iii) of Regulation Crowdfunding. This rule prohibits paid placements of the kind suggested by one commenter. *See* Earlyshares Letter.

[1021] For example, a funding portal may provide the EBITDA of an issuer but it cannot insinuate or state on its platform that the EBITDA corresponds to the advisability of investing in an issuer.

[1022] *See, e.g.,* EMKF Letter; EquityNet Letter.

[1023] *See* EMKF Letter.

[1024] Rule 402(b)(3)(ii) states in part that the ''objective criteria may not include . . . an assessment of any characteristic of the issuer, its business plan, its key management or risks . . . ''

[1025] *See* EquityNet Letter (noting that ''[a]llowing investors the ability to sort through each other's comments or opinions becomes an integral part of any site where commenting is allowed on products'' and that ''[b]ecause sorting comments would require a technological assessment of subjective data, we believe an explicit carve out in the safe harbor provisions is necessary'').

[1026] *See* Rule 402(b)(3) Regulation Crowdfunding. *See also* 158 **CONG. REC.** 2231 (daily ed. Mar. 29, 2012) (statement of Sen. Scott Brown) (''Funding portals should be allowed to organize and sort information based on certain criteria. This will make it easier for individuals to find the types of companies in which they can potentially invest. This type of capability—commonly referred to as curation—should not constitute investment advice.'').

[1027] *See* Rule 402(b)(3) of Regulation Crowdfunding. Rule 402(b)(3)(i) provides examples of search criteria that are consistent with those listed in the Rule 402(b)(2)(ii) safe harbor for highlighting issuers and offerings.

making minor changes from proposed Rule 402(b)(3)(i) and (ii) by deleting the word ''objective'' in the final rules because the term is redundant to the requirement in Rule 402(b)(3) that the criteria be ''objective.'' Further, we are persuaded by one commenter's observation that the use of the word objective in the subparts could be misleading.[1028] The new sentence structure also makes Rule 402(b)(3) consistent with Rule 402(b)(2), which we believe provides additional clarity and consistency for funding portals when complying with the rules.

Rule 402(b)(3) does not preclude the use of computational sorting algorithms using objective searching and sorting criteria.[1029] However, a funding portal must take care not to indicate that the platform's search results or tools, directly or indirectly, correlate to successful investments. Likewise, we believe that the more particular, biased or weighted a funding portal's algorithm or assessment is, the less likely the criteria as a whole will be objective. However, this does not preclude a funding portal from permitting investors with access to its communication channels from rating issuers or offerings (*e.g.,* a star rating) on its platform or searching such ratings, as long as a funding portal (including its associated persons, such as its employees) does not participate in the rating process.[1030]

d. Providing Communication Channels

(1) Proposed Rule

Proposed Rule 402(b)(4) would address the terms under which a funding portal could provide communication channels by which investors can communicate with one another and with representatives of the issuer through the funding portal's platform about offerings conducted through the platform, as required by Rule 303(c). Under the terms of Rule 402(b)(4) as proposed, the safe harbor would apply so long as the funding portal (and its associated persons): (i) Does not participate in these communications, other than to establish guidelines for communication and remove abusive or potentially fraudulent communications; (ii) permits public access to view the discussions made in the communication channels; (iii) restricts posting of comments in the communication channels to those persons who have opened an account on its platform; and (iv) requires that any person posting a comment in the communication channels clearly disclose with each posting whether he or she is a founder or an employee of an issuer engaging in promotional activities on behalf of the issuer, or is otherwise compensated, whether in the past or prospectively, to promote an issuer's offering.

(2) Comments on Proposed Rule

Several commenters supported permitting a funding portal to provide communication channels on its platform through which investors can make comments, rate issuers and provide other feedback, and through which issuers can respond to investor comments.[1031] One of these commenters stated that these capabilities could enable a funding portal to share with investors information related to issuers, capital raised by an issuer, crowd investing, or the crowd-based rating of specific issuers.[1032] Another commenter suggested that funding portals allow investors to assign a quantifiable indicator to each other's comments, so that users can search out the best and worst of the comments and issuers have a chance to respond to investor comments in an open forum.[1033] One commenter recommended that permission to rate issuers or offerings should only be given to investors who actually invested in or committed to invest in the offering.[1034]

(3) Final Rules

We are adopting, as proposed, Rule 402(b)(4) to address the terms under which a funding portal can provide communication channels by which investors can communicate with one another and with representatives of the issuer through the funding portal's platform about offerings conducted through the platform, as required by Rule 303(c).[1035] The safe harbor specifies that a funding portal (including its associated persons, such as its employees) may not participate in these communications, other than to establish guidelines about communication and to remove abusive or potentially fraudulent communications. Under Rule 402(b)(4), a funding portal must make communication channels available to the general public and restrict the posting of comments on those channels to those who have accounts on the funding portal's platform. In addition, the funding portal must require each person posting comments to disclose clearly with each posting in the channel whether he or she is a founder or an employee of an issuer engaging in promotional activities on behalf of the issuer, or is otherwise compensated or will receive any compensation for promoting an issuer.[1036]

We agree with commenters that investors should be permitted to communicate with one other, and with representatives of the issuer, over communication channels on the platform provided by the funding portal.[1037] The communication channel is meant to strengthen and foster the ability of the crowd to communicate. We believe that the capabilities within the communication channel will develop and evolve over time. For example, as noted above, a communication channel may permit investors to rate or comment on an issuer or offering, or to assign quantifiable indicators to one other's comments. Also, a funding portal must make communication channels available for viewing by the general public, and permit anyone who has opened an account on its platform to post comments on the channel.[1038] As we stated in the Proposing Release, requiring investors to have accounts with the funding portal before posting a comment should provide a measure of control over these communications that could aid in promoting accountability for comments made and help ensure that interested persons, such as those associated with the issuer or receiving compensation to promote the issuer, are properly identified.

We reiterate that while a funding portal must provide for a communication channel and may develop certain features or tools as a part of that channel (such as a crowd-based rating system), a funding portal (including its associated persons, such as its employees) may not engage or participate in such communications.[1039]

[1028] *See* EquityNet Letter. However, we do not agree with the commenter's assertion that using the word ''assessment'' in Rule 402(b)(3) equates to a prohibition on the use of computational sorting algorithms using objective searching and sorting criteria because, in this context, assessment is used to refer to subjective criteria.

[1029] In response to one commenter's suggestion that a funding portal should be permitted to use algorithmic scores, the final rule does not preclude the use of algorithms as long as the criteria used by the algorithm are objective. *See* EMKF Letter. Thus, a ''score'' based on an algorithm may be used as long as it does not involve subjective criteria.

[1030] *See* Rule 402(b)(4)(i).

[1031] *See, e.g.,* CFIRA Letter 1; EquityNet Letter; Milken Institute Letter.

[1032] *See* Milken Institute Letter.

[1033] *See* EquityNet Letter.

[1034] *See* CFIRA Letter 1.

[1035] *See* Section II.C.5.b(3) for a discussion of Rule 303(c).

[1036] *See* Rule 402(b)(4)(iv).

[1037] As discussed in Section II.C.5, an issuer, its agents and promoters must identify themselves in all communications through the communication channel.

[1038] *See* Rule 402(b)(4)(i) and (ii).

[1039] *See* Rule 402(b)(4)(i). *See also* Rule 303(c).

In addition, a funding portal should consider whether the tools or features of the communication channels it develops and the guidelines it establishes for the channel would constitute the funding portal providing impermissible investment advice or recommendations. For example, the funding portal may not establish a guideline that permits a person to rate an offering only if the person provides a positive rating, or otherwise incentivizes persons to give positive ratings. However, contrary to what one commenter suggested, we do not believe a funding portal may limit the rating capability to those account holders who have made investment commitments to the relevant offering.[1040] We believe that limiting ratings capability to persons that invest in an offering is likely to skew the ratings, and therefore, we would view such a limitation as inappropriate. Further, such a limitation could prevent persons with relevant and important information about the investment from contributing their views to the crowd.

e. Advising Issuers

(1) Proposed Rule

Proposed Rule 402(b)(5) would permit a funding portal to advise an issuer about the structure or content of the issuer's offering, including assisting the issuer in preparing offering documentation.

(2) Final Rules

We did not receive any comments that specifically addressed the ability of a funding portal to advise issuers and are adopting Rule 402(b)(5) as proposed. The rule permits a funding portal to advise an issuer about the structure or content of the issuer's offering, including preparing offering documentation. We believe funding portals will be in a position to provide experience and assistance to issuers relatively efficiently, and should be able to leverage their expertise to increase the viability of crowdfunding.

We believe that funding portals, as well as broker-dealers, should be permitted to provide certain services to issuers to facilitate the offer and sale of securities in reliance on Section 4(a)(6). Without these services, crowdfunding as a method to raise capital might not be viable. Rule 404(b)(5) permits funding portals to advise an issuer about the structure and content of the issuer's offering in a number of ways. A funding portal can, for example, provide pre-drafted templates or forms for an issuer to use in its offering that will help it comply with its proposed disclosure obligations. Other examples of permissible assistance can include advice about the types of securities the issuer can offer, the terms of those securities and the procedures and regulations associated with crowdfunding.

f. Paying for Referrals

(1) Proposed Rule

Proposed Rule 402(b)(6) would permit a funding portal to compensate a third party for referring a person to the funding portal, so long as the third party does not provide the funding portal with personally identifiable information of any investor and the compensation, other than that paid to a registered broker or dealer, is not based, directly or indirectly, on the purchase or sale of a security in reliance on Section 4(a)(6) of the Securities Act offered on or through the funding portal's platform.

(2) Comment on Proposed Rule

One commenter requested clarification as to: (i) Whether and when compensation paid to a non-broker-dealer will be deemed improperly based on the purchase or sale of a security; (ii) whether a funding portal may pay a registered broker-dealer a referral fee without a formal agreement; and (iii) whether a funding portal may charge issuers fees based on the success of the offering.[1041]

(3) Final Rules

We are adopting Rule 402(b)(6) as proposed. Rule 402(b)(6) permits a funding portal to compensate a third party for referring a person to the funding portal if the third party does not provide the funding portal with personally identifiable information about any investor and the compensation, other than that paid to a registered broker or dealer, is not based, directly or indirectly, on the purchase or sale of a security in reliance on Section 4(a)(6) of the Securities Act offered on or through the funding portal's platform. We believe the safe harbor in this regard addresses the prohibition in Rule 305 against an intermediary compensating any person for providing the intermediary with the personally identifiable information of any investor in securities offered and sold in reliance on Section 4(a)(6). We also believe that Rule 402(b)(6)'s prohibition on funding portals paying transaction-based compensation to third parties, other than that paid to a registered broker or dealer, will help to minimize the incentive for high-pressure sales tactics and other abusive practices in this area. One commenter requested additional guidance as to what types of compensation would equate to compensation based on the offer or sale of a security.[1042] The Commission and courts have interpreted the definition of transaction-based compensation broadly,[1043] and whether compensation is transaction-based is a facts and circumstances determination. Thus, we do not believe that additional guidance is necessary or appropriate in this context.

In response to a commenter's inquiry, a funding portal may not pay a registered broker-dealer a referral fee without a written agreement under the safe harbor. Such an arrangement would be covered by Rule 402(b)(7), which is discussed below.

g. Compensation Arrangements With Registered Broker-Dealers

(1) Proposed Rule

Proposed Rule 402(b)(7) would permit a funding portal to pay or offer to pay any compensation to a registered broker or dealer for services in connection with the offer or sale of securities by the funding portal in reliance on Section 4(a)(6) of the Act, provided that: (i) Such services are provided pursuant to a written agreement between the funding portal and the registered broker or dealer; (ii) such services and compensation are permitted under Regulation Crowdfunding and are not otherwise prohibited under Rule 305; and (iii) such compensation complies with and is not prohibited by the rules of any registered national securities association of which the funding portal is required to be a member.

Proposed Rule 402(b)(8) would permit a funding portal to receive any compensation from a registered broker or dealer for services provided by the funding portal in connection with the offer or sale of securities by the funding portal in reliance on Section 4(a)(6) of the Act, provided that: (i) Such services are provided pursuant to a written agreement between the funding portal and the registered broker or dealer; (ii) such compensation is permitted under Regulation Crowdfunding; and (iii) such compensation complies with and is not prohibited by the rules of any registered national securities association of which the funding portal is required to be a member.

[1040] *See* CFIRA Letter 1.

[1041] *See* ABA Letter.

[1042] *Id.*

[1043] *See, e.g.,* Applicability of Broker-Dealer Registration to Banks, Exchange Act Rel. No. 20,357 at n.14 (Nov. 8, 1983).

(2) Comments on Proposed Rule

Several commenters expressed concerns about the permitted relationships between funding portals and broker-dealers.[1044] One of these commenters stated that the proposed safe harbor is ''overly broad'' and creates ''unmanageable conflicts between funding portals and broker dealers,'' and suggested the Commission prevent these conflicts by prohibiting funding portals from paying broker-dealers any type of compensation in connection with the offer or sale of securities under the crowdfunding exemption.[1045] Another of these commenters suggested that the Commission require relationships between funding portals and brokers to be arms-length and, if they are not, require that the funding portal activity be operated by the broker-dealer entity.[1046]

(3) Final Rules

We are adopting Rule 402(b)(7) generally as proposed, but with minor modifications for clarity and consistency. Rule 402(b)(7) specifies that a funding portal may pay or offer to pay compensation to a registered broker or dealer for services, including for referring a person to the funding portal, in connection with the offer or sale of securities by the funding portal in reliance on Section 4(a)(6) of the Securities Act, provided that (i) such services are provided pursuant to a written agreement between the funding portal and the registered broker or dealer; (ii) such compensation is permitted under Regulation Crowdfunding; and (iii) such compensation complies with the rules of any registered national securities association of which the funding portal is a member. As discussed above, proposed Rule 402(b)(7) did not contain a reference to ''referrals,'' while proposed Rule 402(b)(6) included the language ''for referring a person to the funding portal.'' We have added a reference to ''referrals pursuant to [Rule 402](b)(7)'' to make clear that all payment arrangements with a broker-dealer, including paying a broker-dealer for referrals as permitted under subparagraph (b)(6), must be in writing.

Proposed Rule 402(b)(7)(ii) had also stated that ''such compensation is permitted under this part and is not otherwise prohibited under § 227.305''; and subparagraph (b)(7)(iii) stated ''such compensation complies with and is not prohibited by-the rules of any registered national securities association of which the funding portal is required to be a member.'' We are deleting the phrases ''and is not otherwise prohibited under § 227.305'' and ''and is not prohibited by'' to make the language in Rule 402(b)(7) and Rule 402(b)(8) consistent, and because the phrases are redundant. Also, we are deleting the phrase ''required to be a member'' and replacing it with ''is a member'' in recognition of the fact that additional national securities associations may exist in the future and that a funding portal would only have to be a member of one such association.

Consistent with Rule 402(b)(7), a funding portal may, for example, pay a broker-dealer for certain services, such as information technology services, qualified third party services or referral services, pursuant to a written agreement. Each party to this type of arrangement will need to comply with all applicable regulations, including the rules of the registered national securities association of which it is a member.

Similarly, we are adopting Rule 402(b)(8) as proposed with minor modifications. Rule 402(b)(8) permits a funding portal to provide services to, and receive compensation from, a registered broker-dealer in connection with the funding portal's offer or sale of securities in reliance on Section 4(a)(6), provided that: (i) Such services are provided pursuant to a written agreement between the funding portal and the registered broker or dealer; (ii) such compensation is permitted under Regulation Crowdfunding; and (iii) such compensation complies with the rules of any registered national securities association of which the funding portal is a member. The proposed rules had stated that ''such compensation complies with and is not prohibited by the rules of any registered national securities association of which the funding portal is required to be a member.'' For the reasons discussed above with regard to Rule 402(b)(7)(ii), we are deleting the phrase ''and is not prohibited'' because it is redundant and deleting the phrase ''required to be a member'' and replacing it with ''is a member.''

Pursuant to Rule 402(b)(8), a funding portal may receive compensation, including transaction-based compensation, from a broker-dealer for providing referrals to that broker-dealer relating to an offering made pursuant to Section 4(a)(6). It is important to emphasize that the safe harbor does not permit a funding portal to receive transaction-based compensation for referrals of investors in other types of offerings, such as Rule 506 offerings, that are effected by a registered broker-dealer.[1047] Further, these arrangements must be compliant with Rule 305, which prohibits, with certain exceptions, an intermediary from compensating any person for providing the intermediary with the personally identifiable information of any investor.[1048] As we stated in the Proposing Release, the safe harbor is intended to facilitate intermediaries' cooperation with each other and promote the use of the Section 4(a)(6) exemption to raise capital, while maintaining a written record of compensation payments.

We disagree with the commenter who suggested that Rules 402(b)(7) and (8) create an unmanageable conflict between funding portals and broker-dealers.[1049] We believe that any potential conflict of interest between broker-dealers and funding portals as a result of compensation arrangements is mitigated due to the fact that both entities are registered with the Commission and members of FINRA and because permissible activities under Rule 402(b)(7) and (8) are limited by Regulation Crowdfunding. We also are not prohibiting a registered broker-dealer and a registered funding portal from being affiliated, nor are we requiring that any crowdfunding operation be performed by the registered broker-dealer in such an affiliation.[1050] Because funding portals and broker-dealers are each registered with the Commission and required to be members of a registered national securities association with the attendant rules and oversight, we believe concerns about conflicts of interests among affiliated funding portals and broker-dealers are sufficiently mitigated by this regulatory framework.

While a commenter questioned whether a funding portal may pay introducing brokers a fee for referring persons to the funding portal without a formal written arrangement,[1051] we emphasize that Rule 402(b)(7) requires all such arrangements to be in writing.

[1044] *See, e.g.,* Commonwealth of Massachusetts Letter; RocketHub Letter.

[1045] *See* Commonwealth of Massachusetts Letter.

[1046] *See* RocketHub Letter (expressing concern over broker-dealers creating entities that would register as funding portals so as to evade FINRA oversight as a broker-dealer).

[1047] Receipt of transaction-based compensation in connection with such referrals can cause a funding portal to be a broker required to register with us under Exchange Act Section 15(a)(1) (15 U.S.C. 78*o*(a)(1)).

[1048] *See* Section II.C.7 (discussing Rule 305).

[1049] *See* Commonwealth of Massachusetts Letter.

[1050] *See* RocketHub Letter (expressing concern over broker-dealers creating entities that would register as funding portals, so as to evade FINRA oversight as a broker-dealer).

[1051] *See* ABA Letter.

h. Advertising

(1) Proposed Rule

Proposed Rule 402(b)(9) would permit a funding portal to advertise the existence of the funding portal and identify one or more issuers or offerings available on the portal on the basis of objective criteria, as long as: (i) The criteria are reasonably designed to identify a broad selection of issuers offering securities through the funding portal's platform and are applied consistently to all potential issuers and offerings; (ii) the criteria may include, among other things, the type of securities being offered (for example, common stock, preferred stock or debt securities); the geographic location of the issuer; the industry or business segment of the issuer; the expressed interest by investors, as measured by number or amount of investment commitments made, progress in meeting the issuer's target offering amount or, if applicable, the maximum offering amount; and the minimum or maximum investment amount; and (iii) the funding portal does not receive special or additional compensation for identifying the issuer or offering in this manner.

(2) Comments on Proposed Rule

Several commenters supported the proposed safe harbor on funding portal advertising.[1052] However, commenters were divided on whether funding portals should be permitted to advertise current offerings and issuers in their advertisements. One commenter was supportive of allowing funding portals to ''advertise more generally, as well as highlight ongoing offerings through various communication channels.'' [1053] The same commenter stated that a portal's decision to feature or highlight issues available should not be viewed by the Commission as investment advice, a recommendation, or a solicitation.[1054] This commenter nonetheless cautioned that ''[p]ortals should be barred from language that implicates the level of risk involved in the investment or the overall quality of the investment opportunity'' as well as ''from soliciting investments for any specific campaign by providing offering details outside of the Portal itself.'' [1055] Another commentator expressed opposition to ''a limitation on the funding portal to only advertise its past offerings,'' stating that such a limitation ''would be overly restrictive.'' [1056]

In contrast, one commenter stated that, while funding portals should be allowed to advertise, funding portals should not be able to display specific issuers in their advertising materials.[1057] This commenter stated that ''[t]he concern with displaying individual issuers is that investors will interpret this as a recommendation and endorsement of the issuer.'' [1058] The commenter noted that the prohibition on providing recommendations can be easily circumvented by manipulating otherwise seemingly objective criteria, and that funding portals could advertise offerings based on certain criteria, such as high target offerings, that may generate more money for the funding portal (*i.e.,* a funding portal can mask self-interest by using objective criteria).[1059] This same commenter suggested that the Commission could allow descriptions of the portals themselves and the specific business segments featured on their Web sites, without mentioning specific issuers currently registered with the portal.[1060]

One commenter suggested the Commission clarify that it would be inappropriate for a funding portal to send out soliciting emails recommending investment in particular companies to investors who have signed up with that portal.[1061] Another commenter stated that a funding portal should not be permitted to advertise or otherwise make statements that offerings listed are somehow safer or better than other platforms.[1062]

(3) Final Rules

We are adopting Rule 402(b)(9) as proposed. Rule 402(b)(9) permits a funding portal to advertise its existence and identify one or more issuers or offerings available on the portal on the basis of objective criteria, as long as: (i) The criteria are reasonably designed to identify a broad selection of issuers offering securities through the funding portal's platform and are applied consistently to all potential issuers and offerings; (ii) the criteria may include, among other things, the type of securities being offered (for example, common stock, preferred stock or debt securities); the geographic location of the issuer; the industry or business segment of the issuer; the expressed interest by investors, as measured by number or amount of investment commitments made, progress in meeting the issuer's target offering amount or, if applicable, the maximum offering amount; and the minimum or maximum investment amount; and (iii) the funding portal does not receive special or additional compensation for identifying the issuer or offering in this manner. However, a funding portal may not base its decision as to which issuers to include in its advertisements on whether it has a financial interest in the issuer,, and any advertising may not directly or indirectly favor issuers in which the funding portal has invested or will invest.

After considering the comment letters, we believe that the requirements of the safe harbor, including the requirement for objective criteria designed to result in a broad selection of highlighted issuers or offerings, will result in advertisements that are focused on the funding portal itself, as opposed to recommending a particular offering or offerings.[1063] Funding portals continue to be subject to the statutory prohibition on providing investment advice and recommendations.[1064] An advertisement by a funding portal must not be an implicit (or explicit) recommendation as to whether to invest in the issuer or offering or advice on the advisability of investing in the issuer or offering. Therefore, consistent with the views of one commenter, a funding portal may not advertise in such a way that expresses the funding portal's view that, for example, certain offerings on its platform are of a higher quality, safer or more worthy than others, or that otherwise gives a recommendation.[1065]

We recognize that advertisements can take many varied forms, including non-traditional means, such as blogs, emails through social media or other methods. We believe that these types of communications, when made by a funding portal to investors can be a permissible means of advertising within the scope of Rule 402(b)(9). We agree, however, with a commenter's statement that it would be inconsistent with the statutory prohibition on providing investment advice or recommendations for a funding portal to send out soliciting emails recommending investments in particular companies as part of its advertising.[1066]

[1052] *See, e.g.,* CFIRA Letter 1; Commonwealth of Massachusetts Letter; ABA Letter.

[1053] *See* RocketHub Letter.

[1054] *Id.*

[1055] *Id.*

[1056] *See* CFIRA Letter 1.

[1057] *See* Commonwealth of Massachusetts Letter.

[1058] *Id.*

[1059] *Id.*

[1060] *Id.*

[1061] *See* ABA Letter.

[1062] *See* Milken Institute Letter.

[1063] The safe harbor is limited to identifying one or more issuers. More detailed information about an issuer should be provided on the funding portal's platform.

[1064] *See* Exchange Act Section 3(a)(80)(A).

[1065] *See* Milken Institute Letter.

[1066] *See* ABA Letter.

i. Deny Access to Platform

(1) Proposed Rule

Proposed Rule 402(b)(10) would permit a funding portal to deny access to its platform to, or cancel an offering of, an issuer that the funding portal believes may present the potential for fraud or otherwise raises investor protection concerns.

(2) Comments on Proposed Rule

Some commenters asserted that the proposed rules are ambiguous, and that the lack of specificity exposes funding portals to potential liability. The commenters were concerned that the perceived lack of specificity may also lead funding portals to unintentionally violate the ban on providing investment advice with their attempts to mitigate liability.[1067]

(3) Final Rules

We are adopting Rule 402(b)(10) substantially as proposed with modifications to make it consistent with Rule 301(c)(2), which requires an intermediary to deny access if it has a reasonable basis for believing that the issuer or the offering presents the potential for fraud or otherwise raises concerns about investor protection.[1068] In satisfying this requirement, an intermediary must deny access if it reasonably believes that it is unable to adequately or effectively assess the risk of fraud of the issuer or its potential offering. In addition, if an intermediary becomes aware of information after it has granted access that causes it to reasonably believe that the issuer or the offering presents the potential for fraud or otherwise raises concerns about investor protection, the intermediary must promptly remove the offering from its platform, cancel the offering, and return (or, for funding portals, direct the return of) any funds that have been committed by investors in the offering. Rule 402(b)(10) requires a funding portal to deny access to its platform to, or cancel an offering of an issuer, pursuant to Rule 301(c)(2), if the funding portal has a reasonable basis for believing that the issuer or the offering presents the potential for fraud or otherwise raises concerns.

We changed the standard in Rule 402(b)(10) to a ''reasonable basis for believing''—rather than ''believes''—to conform the safe harbor to the requirements of Rule 301(c)(2) as adopted. Thus, the standard in Rule 402(b)(10) is consistent with the modifications that we made to the standard in Rule 301(c)(2).[1069] We believe this change also should help to address commenters' concerns about the perceived lack of specificity in the proposed safe harbor by providing an objective ''reasonable belief'' standard for the required determinations. Under this standard a funding portal may not ignore facts about an issuer that indicate fraud or investor protection concerns such that a reasonable person would have denied access to the platform. At the same time, a funding portal can also feel assured in its decision to deny an issuer access or cancel an offering if it has a reasonable basis for such a determination. We also believe that including a ''reasonable basis'' standard adds objectivity to a funding portal's determinations regarding which issuers must be denied access to (or removed from) its platform, which is expected to help to address concerns regarding the clarity of the standard under the proposed rule.

j. Accepting Investor Commitments

(1) Proposed Rule

Proposed Rule 402(b)(11) would permit a funding portal to accept, on behalf of an issuer, an investment commitment for securities offered in reliance on Section 4(a)(6) of the Securities Act by that issuer on the funding portal's platform.

(2) Comments on Proposed Rule

One commenter noted that the statute prohibits funding portals from handling investor funds or securities, and that the proposed rule requiring the use of third-party entities would create additional transaction costs for funding portals.[1070] Another commenter stated that the safe harbor for accepting investor commitments should permit a funding portal to assist issuers in handling a direct registration system (DRS) between issuers and investors.[1071]

(3) Final Rules

We are adopting Rule 402(b)(11) as proposed. Rule 402(b)(11) permits a funding portal, on behalf of an issuer, to accept investment commitments from investors for securities offered in reliance on Section 4(a)(6) by that issuer on the funding portal's platform. We are not broadening the safe harbor to permit funding portals to handle customer funds, as suggested by one commenter. Although we recognize that the requirement to use a third party entity to handle customer funds imposes an additional expense on a funding portal, Exchange Act Section 3(a)(80)(D) explicitly prohibits funding portals from handling customer funds and securities. Similarly, we believe it would be inconsistent with the statute for a funding portal to facilitate a securities registration system for issuers and investors because such activity implicitly requires funding portals to handle customer funds and securities, which is prohibited by the statute. In this regard, we note that the activities that a funding portal is permitted to engage in are limited in scope, and as such are subject to a more limited regulatory scheme as compared to registered broker-dealers.

k. Directing Transmission of Funds

(1) Proposed Rule

Proposed Rule 402(b)(12) would permit a funding portal to direct investors where to transmit funds or remit payment in connection with the purchase of securities offered and sold in reliance on Section 4(a)(6) of the Securities Act.

Proposed Rule 402(b)(13) would permit a funding portal to direct a qualified third party, as required by Rule 303(e), to release proceeds to an issuer upon completion of a crowdfunding offering or to return proceeds to investors in the event an investment commitment or an offering is cancelled.

(2) Final Rules

We did not receive comments on the ability of a funding portal to direct investment funds and are adopting Rules 402(b)(12) and (13) as proposed. Rules 402(b)(12) and (13) provide that a funding portal can fulfill its obligations with respect to the maintenance and transmission of funds and securities, as set forth in Rule 303, without violating the prohibition in Exchange Act Section 3(a)(80)(D). Specifically, a funding portal can direct investors where to transmit funds or remit payment in connection with the purchase of securities offered and sold in reliance on Section 4(a)(6),[1072] and as required by Rule 303(e), a funding portal can direct a qualified third party to release the proceeds of an offering to the issuer upon completion of the offering or to return investor proceeds when an

[1067] *See, e.g.,* RocketHub Letter and Seyfarth Letter.

[1068] *See* Section II.C.3 discussing the change to Rule 301(c) to include a ''reasonable basis'' standard.

[1069] *See* Section II.C.3.

[1070] *See* Stephenson, *et al.,* Letter.

[1071] *See* RocketHub (suggesting that a portal should be permitted to provide DRS support to issuers and investors). A DRS allows investors to transfer a security that is registered in the investor's name on the issuer's books, and either the company or its transfer agent holds the security for the investor in book-entry form.

[1072] *See* Rule 402(b)(12) of Regulation Crowdfunding.

investment commitment or offering is cancelled.[1073]

l. Posting News

In the Proposing Release, we asked whether we should adopt a safe harbor that permits a funding portal to post news, such as market news and news about a particular issuer or industry, on its platform. In response to our request for comment, some commenters stated that the safe harbor should permit funding portals to post third party news related to issuers or offerings on their platform.[1074] One commenter cautioned that objective criteria should be used to ensure, for example, that funding portals are not picking out the most flattering or positive news.[1075] Another commenter suggested that funding portals should be aware of the content of materials posted on their portal and held responsible for inappropriate information that is posted.[1076]

While we believe it is possible for funding portals to post news on their platforms in a manner that would not violate the prohibitions in Exchange Act Section 3(a)(80), we are not including such activities within the safe harbor because we believe the permissibility of posting news should be a facts and circumstances determination. When posting news, funding portals will need to ensure that they do not violate the prohibition on giving investment advice and recommendations. For example, if a funding portal selectively determines which news articles to post or posts only flattering or positive news, then the funding portal is more likely to be giving impermissible investment advice or recommendations.

m. No Presumption and Anti-Fraud Provisions

(1) Proposed Rule

Proposed Rule 402(a) also stated that no presumption shall arise that a funding portal has violated the prohibitions under Section 3(a)(80) of the Exchange Act or Regulation Crowdfunding by reason of the funding portal or its associated persons engaging in activities in connection with the offer or sale of securities in reliance on Section 4(a)(6) of the Securities Act that do not meet the conditions specified in the safe harbor and that the antifraud provisions and all other applicable provisions of the federal securities laws continue to apply to the activities described in the safe harbor.

(2) Final Rules

We did not receive any comments on the proposed ''no presumption'' and anti-fraud provisions and are adopting Rule 402(a) as proposed. We also reiterate that Rule 402(b) is a non-exclusive safe harbor. Rule 402(a) expressly provides that the failure of a funding portal to meet the conditions of the safe harbor does not give rise to a presumption that the funding portal is in violation of the statutory prohibitions of Exchange Act Section 3(a)(80) or Regulation Crowdfunding.[1077]

Further, the safe harbor under Rule 402 does not prohibit funding portals from engaging third party service providers to assist the funding portal in operating its platform, such as providers of software, Web site maintenance and development, communication channel applications, recordkeeping systems, and other technology.[1078] However, the funding portal remains responsible for its activities and the operation of its platform and for compliance with Regulation Crowdfunding and other applicable federal securities laws.

4. Compliance

a. Policies and Procedures

(1) Proposed Rule

As proposed, Rule 403(a) would require a funding portal to implement written policies and procedures reasonably designed to achieve compliance with the federal securities laws and the rules and regulations thereunder, relating to its business as a funding portal.[1079]

(2) Comments on the Proposed Rules

One commenter agreed that the Commission should not specify requirements for a funding portal's policies and procedures, while another commenter thought the Commission should provide guidance concerning the policies and procedures.[1080] Another commenter suggested that all changes to a funding portal's policies and procedures should be disclosed within 30 days and publicly announced.[1081] Yet another commenter suggested requiring the SRO to mandate that broker-dealers and funding portals follow the same policies.[1082]

(3) Final Rules

We are adopting Rule 403(a) as proposed. We believe that the requirement to implement written policies and procedures will provide important investor protections as it will necessitate that funding portals remain aware of the various regulatory requirements to which they are subject and take appropriate steps for complying with such requirements. We recognize, however, that funding portals may have various business models and, therefore, consistent with the views of one commenter, we are not imposing specific requirements for a funding portal's policies and procedures, provided the policies and procedures are reasonably designed to achieve compliance with the federal securities laws and the rules relating to their business as funding portals. Rather, we are providing a funding portal with discretion to establish, implement, maintain and enforce its policies and procedures based on its relevant facts and circumstances.

We note, however, that a funding portal may rely on the representations of others when meeting certain requirements under Regulation Crowdfunding, unless the funding portal has reason to question the reliability of those representations. For example, a funding portal may rely on an issuer's representation to establish a reasonable basis for believing that an issuer seeking to offer and sell securities in reliance on Section 4(a)(6) through its platform complies with the requirements in Securities Act Section 4A(b) and the related requirements in Regulation Crowdfunding, unless the funding portal has reason to question the reliability of that representation.[1083] A funding portal may also rely on an investor's representation to establish a reasonable basis for believing that an investor satisfies the investment limits established by Section 4(a)(6)(B), unless the funding portal has reason to question the reliability of that representation.[1084] We believe that when a funding portal relies on the representations of others to form a reasonable basis, the funding portal

[1073] *See* Rule 402(b)(13) of Regulation Crowdfunding.

[1074] *See, e.g.,* CFIRA Letter 1; RoC Letter; StartupValley Letter. *But see* Joinvestor Letter; Wefunder Letter.

[1075] *See* CFIRA Letter 1.

[1076] *See* RoC Letter.

[1077] *See* Rule 402(a) of Regulation Crowdfunding.

[1078] One commenter asked whether funding portals could engage third party service providers consistent with Regulation Crowdfunding. *See* CFIRA Letter 1.

[1079] As a condition to exempting funding portals from the requirement to register as a broker or a dealer under Exchange Act Section 15(a)(1) (15 U.S.C. 78*o*(a)(1)), Exchange Act Section 3(h)(1)(C) provides that registered funding portals must comply with such other requirements as the Commission determines appropriate.

[1080] *See* ASSOB Letter; Consumer Federation of America (''[The Commission] fails to address at all the areas that should be covered by such policies and procedures, or what a funding portal's responsibilities to monitor compliance would be.'').

[1081] *See* Joinvestor Letter.

[1082] *See* Rockethub Letter.

[1083] *See* Rule 301(a).

[1084] *See* Rule 303(b)(1).

should have policies and procedures regarding under what circumstances it can reasonably rely on such representations and when additional investigative steps may be appropriate. We further believe that a funding portal's policies and procedures should cover not only permitted activities, but also address prohibited activities. For example, a funding portal should have policies and procedures on the criteria used to limit, highlight and advertise issuers and offerings.

We note one commenter's suggestion that we require funding portals to update their policies and procedures to reflect changes in applicable rules and regulations within a specified time period after the change occurs. However, as explained in the Proposing Release, we believe that the requirement for reasonably designed policies and procedures includes an ongoing obligation for a funding portal to promptly update its policies and procedures if necessary to reflect changes in applicable rules and regulations, a funding portal's business practices, and/or the marketplace.[1085] Finally, in response to one commenter's suggestion that we require SROs to mandate that broker-dealers and funding portals follow the same policies, as noted above, we believe that funding portals should have flexibility to implement policies and procedures suited to their own facts and circumstances. Moreover, we note that any proposed SRO rules relating to policies and procedures of either broker-dealers or funding portals will be subject to the Exchange Act Section 19(b) SRO rule filing process.[1086]

Commission staff expects to review intermediaries' compliance policies and procedures relating to their activities in connection with the offer or sale of securities in reliance on Section 4(a)(6) during the study of the federal crowdfunding exemption that it plans to undertake no later than three years following the effective date of Regulation Crowdfunding.[1087]

b. Anti-Money Laundering

(1) Proposed Rule

Proposed Rule 403(b) would require that funding portals comply with certain AML provisions,[1088] as set forth in Chapter X of Title 31 of the Code of Federal Regulations. The BSA and its implementing regulations establish the basic framework for AML obligations imposed on financial institutions.[1089] The BSA is intended to facilitate the prevention, detection and prosecution of money laundering, terrorist financing and other financial crimes.

Among other things, the BSA and its implementing regulations require a ''broker or dealer in securities'' (sometimes referred to in the regulations as a ''broker-dealer'') to: (1) Establish and maintain an effective AML program;[1090] (2) establish and maintain a Customer Identification Program; [1091] (3) monitor for and file reports of suspicious activity (SARs); [1092] and (4) comply with requests for information from the Financial Crimes Enforcement Network (''FinCEN'').[1093] For purposes of the BSA obligations, a ''broker or dealer in securities'' is defined as a ''broker or dealer in securities, registered or required to be registered with the Securities and Exchange Commission under the Securities Exchange Act of 1934, except persons who register pursuant to [S]ection 15(b)(11) of the Securities Exchange Act of 1934.'' [1094] As explained above, Exchange Act Section 3(h) expressly directs the Commission, conditionally or unconditionally, to exempt funding portals from the requirement to register as a broker or dealer under Section 15(a). As such, a funding portal is not a broker ''registered or required to be registered'' if it registers as a funding portal with the Commission. We proposed that, notwithstanding this exemption from broker registration, under Rule 401(b) a funding portal would be ''required to be registered'' as a broker or dealer with the Commission under the Exchange Act solely for purposes of Chapter X of Title 31 of the Code of Federal Regulations, thus subjecting funding portals to the AML requirements of Chapter X of Title 31.

(2) Comments on the Proposed Rule

A few commenters generally suggested that since funding portals are prohibited from handling customer funds and securities they should not be required to comply with AML provisions.[1095] Some commenters, however, generally supported requiring funding portals to comply with AML provisions.[1096] One commenter, noting that non-U.S. investors may participate in crowdfunding and use U.S.-based funding portals, requested that the Commission provide advice and suggestions on ''how to prevent anti-money laundering.'' [1097]

(3) Final Rules

Upon further consideration, we have determined not to adopt proposed Rule 403(b). The BSA requirements play a critical role in detecting, preventing, and reporting money laundering and other illicit financing, such as market manipulation and fraud. However, after careful consideration, we believe that AML obligations for funding portals are better addressed outside of the rules that we are currently adopting in this release, and that it would be more appropriate to work with other regulators to develop consistent and effective AML obligations for funding portals.[1098] We note, however, that broker-dealers continue to have their own AML obligations, as do certain other parties involved in transactions

[1085] Consistent with our requirements for broker-dealers, we are not requiring that a funding portal's policies and procedures be made public, as suggested by a commenter.

[1086] Pursuant to Exchange Act Section 19(b) and Rule 19b–4, SROs are required to file proposed new rules and rule changes with the Commission.

[1087] *See* Section II.

[1088] *See also* Section II.D.2. (discussing proposed Rule 401(b)).

[1089] *See* BSA, note 981; 31 CFR Chapter X.

[1090] *See* 31 U.S.C. 5318(h). *See also* 31 CFR 1023.210; FINRA Rule 3310.

[1091] *See* 31 CFR 1023.220.

[1092] *See* 31 CFR 1023.320. *See also* FINRA Rule 3310.

[1093] *See* 31 CFR 1010.520.

[1094] *See* 31 CFR 1010.100(h). As noted above, certain FinCEN regulations apply to a ''broker-dealer,'' which is defined as a ''person registered or required to be registered as a broker or dealer with the Commission under the Securities Exchange Act of 1934 (15 U.S.C. 77a *et seq.*), except persons who register pursuant to 15 U.S.C. 78*o*(b)(11).'' 31 CFR 1023.100(b). Such broker-dealers also would meet the definition of ''broker or dealers in securities'' above.

[1095] *See* PeoplePowerFund Letter; Public Startup 3 Letter; RFPIA Letter; Vann Letter.

[1096] *See* RocketHub Letter (stating that it ''supports the Commissions [sic] interpretation of the exemption, and believes that AML compliance is necessary''); Berlingeri Letter (supporting funding portal ''compliance with existing anti-money laundering provisions and the requirement to report suspicious activity'').

[1097] *See* Zhang Letter.

[1098] FinCEN within the Department of Treasury has primary regulatory responsibility for administering the BSA. We note that FinCEN has included in the Unified Agenda and Regulatory Plan an item that states: ''FinCEN . . . is proposing amendments to the regulatory definitions of 'broker or dealer in securities' under the regulations implementing the Bank Secrecy Act. The proposed changes are intended to expand the current scope of the definitions to include funding portals. In addition, these amendments would require funding portals to implement policies and procedures reasonably designed to achieve compliance with all of the Bank Secrecy Act requirements that are currently applicable to brokers or dealers in securities.'' *See* Office of Mgmt. & Budget, Exec. Office of the President, Office of Info. & Regulatory Affairs, Amendments of the Definition of Broker or Dealer in Securities, RIN 1506–AB29, *available at http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201504&RIN=1506-AB29*. In addition, the Commission has adopted its own rules that require broker-dealers to comply with certain requirements of the BSA's implementing regulations, such as books and records requirements. *See* Exchange Act Rule 17a–8. *See also* Section II.D.5.

conducted pursuant to Section 4(a)(6), such as a bank acting as a qualified third party to hold investor funds.

c. Privacy

(1) Proposed Rule

Section 4A(a)(9) of the Securities Act requires intermediaries to take such steps to protect the privacy of information collected from investors as the Commission shall, by rule, determine appropriate. Proposed Rule 403(c) would implement the requirements of Section 4A(a)(9) by subjecting funding portals to the same privacy rules as those applicable to brokers. Proposed Rule 403(c), therefore, would have required funding portals to comply with Regulation S–P (Privacy of Consumer Financial Information and Safeguarding Personal Information),[1099] Regulation S–AM (Limitations on Affiliate Marketing),[1100] and Regulation S–ID (Identity Theft Red Flags) [1101] (collectively, the ''Privacy Rules'').[1102]

Regulation S–P governs the treatment of nonpublic personal information by brokers, among others.[1103] It generally requires a broker to provide notice to investors about its privacy policies and practices; describes the conditions under which a broker may disclose nonpublic personal information about investors to nonaffiliated third parties; and provides a method for investors to prevent a broker from disclosing that information to most nonaffiliated third parties by ''opting out'' of that disclosure, subject to certain exceptions. Regulation S–AM allows a consumer, in certain limited situations, to block affiliates of covered persons (*i.e.,* brokers, dealers, investment companies and both investment advisers and transfer agents registered with the Commission) from soliciting the consumer based on eligibility information (*i.e.,* certain financial information, such as information about the consumer's transactions or experiences with the covered person) received from the covered person.[1104] Regulation S–ID generally requires brokers to develop and implement a written identity theft prevention program that is designed to detect, prevent and mitigate identity theft in connection with certain existing accounts or the opening of new accounts.[1105]

(2) Comments and Final Rules

We are adopting Rule 403(c) as proposed, but renumbering it as Rule 403(b).[1106] One commenter opposed Proposed Rule 403(c), which would impose the Privacy Rules on funding portals, stating that in its view, funding portals do not raise privacy concerns.[1107] We disagree. We believe that privacy is a concern as it relates to funding portals given that funding portals will collect and maintain sensitive personal information about the investors using their platforms.

d. Inspections and Examinations

(1) Proposed Rule

Exchange Act Section 3(h)(1)(A) specifies that funding portals must remain subject to our examination authority to, among other things, rely on any exemptions from broker-dealer registration that we impose. Under proposed Rule 403(d) of Regulation Crowdfunding, a funding portal would be required to permit the examination and inspection of all of its business and business operations that relate to its activities as a funding portal, such as its premises, systems, platforms and records, by our representatives and by representatives of the registered national securities association of which it is a member.

(2) Comment and Final Rules

We are adopting Rule 403(d) as proposed, but renumbering it as 403(c).[1108] One commenter opposed the Commission's proposed inspections and examinations rules as unnecessary.[1109] As a condition to exempting funding portals from the requirement to register as broker-dealers under Exchange Act Section 15(a)(1), Exchange Act Section 3(h)(1)(A) requires that registered funding portals remain subject to, among other things, our examination authority. We believe that inspections and examinations are an important aspect of our oversight function of funding portals as they will assist us in monitoring the activities of funding portals in light of applicable statutory and regulatory requirements. Therefore, we are adopting Rule 403(c) to implement the statute and retain examination authority over funding portals.

5. Records To Be Created and Maintained by Funding Portals

a. Proposed Rule

As proposed, Rule 404(a) would require funding portals to make and preserve certain records for five years, with the records retained in a readily accessible place for at least the first two years. The required records would include the following:

- All records relating to investors who purchase or attempt to purchase securities through the funding portal; [1110]
- All records relating to issuers that offer and sell, or attempt to offer and sell, securities through the funding portal and to persons having control with respect to those issuers;
- Records of all communications that occur on or through its platform;
- All records related to persons that use communication services provided by a funding portal to promote an issuer's securities or to communicate with potential investors;
- All records demonstrating a funding portal's compliance with requirements of Subparts C (intermediary obligations) and D (additional funding portal requirements); [1111]
- All notices provided by the funding portals to issuers and investors generally through the funding portal's platform or otherwise; [1112]
- All written agreements (or copies thereof) entered into by a funding portal, relating to its business as such;
- All daily, monthly and quarterly summaries of transactions effected through the funding portal; [1113] and

[1099] *See Privacy of Consumer Financial Information (Regulation S–P),* Release No. 34–42974 (June 22, 2000) [65 FR 40334 (June 29, 2000)].

[1100] *See Regulation S–AM: Limitations on Affiliate Marketing,* Release No. 34–60423 (Aug. 4, 2011) [74 FR 40398 (Aug. 11, 2009)].

[1101] *See Identity Theft Red Flags Rules,* Release No. 34–69359 (Apr. 10, 2013) [78 FR 23637 (Apr. 19, 2013)] (adopted jointly with the Commodity Futures Trading Commission).

[1102] *See* 17 CFR part 248.

[1103] *See* 17 CFR part 248, subpart A.

[1104] *See* 17 CFR part 248, subpart B.

[1105] *See* 17 CFR part 248, subpart C.

[1106] The rule is being renumbered to account for the elimination of the proposed AML provision in proposed Rule 403(b), which is discussed in Section II.D.4.b above.

[1107] *See* Public Startup Letter 3.

[1108] The Rule is being renumbered to account for the elimination of the proposed anti-money laundering provision in proposed Rule 403(b), which is described in more detail in Section II.D.4.b. We are also adding the word ''registered'' to ''national securities association'' to be consistent with the rest of the rule text and with Exchange Act Section 3(h)(1)(B).

[1109] *See* Public Startup Letter 3.

[1110] This would include information relating to educational materials provided to investors, account openings and transactions, including notices of investment commitments and reconfirmations.

[1111] This requirement alone would not, however, require the creation of any records or proscribe the format or manner of any records. However, without records, it would be difficult for a funding portal to demonstrate compliance with Subparts C and D to examiners.

[1112] These would include, but not be limited to: (1) Notices addressing hours of funding portal operations (if any); (2) funding portal malfunctions; (3) changes to funding portal procedures; (4) maintenance of hardware and software; (5) instructions pertaining to access to the funding portal; and (6) denials of, or limitations on, access to the funding portal.

[1113] These would include: (1) Issuers for which the target offering amount has been reached and

• A log reflecting the progress of each issuer who offers and sells securities through the funding portal toward meeting the target offering amount.

As proposed, Rule 404(b) would require that a funding portal make and preserve its organizational documents during its operation as a funding portal and also those of any successor funding portal. These would include, but not be limited to: (1) Partnership agreements; (2) articles of incorporation or charter; (3) minute books; and (4) stock certificate books (or other similar type documents).

We also proposed in Rule 404(c) that the records required to be maintained and preserved pursuant to Rule 404(a) be produced, reproduced, and maintained in the original, non-alterable format in which they were created or as permitted under Section 17a–4(f) of the Exchange Act. We proposed in Rule 404(d) to allow third parties to prepare or maintain the required records on behalf of the funding portal, provided that there is a written undertaking in place between the funding portal and the third party stating that the required records are the property of the funding portal and will be surrendered promptly, on request by the funding portal, to the Commission or the national securities association of which the funding portal is a member.[1114] The funding portal also would have been required to file, with the registered national securities association of which it is a member, this written undertaking, signed by a duly authorized representative of the third party. As proposed, an agreement between a funding portal and a third party would not relieve the funding portal of its responsibility to prepare and maintain records, as required under Rule 404 of Regulation Crowdfunding.

As proposed, Rule 404(e) would require all records of a funding portal to be subject at any time, or from time to time, to such reasonable periodic, special or other examination by our representatives and representatives of the registered national securities association of which the funding portal is a member.

Finally, we proposed in Rule 404(f) that funding portals would be required to comply with the reporting, recordkeeping and record retention requirements of Chapter X of Title 31 of the Code of Federal Regulations. Where Chapter X of Title 31 and proposed rules 404(a) and 404(b) would require the same records or reports to be preserved for different periods of time, we proposed requiring the records or reports to be preserved for the longer period of time.

b. Comments on Proposed Rule

Commenters generally did not object to the proposed recordkeeping requirements. Some commenters suggested that the cost for a funding portal to maintain the proposed books and records would not be significant.[1115] A few commenters suggested that funding portals should maintain required records for a longer period of time. One of these commenters recommended a retention period of 10 years,[1116] while the other suggested that issuer data should be kept permanently accessible by the funding portal.[1117] Another commenter suggested that the Commission should require intermediaries, rather than the issuers, to maintain records (or arrange for third-party recordkeeping) of the offering materials used by the issuers, thereby reducing the burden on issuers by no longer requiring them to transcribe offering materials into something that can be filed with EDGAR.[1118]

c. Final Rules

We are adopting Rule 404 as proposed, with a modification to subparagraph (e) to require that books and records subject to review under the subsection be produced promptly to representatives of the Commission and the national securities association of which the funding portal is a member,[1119] and a minor modification to subparagraph (f) related to anti-money laundering related records.[1120] We also made a modification to state that, in addition to being furnished to representatives of the Commission, books and records would have to be furnished to the Commission itself. We are also adding the word ''registered'' to ''national securities association'' to be consistent with the rest of the rule text and with Exchange Act Section 3(h)(1)(B).[1121]

We believe that it is important for funding portals to be subject to the recordkeeping requirements in order to create a meaningful record of crowdfunding transactions and communications. For example, we are requiring records of all notices provided by the funding portals to issuers and investors generally through the funding portal's platform or otherwise. We believe that, in addition to the list of examples provided in the rule, this encompasses any notices relating to the funding portal's business as such, including communications in electronic form sent from an associated person of a funding portal to issuers or investors (including potential investors). Every funding portal is required under Rule 404 to furnish promptly to the Commission and its representatives, and the registered national securities association of which the funding portal is a member, legible, true, complete and current copies of such records of the funding portal that are requested by the representatives of the Commission and the national securities association.[1122]

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funds distributed; and (2) transaction volume, expressed in number of transactions, number of securities involved in a transaction and total amounts raised by and distributed to issuers, as well as total dollar amounts raised across all issuers, expressed in U.S. dollars.

[1114] The written undertaking would be required to include the following provision:

With respect to any books and records maintained or preserved on behalf of [name of funding portal], the undersigned hereby acknowledges that the books and records are the property of [name of funding portal], and hereby undertakes to permit examination of such books and records at any time, or from time to time, during business hours by representatives of the Securities and Exchange Commission, and the national securities association of which the funding portal is a member, and to promptly furnish to the Commission and national securities association of which the funding portal is a member, a true, correct, complete and current hard copy of any, all, or any part of, such books and records.

This provision is consistent with the recordkeeping provisions applicable to brokers under Exchange Act Rules 17a–4(f) (17 CFR 17a–4(f)) and 17a–4(j) (17 CFR 240.17a–4(j)), but has been scaled to be more appropriate for funding portals.

[1115] *See, e.g.,* CFIRA Letter 1, Joinvestor Letter.

[1116] *See* Joinvestor Letter.

[1117] Mollick, *et al* Letter. *See also* Public Startup Letter 5 (suggesting that the Commission should improve ''forensic record-keeping obligations of a funding portal'' by requiring portals to ''maintain the URLs and Web site content in perpetuity for all issuers who use the portal to raise capital from the public.'').

[1118] CFIRA Letter 1.

[1119] We are making this change to remain consistent with the prompt production standard that is required for third party recordkeeping undertakings pursuant to Rule 404(d).

[1120] In the Proposing Release and as noted in this section, we have provided examples of the types of information that would be required to be maintained under each of the specified records. The same guidance applies with respect to application of the final rules.

[1121] Conforming changes were made to both Rules 404(d) and (e).

[1122] The Commission generally interprets the term ''promptly'' or ''prompt'' to mean making reasonable efforts to produce records that are requested by the staff during an examination without delay. The Commission believes that in many cases a funding portal could, and therefore will be required to, furnish records immediately or within a few hours of a request. The Commission expects that only in unusual circumstances would a funding portal be permitted to delay furnishing records for more than 24 hours. *Accord* Security-Based Swap Data Repository Registration, Duties, and Core Principles, Exchange Act Release No. 74246 (Feb. 11, 2015), 80 FR 14438, 14500 n. 846 (Mar. 19, 2015) (similarly interpreting the term ''promptly'' in the context of Exchange Act Rule 13n–7(b)(3)); Registration of Municipal Advisors,

Continued

The requirements will enable regulators to more effectively gather information about the activities in which a funding portal has been engaged, as well as about the other parties involved in crowdfunding (*e.g.,* issuers, promoters, and associated persons), to discern whether the funding portals and the other parties are in compliance with the requirements of Regulation Crowdfunding and any other applicable federal securities laws. We believe the requirements will assist regulators' compliance examinations because, without these records, the Commission and any registered national securities association of which the funding portal is a member may have difficulty examining a funding portal for compliance with the requirements of Regulation Crowdfunding and the federal securities laws.[1123] Therefore, we believe the record retention requirements should be mandatory rather than voluntary as suggested by one commenter. Although we are not requiring that funding portals utilize the record retention services of broker-dealers, as suggested by one commenter, we note that a funding portal may find it cost-effective or otherwise appropriate to use the recordkeeping services of a third party, and the final rules provide the necessary flexibility to allow funding portals to utilize these options.

While some commenters suggest a longer record retention period, we believe the requirement that funding portals preserve their records for five years, with the records retained in a readily accessible place for at least the first two years, provides sufficient investor protection, while not imposing overly burdensome recordkeeping costs.[1124] We are not adopting, as commenters recommended, a requirement that funding portals be required to keep issuer data permanently accessible or maintain URLs and Web site content in perpetuity for all issuers, as we believe the permanent storage of such information could be unduly burdensome and is unnecessary.

Because permissible funding portal activity is far more limited than that of broker-dealers and a relatively high proportion of funding portals will be new market entrants that have not been subject to regulation before (rather than broker-dealers switching their business models to become funding portals) and, therefore, may not have formal recordkeeping practices in place, the recordkeeping requirements for funding portals are relatively streamlined compared to those for broker-dealers. Funding portals are intended to be subject to less regulation than broker-dealers, and recordkeeping requirements adopted in the final rules are consistent with this intent.

Finally, as described above, we are not adopting the proposed requirement that a funding portal comply with the BSA.[1125] Nevertheless, we are revising the final recordkeeping rule to require a funding portal to maintain books and records related to BSA requirements, should funding portals become subject to the requirements of the BSA.[1126]

Commission staff expects to review the books and records practices of intermediaries during the study of the federal crowdfunding exemption that it plans to undertake no later than three years following the effective date of Regulation Crowdfunding.[1127]

E. Miscellaneous Provisions

1. Insignificant Deviations From Regulation Crowdfunding

a. Proposed Rules

We proposed Rule 502 of Regulation Crowdfunding to provide issuers a safe harbor for insignificant deviations from a term, condition or requirement of Regulation Crowdfunding. As proposed in Rule 502(a), to qualify for the safe harbor, the issuer relying on the exemption would have to show that: (1) The failure to comply with a term, condition or requirement was insignificant with respect to the offering as a whole; and (2) the issuer made a good faith and reasonable attempt to comply with all applicable terms, conditions and requirements of Regulation Crowdfunding; and (3) the issuer did not know of the failure to comply, where the failure to comply with a term, condition or requirement was the result of the failure of the intermediary to comply with the requirements of Section 4A(a) and the related rules, or such failure by the intermediary occurred solely in offerings other than the issuer's offering. As proposed in Rule 502(b), notwithstanding this safe harbor, any failure to comply with Regulation Crowdfunding would nonetheless be actionable by the Commission.

b. Comments on the Proposed Rules

Commenters were generally in favor of the proposed safe harbor.[1128] However, some commenters representing state securities regulators suggested that the safe harbor is unnecessary, would be detrimental to state enforcement efforts and would be a burden on regulators when issuers assert the safe harbor, whether or not they were operating in good faith.[1129] These commenters also recommended that the proposed safe harbor, if adopted, should not be a defense to an enforcement action by the states.[1130]

c. Final Rules

We are adopting the Rule 502(a) safe harbor as proposed.[1131] The first two prongs of the safe harbor provision in Rule 502(a) are modeled after a similar provision in Rule 508 of Regulation D,[1132] and we believe a similar safe harbor is appropriate for offerings made in reliance on Section 4(a)(6). We believe that provisions for insignificant deviations serve an important function by allowing for certain errors that can occur in the offering process without causing the issuer to lose the exemption and incur certain consequences, including potential private rights of action for rescission for violations of Section 5 of the Securities Act,[1133] and loss of preemption for state securities law registration requirements. The offering exemption in Section 4(a)(6) was designed to help alleviate the funding gap and the accompanying regulatory challenges faced by startups and small businesses, many of which may not be familiar with the federal securities laws. We continue to believe that issuers should not lose the Section 4(a)(6) exemption because of insignificant deviations from a term,

Exchange Act Release No. 70462 (Sept. 20, 2013), 78 FR 67468, 67578–67579 n. 1347 (Nov. 12, 2013) (similarly interpreting the term ''prompt'' in the context of Exchange Act Rule 15Ba1–8(d)).

[1123] *See, supra,* note 798.

[1124] We note that the record retention period requirement continues for a funding portal after it withdraws its registration. Schedule D of Form Funding Portal requests information about the location(s) of where a funding portal will keep its books and records after withdrawal.

[1125] *See* Section II.D.4.b.

[1126] 15 U.S.C. 5311 *et seq.* To the extent that funding portals become subject to the requirements of the BSA and are required to comply with BSA recordkeeping requirements, we believe that this recordkeeping requirement will be valuable to our regulatory oversight function of funding portals' compliance with such BSA requirements. *See generally Recordkeeping by Brokers and Dealers,* Release No. 34–18321 (Dec. 10, 1981) [46 FR 61454 (Dec. 17, 1981)] (noting the effectiveness of on-site examinations of broker-dealers by the Commission and SROs in enforcing compliance with reporting and recordkeeping requirements when adopting Exchange Act Rule 17a–8). Rule 17a–8 (17 CFR 240.17a–8) requires broker-dealers to comply with the reporting, recordkeeping and record retention rules adopted under the BSA.

[1127] *See* Section II.

[1128] *See, e.g.,* Arctic Island Letter 7; CFIRA Letter 1; Heritage Letter; Joinvestor Letter; Parsont Letter; Schwartz Letter.

[1129] *See* Commonwealth of Massachusetts Letter; NASAA Letter.

[1130] *Id.*

[1131] *See* Rule 502 of Regulation Crowdfunding.

[1132] 17 CFR 230.508.

[1133] *See* Securities Act Section 12(a)

condition or requirement of Regulation Crowdfunding, so long as the issuer, in good faith, attempted to comply with the rules. We note that whether a deviation from the requirements would be significant to the offering as a whole will depend on the facts and circumstances of the offering and the deviation. While such determinations will be based on the particular facts and circumstances, we believe that a deviation from certain fundamental requirements in the rules, such as a failure to adhere to the aggregate offering limit under Rule 100(a)(1), presumptively would not be an insignificant deviation that would allow reliance on this safe harbor.

We are adopting the third prong of the safe harbor in Rule 502(a) because, under the statute, an issuer could lose the exemption and potentially violate Section 5 because of the failure of the intermediary to comply with the requirements of Section 4A(a). We believe that an issuer should not lose the offering exemption due to a failure by the intermediary, which likely will be out of the issuer's control, if the issuer did not know of such failure or such failure related to offerings other than the issuer's offering. Absent this safe harbor, we believe that issuers may be hesitant to participate in offerings in reliance on Section 4(a)(6) due to uncertainty about their ability to rely on, and to control their ongoing eligibility for, the exemption, which could undermine the facilitation of capital raising for startups and small businesses.

We believe that the potential harm to investors that might result from the applicability of this safe harbor would be minimal because the deviations must be insignificant to the offering as a whole for the safe harbor to apply. We also believe the safe harbor appropriately protects an issuer who made a diligent attempt to comply with the rules from losing the exemption as a result of insignificant deviations from Regulation Crowdfunding.

We also are adopting Rule 502(b) largely as proposed to set forth clearly that the safe harbor for insignificant deviations in Rule 502(a) does not preclude the Commission from bringing an enforcement action seeking appropriate relief for an issuer's failure to comply with all applicable terms, conditions, and requirements of Regulation Crowdfunding. Despite the suggestion of two commenters,[1134] we are not extending Rule 502(b) to enforcement actions by the states. While we recognize the concerns of certain state securities regulators that the safe harbor could be detrimental to state enforcement efforts, we believe that a state's review as to whether there is an insignificant deviation from our rules would create undue uncertainty for issuers seeking to rely on the Section 4(a)(6) exemption.[1135] We note that, irrespective of the scope of the safe harbor, states retain antifraud authority in all cases.

2. Restrictions on Resales

a. Proposed Rules

Section 4A(e) provides that securities issued in reliance on Section 4(a)(6) may not be transferred by the purchaser for one year after the date of purchase, except when transferred: (1) To the issuer of the securities; (2) to an accredited investor; (3) as part of an offering registered with the Commission; or (4) to a family member of the purchaser or the equivalent, or in connection with certain events, including death or divorce of the purchaser, or other similar circumstances, in the discretion of the Commission. Section 4A(e) further provides that the Commission may establish additional limitations on securities issued in reliance on Section 4(a)(6).

Proposed Rule 501 largely tracked the provisions of Section 4A(e). We also proposed definitions of ''accredited investor'' and a ''member of the family of the purchaser or the equivalent.'' Under the proposed rules, the term ''accredited investor'' would have the same definition in Rule 501 of Regulation D.[1136]

The statute does not define ''member of the family of the purchaser or the equivalent.'' We proposed to define the phrase to include a ''child, stepchild, grandchild, parent, stepparent, grandparent, spouse or spousal equivalent, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law of the purchaser, and shall include adoptive relationships.'' This definition tracks the definition of ''immediate family'' in Exchange Act Rule 16a–1(e),[1137] but with the addition of ''spousal equivalent.''

b. Comments on the Proposed Rules

Two commenters supported the proposed restrictions on resales,[1138] while several other commenters opposed any resale restrictions.[1139] Two commenters expressed support for the proposal that to sell securities purchased in a transaction made in reliance on Section 4(a)(6) to an accredited investor during the restricted period, the seller of such securities would need to have a reasonable belief that the purchaser is an accredited investor.[1140]

One commenter noted that the investors who are eligible to purchase securities from the initial purchasers in the first year would be able to circumvent the investment limits of the proposed rules by purchasing securities from the initial purchasers in an amount greater than they would be able to purchase through intermediaries.[1141] Another commenter noted that the restrictions on resale appear only to cover the sale by the initial purchaser, thus creating the possibility that securities of a particular issuer could become widely traded within the first year if the initial purchaser sells the securities to an eligible purchaser who then resells them to the public within the first year.[1142]

c. Final Rules

We are adopting the restrictions on resales in Rule 501 as proposed, with certain revisions as described below.[1143] We are concerned that, as noted by several commenters, the restrictions on resales would cover only the sale by the initial purchaser, which creates the possibility that securities of a particular issuer could become widely traded within the first year if the initial purchaser sells the securities to an eligible purchaser who subsequently resells them to the public within the

[1134] *See* Commonwealth of Massachusetts Letter; NASAA Letter.

[1135] Securities Act Section 18(b)(4)(C), as amended by the JOBS Act, preempts state securities laws' registration and qualification requirements for offerings made pursuant to Section 4(a)(6). 15 U.S.C. 77r(b)(4)(C).

[1136] 17 CFR 230.501(a).

[1137] 17 CFR 240.16a–1(e).

[1138] *See* Arctic Island Letter 7; Joinvestor Letter.

[1139] *See, e.g.,* Amram Letter 2 (stating resale restrictions prevent trading liquidity and impede price discovery); Crowdstockz Letter; Hamman Letter; Kickstarter Coaching Letter; Public Startup Letter 2 (recommending a six-month holding period so long as the issuer is current in its filing requirements, except that purchasers who self-certify that they are low-income investors would not be subject to a holding period); Public Startup Letter 3 (also opposing accredited investors having an advantage over other buyers).

[1140] *See* Joinvestor Letter; Public Startup Letter 3.

[1141] *See* Moskowitz Letter.

[1142] CrowdCheck Letter 3 (recommending several alternatives: (1) Designate the securities as ''restricted'' within the meaning of Rule 144; (2) mirror some or all of the issuer's resale restrictions; (3) impose a one-year obligation on the issuer not to register the transfer of securities by any person, except in the four permitted types of transfers; or (4) remove the words ''by the purchaser'' from the first sentence of proposed Rule 501(a)).

[1143] *See* Rule 501 of Regulation Crowdfunding.

first year. Further, the proposed rule could allow, as one commenter noted,[1144] investors to circumvent the investment limits in the first year by purchasing securities from the initial purchasers. In response to these concerns, we have modified Rule 501 from the proposal so that the one-year resale restriction will apply to any purchaser during the one-year period beginning when the securities were first issued, not just the initial purchaser. In addition, we have modified the definition to track more closely the language in Securities Act Rule 501(a) to clarify that the person reselling the securities must have a reasonable belief that the purchaser qualifies as an accredited investor.

As adopted, the rule provides that securities issued in a transaction pursuant to Section 4(a)(6) may not be transferred by any purchaser of such securities during that one-year period unless such securities are transferred: (1) To the issuer of the securities; (2) to an accredited investor; (3) as part of an offering registered with the Commission; or (4) to a member of the family of the purchaser or the equivalent, to a trust controlled by the purchaser, to a trust created for the benefit of a member of the family of the purchaser or the equivalent, or in connection with the death or divorce of the purchaser or other similar circumstance. We recognize that several commenters expressed concerns about the exception for resales to accredited investors and the potential unfair advantage this could provide to such investors. While we appreciate these concerns, we note that this treatment will provide some measure of liquidity for holders of these securities within the first year of the offering without undermining the investor protections otherwise provided by the statute and our rules.

3. Information Available to States

Under Section 4A(d), the Commission shall make available, or shall cause to be made available by the relevant intermediary, the information required under Section 4A(b) and such other information as the Commission, by rule, determines appropriate to the securities commission (or any agency or office performing like functions) of each state and territory of the United States and the District of Columbia. We proposed to require issuers to file on EDGAR the information required by Section 4A(b) and the related rules. Information filed on EDGAR is publicly available and would, therefore, be available to each state, territory and the District of Columbia. As we stated in the Proposing Release, we believe this approach will satisfy the statutory requirement to make the information available to each state and territory of the United States, and the District of Columbia. Commenters who addressed this issue agreed with our proposed approach,[1145] and we are adopting this provision as proposed.

4. Exemption From Section 12(g)

a. Proposed Rule

Section 303 of the JOBS Act amended Exchange Act Section 12(g) to provide that ''the Commission shall, by rule, exempt, conditionally or unconditionally, securities acquired pursuant to an offering made under [S]ection 4[(a)](6) of the Securities Act of 1933 from the provisions of this subsection.'' As amended by the JOBS Act, Section 12(g) requires, among other things, that an issuer with total assets exceeding $10,000,000 and a class of securities held of record by either 2,000 persons, or 500 persons who are not accredited investors, register such class of securities with the Commission.[1146] Crowdfunding contemplates the issuance of securities to a large number of holders, which could increase the likelihood that Section 4(a)(6) issuers would exceed the thresholds for triggering reporting obligations under Section 12(g). As discussed in the Proposing Release, Section 303 could be read to mean that securities acquired in a crowdfunding transaction would be excluded from the record holder count permanently, regardless of whether the securities continue to be held by a person who purchased in the crowdfunding transaction. An alternative reading could provide that securities acquired in a crowdfunding transaction would be excluded from the record holder count only while held by the original purchaser in the Section 4(a)(6) transaction, as a subsequent purchaser of the securities would not be considered to have ''acquired [the securities] pursuant to an offering made under [S]ection 4[(a)](6).''

Consistent with the statute, the Commission's proposed Rule 12g–6 would provide that securities issued pursuant to an offering made under Section 4(a)(6) would be permanently exempted from the record holder count under Section 12(g). An issuer seeking to exclude a person from the record holder count would have the responsibility for demonstrating that the securities held by the person were initially issued in an offering made under Section 4(a)(6).

b. Comments on the Proposed Rules

Commenters generally supported the permanent exemption from the record holder count under Section 12(g).[1147] One commenter recommended that the exemption from the record holder count under Section 12(g) apply to different securities issued in a subsequent restructuring, recapitalization or similar transaction that is exempt from, or otherwise not subject to, the registration requirements of Section 5, if the parties to the transaction are affiliates of the original issuer.[1148] A few commenters recommended conditioning the exemption from the record holder count under Section 12(g) on the issuer's asset value,[1149] while a few others opposed such concept.[1150] Another commenter recommended that issuers that fail to comply with Regulation Crowdfunding's ongoing reporting requirements be disqualified from relying on the exemption from the record holder count under Section 12(g),[1151] while two commenters opposed such concept.[1152]

c. Final Rules

In response to comments received, we are adopting Rule 12g–6 with certain modifications.[1153] The rule provides that securities issued pursuant to an offering made under Section 4(a)(6) are exempted from the record holder count under Section 12(g), provided that the issuer is current in its ongoing annual reports required pursuant to Rule 202 of Regulation Crowdfunding, has total assets as of the end of its last fiscal year not in excess of $25 million, and has engaged the services of a transfer agent

[1144] *See* Moskowitz Letter.

[1145] *See, e.g.,* CFIRA Letter 9; Public Startup Letter 3.

[1146] *See* Section 501 of the JOBS Act. In the case of an issuer that is a bank or a bank holding company, Exchange Act Section 12(g)(1)(B) (15 U.S.C. 78*l*(g)(1)(B)) requires, among other things, that the issuer, if it has total assets exceeding $10,000,000 and a class of securities held of record by 2,000 persons, register such class of securities with the Commission. *See* Section 601 of the JOBS Act.

[1147] *See, e.g.,* ABA Letter; Arctic Island Letter 7; Craw Letter; Heritage Letter; Joinvestor Letter; PeoplePowerFund Letter; Public Startup Letter 3; Wefunder Letter.

[1148] *See* Arctic Island Letter 7. *See also* ABA Letter (recommending that the Commission, at a minimum, exempt from the Section 12(g) record holder count securities issued in a statutory merger to change the domicile of the issuer, in reliance on Securities Act Rule 145(a)(2)).

[1149] *See, e.g.,* ABA Letter ($25 million); PeoplePowerFund Letter.

[1150] *See, e.g.,* Arctic Island Letter 7; Public Startup Letter 3.

[1151] *See* Joinvestor Letter.

[1152] *See* Arctic Island Letter 7; Public Startup Letter 3.

[1153] 17 CFR 240.12g–6.

registered with the Commission pursuant to Section 17A of the Exchange Act.[1154]

An issuer that exceeds the $25 million total asset threshold, in addition to exceeding the thresholds in Section 12(g), will be granted a two-year transition period before it will be required to register its class of securities pursuant to Section 12(g), provided it timely files all its ongoing reports pursuant to Rule 202 of Regulation Crowdfunding during such period.[1155] Section 12(g) registration will be required only if, on the last day of the fiscal year the company has total assets in excess of the $25 million total asset threshold, the class of equity securities is held by more than 2,000 persons or 500 persons who are not accredited investors.[1156] In such circumstances, an issuer that exceeds the thresholds in Section 12(g) and has total assets of $25 million or more will be required to begin reporting under the Exchange Act the fiscal year immediately following the end of the two-year transition period.[1157] An issuer entering Exchange Act reporting will be considered an ''emerging growth company'' to the extent the issuer otherwise qualifies for such status.[1158]

An issuer seeking to exclude a person from the record holder count has the responsibility for demonstrating that the securities held by the person were initially issued in an offering made under Section 4(a)(6). As noted in the proposal, we believe that allowing issuers to sell securities pursuant to Section 4(a)(6) without becoming Exchange Act reporting issuers is consistent with the intent of Title III.[1159] In this regard, we note that Title III provides for an alternative reporting system under which issuers using the crowdfunding exemption are required to file annual reports with the Commission.[1160] We believe that conditionally exempting securities issued in reliance on Section 4(a)(6) from the record holder count under Section 12(g), and thereby from the more extensive reporting obligations under the Exchange Act, is appropriate in light of the existence of the alternative ongoing reporting requirements that are tailored to the types of issuers and offerings we anticipate under Regulation Crowdfunding.

In determining to provide a conditional exemption from the provisions of Section 12(g), we have considered a number of factors. First, we believe that conditioning the exemption on the issuer being current in its ongoing reporting requirements is consistent with the intent behind the original enactment of Section 12(g) because this condition requires that relevant, current information about issuers will be made routinely available to investors and the marketplace.[1161] Second, we believe that conditioning the 12(g) exemption on crowdfunding issuers using a registered transfer agent will provide an important investor protection in this context. As discussed in Section II.C.3 above, regarding the need for an issuer to establish means to keep accurate records of its securities holders, we received a number of comments about the benefits of using a registered transfer agent. As noted above, we are not mandating the use of a transfer agent for all crowdfunding offerings, for both flexibility and cost reasons. However, we believe that requiring the use of a transfer agent is appropriate for those issuers that are seeking to have their crowdfunding securities exempted from the record holder count under Section 12(g). We expect that issuers at a stage at which they are seeking to rely on the Section 12(g) exemption are likely to be larger and thus better able to incur the costs of a transfer agent. In the absence of a conditional exemption from the provisions of Section 12(g), the use of a transfer agent registered under the Exchange Act would be required of issuers when they register under the Exchange Act.[1162] We note that a registered transfer agent is a regulated entity with experience in maintaining accurate shareholder records, and its use will help to ensure that security holder records and secondary trades will be handled accurately. Third, we believe that the condition of total assets not exceeding $25 million will result in phasing out the Section 12(g) exemption once companies grow and expand their shareholder base and is consistent with the intent behind Title III of the JOBS Act, which was enacted to facilitate smaller company capital formation.

Rule 12g–6 does not extend the exclusion from the Section 12(g) record holder count to different securities issued in exchange for Section 4(a)(6)-issued securities in a subsequent restructuring, recapitalization or similar transaction. While some commenters requested such an extension in instances where the parties to the transaction are affiliates of the original issuer, or in certain restructuring transactions, we do not believe that such an expansion in the context of shares initially issued using Regulation Crowdfunding would be appropriate because certain restructuring and recapitalization transactions could change the pool of holders of the securities beyond those who initially acquired the securities in a crowdfunding transaction, denying those holders the protections of Section 12(g) registration.

5. Scope of Statutory Liability

Securities Act Section 4A(c) provides that an issuer will be liable to a purchaser of its securities in a transaction exempted by Section 4(a)(6) if the issuer, in the offer or sale of the securities, makes an untrue statement of a material fact or omits to state a material fact required to be stated or necessary in order to make the statements, in light of the circumstances under which they were made, not misleading, provided that the purchaser did not know of the untruth or omission, and the issuer does not sustain the burden of proof that such issuer did not know, and in the exercise

[1154] *Id.*

[1155] *Id.*

[1156] 15 U.S.C. 78*l*(g).

[1157] 17 CFR 240.12g–6.

[1158] Under Section 2(a)(19) of the Securities Act, an ''emerging growth company'' is defined as, among other things, an issuer that had total annual gross revenues of less than $1 billion during its most recently completed fiscal year. 15 U.S.C. 77b(a)(19). *See also* Section 3(a)(80) of the Exchange Act (which repeats the same definition). 15 U.S.C. 78c(a)(80).

[1159] *See* 158 CONG. REC. S1829 (daily ed. Mar. 20, 2012) (statement of Sen. Jeff Merkley) (''It also provides a very important provision so the small investors do not count against the shareholder number that drives companies to have to become a fully public company. That is critical and interrelates with other parts of the [crowdfunding] bill before us.'').

[1160] *See* Section II.B.2 for a discussion of the requirement to file annual reports.

[1161] Section 12(g) was enacted by Congress as a way to ensure that investors in over-the-counter securities about which there was little or no information, but which had a significant shareholder base, were provided with ongoing information about their investment. *See, generally, Report of the Special Study of Securities Markets of the Securities and Exchange Commission.* House Document No. 95, House Committee on Interstate and Foreign Commerce, 88th Cong., 1st Sess. (1963), at 60–62.

[1162] Section 3(a)(25) of the Exchange Act provides that a ''transfer agent'' is any person who engages on behalf of an issuer of securities or on behalf of itself as an issuer of securities in: (A) Countersigning such securities upon issuance; (B) monitoring the issuance of such securities with a view to preventing unauthorized issuance (*i.e.,* a registrar); (C) registering the transfer of such securities; (D) exchanging or converting such securities; or (E) transferring record ownership of securities by bookkeeping entry without the physical issuance of securities certificates. 15 U.S.C. 78c(a)(25). Section 17A(c)(1) of the Exchange Act generally requires any person performing any of these functions with respect to any security registered pursuant to Section 12 of the Exchange Act to register with the Commission or other appropriate regulatory agency. 15 U.S.C. 78q–1(c)(1).

of reasonable care could not have known, of the untruth or omission. Section 4A(c)(3) defines, for purposes of the liability provisions of Section 4A, an issuer as including ''any person who offers or sells the security in such offering.''

In describing the statutory liability provision in the Proposing Release, the Commission noted that it appears likely that intermediaries would be considered issuers for purposes of the provision. Several commenters agreed that Section 4A(c) liability should apply to intermediaries noting that it ''may serve as a meaningful backstop against fraud'' [1163] and would create a ''true financial incentive'' for intermediaries to conduct checks on issuers and their key personnel.[1164]

However, a large number of other commenters disagreed that Section 4A(c) liability should apply to intermediaries.[1165] Some of these commenters stated their views that applying statutory liability to intermediaries would have a chilling effect on intermediaries' willingness to facilitate crowdfunding offerings.[1166] Others cited the cost of being subject to this liability as overly burdensome on funding portals, to the extent that they may not be able to conduct business.[1167] Several commenters also explained that the nature of funding portals, as intended by Congress, is distinct from that of registered broker-dealers.[1168] According to these commenters, a funding portal's role is not to offer and sell securities, but rather to provide a platform through which issuers may offer and sell securities. As such, these commenters asserted that it would not be appropriate to hold them liable for statements made by issuers.[1169] In addition, one commenter suggested that applying statutory liability to funding portals, while precluding their ability to limit the offerings that they facilitate, is an ''untenable'' framework.[1170] Some commenters stated that the statutory construct could unnecessarily lead to lawsuits against funding portals,[1171] with one of these commenters asserting that such suits would arise ''for any deal that loses money'' because the burden of proof is on the funding portal to prove it could not have known of material misstatements.'' [1172] One commenter stated that risk disclosures should require an explanation to investors that lawsuits by investors are only potentially viable if based on claims sounding in fraud or negligence and that ''lawsuits cannot be filed just because the retail investor loses their risk capital.'' [1173]

One commenter suggested that the Commission retract its statement in the Proposing Release that ''it appears likely that intermediaries, including funding portals, would be considered issuers for purposes of this liability provision.'' [1174] Other commenters suggested that the Commission should take action, such as: (i) Exempting funding portals from liability, provided conditions are met such as compliance with Regulation Crowdfunding [1175] or disclosure of the specific steps the funding portal has taken in its due diligence; [1176] (ii) providing a safe harbor for activities funding portals can undertake in posting issuer materials on their platforms,[1177] and (iii) providing a list of reasonable steps funding portals can take in reviewing an offering in order to rely on the reasonable care defense.[1178]

We have considered the comments both in support of and against funding portals being considered issuers for purposes of Section 4A(c) liability. Specifically, we acknowledge commenters' concerns that statutory liability may adversely affect funding portals, and suggestions that, under the statutory scheme, funding portals and broker-dealers engage in different activities that do not warrant a funding portal being subject to statutory liability. One difference commenters highlighted was the inability of a funding portal to limit the offerings on its platform under the proposed rules, and the untenable position of imposing statutory liability while precluding funding portals' ability to limit the offerings on their platforms. In response to this comment, as described above, we have modified the language of the Rule 402 safe harbor from the proposal to permit funding portals to exercise discretion to limit the offerings and issuers that they allow on their platforms.[1179] We believe this will avoid the ''untenable'' framework that commenters described. We are specifically declining to exempt funding portals (or any intermediaries) from the statutory liability provision of Section 4A(c) or to interpret this provision as categorically excluding such intermediaries. We do not believe that we should preclude the ability of investors to bring private rights of action against funding portals (or any intermediaries). Such a categorical exemption or exclusion could pose undue risks to investors by providing insufficient incentives for intermediaries to take steps to prevent their platforms from becoming vehicles for fraud.

Accordingly, we believe that the determination of ''issuer'' liability for an intermediary under Section 4A(c) will turn on the facts and circumstances of the particular matter in question. While we acknowledge the concerns of commenters about the potential application of Section 4A(c) liability, we note that Congress provided a defense to any such liability if an intermediary did not know, and in the exercise of reasonable care could not have known, of the untruth or omission. We continue to believe, as we identified in the Proposing Release, that there are appropriate steps that intermediaries might take in exercising reasonable care in light of this liability provision. These steps may include establishing policies

[1163] *See, e.g.,* Farnkoff Letter.

[1164] *See, e.g.,* BackTrack Letter. *See also* Patel Letter.

[1165] *See, e.g.,* ABA Letter; AngelList Letter; BetterInvesting Letter; CFIRA Letter 10; City First Letter; EarlyShares Letter; EMKF Letter; FSI Letter; Graves Letter; Guzik Letter 1; IAC Recommendation; Inkshares Letter; Milken Institute Letter; PPA Letter; RocketHub Letter; SBA Office of Advocacy Letter; SBEC Letter; SeedInvest Letter 3; Seyfarth Letter; StartupValley Letter; Wefunder Letter; Winters Letter.

[1166] *See, e.g.,* Guzik Letter 1; Inkshares Letter; RocketHub Letter; StartupValley Letter.

[1167] *See, e.g.,* City First Letter; Guzik Letter 1; SeedInvest Letter 3; Wefunder Letter; Winters Letter.

[1168] *See, e.g.,* Inkshares Letter (likening funding portals to ''impartial engineers of transactions'' similar to online service providers under the Digital Millennium Copyright Act, that exist ''for the transmission of information, and with it securities, between third parties''); RocketHub Letter; SeedInvest Letter 3; Seyfarth Letter.

[1169] *Id.*

[1170] AngelList Letter. *See also, e.g.,* Graves Letter (stating that ''to achieve the appropriate balance of creating a usable crowdfunding model for small businesses while providing adequate protections for investors, the Commission should remove the liability placed on funding portals in the proposed rules or permit them to curate offerings. . . . Otherwise it is highly improbable that any rational business would establish a web portal in a heads-you-win, tails-I-lose environment''); Milken Institute Letter (noting also that funding portals should be permitted to make subjective judgments in deciding which offerings to list, including based on an assessment of the merits or shortcomings of an offering); Wefunder Letter. *See also* Section II.D.3.a (discussing Rule 402(b)(1)).

[1171] *See, e.g.,* Inkshares Letter; SeedInvest Letter3.

[1172] *See* SeedInvest Letter 3.

[1173] *See* CarbonTech Letter.

[1174] *See* SeedInvest Letter 3.

[1175] CFIRA Letter 10; SeedInvest Letter 3 (stating also that directors and officers of funding portals should be excluded from the definition of ''issuer'' for purposes of the statutory provision); StartupValley Letter.

[1176] EarlyShares Letter.

[1177] CFIRA Letter 10; StartupValley Letter.

[1178] CFIRA Letter 10; Milken Institute Letter (stating that funding portals ''should not be required to 'look behind' every material statement in an offering, but rather should be held to a standard of satisfying the statute's and proposed rule's steps for ensuring that an offering does not invoke concerns of fraud or investor protection''); StartupValley Letter.

[1179] *See* Rule 402(b)(1); Section II.D.3.a.

and procedures [1180] that are reasonably designed to achieve compliance with the requirements of Regulation Crowdfunding, and conducting a review of the issuer's offering documents, before posting them to the platform, to evaluate whether they contain materially false or misleading information.

6. Disqualification Provisions

Section 302(d) of the JOBS Act requires the Commission to establish disqualification provisions under which an issuer would not be eligible to offer securities pursuant to Section 4(a)(6) and an intermediary would not be eligible to effect or participate in transactions pursuant to Section 4(a)(6). Section 302(d)(2) specifies that the disqualification provisions must be ''substantially similar'' to the ''bad actor'' disqualification provisions contained in Rule 262 of Regulation A [1181] and they also must cover certain actions by state regulators enumerated in Section 302(d)(2).

The disqualification provisions included in Section 302(d) of the JOBS Act are modeled on the disqualification provisions included in Section 926 of the Dodd-Frank Act, which also required the Commission to adopt rules ''substantially similar'' to Rule 262 of Regulation A that disqualify securities offerings involving certain ''felons and other 'bad actors' '' from reliance on Rule 506 of Regulation D. On July 10, 2013, we adopted rules to implement Section 926 of the Dodd-Frank Act to disqualify certain securities offerings from reliance on Rule 506 of Regulation D.[1182] On March 25, 2015, we adopted amendments to Rule 262 of Regulation A [1183] that made those provisions substantially similar to those adopted under Rule 506 of Regulation D.

a. Issuers and Certain Other Associated Persons

(1) Proposed Rules

As described in more detail below, the proposed disqualification rules as they relate to issuers and certain other associated persons would have been substantially similar to the disqualification rules in Rules 262 and 506. Under those rules, disqualification arises only with respect to events occurring after effectiveness of the rules and disqualified persons may seek a waiver from the Commission from application of the disqualification provisions.

(2) Comments on Proposed Rules

Commenters were generally supportive of the proposed disqualification rules.[1184] A few commenters recommended that pre-existing events should be subject to the disqualification rules,[1185] although another supported the proposed approach of imposing disqualification only for events after effectiveness.[1186] One commenter recommended that the Commission expand the list of covered persons to include transfer agents and lawyers who are subject to certain disqualifications.[1187]

(3) Final Rules

We are adopting bad actor disqualification provisions for Regulation Crowdfunding [1188] substantially as proposed with the exception of several modifications to further align the final rules with similar provisions in Rules 262 and 506. We believe that the final rules are appropriate in light of the JOBS Act Section 302(d) mandate. We further believe that creating a uniform set of bad actor standards for all exemptions that include bad actor disqualification is likely to simplify due diligence, particularly for issuers that may engage in different types of exempt offerings.

Under the final disqualification rules, covered persons include the issuer and any predecessor of the issuer or affiliated issuer; directors, officers, general partners or managing members of the issuer; beneficial owners of 20% or more of the issuer's outstanding voting equity securities (which we believe should be calculated based on the present right to vote for the election of directors, irrespective of the existence of control or significant influence); any promoter connected with the issuer in any capacity at the time of such sale; compensated solicitors of investors; and general partners, directors, officers or managing members of any such solicitor.[1189] We have not expanded the list of covered persons, as suggested by a commenter, because we believe that the limited additional investor protection that such an expansion may provide would not justify the costs that would result from inconsistent bad actor disqualification rules.

The disqualifying events include:

- Felony and misdemeanor convictions within the last five years in the case of issuers, their predecessors and affiliated issuers, and 10 years in the case of other covered persons in connection with the purchase or sale of a security, involving the making of a false filing with the Commission; or arising out of the conduct of the business of an underwriter, broker, dealer, municipal securities dealer, investment adviser, funding portal or paid solicitor of purchasers of securities; [1190]
- injunctions and court orders within the last five years against engaging in or continuing conduct or practices in connection with the purchase or sale of securities; involving the making of any false filing with the Commission; or arising out of the conduct of the business of an underwriter, broker, dealer, municipal securities dealer, investment adviser, funding portal or paid solicitor of purchasers of securities; [1191]
- certain final orders and bars of certain state and other federal regulators; [1192]
- Commission cease-and-desist orders relating to violations of scienter-based anti-fraud provisions of the federal securities laws or Section 5 of the Securities Act; [1193]
- filing, or being named as an underwriter in, a registration statement or Regulation A offering statement that is the subject of a proceeding to determine whether a stop order or

[1180] With respect to intermediaries that are funding portals, see Rule 403(a) of Regulation Crowdfunding and the discussion in Section II.D.4.

[1181] 17 CFR 230.262.

[1182] See Disqualification of Felons and Other ''Bad Actors'' from Rule 506 Offerings, Release No. 33–9414 (July 10, 2013) [78 FR 44729 (July 24, 2013)] (''Disqualification Adopting Release'').

[1183] *See* Rule 506(c) Adopting Release, *supra,* note 5.

[1184] *See, e.g.,* ABA Letter (expressing general support and recommending the Commission provide guidance on the term ''voting securities'' and regarding the waiver process); Commonwealth of Massachusetts Letter; Consumer Federation Letter (expressing an understanding of why the proposed disqualification rules are consistent with those under Regulation D, but noting their belief that those rules were weak when adopted); FundHub Letter 1 (stating that the proposed disqualification rules ''are, to a certain degree, overkill'' and too costly, but that disqualifying bad actors is good for the future of equity crowdfunding); Joinvestor (supporting the proposed look-back periods and waiver rules). *But see* Public Startup Letter 3 (stating the proposed rules are unconstitutional without explaining its reasoning); Public Startup Letter 5 (recommending the Commission establish an ''offender registry'' that requires issuers to maintain a ''public profile'' containing information about potential issuers in a standardized format, similar to FINRA's BrokerCheck).

[1185] *See, e.g.,* Guzik Letter 1; NASAA Letter.

[1186] *See* Joinvestor Letter.

[1187] *See* Brown J. Letter (also recommending the Commission adopt similar bad actor provisions under Rule 504).

[1188] *See* Rule 503 of Regulation Crowdfunding.

[1189] *See* Rule 503(a) of Regulation Crowdfunding.

[1190] *See* Rule 503(a)(1) of Regulation Crowdfunding.

[1191] *See* Rule 503(a)(2) of Regulation Crowdfunding.

[1192] *See* Rule 503(a)(3) of Regulation Crowdfunding.

[1193] *See* Rule 503(a)(5) of Regulation Crowdfunding.

suspension should be issued, or as to which a stop order or suspension was issued within the last five years; [1194]

- United States Postal Service false representation orders within the last five years; [1195] and
- for covered persons other than the issuer:
  - Being subject to a Commission order:
    - revoking or suspending their registration as a broker, dealer, municipal securities dealer, investment adviser or funding portal;
    - placing limitations on their activities as such;
    - barring them from association with any entity; or
    - barring them from participating in an offering of penny stock; [1196] or
  - being suspended or expelled from membership in, or suspended or barred from association with a member of, a registered national securities exchange or national securities association for conduct inconsistent with just and equitable principles of trade.[1197]

Consistent with Rules 262 and 506 and the proposal, we also are adopting provisions allowing for a waiver from and a reasonable care exception to the disqualification provisions.[1198] Under the final rules, an issuer will not lose the benefit of the Section 4(a)(6) exemption if it is able to show that it did not know, and in the exercise of reasonable care could not have known, of the existence of a disqualification.[1199] Further, persons that are disqualified from relying on the exemption may request a waiver of disqualification from the Commission.[1200]

The final rules also specify that triggering events that pre-date effectiveness of the final rules will not cause disqualification, but instead must be disclosed on a basis consistent with Rules 262 and 506(e).[1201] Specifically, issuers will be required to disclose in their offering materials matters that would have triggered disqualification had they occurred after the effective date of proposed Regulation Crowdfunding.[1202] In a change from the proposal, Rule 201(u) does not include the word ''timely'' as is included in Rule 506(e) of Regulation D, because unlike the disclosure associated with Rule 506(e), the disclosure required by Rule 201(u) must be included in an issuer's offering statement and thus is required to be timely to the offering.

We believe this disclosure will put investors on notice of events that would, but for the timing of such events, have disqualified the issuer from relying on Section 4(a)(6). We also believe that this disclosure is particularly important because, as a result of the implementation of Section 302(d), investors may have the impression that all bad actors are disqualified from participating in offerings under Section 4(a)(6). If disclosure of a pre-existing, otherwise disqualifying event is required and not provided to an investor, we would not view this as an insignificant deviation from Regulation Crowdfunding under Rule 502.

Consistent with the proposal and with Rule 506, the final disqualification rules provide that events relating to certain affiliated issuers are not disqualifying if the events pre-date the affiliate relationship. Specifically, Rule 503(c) provides that events relating to any affiliated issuer that occurred before the affiliation arose will be not considered disqualifying if the affiliated entity is not (1) in control of the issuer or (2) under common control with the issuer by a third party that was in control of the affiliated entity at the time of such events.[1203]

We also have modified the final rules to expressly include funding portals in the list of entities that could be subject to felony and misdemeanor convictions, injunctions and court orders that would constitute disqualifying events.[1204] As proposed, funding portals would have been included because they meet the definition of broker; however, for clarity, the final rule expressly includes them.

b. Intermediaries and Certain Other Associated Persons

(1) Proposed Rules

Section 302(d)(1)(B) requires the Commission to establish disqualification provisions under which an intermediary would not be eligible to effect or participate in transactions conducted pursuant to Securities Act Section 4(a)(6). Section 302(d)(2) requires that the disqualification provisions be substantially similar to the provisions of Securities Act Rule 262, which applies to issuers. Exchange Act Section 3(a)(39) [1205] currently defines the circumstances in which a broker would be subject to a ''statutory disqualification'' with respect to membership or participation in a self-regulatory organization such as FINRA or any other registered national securities association. We believe that the definition of ''statutory disqualification'' under Section 3(a)(39) is substantially similar to, while somewhat broader than, the provisions of Rule 262.[1206]

As proposed, Rule 503(d) would have prohibited any person subject to a statutory disqualification as defined in Exchange Act Section 3(a)(39) from acting as, or being an associated person of, an intermediary unless permitted to do so by Commission rule or order. The term ''subject to a statutory disqualification'' has an established meaning under Exchange Act Section 3(a)(39) and defines circumstances that subject a person to a statutory disqualification with respect to membership or participation in, or association with a member of, a self-regulatory organization.[1207] Because funding portals, like broker-dealers, are required to be members of FINRA or any other applicable registered national securities association, we anticipate that funding portals will take appropriate steps to check the background of any person seeking to become associated with them, including whether such

[1194] *See* Rule 503(a)(7) of Regulation Crowdfunding.

[1195] *See* Rule 503(a)(8) of Regulation Crowdfunding.

[1196] *See* Rule 503(a)(4) of Regulation Crowdfunding.

[1197] *See* Rule 503(a)(6) of Regulation Crowdfunding.

[1198] *See* Rule 503(b) of Regulation Crowdfunding.

[1199] *See* Rule 503(b)(4) of Regulation Crowdfunding.

[1200] *See* Rule 503(b)(2) of Regulation Crowdfunding.

[1201] *See* Rules 201(u) and 503(b)(1) of Regulation Crowdfunding.

[1202] *See* Rule 201(u) of Regulation Crowdfunding.

[1203] *See* Rule 503(c) of Regulation Crowdfunding.

[1204] *See* Rules 503(a)(1)(iii) and 503(a)(2)(iii) of Regulation Crowdfunding. Because funding portals are brokers within the meaning of Exchange Act Section (3)(a)(4) (albeit exempt from registration as such), we believe that they would be covered by the term ''broker'' in the final rule. Nevertheless, for clarity, we are adding funding portals to the final rule text to avoid any confusion in this regard.

[1205] 15 U.S.C. 78c(39).

[1206] See the Proposing Release at note 812 for a discussion of differences between Exchange Act Section 3(a)(39) and Rule 262. Despite the differences, we believe that Section 3(a)(39) and Rule 262 are substantially similar, in particular with regard to the persons and events they cover, their scope and their purpose.

[1207] Events that could result in a statutory disqualification for an associated person under Section 3(a)(39) include, but are not limited to: Certain misdemeanor and all felony criminal convictions; temporary and permanent injunctions issued by a court of competent jurisdiction involving a broad range of unlawful investment activities; expulsions (and current suspensions) from membership or participation in an SRO; bars (and current suspensions) ordered by the Commission or an SRO; denials or revocations of registration by the CFTC; and findings by the Commission, CFTC or an SRO that a person: (1) ''willfully'' violated the federal securities or commodities laws, or the Municipal Securities Rulemaking Board (MSRB) rules; (2) ''willfully'' aided, abetted, counseled, commanded, induced or procured such violations; or (3) failed to supervise another who commits violations of such laws or rules. 15 U.S.C. 78c(a)(39).

person is subject to a statutory disqualification.

In addition, we proposed to clarify that associated persons of intermediaries engaging in transactions in reliance on Section 4(a)(6) must comply with Exchange Act Rule 17f–2,[1208] relating to the fingerprinting of securities industry personnel. Under the proposal, Exchange Act Rule 17f–2 would have applied to all brokers, including registered funding portals. The proposed instruction to Rule 503(d) would have clarified that Rule 17f–2 generally requires the fingerprinting of every person who is a partner, director, officer or employee of a broker, subject to certain exceptions.

(2) Final Rules

We are adopting Rule 503(d) as proposed. We received two comments on the proposed rule. One commenter was in favor,[1209] while another commenter was opposed.[1210] The Section 3(a)(39) standard is an established one among financial intermediaries and their regulators. For this reason, we believe the Section 3(a)(39) standard is more appropriate for intermediaries than Rule 262 or the issuer disqualification rules under Regulation Crowdfunding. We are concerned that if we imposed a new or different statutory disqualification standard only for those intermediaries that engage in transactions in reliance on Section 4(a)(6), we may create confusion and unnecessary burdens on market participants. We note that such a divergence in standards would cause brokers that act as intermediaries in reliance on Section 4(a)(6) (and their associated persons) to become subject to two distinct standards for disqualification. Instead, we believe that intermediaries should be subject to the same statutory disqualification standard regardless of whether or not they are engaging in transactions involving the offer or sale of securities in reliance on Section 4(a)(6), and note that applying consistent standards for all brokers and funding portals will also assist FINRA or any other registered national securities association in its oversight of its members. Further, Exchange Act Rule 19h–1 prescribes the form and content of, and establishes the mechanism by which the Commission reviews, proposals submitted by SROs (such as FINRA) for its members, to allow a member or associated person subject to a statutory disqualification to become or remain a member or be associated with a member (''notice of admission or continuance notwithstanding a statutory disqualification,'' as described in Rule 19h–1(a)). Among other things, Rule 19h–1 provides for Commission review of notices filed by SROs proposing to admit any person to, or continue any person in, membership or association with a member notwithstanding a statutory disqualification as defined in Section 3(a)(39). Because intermediaries are required to be members of a registered national securities association (which is an SRO), actions taken by the SRO with respect to a proposed admission or continuance with respect to an intermediary or its associated persons will be subject to Rule 19h–1. Thus, the ''pursuant to Commission rule'' provision in Rule 503(d) will be satisfied if the admission or continuance request was subject to the requirements and process of Exchange Act Rule 19h–1. We also are adopting, as proposed, the instruction to Rule 503(d) clarifying that the Rule 17f–2 fingerprinting requirements are applicable to all associated persons of intermediaries engaging in transactions in reliance on Section 4(a)(6).

7. Secondary Market Trading

In addition to the actions the Commission is taking today to permit the offer and sale of securities in reliance on Section 4(a)(6), the Commission also recently adopted rules that exempt from the registration requirements of the Securities Act certain offerings of up to $50 million of securities annually,[1211] and rules to eliminate the prohibition against general solicitation in certain offerings pursuant to Regulation D under the Securities Act.[1212] The Commission is mindful of the need for market participants to have updated information in connection with the secondary market trading of securities issued pursuant to these rules.[1213]

The anti-fraud provisions of the federal securities laws, and rules adopted thereunder, apply to the secondary market trading of securities, including securities offered and sold in reliance on Section 4(a)(6). For example, Exchange Act Rule 15c2–11 governs broker-dealers' publication of quotations for certain over-the-counter securities in a quotation medium other than a national securities exchange.[1214] The Commission adopted Rule 15c2–11 to prevent fraudulent and manipulative trading schemes that had arisen in connection with the distribution and trading of certain unregistered securities.[1215] The rule prohibits broker-dealers from publishing quotations (or submitting quotations for publication) in a ''quotation medium'' [1216] for covered over-the-counter securities without first reviewing basic information about the issuer, subject to certain exceptions.[1217] A broker-dealer also must have a reasonable basis for believing that the issuer information is accurate in all material respects and that it was obtained from a reliable source.[1218]

To be clear, the rules adopted today do not affect the obligations of a broker-dealer under Exchange Rule 15c2–11 to have a reasonable basis under the circumstances for believing that the information required by Rule 15c2–11 is accurate in all material respects, and that the sources of the information are reliable, prior to publishing any quotation, absent an exception,[1219] for a covered security in any quotation medium.[1220] The staff is directed to

[1208] 17 CFR 240.17f–2.

[1209] *See* NASAA Letter.

[1210] *See* Public Startup Letter 3.

[1211] *See* Regulation A Adopting Release, *supra,* note 506.

[1212] *See* Rule 506(c) Adopting Release, *supra,* note 5.

[1213] As discussed in Section II.E.2, Rule 501 imposes a one-year restriction on the transfer of securities issued in a transaction exempt from registration pursuant to Section 4(a)(6) of the Securities Act, other than to the issuer, an accredited investors, or to a family member of the purchaser or the equivalent in connection with certain specified events.

[1214] 17 CFR 240.15c2–11.

[1215] *See generally* Initiation or Resumption of Quotations by a Broker or Dealer Who Lacks Certain Information, Exchange Act Release No. 9310 (Sept. 13, 1971), 36 FR 18641 (Sept. 18, 1971). *See also* Publication or Submission of Quotations Without Specified Information, Exchange Act Release No. 39670 (Feb. 17, 1998), 63 FR 9661, 9662 (Feb. 25, 1998).

[1216] 17 CFR 240.15c2–11(e)(1) (defining quotation medium as ''any 'interdealer quotation system' or any publication or electronic communications network or other device which is used by brokers or dealers to make known to others their interest in transactions in any security, including offers to buy or sell at a stated price or otherwise, or invitations of offers to buy or sell'').

[1217] 17 CFR 240.15c2–11(a). See Publication or Submission of Quotations Without Specified Information, Exchange Act Release No. 34–39670 (Feb. 17, 1998), 63 FR 9661 (Feb. 25, 1998).

[1218] *Id.*

[1219] *See* 17 CFR 240.15c2–11(f). For example, the rule includes an exception for unsolicited orders. 17 CFR 240.15c2–11(f)(2). We remind broker-dealers that such unsolicited orders must be made by a customer (other than a person acting as or for a dealer) and that broker-dealers should be prepared to demonstrate that a customer initiated the order. 17 CFR 240.15c2–11(b)(1).

[1220] Rule 15c2–11(c) further requires that broker-dealers keep the documents that they reviewed to establish this reasonable basis for believing that the required information is accurate in all material respects for a period of not less than three years. 17 CFR 240.15c2–11(c). The lack of documents used at the time the broker-dealer established the reasonable basis for its belief or presentation of incomplete or non-responsive documents, including later-dated filings, would not be

Continued

begin promptly an evaluation of the operation of Rule 15c2–11, both historically and in light of recent market developments, including Regulation Crowdfunding and earlier proposals for amendments to Rule 15c2–11,[1221] to assess how the rule is meeting regulatory objectives and to recommend any appropriate changes. In addition, and not withstanding any changes which may be made to Rule 15c2–11 in the interim, the staff is also directed to review the development of secondary market trading in these securities during the study it plans to undertake within three years following the effective date of Regulation Crowdfunding, and to recommend to the Commission such additional actions with respect to Rule 15c2–11, as may be warranted.[1222]

III. Economic Analysis

Title III sets forth a comprehensive regulatory structure for startups and small businesses to raise capital through securities-based crowdfunding transactions using the Internet. In particular, Title III provides an exemption from registration for certain offerings of securities by adding Securities Act Section 4(a)(6). In addition, Title III:

- Adds Securities Act Section 4A, which requires, among other things, that issuers and intermediaries that facilitate transactions between issuers and investors provide certain information to investors, take certain actions and provide notices and other information to the Commission;
- adds Exchange Act Section 3(h), which requires the Commission to adopt rules to exempt, either conditionally or unconditionally, funding portals from having to register as broker-dealers or dealers pursuant to Exchange Act Section 15(a)(1);
- mandates that the Commission adopt disqualification provisions under which an issuer would not be able to avail itself of the exemption for crowdfunding if the issuer or other related parties, including an intermediary, were subject to a disqualifying event; and
- adds Exchange Act Section 12(g)(6), which requires the Commission to adopt rules to exempt from Section 12(g), either conditionally or unconditionally, securities acquired pursuant to an offering made in reliance on Section 4(a)(6).

As discussed in detail above, we are adopting Regulation Crowdfunding to implement the requirements of Title III. The final rules implement the new exemption for the offer and sale of securities pursuant to the requirements of Section 4(a)(6) and provide a framework for the regulation of issuers and intermediaries, which include broker-dealers and funding portals engaging in such transactions. The final rules also permanently exempt securities offered and sold in reliance on Section 4(a)(6) from the record holder count under Exchange Act Section 12(g).

We are mindful of the costs imposed by, and the benefits to be obtained from, our rules. Securities Act Section 2(a) and Exchange Act Section 3(f) require us, when engaging in rulemaking that requires us to consider or determine whether an action is necessary or appropriate in the public interest, to consider, in addition to the protection of investors, whether the action will promote efficiency, competition and capital formation. Exchange Act Section 23(a)(2) requires us, when adopting rules under the Exchange Act, to consider the impact that any new rule would have on competition and to not adopt any rule that would impose a burden on competition that is not necessary or appropriate in furtherance of the purposes of the Exchange Act. The discussion below addresses the economic effects of the final rules, including the likely costs and benefits of Regulation Crowdfunding, as well as the likely effect of the final rules on efficiency, competition and capital formation. Given the specific language of the statute and our understanding of Congress's objectives, we believe that it is appropriate for the final rules generally to follow the statutory provisions. We nonetheless also rely on our discretionary authority to adopt certain additional provisions and make certain other adjustments to the final rules. While the costs and benefits of the final rules in large part stem from the statutory mandate of Title III, certain costs and benefits are affected by the discretion we exercise in connection with implementing this mandate. For purposes of this economic analysis, we address the costs and benefits resulting from the mandatory statutory provisions and our exercise of discretion together because the two types of benefits and costs are not separable.

A. Baseline

The baseline for our economic analysis of Regulation Crowdfunding, including the baseline for our consideration of the effects of the final rules on efficiency, competition and capital formation, is the situation in existence today, in which startups and small businesses seeking to raise capital through securities offerings must register the offer and sale of securities under the Securities Act unless they can rely on an existing exemption from registration under the federal securities laws. Moreover, under existing requirements, intermediaries intending to facilitate such transactions generally are required to register with the Commission as broker-dealers under Exchange Act Section 15(a).

1. Current Methods of Raising Up to $1 Million of Capital

The potential economic impact of the final rules, including their effects on efficiency, competition and capital formation, will depend on how the crowdfunding method of raising capital compares to existing methods that startups and small businesses currently use for raising capital. Startups and small businesses can potentially access a variety of external financing sources in the capital markets through registered or unregistered offerings of debt, equity and hybrid securities and bank loans.

Issuers seeking to raise capital must register the offer and sale of securities under the Securities Act or qualify for an exemption from registration. Registered offerings, however, are generally too costly to be viable alternatives for startups and small businesses. Issuers conducting registered offerings incur Commission registration fees, legal and accounting fees and expenses, transfer agent and registrar fees, costs associated with periodic reporting requirements and other regulatory requirements and various other fees. Two surveys concluded that the average initial compliance cost associated with conducting an initial public offering is $2.5 million, followed by an ongoing compliance cost for issuers, once public, of $1.5 million per year.[1223] Hence, for

sufficient to demonstrate that the broker-dealer had satisfied its obligations in this regard. See Initiation or Resumption of Quotations Without Specified Information, Exchange Act Release No 27247 (Sept. 14, 1989), 54 FR 39194, 39196 (Sept. 25, 1989) (''Subject to certain exceptions, the Rule prohibits a broker or dealer from submitting a quotation for a security in a quotation medium unless it has in its records specified information concerning the security and the issuer . . .'').

[1221] *See* Exchange Act Release No. 41110 (Feb. 25, 1999), 64 FR 11124 (Mar. 8, 1999).

[1222] *See* Section II.

[1223] *See* IPO Task Force, *Rebuilding the IPO On-Ramp,* at 9 (Oct. 20, 2011) for the two surveys, *available at http://www.sec.gov/info/smallbus/acsec/rebuilding_the_ipo_on-ramp.pdf* (''IPO Task Force''). These estimates should be interpreted with the caveat that most firms in the IPO Task Force surveys likely raised more than $1 million. The IPO Task Force surveys do not provide a breakdown of costs by offering size. However, compliance related costs of an initial public offering and subsequent compliance related costs of being a reporting company likely have a fixed cost component that would disproportionately affect small offerings.

an issuer seeking to raise less than $1 million, a registered offering may not be economically feasible.[1224] Moreover, issuers conducting registered offerings also usually pay underwriter fees, which are, on average, approximately 7% of the proceeds for initial public offerings, approximately 5% for follow-on equity offerings and approximately 1–1.5% for issuers raising capital through public bond issuances.[1225]

An alternative to raising capital through registered offerings is to offer and sell securities by relying on an existing exemption from registration under the federal securities laws. For example, startups and small businesses could rely on current exemptions from registration under the Securities Act, such as Section 3(a)(11),[1226] Section 4(a)(2),[1227] Regulation D,[1228] and Regulation A.[1229] While we do not have complete data on offerings relying on an exemption under Section 3(a)(11) or Section 4(a)(2), certain data available from Regulation D and Regulation A filings allow us to gauge how frequently issuers seeking to raise up to $1 million use these exemptions.

Based on Regulation D filings by issuers that are not pooled investment vehicles from 2009 to 2014,[1230] a substantial number of issuers chose to raise capital by relying on Rule 506, even though their offering size would qualify for an exemption under Rule 504 or Rule 505.[1231] The 2013 amendment to Rule 506 of Regulation D permits an issuer to engage in general solicitation and general advertising in offering and selling securities pursuant to Rule 506(c), subject to certain conditions,[1232] which can enable issuers to reach a potentially broader base of accredited investors. As shown in the table below, although issuers can raise unlimited amounts of capital relying on the Rule 506(c) exemption, most of the issuers made offers for amounts of up to $1 million.

Regulation D exemption	Offering size			
	≤$1 Million	$1–5 Million	$5–50 Million	>$50 Million
Rule 504	3,643			
Rule 505	501	774		
Rule 506(b)	27,106	25,746	18,670	2,733
Rule 506(c)	588	531	419	89
Total	31,838	27,051	19,089	2,822
Regulation A	5	33		

Note: Data based on Form D, excluding issuers that are pooled investment vehicles, and Form 1–A filings from 2009 to 2014. We consider only new offerings and exclude offerings with amounts sold reported as $0 on Form D. Data on Rule 506(c) offerings covers the period from September 23, 2013 (the day the rule became effective) to December 31, 2014. We also use the maximum amount indicated in Form 1–A to determine offering size for Regulation A offerings.[1233]

Based on the table above, from 2009 to 2014, almost no issuers in offerings of up to $1 million relied on Regulation A. This data does not reflect the recent changes to Regulation A adopted by the Commission on March 25, 2015. Those changes allow issuers to raise up to $50 million over a 12-month period and exempt certain Regulation A offerings (Tier 2 offerings) from state registration requirements. Because these changes are so recent, more time is needed to observe how the amendments to Regulation A will affect capital raising by small issuers.[1234]

Each of these exemptions, however, includes restrictions that may limit its suitability for startups and small businesses. The table below lists the main requirements of these exemptions. For example, the exemption under Securities Act Section 3(a)(11) is limited

Title I of the JOBS Act provided certain accommodations to issuers that qualify as emerging growth companies (EGCs). According to a recent working paper, the underwriting, legal and accounting fees of EGC and non-EGC initial public offerings were similar (based on a time period from April 5, 2012 to April 30, 2014). For a median EGC initial public offering, gross spread comprised 7% of proceeds and accounting and legal fees comprised 2.4% of proceeds. *See* Susan Chaplinsky, Kathleen W. Hanley, and S. Katie Moon, *The JOBS Act and the Costs of Going Public,* Working Paper (2014), *available at http://ssrn.com/abstract_id=2492241.*

[1224] *Id.*

[1225] *See, e.g.,* Hsuan-Chi Chen and Jay R. Ritter, *The Seven Percent Solution,* 55 J. Fin. 1105–1131 (2000); Mark Abrahamson, Tim Jenkinson, and Howard Jones, *Why Don't U.S. Issuers Demand European Fees for IPOs*? 66 J. Fin. 2055–2082 (2011); Shane A. Corwin, *The Determinants of Underpricing for Seasoned Equity Offers,* 58 J. Fin. 2249–2279 (2003); Lily Hua Fang, *Investment Bank Reputation and the Price and Quality of Underwriting Services,* 60 J. Fin. 2729–2761 (2005); Rongbing Huang and Donghang Zhang, *Managing Underwriters and the Marketing of Seasoned Equity Offerings,* 46 J. Fin. Quant. Analysis 141–170 (2011); Stephen J. Brown, Bruce D. Grundy, Craig M. Lewis and Patrick Verwijmeren, *Convertibles and Hedge Funds as Distributors of Equity Exposure,* 25 Rev. Fin. Stud. 3077–3112 (2012).

[1226] Securities Act Section 3(a)(11), generally known as the ''intrastate offering exemption,'' provides an exemption from registration for issuers doing business within a particular state or territory. To qualify for this exemption, the offering must be ''part of an issue offered and sold only to persons resident within a single State or Territory, where the issuer of such security is a person resident and doing business within, or, if a corporation, incorporated by and doing business within, such State or Territory.''

[1227] Securities Act Section 4(a)(2) provides that the registration provisions of the Securities Act shall not apply to ''transactions by an issuer not involving a public offering.''

[1228] Regulation D provides exemptions and a nonexclusive safe harbor from registration for certain types of securities offerings.

[1229] Regulation A provides a conditional exemption from registration for certain small issuances.

[1230] *See* Scott Bauguess, Rachita Gullapalli, and Vladimir Ivanov, *Capital Raising in the U.S.: An Analysis of the Market for Unregistered Securities Offerings, 2009–2014* (October 2015) (''*Unregistered Offerings White Paper*''), *available at: http://www.sec.gov/dera/staff-papers/white-papers/unregistered-offering10-2015.pdf.*

[1231] This tendency could, in part, be attributed to two features of Rule 506: preemption from state registration (''blue sky'') requirements and an unlimited offering amount. *See also* U.S. Government Accountability Office, *Factors That May Affect Trends in Regulation A Offerings,* GAO–12–839 (Jul. 3, 2012), *available at http://www.gao.gov/products/GAO-12-839* (''GAO Report'').

[1232] In particular, all purchasers of securities sold in any offering under the exemption must be accredited investors, and the issuer must take reasonable steps to verify that purchasers of securities sold in any offering are accredited investors (17 CFR 230.506). *See* Rule 506(c) Adopting Release, *supra,* note 5.

[1233] We only consider Regulation A offerings that have been qualified by the Commission. For purposes of counting filings, we exclude amendments or multiple Form 1–A filings by the same issuer in a given year. For purposes of determining the offering size for Regulation A offerings, we use the maximum amount indicated on the latest pre-qualification Form 1–A or amended Form 1–A. We reclassify two offerings that are dividend reinvestment plans with unclear offering amounts as having the maximum permitted offering amount.

[1234] *See Regulation A Adopting Release.*

to intrastate offerings.[1235] Issuers conducting a Regulation A offering may be required to register their offerings with states or meet additional regulatory requirements, such as investment limitations (if the investor is not an accredited investor), audited financial statements and ongoing reporting. In addition, issuers in all Regulation A offerings are required to file with the Commission an offering document on Form 1–A. Such compliance related costs may be a more significant constraint on issuers in offerings of up to $1 million.[1236] Issuers of securities pursuant to Securities Act Section 4(a)(2) and Rules 504, 505 and 506(b) under Regulation D generally may not engage in general solicitation and general advertising to reach investors, which also can place a significant limitation on offerings by startups and small businesses. While Rule 506 under Regulation D preempts the applicability of state registration requirements and new Rule 506(c) permits general solicitation and general advertising, an issuer seeking to rely on Rule 506(c) is limited to selling securities only to accredited investors.[1237]

The table below summarizes the main features of each exemption.

Type of offering	Offering limit[1238]	Solicitation	Issuer and investor requirements	Filing requirement	Resale restrictions	Blue sky law preemption
Section 3(a)(11)	None	All offerees must be resident in state.	All issuers and investors must be resident in state.	None	No[1239]	No
Section 4(a)(2)	None	No general solicitation.	Transactions by an issuer not involving any public offering[1240].	None	Restricted securities.	No
Regulation A	Tier 1: $20 million with $6 million limit on secondary sales by affiliates of the issuer; Tier 2: $50 million with $15 million limit on secondary sales by affiliates of the issuer.	Testing the waters permitted both before and after filing the offering statement.	U.S. or Canadian issuers, excluding investment companies, blank-check companies, reporting companies, and issuers of fractional undivided interests in oil or gas rights, or similar interests in other mineral rights[1241].	File testing the waters materials and Form 1–A for Tiers 1 and 2; file annual, semi-annual, and current reports for Tier 2; file exit report for Tier 1 and to suspend or terminate reporting for Tier 2.	No	Tier 1: No Tier 2: Yes
Rule 504 Regulation D.	$1 million	General solicitation permitted in some cases[1242].	Excludes investment companies, blank-check companies, and Exchange Act reporting companies.	File Form D[1243]	Restricted in some cases[1244].	No
Rule 505 Regulation D.	$5 million	No general solicitation.	Unlimited accredited investors and up to 35 non-accredited investors.	File Form D[1245]	Restricted securities.	No
Rule 506(b) Regulation D.	None	No general solicitation.	Unlimited accredited investors and up to 35 non-accredited investors.	File Form D[1246]	Restricted securities.	Yes
Rule 506(c) Regulation D.	None	General solicitation is permitted subject to certain conditions[1247].	Unlimited accredited investors; no non-accredited investors.	File Form D[1248]	Restricted securities.	Yes

2. Current Sources of Funding for Startups and Small Businesses That Could Be Substitutes or Complements to Crowdfunding

At present, startups and small businesses can raise capital from several sources that could be close substitutes for or complements to crowdfunding transactions that rely on Section 4(a)(6). This capital raising generally is conducted through unregistered securities offerings, involves lending by financial institutions or derives from family and friends.

a. Family and Friends

Family and friends are sources through which startups and small businesses can raise capital. This source of capital is usually available early in the lifecycle of a small business, before the business engages in arm's-length and more formal funding channels.[1249] Among other things, family and friends may donate funds, loan funds or acquire an equity stake in the business. A recent study of the financing choices of startups finds that most of the capital supplied by friends and family is in the form of loans.[1250] In contrast to a commercial lender that, for example, would need to assess factors such as the willingness and ability of a borrower to

[1235] *See* note 1226.

[1236] *See* Rutheford B. Campbell, Jr., *Regulation A: Small Businesses' Search for* ''*A Moderate Capital*'', 31 Del. J. Corp. L. 77, 106 (2006). *See also GAO Report,* note 1231.

[1237] *See Rule 506(c) Adopting Release,* note 5.

[1238] Aggregate offering limit on securities sold within a twelve-month period.

[1239] Although Section 3(a)(11) does not have explicit resale restrictions, the Commission has explained that ''to give effect to the fundamental purpose of the exemption, it is necessary that the entire issue of securities shall be offered and sold to, and come to rest only in the hands of residents within the state.'' *See* SEC Rel. No. 33–4434 (Dec. 6, 1961) [26 FR 11896 (Dec. 13, 1961)]. State securities laws, however, may have specific resale restrictions. Securities Act Rule 147, a safe harbor under Section 3(a)(11), limits resales to persons residing in-state for a period of nine months after the last sale by the issuer. [17 CFR 230.147].

[1240] Section 4(a)(2) of the Securities Act provides a statutory exemption for ''transactions by an issuer not involving any public offering.'' *See SEC* v. *Ralston Purina Co.* 346 U.S. 119 (1953) (holding that an offering to those who are shown to be able to fend for themselves is a transaction ''not involving any public offering.'')

[1241] The Regulation A exemption also is not available to companies that have been subject to any order of the Commission under Exchange Act Section 12(j) entered within the past five years; have not filed ongoing reports required by the regulation during the preceding two years, or are disqualified under the regulation's ''bad actor'' disqualification rules.

[1242] No general solicitation or advertising is permitted unless the offering is registered in a state requiring the use of a substantive disclosure document or sold under a state exemption for sales to accredited investors with general solicitation.

[1243] Filing is not a condition of the exemption, but it is required under Rule 503.

[1244] Restricted unless the offering is registered in a state requiring the use of a substantive disclosure document or sold under a state exemption for sale to accredited investors.

[1245] Filing is not a condition of the exemption, but it is required under Rule 503.

[1246] Filing is not a condition of the exemption, but it is required under Rule 503.

[1247] General solicitation and general advertising are permitted under Rule 506(c), provided that all purchasers are accredited investors and the issuer takes reasonable steps to verify accredited investor status.

[1248] Filing is not a condition of the exemption, but it is required under Rule 503.

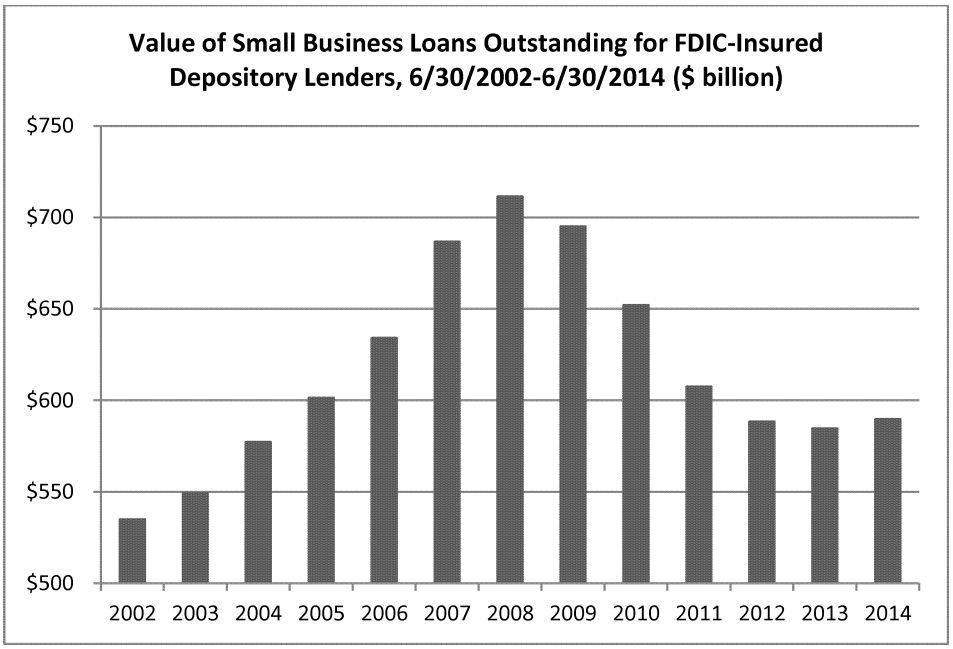
[1249] *See* Paul Gompers and Josh Lerner, The Venture Capital Cycle (MIT Press 2006) (''Gompers''); Alicia M. Robb and David T. Robinson, *The Capital Structure Decisions of New Firms,* 27 Rev. Fin. Stud. 153–179 (2014) (''Robb'').

[1250] *See* Robb, note 1249.

repay the loan and the viability of its business, family and friends may be willing to provide capital based primarily or solely on personal relationships. Family and friends, however, may be able to provide only a limited amount of capital compared to other sources. In addition, financial arrangements with family and friends may not be an optimal source of funding if any of the parties is not knowledgeable about the structuring of loan agreements, equity investments or related areas of accounting. We do not have data available on these financing sources that allow us to quantify their magnitude and compare them to other current sources of capital.

b. Commercial Loans, Peer-to-Peer Loans and Microfinance

Startups and small businesses also may seek loans from financial institutions.[1251] A 2014 study of the financing choices of startups suggests that they resort to bank financing early in their lifecycle.[1252] The study finds that businesses rely heavily in the first year after being formed on external debt sources such as bank financing, mostly in the form of personal and commercial bank loans, business credit cards and credit lines. Another recent report, however, suggests that bank lending to small businesses fell by $100 billion from 2008 to 2011 and that, by 2012, less than one-third of small businesses reported having a business bank loan.[1253] Trends in small business lending by FDIC-insured depository institutions are illustrated in the figure below. As of June 2014, business loans of up to $1 million amounted to approximately $590 billion, approximately 17% lower than the 2008 level.[1254]



Additionally, although covering the pre-recessionary period, a Federal Reserve Board staff study analyzing data from the 2003 Survey of Small Business Finance suggests that 60 percent of small businesses have outstanding credit in the form of a credit line, a loan or a capital lease.[1255] These loans were borrowed from two types of financial institutions—depositary and non-depositary institutions (*e.g.,* finance companies, factors or leasing companies).[1256] Lines of credit were the most widely used type of credit.[1257] Other types included mortgage loans, equipment loans and motor vehicle loans.[1258]

Various loan guarantee programs of the Small Business Administration (''SBA'') make credit more accessible to small businesses by either lowering the interest rate of the loan or enabling a market-based loan that a lender would not be willing to provide absent a guarantee.[1259] Although the SBA does

[1251] Using data from the 1993 Survey of Small Business Finance, one study indicates that financial institutions account for approximately 27% of small firms' borrowings. *See* Allen N. Berger and Gregory F. Udell, *The Economics of Small Business Finance: The Roles of Private Equity and Debt Markets in the Financial Growth Cycle,* 22 J. Banking & Fin. 613 (1998). *See also* 1987, 1993, 1998 and 2003 Surveys of Small Business Finances, *available at http://www.federalreserve.gov/pubs/oss/oss3/nssbftoc.htm.* The Survey of Small Business Finances was discontinued after 2003. Using data from the Kauffman Foundation Firm Surveys, one study finds that 44% of startups use loans from financial institutions. *See* Rebel A. Cole and Tatyana Sokolyk, *How Do Start-Up Firms Finance Their Assets? Evidence from the Kauffman Firm Surveys* (2012), *available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2028176.*

[1252] *See* Robb, note 1249.

[1253] *See* The Kauffman Foundation, *2013 State of Entrepreneurship Address* (Feb. 5, 2013), *available at http://www.kauffman.org/uploadedFiles/DownLoadableResources/SOE%20Report_2013pdf.* The report cautions against prematurely concluding that banks are not lending enough to small businesses as the sample period of the study includes the most recent recession.

[1254] We define small business loans to include commercial and industrial loans to U.S. addressees of up to $1 million and loans secured by nonfarm nonresidential properties. *See* Federal Deposit Insurance Corporation, *Statistics on Depository Institutions Report, available at http://www2.fdic.gov/SDI/SOB/* (''FDIC Statistics'').

[1255] *See* Federal Reserve Board, *Financial Services Used by Small Businesses: Evidence from the 2003 Survey of Small Business Finances* (October 2006), *available at http://www.federalreserve.gov/pubs/bulletin/2006/smallbusiness/smallbusiness.pdf* (''2003 Survey'').

[1256] *See* Rebel Cole, *What Do We Know About the Capital Structure of Privately Held Firms? Evidence from the Surveys of Small Business Finance,* 42 Fin. Management 777–813 (2013).

[1257] *See* 2003 Survey, note 1255 (estimating that 34% of small businesses use lines of credit).

[1258] *Id.*

[1259] Numerous states also offer a variety of small business financing programs, such as Capital Access Programs, collateral support programs and loan guarantee programs. These programs are eligible for support under the State Small Business

Continued

not itself act as a lender, the agency guarantees a portion of loans made and administered by lending institutions. SBA loan guarantee programs include 7(a) loans [1260] and CDC/504 loans.[1261] For example, in SBA fiscal year 2014, the SBA supported approximately $28.7 billion in 7(a) and CDC/504 loans distributed to approximately 51,500 small businesses.[1262] SBA-guaranteed loans, however, currently account for a relatively small share (18 percent) of the balances of small business loans outstanding.[1263] The SBA also offers the Microloan program, which provides funds to specially designated intermediary lenders that administer the program for eligible borrowers.[1264]

Many startups and small businesses may find loan requirements imposed by financial institutions difficult to meet and may not be able to rely on these institutions to secure funding. For example, financial institutions generally require a borrower to provide collateral and/or a guarantee,[1265] which startups, small businesses and their owners may not be able to provide. Collateral and/or a guarantee may similarly be required for loans guaranteed by the SBA.

Another source of debt financing for startups and small businesses is peer-to-peer lending, which began developing in 2005.[1266] Such debt transactions are facilitated by online platforms that connect borrowers and lenders and potentially offer small businesses additional flexibility on pricing, repayment schedules, collateral or guarantee requirements, and other terms. Some market participants offer a secondary market for loans originated on their own sites.[1267] At least one of the platforms sells third-party issued securities to multiple individual investors, thus improving the liquidity of these securities.[1268] Like in any traditional lending arrangement, however, borrowers are required to make regular payments to their lenders. This requirement could make it a less attractive option for small businesses with negative cash flows and short operating histories, both of which may make it more difficult for such businesses to demonstrate their ability to repay loans. According to some estimates, the global volume of ''lending-based'' crowdfunding, which includes peer-to-peer lending to consumers and businesses, had risen to approximately $11.08 billion in 2014.[1269]

Technology has facilitated the growth of alternative models of small business lending. According to one study,[1270] the outstanding portfolio balance of online lenders has doubled every year, although this market represents less than $10 billion in outstanding loan capital as of the fourth quarter of 2013. Several models of online small business lending have emerged: Online lenders raising capital from institutional investors and lending on their own account (for example, short-term loan products similar to a merchant cash advance); peer-to-peer platforms; and ''lender-agnostic'' online marketplaces that facilitate small business borrower access to various loan products (such as term loans, lines of credit, merchant cash advances and factoring products) from traditional and alternative lenders.[1271] According to the 2014 Small Business Credit survey,[1272] 18% of all small businesses surveyed applied for credit with an online lender. The survey also showed differences in the use of online lenders by type of borrower: 22% of small businesses categorized in the survey as ''startups'' (*i.e.,* businesses that have been in business for less than five years) applied for credit with online lenders. By comparison, 8% of small businesses categorized in the survey as ''growers'' (*i.e.,* businesses that were profitable and experienced an increase in revenue) applied with online lenders, and 3% of small businesses categorized in the survey as ''mature firms'' (*i.e.,* businesses that have been in business for more than five years, had over ten employees, and had prior debt) applied with an online lender. The latter two categories of small businesses were more likely to apply for credit with bank lenders than with online lenders.

Microfinance is another source of debt financing for startups and small businesses. Microfinance consists of small, working capital loans provided by microfinance institutions (''MFIs'') that are invested in microenterprises or

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Credit Initiative, *available at http://www.treasury.gov/resource-center/sb-programs/Pages/ssbci.aspx.*

[1260] 15 U.S.C. 631 *et se.* The 7(a) loans provide small businesses with financing guarantees for a variety of general business purposes through participating lending institutions.

[1261] 15 U.S.C. 695 *et se.* The CDC/504 loans are made available through ''certified development companies'' or ''CDCs,'' typically structured with the SBA providing 40% of the total project costs, a participating lender covering up to 50% of the total project costs and the borrower contributing 10% of the total project costs.

[1262] *See* U.S. Small Business Administration, *FY 2016 Congressional Budget Justification and FY 2014 Annual Performance Report,* available at *https://www.sba.gov/content/fiscal-year-2016-congressional-budget-justificationannual-performance-report* (''2014 Annual Performance Report'').

[1263] As of the end of SBA fiscal year 2014, the SBA-guaranteed business loans outstanding (including 7(a) and 504 loans) equaled $107.5 billion. *See Small Business Administration Unpaid Loan Balances by Program, available at https://www.sba.gov/sites/default/files/files/WDS_Table1_UPB_Report.pdf.* This comprises approximately 18% of the approximately $590 billion in outstanding small business loans for commercial real estate and commercial and industrial loans discussed above. In 2014 the SBA expanded eligibility for loans under its business loan programs. *See* SBA *504 and 7(a) Loan Programs Updates* (Mar. 21, 2014) [79 FR 15641 (Apr. 21, 2014)]. In addition to loan guarantees, the SBA program portfolio also includes direct business loans, which are mainly microloans (outstanding direct business loans equaled $137.1 billion), and disaster loans.

[1264] 15 U.S.C. 631 *et se.* The Microloan program provides small, short-term loans to small businesses and certain types of not-for-profit childcare centers. The maximum loan amount is $50,000, but the average microloan is about $13,000. Intermediaries are nonprofit community-based organizations with experience in lending, as well as management and technical assistance. Intermediaries set their own lending requirements and generally require some type of collateral as well as the personal guarantee of the business owner. *See Microloan Program,* U.S. Small Business Administration, *available at http://www.sba.gov/content/microloan-program.*

As of the end of SBA fiscal year 2014, the SBA Microloans outstanding equaled $136.7 billion. *See Small Business Administration Unpaid Loan Balances by Program, available at https://www.sba.gov/sites/default/files/files/WDS_Table1_UPB_Report.pdf.*

[1265] Approximately 92% of all small business debt to financial institutions is secured, and about 52% of that debt is guaranteed, primarily by the owners of the firm. *See* Berger, note 1251.

[1266] *See* Ian Galloway, *Peer-to-Peer Lending and Community Development Finance,* Federal Reserve Bank of San Francisco, Working Paper (2009), available at *http://www.frbsf.org/publications/community/wpapers/2009/wp2009-06.pdf.*

[1267] *Id.*

[1268] *Id.* We note that under current law, this activity would require broker-dealer registration.

[1269] *See* Massolution, *2015CF Crowdfunding Industry Report: Market Trends, Composition and Crowdfunding Platforms, available at http://reports.crowdsourcing.org/index.php?route=product/product&product_id=54* (''Massolution 2015'') at 56. The Massolution 2015 report refers to peer-to-peer lending to consumers and peer-to-business lending to small businesses as ''lending-based'' crowdfunding. The discussion in this economic analysis refers to peer-to-peer business lending more broadly in a sense synonymous with ''lending-based'' crowdfunding.

[1270] *See* Karen Gordon Mills and Brayden McCarthy, *The State of Small Business Lending: Credit Access during the Recovery and How Technology May Change the Game,* Harvard Business School Working Paper 15–004 (2014), *available at http://ssrn.com/abstract=2470523.*

[1271] *Id.*

[1272] The survey was conducted by the Federal Reserve Banks of New York, Atlanta, Cleveland, and Philadelphia between September and November of 2014. It focused on credit access among businesses with fewer than 500 employees in Alabama, Connecticut, Florida, Georgia, Louisiana, New Jersey, New York, Ohio, Pennsylvania, and Tennessee. The survey authors note that since the sample is not a random sample, results were reweighted for industry, age, size, and geography to reduce coverage bias. *See* Federal Reserve Banks of New York, Atlanta, Cleveland and Philadelphia, *Joint Small Business Credit Survey Report* (2014), *available at http://www.newyorkfed.org/smallbusiness/SBCS-2014-Report.pdf.*

income-generating activities.[1273] The typical users of microfinance services and, in particular, of microcredit are family-owned enterprises or self-employed, low-income entrepreneurs, such as street vendors, farmers, service providers, artisans and small producers, who live close to the poverty line in both urban and rural areas.[1274]

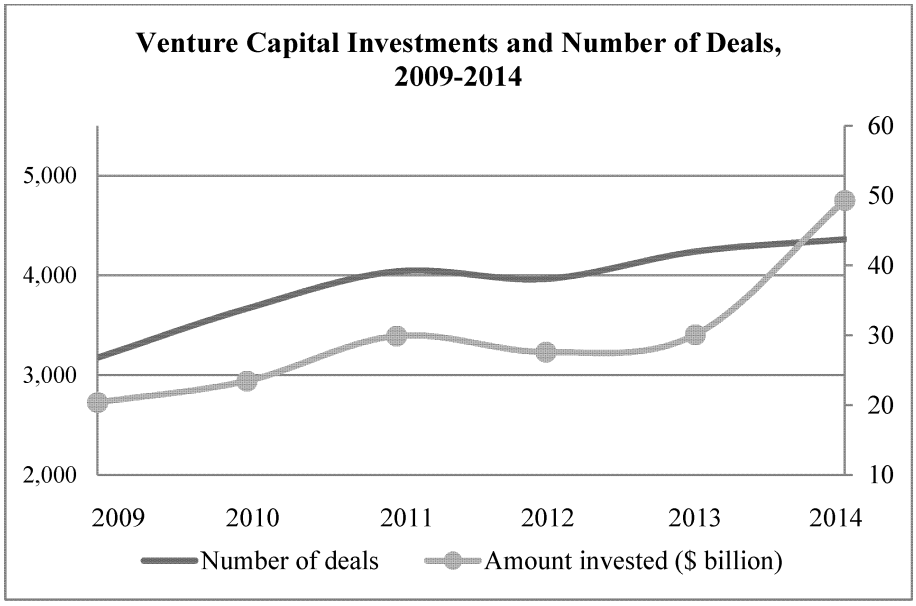
The microfinance market has evolved and grown considerably in the past decades. While data on the size of the overall industry is sparse, according to one report, in fiscal year 2012, the U.S. microfinance industry was estimated to have disbursed $292.1 million across 36,936 microloans and was estimated to have $427.6 million in outstanding microloans (across 45,744 in microloans).[1275] As of 2013, this report identified 799 microenterprise programs that provide loans, training, technical assistance and other microenterprise services directly to micro-entrepreneurs.[1276]

c. Venture Capitalists and Angel Investors

Startups and small businesses also may seek funding from venture capitalists (''VCs'') and angel investors. Entrepreneurs seek VC and angel financing usually after they have exhausted sources of capital that generally do not require the entrepreneurs to relinquish control rights (*e.g.,* personal funds from family and friends).

According to data from the National Venture Capital Association, in calendar year 2014, VCs invested approximately $49.3 billion in 4,361 transactions involving 3,665 companies, which included seed, early-stage, expansion, and late-stage companies. Seed and early-stage deals represented 1.5% and 32.2%, respectively, of the dollar volume of deals and 4.4% and 49.7%, respectively of the overall number of VC deals.[1277]

Some startups, however, may struggle to attract funding from VCs because VCs tend to invest in startups with certain characteristics. A defining feature of VCs is that they tend to focus on startup companies with high-growth potential and a high likelihood of going public after a few years of financing. VCs also tend to invest in companies that have already used some other sources of financing, tend to be concentrated in certain geographic regions (*e.g.,* California and Massachusetts) and often require their investments to have an attractive business plan, meet certain growth benchmarks or fill a specific portfolio or industry niche.[1278] In addition, when investing in companies, VCs tend to acquire significant control rights (*e.g.,* board seats, rights of first refusal, *etc.*), which they gradually relinquish as the company approaches an initial public offering.[1279] In 2014, according to an industry source, information technology and medical/health/life sciences deals attracted the largest dollar volume of VC financing.[1280] According to a 2012 academic study, VCs appear to focus on scale or potential for scale rather than short-term profitability in their selection of targets, and firms that receive VC financing tend to be significantly larger than non-VC firms, based on employment and sales.[1281]



According to a recent report, angel investments amounted to $24.1 billion in 2014, with approximately 73,400 entrepreneurial ventures receiving angel funding and approximately 316,600 active angel investors.[1282] In 2014, angel

[1273] *See* Craig Churchill and Cheryl Frankiewicz, *Making Microfinance Work: Managing for Improved Performance,* Geneva International Labor Organization (2006).

[1274] *See* Joanna Ledgerwood, *Microfinance Handbook: An Institutional and Financial Perspective,* Washington DC, World Bank Publications (1999).

[1275] *See* FIELD at the Aspen Institute, *U.S. Microenterprise Census Highlights,* FY 2012, *available at http://fieldus.org/Publications/CensusHighlightsFY2012.pdf.*

[1276] *Id. See also* note 1264 (describing the SBA Microloan program).

[1277] *See* National Venture Capital Association, *2015 National Venture Capital Association Yearbook, available at http://nvca.org/?ddownload=1868* (''NVCA'').

[1278] *See* Gompers, note 1249.

[1279] *See* Steven N. Kaplan and Per Stromberg, *Financial Contracting Meets the Real World: An Empirical Analysis of Venture Capital Contracts,* 70 Rev. Econ. Stud. 281–316 (2003).

[1280] *See* NVCA, note 1277.

[1281] *See* Manju Puri and Rebecca Zarutskie, *On the Life Cycle Dynamics of Venture-Capital- and Non-Venture-Capital-Financed Firms,* 67 J. Fin., 2247–2293 (2012) (''Puri'').

[1282] *See* Jeffrey Sohl, *The Investor Angel Market in 2014: A Market Correction in Deal Size, Center for Venture Research,* May 14, 2015, *available at https://paulcollege.unh.edu/sites/paul*

Continued

investments were concentrated in software, healthcare, and IT services. The average angel deal size was approximately $328,500. Seed/startup stage deals accounted for 25% and early stage deals accounted for 46%.[1283] As suggested by an academic study, angel investors tend to invest in younger companies than VCs.[1284]

3. Current Crowdfunding Practices

A recent crowdfunding industry report [1285] defines the current crowdfunding activity in the United States generally as ''lending-based,'' [1286] ''reward-based,'' ''donation-based,'' ''royalty-based,'' ''equity-based,'' [1287] and ''hybrid.'' We note that the definitions of crowdfunding types used in this industry report and the characteristics of crowdfunding activity currently in existence are not directly comparable to the contours of security-based crowdfunding transactions contemplated by the rules being adopted today. Thus, considerable caution must be exercised when generating projections of future crowdfunding volume from current activity broadly attributed to the ''crowdfunding'' industry. In particular, the industry report defines reward-based crowdfunding as a model where funders receive a ''reward,'' such as a perk or a pre-order of a product, and it defines donation-based crowdfunding as a model where funders make philanthropic donations to causes that they want to support, with no return on their investment expected.[1288] According to the industry report, royalty-based crowdfunding, which involves a percentage of revenue from a license or a usage-based fee for the other parties' right to the ongoing use of an asset, continues to grow.[1289]

The industry report indicates that, in 2014, crowdfunding platforms raised approximately $16.2 billion globally, which represented a 167% increase over the amount raised in 2013.[1290] These amounts include various types of crowdfunding: lending-based crowdfunding accounted for the largest share of volume (approximately $11.08 billion) followed by equity-based crowdfunding (approximately $1.11 billion), reward-based crowdfunding (approximately $1.33 billion), donation-based crowdfunding (approximately $1.94 billion), royalty-based crowdfunding (approximately $273 million), and hybrid crowdfunding (approximately $487 million).[1291] In 2014, North American crowdfunding volume was approximately $9.46 billion, which represented a 145% increase over the amount raised in 2013 [1292] (including approximately $1.23 billion in reward-based crowdfunding, approximately $959 million in donation-based crowdfunding, and approximately $787.5 million in equity-based crowdfunding, with the remainder comprised of lending-based, royalty-based, and hybrid models [1293]). The industry report further indicates that global equity-based crowdfunding volume grew by 182% in 2014.[1294] According to the report, this rapid growth in equity-based crowdfunding has been driven largely by North America and Europe.[1295]

The industry report further indicates that, in 2014 the worldwide average size of a funded campaign was less than $4,000 for consumer lending-based, reward-based, and donation-based crowdfunding types.[1296] Crowdfunded business loans and equity-based campaigns, however, were substantially higher. In 2014, the global average size of a funded peer-to-business lending-based crowdfunding campaign was $103,618.[1297] In 2014, a typical equity-based campaign was larger, with the global average size of $275,461.[1298] These figures suggest that the types of ventures financed through equity-based crowdfunding could be different than those financed through other crowdfunding methods. In 2014, the average size of a funded equity-based campaign in North America was $175,000.[1299]

Since the passage of the JOBS Act, many U.S. states have made changes to their securities laws to accommodate intrastate securities-based crowdfunding transactions. Based on information from NASAA, as of September 2015, 29 states and the District of Columbia have enacted state crowdfunding provisions that rely, at the federal level, on the intrastate offering exemptions under Securities Act Section 3(a)(11) and Rule 147 or on Rule 504 of Regulation D. These state crowdfunding rules allow businesses in a state to use securities-based crowdfunding to raise capital from investors within that state.[1300] There is limited information available to us about the scope of domestic crowdfunding activity in reliance on the intrastate exemptions. Since December 2011, when the first state (Kansas) enacted its crowdfunding provisions, 118 state crowdfunding offerings have been reported to be filed with the respective state regulator and 102 were reported to be approved or cleared, as of August 1, 2015.[1301]

4. Survival Rates for Startups and Small Businesses

Startups and small businesses that lack tangible assets or business experience needed to obtain conventional financing might turn to

college.unh.edu/files/webform/2014%20Analysis%20Report.pdf (''Sohl'').

[1283] *Id.*

[1284] *See Gumpers, note 1249.*

[1285] *See* Massolution 2015.

[1286] *Id.* In this industry report, ''lending-based'' crowdfunding includes peer-to-peer lending to consumers and peer-to-business lending.

[1287] The report does not identify which jurisdictions were represented in the survey. For example, France, Italy, Japan, and the UK have adopted specialized equity crowdfunding regimes. It should be noted that ''equity-based'' crowdfunding is not a one-size-fits-all model. The crowdfunding regimes in these four countries differ on a number of dimensions (*e.g.,* securities allowed to be sold by issuers, or types of issuers allowed to use the exemption), amongst themselves and when compared to Regulation Crowdfunding. Some number also allow equity crowdfunding through their general securities laws. *See Eleanor Kirby and Shane Worner, Crowd-funding: An Infant Industry Growing Fast,* Staff Working Paper of the IOSCO Research Department, *available* at *http://www.iosco.org/research/pdf/swp/Crowd-funding-An-Infant-Industry-Growing-Fast.pdf.*

[1288] *See* Massolution 2015 at 42. Many of the current domestic crowdfunding offerings relate to individual projects and may not have a defined or sustained business model commensurate with typical issuers of securities.

[1289] *Id.* at 43. The Massolution 2015 report did not provide separate statistics on royalty-based and hybrid crowdfunding models prior to the 2013 report.

[1290] *Id.* at 13.

[1291] *Id.* at 14.

[1292] *Id.* at 53.

[1293] *Id.* at 55.

[1294] *Id.* at 14. By comparison, in 2014, ''reward-based'' crowdfunding grew by 84%, ''lending-based'' crowdfunding by 223%; ''donation-based'' crowdfunding by 45%; ''royalty-based'' crowdfunding by 336%; and ''hybrid'' crowdfunding by 290%.

[1295] *Id.* at 55. ''Equity-based'' crowdfunding in North America ($787.5 million) and Europe ($177.5 million) grew by 301% and 145%, respectively.

[1296] *Id.* at 59.

[1297] *Id.* at 60.

[1298] *Id.* at 60.

[1299] *Id.* at 60. The report does not provide the average size of North American donation-based, reward-based, or lending-based crowdfunding campaigns. The report notes that, in 2014, the average funded North American donation-based and reward-based campaigns were 56% and 54%, respectively, of the average size of funded European donation-based and reward-based campaigns. *Id.* at 60.

[1300] *See* NASAA's Intrastate Crowdfunding Resource Center at *http://www.nasaa.org/industry-resources/corporation-finance/instrastate-crowdfunding-resource-center/*, accessed in September 2015. *See also* NASAA's State Crowdfunding Update, *available at: http://nasaa.cdn.s3.amazonaws.com/wp-content/uploads/2014/12/Intrastate-Crowdfunding-Overview-2015.pdf.*

[1301] Based on information provided by NASAA. The jurisdictions included in the estimate are Alabama, District of Columbia, Georgia, Idaho, Indiana, Kansas, Maine, Maryland, Massachusetts, Michigan, Oregon, Texas, Vermont, Washington, and Wisconsin.

securities-based crowdfunding in reliance on Section 4(a)(6) as an attractive potential source of financing. There is broad evidence that many of these potential issuers are likely to fail after receiving funding. For example, a 2010 study reports that of a random sample of 4,022 new high-technology businesses started in 2004, only 68% survived by the end of 2008.[1302]

Similarly, other studies suggest that startups and small businesses financed by venture capitalists also tend to have high failure rates. One study finds that for 16,315 VC-backed companies that received their first institutional funding round between 1980 and 1999, approximately one-third failed after the first funding round.[1303] Additionally, another study of more than 2,000 companies that received at least $1 million in venture funding, from 2004 through 2010, finds that almost three-quarters of these companies failed.[1304] Another study, based on a sample ending in 2005, found cumulative failure rates of 34.1% for VC-financed firms and 66.3% for non-VC-financed firms, with the difference driven by lower failure rates of VC-financed firms in the initial years after receiving VC financing.[1305]

Taken all together, the failure rates documented in these studies are high for startups and small businesses, even with the involvement of sophisticated investors like VCs. Because we expect that issuers that will engage in offerings made in reliance on Section 4(a)(6) will be in an earlier stage of business development than the businesses included in the above studies, we believe that issuers that engage in securities-based crowdfunding may have higher failure rates than those in the studies cited above.

5. Market Participants

The final rules will have their most significant impact on the market for the financing of startups and small businesses. The number of participants in this market and the amounts raised through alternative sources indicate that this is a large market. In 2013, there were more than 5 million small businesses, defined by the U.S. Census Bureau as having fewer than 500 paid employees.[1306] As of June 2014, FDIC-insured depositary institutions held approximately $590 billion in approximately 23.4 million small business loans.[1307] According to the SBA's fiscal year 2014 annual performance report, approximately 51,500 small businesses received funding in 2014 through SBA's main lending programs, 7(a) and 504 loans.[1308] In 2014, VCs invested $49.3 billion of capital in in 4,361 transactions involving 3,665 startups, according to an industry source.[1309] In 2014, angel investors contributed $24.1 billion, with approximately 73,400 entrepreneurial ventures receiving angel funding.[1310]

Below, we analyze the economic effect of the final rules on the following parties: (1) Issuers, typically startups and small businesses, that seek to raise capital by issuing securities; (2) intermediaries through which issuers seeking to engage in transactions in reliance on Section 4(a)(6) will offer and sell their securities; (3) investors who purchase or may consider purchasing securities in such offerings; and (4) other capital providers, broker-dealers and finders who currently participate in private offerings. The potential economic impact of the final rules will depend on how these market participants respond to the final rules. Each of these parties is discussed in further detail below.

a. Issuers

The final rules will permit certain entities to raise capital by issuing securities for the first time. The number, type and size of the potential issuers that will seek to use crowdfunding to offer and sell securities in reliance on Section 4(a)(6) is uncertain, but data on current market practices may help identify the number and characteristics of potential issuers.

It is challenging to precisely predict the number of future securities offerings that might rely on Section 4(a)(6), particularly because rules governing the process are being adopted today.[1311]

According to filings made with the Commission, from 2009 to 2014, there were approximately 4,559 issuers per year in new Regulation D offerings with offer sizes of up to $1 million (excluding issuers that are pooled investment vehicles), including approximately 1,020 (22%) per year that reported having no revenue and approximately 861 (19%) per year that reported revenues of up to $1 million.[1312] Among issuers in new Regulation D offerings with offer sizes of up to $1 million (excluding issuers that are pooled investment vehicles) during this period, the overwhelming majority of issuers (approximately 80%) are younger than 5 years old, with the median age of approximately one year. Approximately 92% of these issuers were organized as either a corporation or a limited liability company.

It is expected that many future issuers of securities in crowdfunding offerings would have otherwise raised capital from one of the alternative sources of financing discussed above, while others would have been financed by friends and family or not financed at all. Due to the differences between small business loans (including SBA-guaranteed loans) and securities-based crowdfunding offerings that can be conducted under the final rules, we are not able to estimate how many small businesses utilizing these forms of financing may instead pursue an offering in reliance on Section 4(a)(6). Similarly, due to the differences between the terms of crowdfunding campaigns in existence today and the provisions of the final rules, is not clear how many current campaigns can instead become offerings in reliance on Section 4(a)(6).[1313]

[1302] *See* Alicia Robb, E.J. Reedy, Janice Ballou, David DesRoches, Frank Potter and Zhanyun Zhao, *An Overview of the Kauffman Firm Survey: Results from the 2004–2008 Data,* Kauffman Foundation, *available at http://www.kauffman.org/uploadedFiles/kfs_2010_report.pdf* (''Kauffman Firm Survey'').

[1303] *See* Yael V. Hochberg, Alexander Ljungqvist and Yang Lu, *Whom You Know Matters: Venture Capital Networks and Investment Performance,* 62 J. of Fin. 251–301 (2007).

[1304] *See* Deborah Gage, *The Venture Capital Secret: 3 Out of 4 Start-Ups Fail,* Wall St. J., Sept. 19, 2012.

[1305] *See* Puri, note 1281. According to this study, the difference in the outcomes of VC-financed and non-VC-financed firms decreases after accounting for observable differences in firm characteristics, but it does not disappear. However, as the study notes, in evaluating the remaining differences in the outcomes of VC-financed and non-VC-financed firms, it is not possible to fully differentiate the effects of superior selection on the basis of unobservable firm characteristics from the effects of VC monitoring and expertise.

[1306] *See* U.S. Department of Commerce, United States Census Bureau, *Business Dynamics Statistics, Data: Firm Characteristics* (2013), *available at http://www.census.gov/ces/dataproducts/bds/data_firm.html.*

[1307] For the purposes of this figure, small business loans are defined as loans secured by nonfarm nonresidential properties and commercial and business loans of $1,000,000 or less. *See* FDIC Statistics, note 1254.

[1308] *See* 2014 Annual Performance Report, note 1262.

[1309] *See* NVCA, note 1277.

[1310] *See* Sohl, note 1282.

[1311] *See also* Section IV.B.1.

[1312] In addition, in an average year, approximately 50% of issuers in new Regulation D offerings with offer sizes of up to $1 million (excluding issuers that are pooled investment vehicles) declined to disclose their revenues. It is also possible that some issuers in Regulation D offerings that report revenues in excess of $1 million may participate in offerings in reliance on Section 4(a)(6).

[1313] A recent industry report estimated that the equity-based crowdfunding volume in North America in 2014 was $787.5 million and the average size of a successful equity-based crowdfunding campaign was $175,000. *See* Massolution 2015 at 55 and 60. This allows us to estimate approximately 4,500 successful equity-based crowdfunding campaigns for North America

Continued

Hence, while some of the businesses using these alternative funding sources may become issuers offering and selling securities in reliance on Section 4(a)(6) in the future, we cannot know how many of these businesses will elect securities-based crowdfunding in reliance on Section 4(a)(6) once it becomes available, nor can we know how many future businesses may not be financed at all.

We believe that many potential issuers of securities through crowdfunding will be startups and small businesses that are close to the ''idea'' stage of the business venture and that have business plans that are not sufficiently well-developed or do not offer the growth potential or business model to attract VCs or angel investors. In this regard, a study of one large platform revealed that relatively few companies on that platform operate in technology sectors that typically attract VC investment activity.[1314]

b. Intermediaries

Section 4(a)(6)(C) requires that an offer and sale of securities in reliance on Section 4(a)(6) be conducted through a registered funding portal or a broker. Registered broker-dealers, both those that are already registered with the Commission and those that will register, might wish to facilitate securities-based crowdfunding transactions. New entrants that do not wish to register as broker-dealers might decide to register as funding portals to facilitate securities-based crowdfunding transactions in reliance on Section 4(a)(6). Donation-based or reward-based crowdfunding platforms with established customer relationships might seek to leverage these relationships and register as funding portals, or register as or associate with registered broker-dealers. Although the number of potential intermediaries that will fill these roles is uncertain, practices of existing broker-dealers and crowdfunding platforms provide insight into how the market might develop.

Based on FOCUS Reports filed with the Commission, as of December 2014, there were 4,267 broker-dealers registered with the Commission, with average total assets of approximately $1.1 billion per broker-dealer. The aggregate total assets of these registered broker-dealers are approximately $4.9 trillion. Of these registered broker-dealers, 816 also are dually registered as investment advisers.

Existing crowdfunding platforms are diverse and actively involved in financing, allowing thousands of projects to search for capital. A recent industry report estimates that, as of 2014, 1,250 crowdfunding platforms were operating worldwide, including 375 platforms operating in North America.[1315] Globally, approximately 19% (236) of platforms were engaged in equity-based crowdfunding, 18.3% in lending-based crowdfunding, 22.6% in donation-based crowdfunding, 28.9% in reward-based crowdfunding, with the remainder engaged in royalty-based and hybrid crowdfunding.[1316] An earlier industry report indicated that crowdfunding platforms typically charge entrepreneurs a ''transaction fee'' that is based on how large the target amount is and/or upon reaching the target and that fees from survey participants worldwide ranged from 2% to 25%, with an average of 7% in North America and Europe.[1317] The 2012 industry report provides one case study of fees for a ''large-securities-based CFP'' stating ''[t]here are no management fees for uncommitted capital, but a ''2 and 20'' arrangement is set on deals funded.'' [1318]

We do not know at present which market participants will become intermediaries under Section 4(a)(6) and Regulation Crowdfunding, but we believe that existing crowdfunding platforms might seek to leverage their already-existing Internet-based platforms, brand recognition and user bases to facilitate offerings in reliance on Section 4(a)(6).[1319]

Under the statute and the final rules, funding portals are constrained in the services they can provide, and persons (or entities) seeking the ability to participate in activities unavailable to funding portals, such as offering investment advice or holding, managing, possessing or otherwise handling investor funds, would instead need to register as broker-dealers or investment advisers, depending on their activities. Although we expect that initially, upon adoption of the final rules, more new registrants will register as funding portals than as broker-dealers given the less extensive regulatory requirements imposed on funding portals, it is possible that market competition to offer broker-dealer services as part of intermediaries' service capabilities might either drive more broker-dealer growth in the longer term or provide registered funding portals with the incentive to form long-term partnerships with registered broker-dealers. One commenter suggested that funding portals may find it beneficial to cooperate with registered broker-dealers and transfer agents.[1320] Other commenters on the proposal did not provide additional information on this issue. There is anecdotal evidence that such partnerships are already forming under existing regulations in crowdfunding transactions involving accredited investors.[1321] The final rules provide that intermediaries will be deemed to have satisfied the requirement to have a reasonable basis for believing that an issuer has established means to keep accurate records of the holders of the securities it would offer and sell through the

in 2014. The report does not provide statistics for the United States alone. Equity-based crowdfunding campaigns in the United States are currently limited to accredited investors or intrastate offerings in certain jurisdictions. Further, the industry report does not provide information that would allow us to estimate the number of crowdfunding campaigns of other types (such as reward-based or donation-based) in North America or the United States in 2014. We note that many such campaigns, particularly those that relate to individual projects, may not have a defined or sustained business model commensurate with typical issuers of securities. In particular, many of the current reward-based or donation-based crowdfunding projects likely entail endeavors that may not be suitable to a long-lived securities issuance (*e.g.,* certain artistic endeavors or artistic projects).

[1314] *See* Ethan R. Mollick, *The Dynamics of Crowdfunding: An Exploratory Study,* Working Paper (June 26, 2013), *available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2088298.*

[1315] *See* Massolution 2015 at 84. The report does not provide separate statistics for the United States.

[1316] *Id.* at 89.

[1317] *See* Massolution *Crowdfunding Industry Report: Market Trends, Composition and Crowdfunding Platforms* (May 2012) (''Massolution 2012'') at 38.

[1318] *Id.*

[1319] For example, the Massolution 2012 industry report suggests that funding portal reputation is important in the crowdfunding market, especially for equity-based crowdfunding. *See* Massolution 2012 at 46.

[1320] *See* TinyCat Letter (but noting that such partnerships should be optional).

[1321] *See* David Drake, *Rich Man's Crowd Funding,* Forbes, Jan. 15, 2013, *available at http://www.forbes.com/sites/groupthink/2013/01/15/rich-mans-crowd-funding/. See also* Mohana Ravindranath, *For broker/dealers, crowdfunding presents new opportunity, Wash. Post*, Mar. 29, 2013, *available at http://www.washingtonpost.com/business/on-small-business/for-brokerdealers-crowdfunding-presents-new-opportunity/2013/03/28/bb835942–8075–11e2–8074-b26a871b165a_story.html*; J.J. Colao, *In the Crowdfunding Gold Rush, This Company Has a Rare Edge,* Forbes, June 5, 2013, *available at http://www.forbes.com/sites/jjcolao/2013/06/05/in-the-crowdfunding-gold-rush-this-company-has-a-rare-edge/*; Arina Shulga, *Crowdfunding Right Now (Fund Model, Broker-Dealer Model, Lending Platforms and Intrastate Offerings)*, LexisNexis.com, Aug. 7, 2014, *available at http://www.lexisnexis.com/legalnewsroom/banking/b/venture-capital/archive/2014/08/07/crowdfunding-right-now-fund-model-broker-dealer-model-lending-platforms-and-intrastate-offerings.aspx*; Alessandra Malito, *Broker-dealer expands crowdfunding reach with new partnership,* InvestmentNews, Apr. 14, 2015, *available* at *http://www.investmentnews.com/article/20150414/FREE/150419972/broker-dealer-expands-crowdfunding-reach-with-new-partnership.*

intermediary's platform if the issuer has engaged the services of a registered transfer agent.[1322] This registered transfer agent safe harbor may lead intermediaries to encourage issuers to use a registered transfer agent.

c. Investors

It is unclear what types of investors will participate in offerings made in reliance on Section 4(a)(6), but given the investment limitations in the final rules, we believe that many investors affected by the final rules will likely be individual retail investors who currently do not have broad access to investment opportunities in early-stage ventures. Offerings made in reliance on Section 4(a)(6) may provide retail investors with additional investment opportunities, although the extent to which they invest in such offerings will likely depend on their view of the potential return on investment as well as the risk for fraud.

In contrast, larger, more sophisticated or well-funded investors may be less likely to invest in offerings made in reliance on Section 4(a)(6). The relatively low investment limits set by the statute for crowdfunding investors may make these offerings less attractive for professional investors, including VCs and angel investors.[1323] While an offering made in reliance on Section 4(a)(6) can bring an issuer to the attention of these investors, it is possible that professional investors will prefer, instead, to invest in offerings in reliance on Rule 506, which are not subject to the investment limitations applicable to offerings made in reliance on Section 4(a)(6).

d. Other Capital Providers, Broker-Dealers and Finders in Private Offerings

The final rules may affect other parties that provide sources of capital, such as small business lenders, VCs, family and friends and angel investors that currently finance small private businesses. The current scope of financing provided by these capital providers is discussed above. As discussed below, the magnitude of the final rules' economic impact will depend on whether crowdfunding in reliance on Section 4(a)(6) emerges as a substitute or a complement to these financing sources.

In addition, issuers conducting private offerings may, outside of offerings in reliance on Section 4(a)(6), currently use broker-dealers to help them with various aspects of the offering and to help ensure compliance with the ban on general solicitation and advertising that exists for most private offerings. Private offerings also could involve finders who connect issuers with investors for a fee.[1324] These private offering intermediaries also may be affected by the final rules, because once issuers can undertake offerings in reliance on Section 4(a)(6), some issuers might no longer need the services of those broker-dealers and finders.

Although we are unable to predict the exact size of the market for broker-dealers and finders in private offerings that are comparable to those that the final rules permit, data on the use of broker-dealers and finders in the Regulation D markets suggest that they may not currently play a large role in private offerings. Based on a staff study, only 21% of all new Regulation D offerings from 2009 to 2014 used an intermediary such as a broker-dealer or a finder.[1325] The use of a broker-dealer or a finder increased with offering size; they participated in approximately 17% of offerings for up to $1 million and 30% of offerings for more than $50 million. Moreover, the fee tends to decrease with offering size. Unlike the gross spreads in registered offerings, the differences in fees for Regulation D offerings of different sizes are large: the average total fee (commission plus finder fee) paid by issuers conducting offerings of up to $1 million (6.4% in 2014) is almost three times larger on a percentage basis than the average total fee paid by issuers conducting offerings of more than $50 million (1.9% in 2014).[1326] These estimates, however, only reflect practices in the Regulation D market. It is possible that issuers engaging in other types of private offerings (*e.g.,* those relying on Section 4(a)(2)), for which we do not have data, may use broker-dealers and finders more frequently and have different fee structures.

B. Analysis of Final Rules

As noted above, we are mindful of the costs and benefits of the final rules, as well as the impact that the final rules may have on efficiency, competition and capital formation. In enacting Title III, Congress established a framework for a new type of exempt offering and required us to adopt rules to implement that framework. To the extent that crowdfunding rules are successfully utilized, the crowdfunding provisions of the JOBS Act are expected to provide startups and small businesses with the means to raise relatively modest amounts of capital, from a broad cross section of investors, through securities offerings that are exempt from registration under the Securities Act. They also are expected to permit small investors to participate in a wider range of securities offerings than may be currently available.[1327] Specifically, the statutory provisions and the final rules address several challenges specific to financing startups and small businesses, including, for example, accessing a large number of investors, the regulatory requirements associated with issuing a security, protecting investors and making such securities offerings cost-effective for the issuer.

In the sections below, we analyze the costs and benefits associated with the crowdfunding regulatory regime, as well as the potential impacts of such a regulatory regime on efficiency, competition and capital formation, in light of the baseline discussed above.

1. Broad Economic Considerations

In this release, we discuss the potential costs and benefits of the final rules. Many of these costs and benefits are difficult to quantify or estimate with any degree of certainty, especially considering that Section 4(a)(6) provides a new method for raising capital in the United States. Some costs are difficult to quantify or estimate because they represent transfers between various participants in a market that does not yet exist. For instance, costs to issuers can be passed on to investors and costs to intermediaries can be passed on to issuers and investors. These difficulties in estimating and quantifying such costs are exacerbated by the limited public data that indicates how issuers, intermediaries and investors will respond to these new capital raising opportunities.

The discussion below highlights several general areas where uncertainties about the new crowdfunding market might affect the potential costs and benefits of the final rules, as well as our ability to quantify those costs and benefits. It also highlights the potential effects on

[1322] *See* Rule 301(b) of Regulation Crowdfunding.

[1323] An observer suggests that, unlike angels, VCs may be less interested in crowdfunding because, if VCs rely on crowdfunding sites for their deal flow, it would be difficult to justify charging a 2% management fee and 20% carried interest to their limited partners. *See* Ryan Caldbeck, *Crowdfunding—Why Angels, Venture Capitalists And Private Equity Investors All May Benefit,* Forbes, Aug. 7, 2013.

[1324] Depending on their activities, these persons may need to be registered as broker-dealers.

[1325] *See Unregistered Offerings White Paper,* note 1230.

[1326] *ID.*

[1327] *See, e.g.,* 158 Cong. Rec. S1781 (daily ed. Mar. 19, 2012) (statement of Sen. Carl Levin) (''Right now, the rules generally prohibit a company from raising very small amounts from ordinary investors without significant costs.'').

efficiency, competition and capital formation.

The extent to which the statute and the final rules affect capital formation and the cost of capital to issuers depends in part on the issuers that choose to participate. In particular, if offerings in reliance on Section 4(a)(6) only attract issuers that are otherwise able to raise capital through another type of exempt offering, the statute and the final rules may result in a redistribution of capital flow, which may enhance allocative efficiency but have a limited impact on the aggregate level of capital formation.[1328]

Notwithstanding the existence of these alternative methods of capital raising, we believe that offerings pursuant to Section 4(a)(6) will likely represent a new source of capital for many small issuers that currently have difficulty raising capital. Startups and small businesses usually have smaller and more variable cash flows than larger, more established companies, and internal financing from their own business operations tends to be limited and unstable. Moreover, these businesses tend to have smaller asset bases [1329] and, thus, less collateral for traditional bank loans. As discussed above, startups and small businesses, which are widely viewed to have more financial constraints than publicly-traded companies and large private companies, could therefore benefit significantly from a securities-based crowdfunding market. Some small businesses may not qualify for traditional bank loans and may find alternative debt financing too costly or incompatible with their financing needs. While some small businesses may attract equity investments from angel investors or VCs, other small businesses, particularly, businesses at the seed stage may have difficulty obtaining external equity financing from these sources. We believe that the statute, as implemented by the final rules, may increase both capital formation and the efficiency of capital allocation among small issuers by expanding the range of methods of external financing available to small businesses and the pool of investors willing to finance such types of businesses. The extent to which such issuers will use the Section 4(a)(6) offering exemption, however, is difficult to assess.

If startups and small businesses find other capital raising options more attractive than securities-based crowdfunding, the impact of Section 4(a)(6) on capital formation may be limited. Even so, the availability of securities-based crowdfunding as a financing option may increase competition among suppliers of capital, resulting in a potentially lower cost of capital for all issuers, including those that choose not to use securities-based crowdfunding.

For issuers that pursue offerings in reliance on Section 4(a)(6), establishing an initial offering price might be challenging. Offerings relying on Section 4(a)(6) will not involve an underwriter who, for larger offerings, typically assists the issuer with pricing and placing the offering. Investors in offerings relying on Section 4(a)(6) may lack the sophistication to evaluate the offering price. Thus, the involvement of these investors, who are likely to have a more limited capacity for conducting due diligence on deals, may contribute to less accurate valuations.

Moreover, because of the investment limitations in securities-based crowdfunding transactions, there may not be a strong incentive, even assuming adequate knowledge and experience, for an investor to perform a thorough analysis of the issuer disclosures. To the extent that these potential information asymmetries resulting from the lack of a thorough analysis of the disclosures are anticipated by prospective investors, investor participation in offerings made in reliance on Section 4(a)(6) may decline and the associated benefits of capital formation may be lower.

Uncertainty surrounding exit strategies for investors in crowdfunding offerings also may limit the benefits. In particular, it is unlikely that purchasers in crowdfunding transactions will be able to follow the typical path to liquidity that investors in other exempt offerings follow. For instance, investors in a VC-backed startup may eventually sell their securities in an initial public offering on a national securities exchange or to another company in an acquisition.[1330] We anticipate that most businesses engaging in offerings in reliance on Section 4(a)(6) will be unlikely to progress directly to an initial public offering on a national securities exchange given their small size,[1331] and investors may lack adequate strategies or opportunities to eventually divest their holdings.[1332] A sale of the business will require the issuer to have a track record in order to attract investors with the capital willing to buy the business.

Further, the likely broad geographical dispersion of crowdfunding investors may make shareholder coordination difficult. It may also exacerbate information asymmetries between issuers and investors, if the distance between them diminishes the ability for investors to capitalize on local knowledge that may be of value in assessing the viability of the issuer's business. The use of electronic means may mitigate some of these difficulties. Even if an issuer can execute a sale or otherwise offer to buy back or retire the securities, it might be difficult for investors to determine whether the issuer is offering a fair market price. These uncertainties may limit the use of the Section 4(a)(6) exemption.

The potential benefits of the final rules also may depend on how investors respond to potential liquidity issues unique to the securities-based crowdfunding market. It is currently unclear how securities offered and sold in transactions conducted in reliance on Section 4(a)(6) will be transferred in the secondary market after the one-year restricted period ends, and investors who purchased securities in transactions conducted in reliance on Section 4(a)(6) and who seek to divest their securities may not find a liquid market.[1333] Assuming a secondary market develops, securities may be quoted on the over-the-counter market or on trading platforms for shares of private companies.[1334] Nevertheless, it

[1328] For example, a 2012 GAO report on Regulation A offerings suggests that a significant decline in the use of this funding alternative after 1997 could be partially attributed to a shift to Rule 506 offerings under Regulation D, as a result of the preemption of state law registration requirements for Rule 506 offerings that occurred in 1996. *See* GAO Report, note 1231.

[1329] *See, e.g.,* John Asker, Joan Farre-Mensa and Alexander Ljungqvist, *Corporate Investment and Stock Market Listing: A Puzzle?* European Corporate Governance Institute Finance Working Paper (June 2012), *available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1603484.*

[1330] *See* Gompers, note 1249.

[1331] As noted, under the statute and the final rules, issuers relying on Section 4(a)(6) would be limited to raising an aggregate of $1 million during a 12-month period. By contrast, as noted in the IPO Task Force, the size of an initial public offering generally exceeds $50 million. *See* IPO Task Force, note 1223.

[1332] In contrast, given the required investor qualifications and offering limit amounts, Regulation D offerings may generally attract issuers that are more experienced and better capitalized. Moreover, such offerings are likely to have a larger proportion of accredited investors because, in contrast to securities-based crowdfunding, there are no limitations on individual investment amounts. As a result, we believe that Regulation D issuers and investors are more likely to have potential exit strategies in place.

[1333] Academic studies have shown that the over-the-counter market is less liquid than the national exchanges. *See* Nicolas Bollen and William Christie, *Market Microstructure of the Pink Sheets,* 33 J. Banking & Fin. 1326–1339 (2009); Andrew Ang, Assaf Shtauber and Paul Tetlock, *Asset Pricing in the Dark: The Cross Section of OTC Stocks,* 26 Rev. Fin. Stud. 2985–3028 (2013).

[1334] Given the services that funding portals are permitted to provide under the statute and the final

is possible that secondary trading costs for investors may be substantial, effective and quoted spreads may be wide, trading volume may be low, and price volatility may be high compared to those of listed securities.[1335] Illiquidity, to different degrees, remains a concern for other exempt offerings and for registered offerings by small issuers. However, because investors purchasing securities sold in reliance on Section 4(a)(6) may be less sophisticated than investors in other private offerings due to the fact that there are no investor qualification requirements, they may face additional challenges in addressing the impact of illiquidity, either in finding a suitable trading venue or negotiating with the issuer for an alternative liquidity option. The potentially high degree of illiquidity associated with securities purchased in reliance on Section 4(a)(6) may discourage some investors from investing in issuers through such offerings, thus limiting the potential efficiency, competition and capital formation benefits of the final rules.

Even with the mandated disclosures, unsophisticated investors purchasing securities issued in reliance on Section 4(a)(6) may face certain expropriation risks, potentially limiting the upside of their investment, even when they select investments in successful ventures. This can occur if issued securities include certain features (*e.g.,* callable securities or securities with differential control rights) or if issuers conduct insider-only financing rounds or financing rounds at reduced prices (so-called ''down rounds'') that have the effect of diluting an investor's interest or otherwise diminishing the value of the securities offered and sold in reliance on Section 4(a)(6). Investors purchasing securities issued in reliance on Section 4(a)(6) may not have the experience or the market power to negotiate various anti-dilution provisions, right of first refusal, tag-along rights, superior liquidation preferences and rights upon a change in control that have been developed by institutional and angel investors as protections against fundamental changes in a business.[1336] Moreover, the disperse ownership stakes of investors in securities-based crowdfunding offerings may weaken their incentives to monitor the issuer to minimize the risk of expropriation. The ensuing expropriation risk may discourage some investors from participating in offerings made in reliance on Section 4(a)(6), potentially limiting the efficiency, competition and capital formation benefits of the final rules.

The final rules also may have an effect on broker-dealers and finders participating in private offerings. Some issuers that previously relied on broker-dealers and finders to assist with raising capital through private offerings may, instead, begin to rely on the Section 4(a)(6) exemption to find investors. The precise impact of the final rules on these intermediaries will depend on whether (and, if so, to what extent) issuers switch from using existing exemptions to using the exemption provided by Section 4(a)(6) or whether the final rules primarily attract new issuers. The impact of the final rules on registered broker-dealers will also depend on the extent to which broker-dealers participate as intermediaries in the securities-based crowdfunding market. If a significant number of issuers switch from raising capital under existing private offering exemptions to relying on the exemption provided by Section 4(a)(6), this may negatively affect the revenue of finders and broker-dealers in the private offerings market. While this may disadvantage existing private offering market intermediaries, the new competition may ultimately lead to more efficient allocation of capital.

If securities-based crowdfunding primarily attracts new issuers to the market, the impact on broker-dealers and finder revenue may be negligible and the final rules may even have a positive effect on their revenues by revealing more potential clients for them, particularly to the extent that they chose to operate a funding portal. Additionally, greater investor interest in private company investment may increase capital formation, creating new opportunities for broker-dealers and finders that otherwise would have been unavailable.

The final rules also may encourage current participants in the crowdfunding market to diversify their funding models to attract a broader group of companies and to provide additional investment opportunities for investors. For example, donation-based crowdfunding platforms that currently offer investment opportunities in micro-loans generally do not permit donors to collect interest on their investments because of concerns that this activity will implicate the federal securities laws unless an exemption from registration is available.[1337] Under the final rules, these platforms may choose to register as funding portals and permit businesses to offer securities that provide investors with the opportunity to obtain a return on investment. This can broaden their user base and attract a group of investors different from those already participating in reward-based or donation-based crowdfunding. It is likely that some registered broker-dealers will find it profitable to enter the securities-based crowdfunding market and operate funding portals as well. Such an entry will increase the competition among intermediaries and likely lead to lower issuance costs for issuers.

However, many projects that are well suited for reward-based or donation-based crowdfunding (*e.g.,* because they have finite lives, their payoffs to investors could come before the project is completed or could be contingent on the project's success, etc.) may have little in common with startups and small businesses that are well suited for an offering in reliance on Section 4(a)(6). As a result, diversification among existing platforms may not always be optimal or preferred, particularly if complying with the final rules proves disproportionately costly compared to the potential amount of capital to be raised.

2. Crowdfunding Exemption

a. Limitation on Capital Raised

The statute imposes certain limitations on the total amount of securities that may be sold by an issuer during the 12-month period preceding the date of the transaction made in reliance on Section 4(a)(6). Specifically, Section 4(a)(6)(A) provides for a maximum aggregate amount of $1 million sold in reliance on the exemption during a 12-month

rules, investors will not be able to use funding portals to trade in securities offered and sold in reliance on Section 4(a)(6) in the secondary market.

[1335] Academic studies show that reducing the information transparency about an issuer increases the effective and quoted spreads of its shares, reduces share price and increases price volatility. Specifically, percentage spreads triple and volatility doubles when NYSE issuers are delisted to the Pink Sheets. *See* Jonathan Macey, Maureen O'Hara and David Pompilio, *Down and Out in the Stock Market: The Law and Finance of the Delisting Process,* 51 J.L. & Econ 683–713 (2008). When NASDAQ issuers delist and subsequently trade on the OTC Bulletin Board and/or the Pink Sheets, share volume declines by two-thirds, quoted spreads more than double, effective spreads triple and volatility triples. *See* Jeffrey H. Harris, Venkatesh Panchapagesan and Ingrid M. Werner, *Off But Not Gone: A Study of NASDAQ Delistings,* Fisher College of Business Working Paper No. 2008–03–005 and Dice Center Working Paper No. 2008–6 (Mar. 4, 2008), *available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=628203*. One factor that may alleviate transparency concerns is the fact that issuers that sold securities in an offering made in reliance on Section 4(a)(6) will have an ongoing reporting obligation, so disclosure of information about the issuer will continue to be required.

[1336] *See* Kaplan, note 1279.

[1337] *See, e.g., Deutsche Bank Microcredit Development Fund, Inc.,* SEC No-Action Letter (Apr. 8, 2012).

period.[1338] The final rules preserve the $1 million limit. The limitation on the amount that may be raised is expected to benefit investors by reducing the potential loss from dilution or fraud [1339] in the securities-based crowdfunding market. However, we recognize that this limit on the amount that may be sold in reliance on Section 4(a)(6) also can prevent certain issuers from raising all the capital they need to make their businesses viable, which in turn can result in lost opportunities, as indicated by various commenters.[1340] It also is likely to limit efficiency to the extent that capital cannot be channeled to the most productive use. Due to the lack of data, however, we are not able to quantify the unrealized efficiency or capital formation associated with the adoption of the $1 million limit instead of the alternative of a higher limit. Since issuers in securities-based crowdfunding offerings bear certain fixed costs, as discussed in Section III.B.3., offering costs as a percentage of offering proceeds will be larger under the $1 million limit than under the alternative of a higher limit.

As an alternative, we could have defined the $1 million limit to be net of intermediary fees, as suggested by some commenters.[1341] If a funding portal announces in advance the fees it charges for a given transaction (fixed or variable), the economic effects of such an alternative definition would be qualitatively similar to the effects of raising the offering limit. If the funding portal fees are not known in advance, then this alternative may also create uncertainty for issuers about how much capital they would be able to raise. Several commenters opposed such an alternative.[1342]

The costs associated with not increasing the investment limit above $1 million are mitigated in part by the ability of issuers to concurrently seek additional financing in reliance on another type of exempt offering, such as Regulation D or Regulation A, in addition to the offering in reliance on Section 4(a)(6). In this release, we provide guidance clarifying our view that issuers may conduct other exempt offerings without having those offerings integrated with the offering made in reliance on Section 4(a)(6), provided that each offering complies with the applicable exemption relied upon for that particular offering. Several commenters opposed this approach on the ground that it could result in fewer investor protections than if the offerings were integrated. Some commenters noted that a potential cost to investors associated with not requiring integration is a reduction in investor protection due to the possibility of an issuer's use of advertising for one offering to indirectly promote another exempt offering that would have been subject to more stringent advertising restrictions.[1343] While we recognize this concern, we note that the final rules do not provide a blanket exemption from integration with other private offerings that are conducted simultaneously with, or around the same time as, a Section 4(a)(6) offering. Rather, we provide guidance that an offering made in reliance on Section 4(a)(6) is not required to be integrated with another exempt offering made by the issuer to the extent that each offering complies with the requirements of the applicable exemption that is being relied upon for that particular offering. As mentioned earlier, an issuer conducting a concurrent exempt offering for which general solicitation is not permitted will need to be satisfied that purchasers in that offering were not solicited by means of the offering made in reliance on Section 4(a)(6). Alternatively, an issuer conducting a concurrent exempt offering for which general solicitation is permitted, for example, under Rule 506(c), cannot include in any such general solicitation an advertisement of the terms of an offering made in reliance on Section 4(a)(6), unless that advertisement otherwise complies with Section 4(a)(6) and the final rules. This may partly alleviate some of commenters' concerns because each offering will have the investor protections of the offering exemption upon which it relies.

As an alternative, in line with the suggestions of some commenters,[1344] we could have provided guidance that the amounts offered in reliance on Section 4(a)(6) should be integrated with the amounts offered pursuant to other exempt offerings. Under such an alternative, the amounts raised in other exempt offerings would count toward the maximum offering amount under Section 4(a)(6). Such an alternative would potentially limit the amount of capital raised by issuers, including the set of issuers eligible to conduct an exempt offering relying on Section 4(a)(6), and thus potentially limit the capital formation benefits of the final rules. Compared to this alternative, the ability of issuers to conduct other exempt offerings that do not count toward the maximum offering amount under Section 4(a)(6) may alleviate some of the concerns that certain issuers will not be able to raise sufficient capital. The net effect on capital formation will also depend on whether issuers seeking an aggregate exempt offering amount in excess of $1 million elect to rely on Regulation Crowdfunding as part of their capital raising or elect to rely on a different exemption, such as Rule 506 of Regulation D. These considerations and the relative differences in the investor protections associated with the different offering exemptions will determine the net effect on the amount of information about issuers available to market participants and the level of investor protection.

b. Investment Limitations

Since offering documents for offerings made in reliance on Section 4(a)(6) will not be subject to review by Commission staff prior to the sale of securities, we are sensitive to potential investor protection concerns arising from the participation of less sophisticated investors in these exempt offerings. Some commenters [1345] raised concerns that the ''wisdom of the crowd'' will not result in investors pooling information so as to lead to better informed

[1338] *See also* Rule 100(a)(1) of Regulation Crowdfunding.

[1339] While we lack information to predict the potential incidence of fraud in securities-based crowdfunding offerings made in reliance on Section 4(a)(6) and note that current crowdfunding practices differ significantly from the securities-based crowdfunding market that may develop upon effectiveness of the final rules, some concern has been expressed about the potential for fraud in this area. *See, e.g.,* NASAA Enforcement Report: 2015 Report on 2014 data, September 2015, available at *http://nasaa.cdn.s3.amazonaws.com/wp-content/uploads/2011/08/2015-Enforcement-Report-on-2014-Data_FINAL.pdf* (listing Internet fraud (including social media and crowdfunding) among the products and schemes that are frequently investigated by states, without statistics specific to securities-based crowdfunding).

[1340] *See, e.g.,* Advanced Hydro Letter; Bushroe Letter; Cole D. Letter; Concerned Capital Letter; Hamman Letter; Harrison Letter; Hillside Letter; Jazz Letter; Kickstarter Coaching Letter; McCulley Letter; McGladrey Letter; Meling Letter; Miami Nation Enterprises Letter; Multistate Tax Service Letter; Peers Letter; Pioneer Realty Letter; Public Startup Letter 2; Qizilbash Letter; Rosenthal O. Letter; Sarles Letter; SBM Letter; Taylor R. Letter; Taylor T. Letter; Wales Capital Letter 1; Wales Capital Letter 3; WealthForge Letter; Wear Letter; Wilhelm Letter; Winters Letter; Yudek Letter.

[1341] *See, e.g.,* Benjamin Letter; FundHub Letter 1; Hackers/Founders Letter; Joinvestor Letter; Odhner Letter; Omara Letter; Public Startup Letter 2; RFPIA Letter; RoC Letter; RocketHub Letter; Seed&Spark Letter; Thomas Letter 1; Wales Capital Letter 1; Whitaker Chalk Letter; Wilson Letter.

[1342] *See, e.g.,* Arctic Island Letter 4; ASSOB Letter; Commonwealth of Massachusetts Letter; MCS Letter; PeoplePowerFund Letter.

[1343] *See* AFR Letter; BetterInvesting Letter; Consumer Federation Letter; Fund Democracy Letter; IAC Recommendation; MCS Letter.

[1344] *See, e.g.,* AFL–CIO Letter; Brown J. Letter; Consumer Federation Letter; Fund Democracy Letter; MCS Letter; NASAA Letter.

[1345] *See, e.g.,* AFR Letter; Brown J. Letter; Consumer Federation Letter.

investment decisions.[1346] While we acknowledge these concerns, we note that, by adding Section 4(a)(6) to the Securities Act, Congress made an express determination to facilitate securities-based crowdfunding transactions under the federal securities laws, subject to certain specified investor protections.

Consistent with the statute, the final rules incorporate several important investor protections, including limits on the amount that can be raised, issuer eligibility criteria, and issuer and intermediary requirements, including statutorily mandated investor education requirements. The statute and the final rules also impose certain limitations on the aggregate dollar amount of securities in offerings in reliance on Section 4(a)(6) that may be sold to an investor during a 12-month period.[1347] These provisions are designed to limit the potential investment and, consequently, the potential losses for any single investor, thus providing downside protection for investors.

We recognize that these provisions also will limit the potential upside for investors. This may particularly affect the decisions of investors with large portfolios who might be able to absorb losses and understand the risks associated with risky investments and who may have more expertise and stronger incentives to acquire and analyze information about an issuer. For these investors, the $100,000 aggregate limit may reduce their incentive to participate in the securities-based crowdfunding market, compared to other types of investments, potentially depriving the securities-based crowdfunding market of more experienced and knowledgeable investors and impeding capital formation. Moreover, limiting the participation of such investors may negatively affect the informational efficiency of the securities-based crowdfunding market because sophisticated investors are better able to accurately price such offerings. These investors also can add value to the discussions taking place through an intermediary's communication channels about a potential offering by providing their views on the issuer's financial viability and potential for fraud. Persons with larger portfolios are also likely to be in a better position to monitor the issuer's insiders, which can reduce the extent of moral hazard and the risk of fraud on the part of the issuer and the issuer's insiders, yielding benefits for all investors. Such investors also can add value by advising the issuer and contributing strategic expertise, which can be particularly beneficial for early-stage issuers. Some of these potential benefits, however, may still be available to issuers that seek to attract such investors through another type of exempt offering, such as a Regulation D offering.

The aggregate limit on crowdfunding investments also can impede the ability of investors to diversify within the securities-based crowdfunding market. As securities-based crowdfunding investments might have inherently high failure rates,[1348] investors who do not or cannot diversify their investments across a number of offerings can face an increased risk of incurring large losses, relative to their investments, even when they investigate offerings thoroughly. By comparison, VC firms typically construct highly diversified portfolios with the understanding that many ventures fail, resulting in a complete loss of some investments, but with the expectation that those losses will be offset by the large upside of the relatively fewer investments that succeed.[1349] The securities-based crowdfunding market is expected to involve earlier-stage financing compared to venture capital financing, and therefore, the chances of investment success may be lower.[1350] The statutory caps on aggregate securities-based crowdfunding investments under Section 4(a)(6) may limit an investor's ability to choose a sufficiently large number of investments to offset this risk and to recover the due diligence costs of sufficiently investigating individual investments. One potential solution to this diversification problem is to invest smaller amounts in a greater number of ventures. However, such a strategy has limited benefit to the extent that there is a fixed cost to the due diligence associated with identifying and reviewing each investment opportunity, making it more costly to implement than a strategy that relies on the selection of fewer investment opportunities.

In a change from the proposed rules, both the investor's annual income and net worth must be above $100,000 for the 10 percent limitation to apply. This change is intended to strengthen investor protections for investors whose annual income or net worth is below $100,000. Such investors may not be as well situated to bear the risk of loss (*e.g.,* in the event of fraud on the part of an issuer) as investors with both income and net worth of $100,000 or more. According to Commission staff analysis of the data in the 2013 Survey of Consumer Finances, approximately 17% of U.S. households have both income and net worth of $100,000 or higher. By comparison, 39% of U.S. households have either income or net worth of $100,000 or higher.[1351] Thus, approximately 22% of households will be subject to a lower investment limit under the final rules than under the proposal. We note that these figures are only available at the household level rather than at the individual level. We further note that these figures do not account for the fact that only some households might seek to invest in an offering in reliance on Section 4(a)(6). Thus, we are not able to determine the

[1346] Predictions in research studies regarding the impact of social interaction on investor decisions are mixed. On the one hand, a recent study of opinions that were posted on the Internet Web site *http://seekingalpha.com* finds evidence of predictability of earnings surprises and returns that is interpreted as potentially suggesting the value relevance of user opinions rather than a naïve investor reaction. *See* Hailiang Chen, Prabuddha de, Yu Hu, and Byoung-Hyoun Hwang, *Wisdom of Crowds: The Value of Stock Opinions Transmitted Through Social Media,* 27 Rev. Fin. Stud. 1367–1403 (2014). An earlier theoretical paper shows that word-of-mouth can, under some circumstances, result in superior decisions. *See* Glenn Ellison and Drew Fudenberg, *Word-of-Mouth Communication and Social Learning,* 110 Quarterly J. Econ. 93–125 (1995). On the other hand, some behavioral finance literature examines irrational herding and contagion of thought and behavior through social interaction, such as the propagation of investing memes, which need not be predictive of superior trading performance. For example, one article characterizes memes as ''mental representation (such as an idea, proposition, or catchphrase) that can be passed from person to person''. The article provides an example of investors using ''verbal 'reasons' to decide how to trade'' and notes that these reasons ''are often not cogent''. The article notes that such reasons, or financial memes, can be simple or can be elaborate structures of analysis, examples, terminology, catchphrases, and modeling. *See* for example, David A. Hirshleifer and Siew Hong Teoh, *Thought and Behavior Contagion in Capital Markets,* Handbook of Financial Markets: Dynamics and Evolution (2009). Another article compares the investment decisions of stock clubs and individuals. It finds that while both individuals and clubs are more likely to purchase stocks that are associated with ''good reasons'' (such as a company that is featured on a list of ''most-admired'' companies), stock clubs favor such stocks more than individuals, despite the fact that such reasons do not improve performance. The article analyzes social dynamics that may make ''good reasons'' more important for groups than individuals. *See* Brad Barber, Chip Heath, and Terrance Odean, *Good Reasons Sell: Reason-Based Choice Among Group and Individual Investors in the Stock Market,* 49 Management Science 1636–1652 (2003).

[1347] *See* Section 4(a)(6)(B). *See also* Rule 100(a)(2) of Regulation Crowdfunding.

[1348] *See* discussion in Section III.A.4 above.

[1349] *See, e.g.,* John Cochrane, *The Risk and Return of Venture Capital,* 75 J. of Fin. Econ. 3 (2005).

[1350] *See* Rajshree Agarwal and Michael Gort, *Firm and Product Life Cycles and Firm Survival,* 92 Am. Econ. Rev. 184–190 (2002).

[1351] Based on data from the 2013 Survey of Consumer Finances, a triennial survey sponsored by the Federal Reserve Board, *available* at *http://www.federalreserve.gov/econresdata/scf/scfindex.htm.*

actual percentage of investors affected by this change in the final rules relative to the proposal.

Within each investment limitation tier, the investment limitation percentage is multiplied by the ''lesser of'' an investor's annual income or net worth in the investment limitation calculation, which was suggested by several commenters.[1352] This change from the proposal is expected to reduce the permitted investment limit for each individual investor because most investors are unlikely to have annual income and net worth amounts that are identical.[1353]

Investment limitations will likely have a negative effect on capital formation. For example, investment limitations may make it more difficult for some issuers to reach their funding targets. However, these limits also are expected to reduce the risk and impact of potential loss for investors that accompany the high failure rates associated with investments in small businesses and startups, thus potentially improving investor protection. There is no available market data that would allow us to empirically evaluate the magnitude of these effects.

Consistent with the proposed rules, the final rules allow an issuer to rely on the efforts that an intermediary is required to undertake in order to determine that the aggregate amount of securities purchased by an investor will not cause the investor to exceed the investor limits, provided that the issuer does not have knowledge that the investor had exceeded, or would exceed, the investor limits as a result of purchasing securities in the issuer's offering, which was supported by various commenters.[1354] This may result in aggregate verification cost savings since a given intermediary may be involved in and have information on crowdfunding transactions pertaining to the offerings of multiple issuers, which makes it potentially less costly to identify investors that exceed the investment limitation. As a potential alternative, we could have imposed more extensive verification requirements on issuers, which would have resulted in larger compliance costs for issuers but could have potentially increased investor compliance with the investment limitations, with corresponding investor protection benefits. As noted above, we believe the final rules appropriately consider investor protection and facilitating capital formation.

c. Issuer Eligibility

Section 4A(f) of the statute excludes certain categories of issuers from eligibility to engage in securities-based crowdfunding transactions in reliance on Section 4(a)(6). The final rules exclude those categories of issuers.[1355] The final rules also exclude two additional categories of issuers, beyond those identified in the statute, from being eligible to rely on Section 4(a)(6) to engage in crowdfunding transactions. First, the final rules exclude issuers that sold securities in reliance on Section 4(a)(6) and have not filed with the Commission and provided to investors the ongoing annual reports required by Regulation Crowdfunding during the two years immediately preceding the filing of the required offering statement,[1356] which is generally consistent with suggestions from several commenters.[1357] This additional exclusion is not expected to impose any additional burdens and costs on an issuer that it would not have already incurred had it complied with the ongoing reporting requirements as they came due. Further, the requirement that a delinquent issuer prepare and file up to two annual reports at one time in order to become eligible to rely on Section 4(a)(6) is expected to incentivize issuers to provide updated and current information to investors, if they intend to rely again on Section 4(a)(6) to raise additional capital, without necessarily requiring an issuer to become fully current in its reporting obligations. We recognize that conditioning an issuer's Section 4(a)(6) eligibility on the requirement that issuers provide ongoing reports for only the previous two years may result in less information being available to investors in some periods, with potential adverse effects on the price formation and liquidity of the securities in the secondary market. The potential damage to an issuer's reputation resulting from being delinquent along with potential enforcement action for failure to comply with a regulatory reporting obligation and the modification from the proposed rules to require an issuer to disclose in its offering statement if it or any of its predecessors previously failed to comply with the ongoing reporting requirements of Rule 203 of Regulation Crowdfunding, however, may help to mitigate these potential adverse effects. As an alternative, we could have chosen not to impose this exclusion or adopted a shorter look-back period, as suggested by some commenters.[1358] Compared to the provisions in the final rules, either of these alternatives could result in less information being available to investors and reduced informational efficiency of securities prices or possibly increased likelihood of issuer misconduct in offerings made in reliance on Section 4(a)(6).

Second, the final rules exclude a company that has no specific business plan or has indicated that its business plan is to engage in a merger or acquisition with an unidentified company or companies, as suggested by several commenters.[1359] This requirement is intended to help ensure that investors have adequate information about the issuer's proposed business plan to make an informed investment decision, which may increase investor protection in some instances. As an alternative, we could have chosen not to impose this exclusion or to impose a less restrictive exclusion, as suggested by several commenters.[1360] Although these alternatives might increase capital formation by allowing a subset of additional issuers to rely on Section 4(a)(6), they may also result in less

[1352] *See, e.g.,* AFR Letter; BetterInvesting Letter; Consumer Federation Letter; Fund Democracy Letter; Fryer Letter; Growthfountain Letter; IAC Recommendation (but also stating that the ''greater of'' approach would be appropriate for accredited investors); Merkley Letter; NASAA Letter; Schwartz Letter; Zhang Letter (recommending that net worth not be used to calculate the investment limit).

[1353] Although we lack information to determine the average change in the applicable investment limit resulting from this change, based on Commission staff analysis of the 2013 Survey of Consumer Finances, a larger percentage of households exceeded a particular dollar threshold, such as $100,000 or $200,000, based on the net worth standard than the percentage of households that exceeded the same dollar threshold based on the income standard.

[1354] *See, e.g.,* Arctic Island Letter 4; CFA Institute Letter; Consumer Federation Letter; CrowdBouncer Letter; EarlyShares Letter; EMKF Letter; Finkelstein Letter; Fund Democracy Letter; Heritage Letter; Joinvestor Letter; Public Startup Letter 2; RoC Letter; RocketHub Letter; Vann Letter; Wefunder Letter; Whitaker Chalk Letter.

[1355] These categories of issuers are: (1) Issuers that are not organized under the laws of a state or territory of the United States or the District of Columbia; (2) issuers that are subject to Exchange Act reporting requirements; (3) investment companies as defined in the Investment Company Act or companies that are excluded from the definition of investment company under Section 3(b) or 3(c) of the Investment Company Act. *See* Section 4A(f). *See also* Rule 100(b) of Regulation Crowdfunding.

[1356] *See* discussion in Section II.A.4 above.

[1357] *See, e.g.,* ASSOB Letter; Commonwealth of Massachusetts Letter; Consumer Federation Letter; Fund Democracy Letter; Grassi Letter; Joinvestor Letter; NASAA Letter; Wefunder Letter.

[1358] *See, e.g.,* ABA Letter; Parsont Letter; Projectheureka Letter; Public Startup Letter 2; RocketHub Letter.

[1359] *See, e.g.,* Anonymous Letter 2; CFA Institute Letter; CFIRA Letter 7; Commonwealth of Massachusetts Letter; Consumer Federation Letter; NASAA Letter; ODS Letter; Traklight Letter; Whitaker Chalk Letter.

[1360] S*ee, e.g.,* ABA Letter; FundHub Letter 1; Projectheureka Letter; Public Startup Letter 2; RoC Letter; RocketHub Letter; SBM Letter; Wilson Letter.

informed investor decisions in such offerings.

Overall, categories of issuers that are excluded from eligibility under the final rules may be at a competitive disadvantage relative to those that are eligible to offer securities under the final rules, to the extent that excluded issuers may raise less external capital or incur a higher direct or indirect cost of financing, or additional restrictions, when seeking financing from alternative sources.

3. Issuer Requirements

a. Issuer Costs

We recognize that there are benefits and costs associated with Regulation Crowdfunding's requirements pertaining to issuers, including the final rule's disclosure requirements. In the Proposing Release, we provided cost estimates for each of these requirements and requested comment on our estimates.[1361] In response, we received several comment letters providing alternative cost estimates, some of which were lower and some of which were higher than the cost estimates in the Proposing Release.[1362] For example, one commenter [1363] provided the following cost estimates: Portal fees of 6% to 15% [1364]; accounting review fees of $1,950 to $9,000; accounting audit fees of $3,100 to $9,000; financial statements/projections costs of $2,000 to $5,000; Title III disclosure/compliance costs of $1,000 to $4,000; and corporate formation costs of $300 to $500.[1365] In addition, the commenter estimated the total cost to raise $99,000 of capital under the proposed rules to be $9,300 to $24,500 (9.4% to 24.7%); to raise $499,000 of capital to be $33,240 to $84,750 (6.7% to 17%); and to raise $1 million of capital to be $72,800 to $168,500 (7.3% to 16.9%). The commenter stated that the entry of new vendors into the market and ensuing competition may lead to a decline in some of these costs over time. Another commenter [1366] estimated that a $200,000 offering will incur the following average costs: Legal fees of $10,000; intermediary fees of $20,000 (10%); accounting fees of $5,000; accounting review fees of $8,000; and other fees (transfer agent, campaign development, filing and other) of $7,000. A different commenter estimated that the cost to issuers could range from 26% to 601% of the offering amount over a five-year period, depending on the size of the offering, which does not account for additional estimated opportunity costs of internal personnel time of $35,000 to $85,000 over a five-year period.[1367] Some commenters referred to estimates of total costs without estimating individual components of those costs.[1368] Other commenters provided additional analysis of costs under different scenarios and offering sizes based on the estimates in the Proposing Release.[1369]

In general, commenters identified the following as the main costs for issuers in securities-based crowdfunding offerings: The intermediary fees; the costs of preparing, ensuring compliance with, and filing of Form C and Form C–AR; and the cost of accounting review or audit of financial statements.[1370] Below we discuss the comments received on each of these costs and any revisions to our estimates made in response.

With regard to intermediary fees, the estimates of the commenters that quantified these fees [1371] were generally very close to our estimates in the Proposing Release (5% to 15%). We agree with the commenter that suggested that there is likely to be a fixed component to these costs that reflects a certain necessary level of due diligence and background screening, which will result in these costs as a percentage of offering size being higher for smaller offerings.[1372] Thus, we have revised our intermediary fee estimates in the following way: We project (as a percentage of offering proceeds) 5% to 15% for offerings of $100,000 or less, 5% to 10% for offerings between $100,000 and $500,000, and 5% to 7.5% for offerings above $500,000. Data on Regulation D offerings that involve intermediaries suggests that offerings of up to $1 million have an intermediary fee (commission and/or finder fee) of approximately 6.5% on average, which is within the range we estimate for larger crowdfunding offerings. Although crowdfunding intermediaries are not expected to provide issuers with services commensurate with those provided by underwriters in registered offerings (and, in fact, funding portals would be prohibited from doing so), the fees charged in a crowdfunding offering can be significantly larger on a percentage basis relative to the underwriting fees for registered offerings, which range from as high as 7% for initial public offerings to less than 1% for certain bond issuances.[1373] In general, to the extent that a significant component of these fees is fixed, the transaction costs for issuers will make smaller offerings more

[1361] *See* Proposing Release, Section III.B.3.

[1362] *See, e.g.,* StartEngine Letter 2; FundHub Letter 2; Heritage Letter; SeedInvest Letter 1; SeedInvest Letter 2; Traklight Letter.

[1363] *See* StartEngine Letter 2.

[1364] The commenter does not specify whether these fees are expressed as a percentage of the amount sought or raised in the offering.

[1365] We do not consider the costs associated with the incorporation or formation of the business itself to be part of the incremental costs of Regulation Crowdfunding, as these are costs associated with forming any business endeavor that relies on outside sources of capital.

[1366] *See* Grassi Letter.

[1367] *See* SeedInvest Letter 1.

[1368] *See, e.g.,* WealthForge Letter (suggesting that the costs associated with completing a crowdfunding transaction under the current regulations can be as high as one hundred thousand dollars, including audit fees, intermediary fees, legal fees and other offering costs); Berlingeri Letter (suggesting that the total cost would amount to between 15% and 20% of the offering); Traklight Letter (suggesting that the total cost would amount to between 15% and 20% of the offering for offerings above $100,000); FundHub Letter 1 (referring to potential costs, based on the Commission's estimates and the commenter's assumptions, of between $15,000 and $25,000 associated with raising $100,000); Harrison Letter and Ramsey Letter (referencing a Forbes estimate that the costs of disclosure documents, engaging an intermediary, performing background checks, and filing annual reports with the Commission might be upwards of $100,000). *See also SEC Proposes Crowdfunding Rules,* Forbes, Oct. 23, 2013, *http://www.forbes.com/sites/deborahljacobs/2013/10/23/sec-proposes-crowdfunding-rules/.*

[1369] *See, e.g.,* EarlyShares Letter; RocketHub Letter; SeedInvest Letter 1.

[1370] *But see* Growthfountain Letter (suggesting that crowdfunding issuers will also incur investor relations costs). We do not consider investor relations costs to be incremental to Regulation Crowdfunding, as these costs may be incurred by any business that relies on outside sources of capital and a widely dispersed investor base. However, to the extent that investment limitations in crowdfunding offerings increase the number of investors in a typical offering and to the extent that some investor relations costs are variable, issuers in crowdfunding offerings may incur higher investor relations costs than issuers in types of offerings that typically have fewer investors.

[1371] *See* StartEngine Letter 2 (estimating portal fees of 6–15%). *See also* Grassi Letter (estimating an intermediary fee of $20,000 for a $200,000 offering, which amounts to 10% of the offering). *But see* Wefunder Letter (noting that, in contrast to the assumption in the Proposing Release, ''good startups will pay a maximum of $0'' and citing three accredited investor crowdfunding platforms that use a ''carried interest'' model for Rule 506 offerings, including the example of the commenter itself that does not charge a fee to startups but that charges investors a $25 fee and 10% carried interest (share of profits upon acquisition or initial public offering)).

[1372] *See* Heritage Letter.

[1373] *See, e.g.,* Hsuan-Chi Chen and Jay R. Ritter, *The Seven Percent Solution,* 55 J. Fin. 1105 − 1131 (2000); Mark Abrahamson, Tim Jenkinson, and Howard Jones, *Why Don't U.S. Issuers Demand European Fees for IPOs*? 66 J. Fin. 2055–2082 (2011); Shane A. Corwin, *The Determinants of Underpricing for Seasoned Equity Offers,* 58 J. Fin. 2249 − 2279 (2003); Lily Hua Fang, *Investment Bank Reputation and the Price and Quality of Underwriting Services,* 60 J. Fin. 2729 − 2761 (2005); Rongbing Huang and Donghang Zhang, *Managing Underwriters and the Marketing of Seasoned Equity Offerings,* 46 J. Fin. Quant. Analysis 141–170 (2011); Stephen J. Brown, Bruce D. Grundy, Craig M. Lewis and Patrick Verwijmeren, *Convertibles and Hedge Funds as Distributors of Equity Exposure,* 25 Rev. Fin. Stud. 3077 − 3112 (2012).

expensive on a percentage basis. As previously discussed, we believe that competition among crowdfunding venues and the potential development of new products and services may have a significant impact on these estimates over time.

The next major cost driver for issuers in securities-based crowdfunding offerings, as suggested by commenters, is the cost of preparing and filing disclosure documents and the internal burden of ensuring compliance with the disclosure requirements of the final rules. Issuers will incur costs to comply with the disclosure requirements and file the information in the new Form C: Offering Statement and Form C–U: Progress Update before the offering is funded. Thus, issuers will incur those costs regardless of whether their offerings are successful. In addition, for successful offerings, issuers will incur costs to comply with the ongoing reporting requirements and file information in the new Form C–AR: Annual Report.[1374]

Several commenters provided estimates of these costs. One commenter stated that Form C could be prepared by third-party service providers, such as itself, at much lower costs than those estimated by the Commission, noting that it can prepare Form C and other required disclosure documents, perform ''bad actor'' checks, verify investor status and fulfill other compliance requirements for an estimated total cost of $2,500 for an offering of $100,000 and that, in most cases, its services and associated legal fees will cost an issuer between $2,500 and $5,000 for an offering up to $500,000 and between $5,000 and $10,000 for an offering between $500,000 and $1,000,000.[1375]

Other commenters indicated that the compliance costs for issuers are likely to be higher than the Commission's estimates. One commenter indicated that the burden of completing Form C would likely exceed the 60 burden hours estimated by the Commission in the proposed rules and that the sum of attorney and accounting fees and management and administrative time and other costs to prepare these required disclosures will likely exceed $10,500, except in cases of start-ups with no operating history.[1376] The commenter also noted that most Regulation D offerings, which tend to be less complex than crowdfunding offerings, based on the requirements in the proposed rules, incur accounting and legal fees above $2,500.[1377] Another commenter noted that issuers and intermediaries will likely incur higher attorney and accounting fees and financial and administrative burdens than estimated in the proposed rules but did not provide estimates.[1378]

One commenter submitted several estimates of the compliance costs associated with the final rules' disclosure requirements. In one comment letter, the commenter estimated the upfront compliance costs of the proposed rules to be potentially hundreds of hours in internal company time and $20,000 to $50,000 in outside professional costs and noted that such costs will likely be a significant deterrent to crowdfunding.[1379] In a different comment letter,[1380] this commenter stated that, based on an informal survey of potential vendors, it believes the costs of preparing a Form C–AR would range from $6,000 to $20,000, with the median being roughly $10,000. The commenter [1381] further estimated that an additional $15,000 worth of internal burden per year would be required to prepare Form C–AR and an additional $5,000 to $10,000 worth of internal burden would be required to prepare financial statements. In yet another comment letter,[1382] this commenter estimated the cost of ongoing disclosure obligations and ongoing requirements to file financial statements under the proposed rules to be upwards of $10,000 to $40,000 per year.

Based on these comments, we have revised our estimates of the compliance costs associated with the disclosure requirements of the final rules and Forms C and C–AR. On the lower end of the spectrum, one commenter suggested that the cost of preparing and filing these forms and the associated compliance costs would range from $3,000 to $9,000.[1383] Another commenter estimated preparation and compliance costs of $2,500 for an offering of $100,000, between $2,500 and $5,000 for an offering between $100,000 and $500,000, and between $5,000 and $10,000 for an offering between $500,000 and $1,000,000.[1384] We rely on this commenter's estimates of the costs of preparing and filling Form C for offerings of up to $100,000 and offerings between $100,000 and $500,000. Another commenter presented higher estimates, ranging from $6,000 to $20,000, with a median cost of $10,000, but did not provide estimates for different offering sizes.[1385] Given commenters' estimates, we think that the $6,000 to $20,000 estimate is more appropriate for larger offerings (of more than $500,000). Thus, to estimate the costs of preparing, filing, and complying with Form C for large offerings, we combine the cost ranges provided by the two commenters for these types of offerings, resulting in a cost estimate between $5,000 and $20,000. As in the Proposing Release, we estimate that the cost of preparing and complying with the requirements related to Form C–AR will be approximately two-thirds of that for Form C. We base this estimate on the fact that no offering-specific information will be required in Form C–AR and issuers may thus be able to update disclosure previously provided on Form C. Our estimates of the costs of Forms C and C–AR are exclusive of the costs of an accounting review or audit, which are discussed separately below.

We expect that the cost of preparing and filing Forms C and C–AR will vary based on the characteristics of issuers, but we do not have the information to quantify such variation. For example, issuers with little operating activity may have less to disclose than issuers with more complex operations. Further, some issuers may rely to a greater extent on the services of outside professionals in preparing the required filings,[1386] while other issuers may choose to prepare and file the required forms without seeking the assistance of outside professionals.[1387] We also recognize the possibility that many if not all of the filing requirements may ultimately be performed by funding portals on behalf of issuers using their platforms.

The other significant cost for crowdfunding issuers, as identified by commenters, is the cost of an independent accounting review or audit. As discussed above, reviewed financial statements will be required in offerings of more than $100,000 but not more than $500,000, unless the issuer has audited statements otherwise available. Audited financial statements

[1374] *See* Rule 203(b) of Regulation Crowdfunding. *See also* Section II.B.3 above.

[1375] *See* FundHub Letter 2.

[1376] *See* Heritage Letter.

[1377] *Id.*

[1378] *See* NSBA Letter.

[1379] *See* SeedInvest Letter 2.

[1380] *See* SeedInvest Letter 1.

[1381] *Id.*

[1382] *See* SeedInvest Letter 4.

[1383] *See* StartEngine Letter 2.

[1384] *See* FundHub Letter 2.

[1385] *See* SeedInvest Letter 1.

[1386] *See, e.g.,* McGladrey Letter (suggesting that issuers that are startups may rely on outside professional services to a greater extent, which would increase costs).

[1387] For purposes of the PRA, we estimate that, for the average issuer, 25 percent of the burden associated with preparing and filing Form C and Form C–AR will be carried by outside professionals. *See* Section IV.C.1.a below.

are required in offerings of more than $500,000.

In a change from the proposal, issuers that have not previously sold securities in reliance on Section 4(a)(6) will be permitted to provide reviewed financial statements in offerings of more than $500,000 but not more than $1,000,000, unless the issuer has audited statements otherwise available. This change is expected to greatly reduce the initial costs associated with providing financial statements for first-time crowdfunding issuers offering more than $500,000 but not more than $1,000,000. According to one commenter, the difference in cost for reviewed versus audited financial statements could easily run into tens of thousands of dollars.[1388]

Some commenters argued that the cost of reviewed or audited financial statements of startup companies, which is the type of companies expected to use Regulation Crowdfunding, would be lower than our estimates because such companies would be less complex and because a competitive industry would develop to support the compliance and disclosure needs of securities-based crowdfunding issuers.[1389] Commenters provided estimates for the cost of an accounting review of financial statements that generally ranged from $1,500–$10,000.[1390] One commenter suggested that the cost of an accounting review is approximately 60% of the cost of an audit.[1391] Consistent with this comment, we also use an alternative way to estimate the cost of an accounting review: indirectly, from the cost of an audit.

Commenters provided several estimates of the cost of an audit for securities-based crowdfunding issuers, most of which ranged from $2,500 to $10,000.[1392] Other commenters, however, provided higher annual audit cost estimates of up to $20,000–$30,000.[1393] Based on a compilation of audit fee data from reporting companies for fiscal year 2014, the average cost of an audit for an issuer with less than $1 million in market capitalization and less than $1 million in revenues is approximately $20,000.[1394] We estimate the audit cost to be approximately $2,500 to $30,000. In the Proposing Release, we estimated the audit cost to be $28,700, which falls within this range. Assuming that, as suggested by one commenter,[1395] the accounting review cost is approximately 60% of the audit cost, this range of audit costs yields an estimate of the accounting review cost of approximately $1,500 to $18,000. In the Proposing Release, we estimated the accounting review cost to be $14,350, which falls within this range. Estimates of the cost of an accounting review that we received from commenters also fall within this range. In light of the wide range of estimates provided by commenters for the cost of a review or audit of financial statements, we use in this release a range of estimates ($1,500–$18,000 for the accounting review cost and $2,500–$30,000 for the audit cost) instead of a single point estimate for these anticipated costs for offerings.

As discussed below, in a change from the proposal, the final rules do not require issuers to provide reviewed or audited financial statements in the annual report, unless such statements are otherwise available, which is expected to yield cost savings on an annual basis compared with the proposal.

The table below presents the main adjusted cost estimates for the final rules.[1396]

	Offerings of $100,000 or less	Offerings of more than $100,000, but not more than $500,000	Offerings of more than $500,000
Fees paid to the intermediary.[1397]	$2,500–$7,500	$15,000–$30,000	$37,500–$56,250.
Costs per issuer for preparation and filing of Form C for each offering and related compliance costs.	$2,500	$2,500–$5,000	$5,000–$20,000.

[1388] *See* FundHub Letter 1. The comment letter also cites the commenter's article, which notes that ''while a review could be in the range of $1000 in some cases, a formal audit by a CPA typically starts at $5,000 and could be much more.'' *See* Kendall Almerico, *Has The SEC Made Equity Crowdfunding Economically Unfeasible?* Crowdfund Insider (Nov. 21, 2014), *available* at *http://www.crowdfundinsider.com/2013/11/26291-sec-made-equity-crowdfunding-economicallyunfeasible.*

[1389] *See, e.g.,* CrowdFunding Network Letter; dbb*mckennon* Letter; Denlinger Letter 2; FundHub Letter 2; Holm Letter; StartEngine Letter 1; StartEngine Letter 2.

[1390] *See, e.g.,* Grassi Letter (estimating the cost of accounting review for a $200,000 offering as $8,000); NPCM Letter (suggesting that the minimum cost to obtain an audit, or even a review, would be $5,000); StartEngine Letter 1 (estimating accounting review and audit costs of $1,500–$10,000 for smaller, newer companies); StartEngine Letter 2 (estimating accounting review costs of $1,950–$9,000).

[1391] *See* Traklight Letter.

[1392] *See, e.g.,* dbb*mckennon* Letter (estimating audit costs of $4,000–$9,000 for new companies with limited historical operations); Denlinger Letter 2 (noting that audit costs may be in the range of $2,000–$4,000 for a pre-revenue startup); FundHub Letter 2 (noting the emergence of CPA firms willing to perform a complete audit for a startup for $2,500 or less); NPCM Letter (suggesting that the minimum cost to obtain an audit, or even a review, would be $5,000); StartEngine Letter 1 (estimating accounting review and audit costs of $1,500–$10,000 for smaller, newer companies); StartEngine Letter 2 (estimating audit costs of $3,100–$9,000).

[1393] *See, e.g.,* Frutkin Letter (suggesting a ''rough estimate of $30,000 per audit''); Graves Letter (suggesting that audit costs can be upwards of $18,000 to $25,000); Startup Valley Letter (suggesting that audit fees can be up to $10,000 for small startups with no financials and can exceed $20,000 for companies that have been in business for a few years); Traklight Letter (suggesting that audit costs can be up to $20,000).

[1394] *See Audit Analytics, Auditor-Fees, available at http://www.auditanalytics.com/0002/audit-data-company.php.* The auditor fee database contains fee data disclosed by Exchange Act reporting companies in electronic filings since January 1, 2001. For purposes of our calculation, we averaged the auditor fee data for companies with both market capitalization and revenues of greater than zero and less than $1 million (the smallest subgroup of companies for which data is compiled). We note that the cost of an audit for many issuers conducting a securities-based crowdfunding offering in reliance on Section 4(a)(6) is likely to be lower than for the subset of Exchange Act reporting companies referenced above, because they likely would be at an earlier stage of development than issuers that file Exchange Act reports with us and, thus, could be less complex to audit.

[1395] *See* Traklight Letter.

[1396] In addition to the compliance costs outlined in the table, issuers also will incur costs to (1) obtain EDGAR access codes on Form ID; (2) prepare and file progress updates on Form C–U; and (3) prepare and file Form C–TR to terminate ongoing reporting. These additional compliance costs are discussed further below. In addition, for purposes of the Paperwork Reduction Act (''PRA''), we provide burden estimates for each of these filings obligations in Section IV.C.1, below.

[1397] For purposes of the table, we estimate the range of fees that an issuer would pay the intermediary assuming the following: (1) The fees would be calculated as a percentage of the offering amount ranging from 5% to 15% of the total offering amount for offerings of $100,000 or less, 5% to 10% for offerings between $100,000 and $500,000, and 5% to 7.5% for offerings of more than $500,000; and (2) the issuer is offering $50,000, $300,000 and $750,000, which are the mid-points of the offering amounts under each of the respective columns. The fees paid to the intermediary may, or may not, cover services to an issuer in connection with the preparation and filing of the forms identified in this table.

	Offerings of $100,000 or less	Offerings of more than $100,000, but not more than $500,000	Offerings of more than $500,000
Costs per issuer for preparation and filing of annual report on Form C–AR[1398] and related compliance costs.	$1,667	$1,667–$3,333	$3,333–$13,333.
Costs per issuer for review or audit of financial statements.	Not required	$1,500–$18,000	$2,500–$30,000. ($1,500–$18,000 for first-time issuers raising more than $500,000 but not more than $1,000,000.)[1399]

We do not have additional data on the costs likely to be incurred by crowdfunding issuers to prepare the required disclosures beyond the information discussed above. Overall, we recognize that cost estimates may vary from issuer to issuer and from service provider to service provider. However, even with the additional accommodations provided in the final rules, the costs of compliance may be significant for some issuers.

b. General Disclosure Requirements

The statute and the final rules related to issuer disclosures are intended to reduce the information asymmetries that currently exist between small businesses and investors. Small private businesses typically do not disclose information as frequently or as extensively as public companies, if at all. Moreover, unlike public companies, small private businesses generally are not required to hire an independent accountant to review financial statements. When information about a company is difficult to obtain or the quality of the information is uncertain, investors are at risk of making poorly-informed investment decisions about that company.

Such information asymmetries may be especially acute in the securities-based crowdfunding market because the market includes startups and small businesses that have significant risk factors and other characteristics that may have led them to be rejected by other potential funding sources, including banks, VCs and angel investors. In addition, the securities-based crowdfunding market may attract unsophisticated investors who may not have the resources necessary to gather and analyze information about issuers before investing or to effectively monitor issuers after investing. Moreover, investment limits in securities-based crowdfunding offerings in reliance on Section 4(a)(6) will likely lead to investors having smaller stakes in the firm, which may reduce their incentives to monitor or gather information for a given investor. These considerations may give rise to adverse selection and moral hazard in offerings in reliance on Section 4(a)(6). For instance, some issuers may use capital to fund riskier projects than what was disclosed to investors, or they may not pursue their stated business objectives. If investors in securities-based crowdfunding have limited information about issuers or a limited ability to monitor such issuers, they may seek higher returns for their investment or choose to withdraw from the securities-based crowdfunding market altogether, which would increase the cost of capital to issuers and limit the capital formation benefits of the final rules. In addition, investors in offerings made in reliance on Section 4(a)(6) may make relatively small investments, due in part to the application of investment limitations. This potential dispersed investor base may make it difficult for investors to solve collective action problems in monitoring the issuer.

The statute and the final rules seek to reduce information asymmetries by requiring issuers to file specified disclosures with the Commission for offerings made in reliance on Section 4(a)(6) during the offering and on an annual basis thereafter.[1400] Issuers also are required to provide these disclosures to investors and, in the case of offering documents, to investors and the relevant intermediary. The disclosure requirements, which are described above,[1401] are more extensive than those required under some other existing exemptions from registration. For example, although the current requirements of Tier 1 Regulation A offerings include similar initial financial disclosures, issuers in Tier 1 offerings are not required to file ongoing reports.[1402] Issuers using the Rule 504 exemption under Regulation D to raise up to $1 million are not required to provide audited financial statements, and there are no periodic disclosure requirements. Regulation D offerings under Rules 505 and 506 for up to $2 million require issuers to provide audited current balance sheets (and unaudited statements of income, cash flows and changes in stockholders' equity) to non-accredited investors, but there are no periodic reporting requirements. The disclosure requirements in Regulation Crowdfunding are expected to benefit investors by enabling them to better evaluate the issuer and the offering, monitor how the issuer is performing over time and be aware of when the issuer may terminate its ongoing reporting obligations. This will allow investors with various risk preferences to invest in the offerings best suited for their risk tolerance, thus improving allocative efficiency.

The disclosure requirements also may improve informational efficiency in the market. Specifically, the required disclosure may provide investors with a useful benchmark to evaluate the issuer and compare the issuer to other private issuers both within and outside of the securities-based crowdfunding market.[1403] Additionally, disclosure by issuers engaging in crowdfunding transactions in reliance on Section 4(a)(6) may inform financial markets more generally about new consumer trends and new products, thus creating externalities that benefit other types of investors and issuers.

[1398] As noted above, we estimate that these costs are approximately two-thirds of the costs for preparation and filing of Form C.

[1399] First-time crowdfunding issuers within this offering range will be permitted to provide reviewed financial statements.

[1400] *See* Section 4A(b). *See also* Rules 201, 202 and 203 of Regulation Crowdfunding.

[1401] *See* Section II.B.1 above.

[1402] However, issuers in Tier 1 Regulation A offerings are required to provide information about sales in such offerings and to update certain issuer information by electronically filing a Form 1–Z exit report with the Commission not later than 30 calendar days after the termination or completion of an offering. Further, Tier 1 offerings must be qualified by the Commission and are subject to state registration requirements. Issuers in Tier 2 offerings are subject to annual, semiannual and current reporting requirements. *See Regulation A Adopting Release.*

[1403] *See* Christian Leuz and Peter Wysocki, *Economic Consequences of Financial Reporting and Disclosure Regulation: A Review and Suggestions for Future Research,* (Working Paper, University of Chicago) (2008), *available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1105398.*

We recognize, however, that the disclosure requirements also will have associated limitations and costs, including the direct costs of preparation, certification, independent accounting review (when necessary) and dissemination of the disclosure documents. As noted above, the disclosure requirements for offerings made in reliance on Section 4(a)(6) are more extensive, in terms of breadth and frequency, than those for other exempt offerings. The statute also provides us with the discretion to impose additional requirements on issuers engaging in crowdfunding transactions, and in some cases, the final rules require issuers to disclose information beyond what is specifically mandated by the statute.[1404] We recognize that these additional discretionary disclosure provisions may impose additional compliance costs on issuers compared with the proposal. However, we believe these provisions will improve investor decision-making and may ultimately benefit issuers by improving price efficiency in the securities-based crowdfunding market. Although requiring less disclosure could impose lower compliance costs, we believe that the disclosure requirements we are adopting appropriately consider the need to enhance the ability of issuers relying on Section 4(a)(6) to raise capital while enabling investors to make informed investment decisions. In response to the suggestion by some commenters that issuers not be required to disclose information in multiple places,[1405] under the final rules, an issuer is not required to repeat disclosure that is already provided in the issuer's financial statements. This may help to mitigate the cost of compliance for issuers.

We note that the disclosure requirements may have indirect costs to the extent that information disclosed by issuers relying on Section 4(a)(6) can be used by their competitors, resulting in a potential loss of a competitive advantage or intellectual property, particularly for high-growth issuers and issuers engaged in significant research and development. Requiring significant levels of disclosure at an early stage of an issuer's lifecycle may affect an issuer's competitive position and may limit the use of the exemption in Section 4(a)(6) by issuers who are especially concerned with confidentiality. These disclosure costs also may make other types of private offerings more attractive to potential securities-based crowdfunding issuers. For example, the 2013 changes to Rule 506 of Regulation D,[1406] which allow for general solicitation, subject to certain conditions, may make it a more attractive option for small business financing and, thus, may divert potential issuers from crowdfunding.

In addition, under the statute and the final rules, issuers that complete a crowdfunding offering in reliance on Section 4(a)(6) are subject to ongoing reporting requirements,[1407] which will increase compliance costs. The ongoing reporting, however, may provide a liquidity benefit for secondary sales of securities issued in crowdfunding transactions and make the prices of such securities more informationally efficient, should a secondary market develop.

c. Financial Condition and Financial Statement Disclosure Requirements

Consistent with the statute, the final rules require narrative disclosure about the issuer's financial condition, including, to the extent material, liquidity, capital resources and the issuer's historical results of operations.[1408] We expect that this discussion will inform investors about the financial condition of the issuer, without imposing significant costs on issuers, because issuers likely will already have such information readily available. In addition, the final rules do not prescribe the content or format for this information.

With respect to the requirement to provide financial statements, the final rules implement tiered financial disclosure requirements based on the aggregate amount of securities offered and sold in reliance on Section 4(a)(6) during the preceding 12-month period, inclusive of the offering amount in the offering for which disclosure is being provided.[1409] The disclosure requirements will provide investors with more information than might otherwise be obtained in private offerings, but also may create additional costs for those issuers that have limited financial and accounting expertise necessary to produce the financial disclosures envisioned by the statute and the final rules.

The final rules, consistent with the proposed rules, require issuers to provide a complete set of their financial statements (balance sheets, statements of comprehensive income, statements of cash flows and statement of changes in stockholders' equity) that are prepared in accordance with U.S. GAAP and cover the shorter of the two most recently completed fiscal years or the period since inception.[1410] We could have chosen an alternative that allows financial statements to be prepared in accordance with other comprehensive bases of accounting, as some commenters suggested.[1411] Such an alternative may have mitigated costs for some issuers, especially those smaller issuers that historically have prepared their financial statements in accordance with other comprehensive bases of accounting rather than U.S. GAAP. However, as we discussed above, this alternative would reduce the comparability of financial statements across issuers and might not provide investors with a fair representation of a company's financial position and results of operations. Further, it may be difficult for investors to determine whether the issuer complied with such basis of accounting.[1412]

The final rules also specify that an issuer may conduct an offering in reliance on Section 4(a)(6) using financial statements for the fiscal year prior to the most recently completed fiscal year, provided that not more than 120 days have passed since the end of the issuer's most recently completed fiscal year, and financial statements for the most recently completed fiscal year are not otherwise available.[1413] This may impose a cost on investors to the extent that the investors do not have more current financial information about the issuer. However, this concern is somewhat mitigated by the requirement that issuers include a discussion of any material changes or trends known to management in the financial condition and results of

[1404] *See* Section 4A(b)(5). *See also* Section II.B.1.a.i(g) for a description of the additional disclosure requirements.

[1405] *See, e.g.,* EY Letter (noting that certain required disclosure would be included in an issuer's financial statements); Grassi Letter (same).

[1406] *See Rule 506(c) Adopting Release,* note 5.

[1407] *See* Rule 202 of Regulation Crowdfunding.

[1408] *See* Rule 201(s) of Regulation Crowdfunding. *See also* Section II.B.1.a.(ii)(a) above.

[1409] *See* Rule 201(t) of Regulation Crowdfunding. *See also* Section II.B.1.a.(ii)(b) above.

[1410] *See* Instruction 3 to paragraph (t) of Rule 201 of Regulation Crowdfunding.

[1411] *See, e.g.,* ABA Letter (for offerings of $100,000 or less, but stating that the Commission could require providing U.S. GAAP financial statements if available); AICPA Letter; CFIRA Letter 5; CFIRA Letter 7; CrowdCheck Letter 4; EarlyShares Letter; EY Letter (for offerings of $100,000 or less, unless U.S. GAAP financial statements are available); Grassi Letter; Graves Letter (for issuers with less than $5 million in revenue); Mahurin Letter (stating that simple Excel spreadsheets accompanied by bank records should meet the financial statement requirements); Milken Institute Letter (for early-stage issuers); NFIB Letter; SBEC Letter; StartupValley Letter; Tiny Cat Letter (for offerings of less than $500,000); Whitaker Chalk Letter (for offerings of less than $500,000 if the issuer has an asset or income level below a certain level).

[1412] *See* Section II.B.1.a.(ii)(b) above.

[1413] *See* Instruction 10 to paragraph (t) of Rule 201 of Regulation Crowdfunding.

operations subsequent to the period for which financial statements are provided.[1414]

Requiring financial statements covering the two most recently completed fiscal years is expected to benefit investors by providing a basis for comparison against the most recently completed fiscal year and by allowing investors to identify changes in the development of the business. Compared to an alternative that we could have selected, that of requiring financial statements covering only the most recently completed fiscal year, as some commenters suggested,[1415] requiring a second year of financial statements will to some degree increase the cost for the issuer. Also, to the extent that the issuer had little or no operations in the prior year, the benefit of comparability may not be realized. We recognize that many crowdfunding issuers may not have any financial history, and investors may make investment decisions without a track record of issuer performance, relying largely on the belief that an issuer can succeed based on their business plan and other factors. Nevertheless, for those issuers that do have a financial history, we believe this disclosure can contribute to better informed investment decisions and improve the overall allocative efficiency of the securities-based crowdfunding market.

For offerings of $100,000 or less, the final rules require the issuer to provide financial statements that are certified by the principal executive officer to be true and complete in all material respects.[1416] The final rules include a form of certification for the principal executive officer to provide in the issuer's offering statement, which we believe will help issuers comply with the certification required by the statute and the final rules.[1417] However, if reviewed financial statements or audited financial statements are otherwise available, they must be provided.[1418]

The proposed rules would have required income tax returns for the most recently completed year (if any). In a change from the proposed rules, consistent with the suggestions of some commenters and to respond to privacy concerns,[1419] the final rules do not require complete tax returns and instead require that an issuer disclose its total income, taxable income and total tax, or the equivalent line items from the applicable form, and have the principal executive officer certify that those amounts reflect accurately the information in the issuer's federal income tax returns.[1420] We believe that the requirement to provide selected items from the return, rather than the return itself, will alleviate some of the privacy concerns for issuers. This change may increase record keeping costs for issuers and give rise to potential transcription errors. It also may reduce the amount of information available to investors, but as we noted in the Proposing Release, it is not clear to what extent all of the information presented in a tax return would be useful for an investor evaluating whether or not to purchase securities from the issuer. Finally, although principal executive officers will incur some incremental liability for their certification that these amounts reflect accurately the information in the issuer's federal income tax return, we do not expect this change from the proposal to impose substantial additional costs on officers or issuers given the limited scope of the required certification.

Moreover, the final rules specify that if an issuer is offering securities in reliance on Section 4(a)(6) before filing a tax return for the most recently completed fiscal year, the issuer may use information from the tax return filed for the prior year, on the condition that the issuer provides information from the tax return for the most recently completed fiscal year when it is filed, if it is filed during the offering period.[1421] This accommodation is expected to benefit issuers by enabling them to engage in transactions during the time period between the end of their fiscal year and when they file their tax return for that year. This may impose a cost on investors because they might not receive the most up-to-date tax information about the issuer.

The proposed rules would have required financial statements for offerings exceeding $100,000 but not exceeding $500,000 to be reviewed by a public accountant independent of the issuer and financial statements for offerings exceeding $500,000 to be audited by a public accountant independent of the issuer. The final rules specify that the required financial statements must be reviewed by a public accountant that is independent of the issuer for offerings exceeding $100,000 but not exceeding $500,000.[1422] If, however, financial statements of the issuer are available that have been audited by a public accountant that is independent of the issuer, the issuer must provide those financial statements instead and need not include the reviewed financial statements.[1423]

Similar to the proposal, issuers in offerings exceeding $500,000 must provide audited financial statements. In a change from the proposal, the final rules specify that issuers that have not previously sold securities in reliance on Section 4(a)(6) and are conducting offerings with a target offering amount exceeding $500,000 but not exceeding $1,000,000 can provide reviewed financial statements, unless audited financial statements are otherwise available.[1424] Audited financial statements can benefit investors in evaluating offerings by issuers with substantive prior business activity by providing them with potentially higher-quality financial statements. However, as noted by a number of commenters [1425] and discussed above, requiring audited financial statements could significantly increase the cost to issuers compared to requiring reviewed financial statements.[1426] Further, for issuers that are newly formed, with no or very limited operations, and for small issuers, the benefit of the audit may not justify its cost.

As discussed above [1427] the approach in the final rules of requiring reviewed financial statements rather than audited financial statements, unless otherwise

[1414] *See* Rule 201(s) of Regulation Crowdfunding.

[1415] *See, e.g.,* Denlinger Letter 1; EY Letter; Fryer Letter; Grassi Letter; Joinvestor Letter; Public Startup Letter 2; RFPIA Letter; RocketHub Letter.

[1416] *See* Section 4A(b)(1)(D)(i). *See also* Rule 201(t)(1) of Regulation Crowdfunding.

[1417] *See* Instruction 4 to paragraph (t) of Rule 201 of Regulation Crowdfunding.

[1418] *See* Rule 201(t)(1) of Regulation Crowdfunding.

[1419] *See, e.g.,* AICPA Letter (stating that disclosure of an issuer's tax return ''. . . has the potential to cause serious problems. Tax returns are intended to be confidential and should remain so.''); Public Startup Letter 2; RocketHub Letter; SBM Letter; Wilson Letter (suggesting that personal income tax information should be on a voluntary basis only); Zhang Letter.

[1420] *See* Rule 201(t)(1) of Regulation Crowdfunding.

[1421] *See* Instruction 6 to paragraph (t) of Rule 201 of Regulation Crowdfunding.

[1422] *See* Rule 201(t)(2) of Regulation Crowdfunding.

[1423] *Id.*

[1424] *See* Rule 201(t)(3) of Regulation Crowdfunding. *See also* Section II.B.1.a.ii.

[1425] *See, e.g.,* AEO Letter; Angel Letter 1; AWBC Letter; CFIRA Letter 5; CfPA Letter; CrowdFundConnect Letter; EarlyShares Letter; EMKF Letter; EY Letter; Finkelstein Letter; FundHub Letter 1; Generation Enterprise Letter; Grassi Letter; Graves Letter; Guzik Letter 1; Hakanson Letter; Holland Letter; Johnston Letter; Kickstarter Coaching Letter; McGladrey Letter; Milken Institute Letter; NACVA Letter; NFIB Letter; NPCM Letter; NSBA Letter; PBA Letter; Reed Letter; RocketHub Letter; Saunders Letter; SBA Office of Advocacy Letter; SBEC Letter; SBM Letter; Seyfarth Letter; Verrill Dana Letter; WealthForge Letter; Wefunder Letter; Woods Letter; Zeman Letter.

[1426] *See also* Section III.B.3.a.

[1427] *Id.*

available, for first-time crowdfunding issuers that undertake offerings of more than $500,000 but not more than $1,000,000 is expected to reduce the costs associated with financial statements for such first-time issuers compared to the proposed requirement of audited financial statements for all issuers in offerings of more than $500,000. This accommodation is expected to alleviate the significant upfront cost of an audit for first-time issuers that have not yet raised capital in a crowdfunding offering and may be more financially constrained. To the extent that their financing needs have not been met through alternative financing methods, first-time crowdfunding issuers are likely to be more financially constrained than issuers that have already established a track record of successful crowdfunding offerings. We recognize, however, that there are costs associated with this accommodation. Not requiring audited financial statements for offerings of more than $500,000 but not more than $1,000,000 by first-time issuers may reduce the quality of financial disclosure, which may be a more significant concern for new crowdfunding issuers due to the fact that their more limited track record may translate into a higher level of information asymmetry between issuers and investors. The potentially reduced quality of financial disclosure associated with offerings of more than $500,000 by first-time issuers may affect the likelihood of detecting fraud, which would decrease investor protection. To the extent that investors anticipate such increased risks, issuers may face a higher cost of capital or be unable to raise the entire amount offered, which would diminish the capital formation benefits of the final rule. We note that some first-time issuers in offerings of more than $500,000 but not more than $1,000,000 may have audited statements otherwise available, which could partly mitigate the described effects. We also note that some first-time issuers concerned about investor confidence in the quality of their financial statements may voluntarily provide audited financial statements.

Tiered disclosure requirements aim to partially mitigate the impact of the fixed component of compliance costs on issuers in smaller securities-based crowdfunding offerings. However, it is possible that the thresholds may have an adverse competitive effect on some issuers. For example, the cost of reviewed financial statements may cause issuers in offerings exceeding but close to $100,000 to incur significantly higher offering costs as a percentage of the amount offered compared to issuers offering less than but close to $100,000. Similarly, the cost of audited financial statements may cause issuers in follow-on crowdfunding offerings exceeding but close to $500,000 to incur significantly higher offering costs as a percentage of the amount offered compared to issuers in offerings of less than but close to $500,000. We note, however, that the issuer has the ability to select its offering amount, and since the choice of offering amount determines which financial statement requirements will apply to its offering, the issuer, by choosing its offering amount, effectively also chooses its financial statement requirements.

We considered the alternative of exempting issuers with no operating history or issuers that have been in existence for fewer than 12 months from the requirement to provide financial statements. We believe that financial statements contain valuable information that can aid investors in making better informed decisions, particularly, when evaluating early-stage issuers characterized by a high degree of information asymmetry. We also expect that other accommodations in the final rules will help alleviate some of these issuer compliance costs.

Similar to the proposed rules, financial statements must be reviewed in accordance with SSARS issued by the AICPA.[1428] Although we could have chosen to develop a new review standard for purposes of the final rules, we believe that issuers will benefit from using the AICPA's widely-utilized review standard. We believe that many accountants reviewing financial statements of issuers raising capital in reliance on Section 4(a)(6) are familiar with the AICPA's standards and procedures for review, which should help to partly mitigate review costs.

As described above, the final rules require certain financial statements to be reviewed or audited by a public accountant that is independent of the issuer.[1429] In a change from the proposed rules, the final rules permit the use of independence standards set forth in Rule 2–01 of Regulation S–X or the independence standards of the AICPA.[1430] This change to allow the use of AICPA standards may reduce issuer compliance costs to the extent that there are higher costs associated with engaging an accountant that satisfies the independence standards set forth in Rule 2–01 of Regulation S–X. The change also will increase the number of public accountants able to perform the reviews or audits, which may lead to a decrease in the price of their services and thus a decrease in the direct issuance costs to issuers compared with the proposal. The benefit from this change will accrue to issuers making offerings of $100,000 to $1,000,000. To the extent that the AICPA independence standards impose fewer restrictions with respect to potential conflicts of interest than the independence standards in Rule 2–01 of Regulation S–X, however, this accommodation may weaken investor protection. Moreover, any decrease in investor confidence in the reliability of financial statements as a result of this change will limit the capital formation benefits of the final rules.

In addition, the final rules require an issuer to file a signed review report or audit report, whichever is applicable, and notify the public accountant of the issuer's intended use of the report in the offering.[1431] This can impose an additional cost on issuers to the extent that the accountant or auditor increases the fee associated with the review or audit to compensate for any additional liability that may result from the requirement to file the report. As discussed above,[1432] in a change from the proposal, the final rules do not permit qualified audit reports. This change may impose an additional cost on issuers, which we are not able to quantify. However, this change is expected to provide investors with more reliable financial statements, which should enable investors to better evaluate the prospects of issuers relying on Section 4(a)(6) and thus make better informed investment decisions. By providing investors with a greater degree of confidence in the reliability of the financial information, audited financial statements will reduce the information asymmetry about the issuer's financial condition that exists between issuers and potential investors. This decrease in information asymmetry may lead to greater capital formation.

In a change from the proposed rules, the final rules do not require financial statements in the annual report that meet a standard of review equal to the highest standard provided in a prior offering.[1433] The final rules require an annual report to include financial statements of the issuer to be certified

[1428] *See* Rule 201(t)(2) of Regulation Crowdfunding. *See also* Instruction 8 to paragraph (t) of Rule 201 of Regulation Crowdfunding.

[1429] *See* Section II.B.1 above.

[1430] *See* Instruction 10 to paragraph (t) of Rule 201 of Regulation Crowdfunding.

[1431] *See* Instructions 8 and 9 to paragraph (t) of Rule 201 of Regulation Crowdfunding.

[1432] *See* Section II.B.1.a.(ii)(b) above.

[1433] *See* Section II.B.2.c above.

by the principal executive officer of the issuer as true and complete in all material respects.[1434] Issuers that otherwise have available financial statements that have been reviewed or audited by an independent certified public accountant, must provide them and will not be required to have the principal executive officer certification.[1435] As discussed above, these changes will reduce the compliance costs to issuers compared with the proposal.[1436] At the same time, they may reduce the quality of the ongoing financial statements, resulting in a potential decrease in investor protection and investor confidence in the quality of these financial statements. We note that some issuers may have reviewed or audited financial statements otherwise available, which would partly mitigate this concern. In addition, an issuer is able to voluntarily provide financial statements that meet a higher standard, so if an issuer is concerned about investor confidence in the quality of financial statements, it can choose to provide reviewed or audited financial statements.

d. Issuer Filing Requirements

As discussed above, issuers will incur costs to prepare and file the various disclosures required under Regulation Crowdfunding.[1437] The statute requires issuers to file and provide to investors certain specified information at the time of offering, such as information about the issuer, officers and directors, and certain shareholders, a description of the business, a description of the purpose and intended use of proceeds, target offering amount and the deadline to reach it, offering price (or the method for determining the price) and other terms of the offering, a description of the financial condition of the issuer, as well as certain other disclosures.[1438] These disclosure requirements are expected to strengthen investor protection and enable investors to make better informed investment decisions. The statute does not specify a format that issuers must use to present the required disclosures to the Commission. As noted above, the final rules require issuers to file the mandated disclosure on EDGAR using new Form C.[1439]

Form C requires certain disclosures to be submitted using an XML-based filing,[1440] while allowing the issuer to customize the presentation of other required disclosures. This approach provides issuers with the flexibility to present the required disclosures in a cost-effective manner, while also requiring the disclosure of certain key offering information in a standardized format, which we believe will benefit investors and help facilitate capital formation.

We expect that requiring certain disclosures to be submitted using XML-based filings will produce benefits for issuers, investors and the Commission. For instance, using information filed pursuant to these requirements, investors can track capital generated through crowdfunding offerings without manually inspecting each filing. The ability to efficiently collect information on all issuers also can provide an incentive for data aggregators or other market participants to offer services or analysis that investors can use to compare and choose among different offerings. For example, reporting key financial information using XML-based filings will allow investors, analysts and data aggregators to more easily compile, analyze and compare information about the capital structure and financial position of various issuers. XML-based filings also will provide the Commission with data about the use of the new crowdfunding exemption that will allow the Commission to evaluate whether the rules implementing the exemption include appropriate investor protections and are effectively facilitating capital formation.

Certain provisions of the filing requirements in the final rules provide flexibility and potentially reduce the compliance burden compared with the proposal. The final rules allow issuers to customize the presentation of their non-XML disclosures and file those disclosures as exhibits to Form C in PDF format as official filings, consistent with the suggestions of some commenters.[1441] In addition, the final rules include an optional Question and Answer (''Q&A'') format that issuers may opt to use to provide the disclosures that are not required to be filed in XML format.[1442] Relative to some other possible formats, this Q&A format may facilitate the preparation of the Form C disclosures by crowdfunding issuers. To the extent that this provision lowers the compliance cost for issuers, it may encourage greater use of Regulation Crowdfunding for raising capital.

The final rules require that issuers file a Form C–U: Progress Update to describe the progress of the issuer in meeting the target offering amount.[1443] In a change from the proposed rules, based on concerns expressed by commenters, the final rules permit issuers to satisfy the progress update requirement by relying on the relevant intermediary to make publicly available on the intermediary's platform frequent updates about the issuer's progress toward meeting the target offering amount. This change is expected to mitigate some of the direct cost for the issuer without reducing the amount of contemporaneous information available to investors. However, an issuer relying on the intermediary to make publicly available frequent progress updates must still file a Form C–U at the end of the offering to disclose the total amount of securities sold in the offering.[1444] Although the final offering information likely will be available on the registered intermediary's Web site, having the information available on EDGAR will allow comparisons across platforms and provide ongoing access to historical information for future investor analyses that may otherwise be difficult or impossible to perform by accessing information from each individual portal. We expect the costs of preparing updates on Form C–U to vary among issuers but to be relatively small.[1445]

As noted above, the statute also requires an issuer to file and provide to investors information about the issuer's financial condition on at least an annual basis, as determined by the Commission.[1446] Ongoing disclosure requirements are expected to strengthen investor protection. Ongoing disclosure requirements are also expected to facilitate better informed investment decisions in secondary market transactions and enhance the informational efficiency of prices of crowdfunding securities, should a secondary market for such securities develop. To implement this statutory requirement, the final rules require any

[1434] *See* Rule 202(a) of Regulation Crowdfunding.

[1435] *Id.*

[1436] *See* Section III.B.3.a. above.

[1437] *See* Section III.B.3.a. above.

[1438] *See* Rule 201 of Regulation Crowdfunding. *See also* Section II.B.1 above.

[1439] *See* Rule 203(a) of Regulation Crowdfunding. *See also* Section II.B.3 above.

[1440] *See* Instruction to paragraph (a)(1) of Rule 203 of Regulation Crowdfunding. *See also* Section II.B.3 above.

[1441] *See, e.g.,* CFIRA Letter 6; CFIRA Letter 7; CrowdCheck Letter 1; Grassi Letter; Hackers/Founders Letter; RocketHub Letter; Wefunder Letter; Wilson Letter.

[1442] *See* Item 1 of General Instruction III to Form C.

[1443] *See* Rule 203(a)(3) of Regulation Crowdfunding. *See also* Sections II.B.1.b and II.B.3 above.

[1444] *See* Rule 203(a)(3)(iii) of Regulation Crowdfunding.

[1445] For purposes of the PRA, we estimate that an issuer's compliance with the Form C–U requirement will result, on average, in approximately 0.50 burden hours per issuer. *See* Section IV.C.1.a below.

[1446] *See* Section 4A(b)(4).

issuer that has sold securities in a crowdfunding transaction in reliance on Section 4(a)(6) to file annually with the Commission a new Form C–AR: Annual Report, no later than 120 days after the end of each fiscal year covered by the report.[1447] We believe that annual reports will inform investors in their portfolio decisions and can enhance price efficiency. Moreover, as discussed above, under the statute and the final rules, the securities will be freely tradable after one year,[1448] and therefore, this information also will benefit potential future holders of the issuer's securities by enabling them to update their assessments as new information is made available through the annual updates, potentially allowing for more efficient pricing. More generally, these continued disclosures also may help facilitate the transfer of securities in secondary markets after the one-year restricted period ends, which can mitigate some of the potential liquidity issues that are unique to the securities-based crowdfunding market, as discussed above.

As an alternative, we could have added a current reporting requirement, consistent with the view of some commenters that there may be major events that occur between annual reports about which investors would want to be updated.[1449] Such an alternative could result in better informed investment decisions. We are concerned, however, that the benefits of a current reporting requirement may not justify the additional compliance costs associated with such a requirement, especially given the size and early stage of development of the issuers likely to be involved in offerings in reliance on Section 4(a)(6).

Any issuer terminating its annual reporting obligations will be required to file a notice under cover of Form C–TR: Termination of Reporting to notify investors and the Commission that it will no longer file and provide annual reports pursuant to the requirements of Regulation Crowdfunding.[1450] The final rules enable issuers to terminate reporting if: (1) The issuer becomes a reporting company required to file reports under Exchange Act Sections 13(a) or 15(d); (2) the issuer or another party repurchases all of the securities issued pursuant to Securities Act Section 4(a)(6), including any payment in full of debt securities or any complete redemption of redeemable securities; or (3) the issuer liquidates or dissolves its business in accordance with state law.[1451] We expect the costs of preparing Form C–TR to vary among issuers but to be relatively small.[1452]

In a change from the proposed rules, after considering the comments, the final rules also permit termination of ongoing reporting in two additional circumstances: (1) The issuer has filed at least one annual report and has fewer than 300 holders of record, or (2) the issuer has filed annual reports for at least the three most recent years and has total assets not exceeding $10,000,000.[1453] This change is expected to mitigate some of the compliance cost for small issuers and make the final rules a more attractive option for capital formation among small issuers, and at the same time, help to ensure that larger issuers with a significant number of investors continue to provide relevant disclosure.

This change may, however, make relevant information about the financial condition of certain issuers no longer available to investors, resulting in less informed investor decisions. This change may affect a large number of securities-based crowdfunding offerings, since it is likely that many crowdfunding issuers will either have fewer than 300 holders of record or assets below $10 million. Termination of ongoing reporting may result in a decrease in investor protection, particularly in the presence of an investor base with a limited degree of sophistication. Allowing issuers to terminate ongoing reporting can make monitoring of the issuer more difficult for investors and can potentially make it more difficult to detect fraud. We note, however, that the investment limits in the final rules serve to limit the amount of each investor's capital that is exposed to these and other risks of securities-based crowdfunding offerings. We further note that the investment amounts involved in these transactions might limit a typical investor's incentives to analyze the information contained in ongoing disclosures and to monitor issuers, even if all issuers are required to provide ongoing disclosures.

Nevertheless, the risk that an issuer in a securities-based crowdfunding offering may terminate ongoing reporting in the future may discourage prospective investors from making an initial investment in offerings in reliance on Section 4(a)(6) or may cause issuers to obtain lower valuations for the securities they offer, which may limit some of the capital formation benefits of the final rules. We note that issuers who believe that increased investor confidence justifies the cost of annual reporting would be able to continue ongoing reporting voluntarily.

Termination of ongoing reporting may also reduce the informational efficiency of prices and secondary market liquidity, making it more difficult for investors to exit their holdings after the expiration of resale restrictions. A lack of ongoing reporting may reduce the likelihood that a secondary market for such securities develops. We recognize, however, that a secondary market for securities in offerings in reliance on Section 4(a)(6) may not develop even if all issuers are required to provide ongoing reports.

The asset size cap in one of the termination thresholds may create adverse competitive effects for issuers close to but above the termination threshold.

e. Advertising—Notice of Offering

The statute and the final rules prohibit an issuer from advertising the terms of the offering, except for notices that direct investors to an intermediary's platform.[1454] The terms of the offering include the amount offered, the nature of the securities, price of the securities and length of the offering period.[1455] The final rules allow an issuer to publish a notice about the terms of the offering made in reliance on Section 4(a)(6), subject to certain limitations on the content of the notice.[1456] The notices are similar to the ''tombstone ads'' permitted under Securities Act Rule 134,[1457] except that the final rules require the notices to direct investors to the intermediary's platform, through which the offering made in reliance on Section 4(a)(6) is being conducted.

We believe this approach will allow issuers to generate interest in offerings and to leverage the power of social media to attract investors, potentially resulting in enhanced capital formation. At the same time, we believe it also will protect investors by limiting the ability of issuers to provide certain advertising materials without also directing

[1447] *See* Rule 202(a) of Regulation Crowdfunding. *See also* Section II.B.2 above for a discussion of the disclosure requirements of Form C–AR.

[1448] *See* Section 4A(e). *See also* Rule 501 of Regulation Crowdfunding.

[1449] *See, e.g.,* ABA Letter; Angel Letter 1; Denlinger Letter 1; EY Letter; Grassi Letter; Hackers/Founders Letter; RocketHub Letter.

[1450] *See* Rule 203(b)(3) of Regulation Crowdfunding.

[1451] *See* Rule 202(b) of Regulation Crowdfunding.

[1452] For the purposes of the PRA, we estimate that issuers will spend, on average, approximately 1.5 burden hours to complete this task. *See* Section IV.C.1.a below.

[1453] *Id.*

[1454] *See* Section 4A(b)(2). *See also* Rule 204 of Regulation Crowdfunding.

[1455] *See* Instruction to Rule 204 of Regulation Crowdfunding.

[1456] *See* Rule 204(b) of Regulation Crowdfunding. *See also* Section II.B.4 above.

[1457] 17 CFR 230.134.

investors to the disclosures, available on the intermediary's platform, that are required for an offering made in reliance on Section 4(a)(6). Moreover, this requirement is not expected to impose costs on market participants.

As an alternative, we could have required communications about the offering to be conducted through the intermediary, as suggested by some commenters.[1458] To the extent that an issuer might be able to inform more investors about its offering if it is not limited to communications through the intermediary's platform, this alternative might limit the issuer's ability to inform a wide range of investors about its offering. Limited recognition among prospective investors might be a particularly significant hurdle for early-stage or small issuers. As another alternative, we could have required issuers to file advertising notices with the Commission and/or the relevant intermediary, as suggested by other commenters.[1459] While this could increase the likelihood of issuer compliance with advertising restrictions, it also would impose an additional cost on the issuer. Overall, in light of the restrictions on advertising already in place, it is not clear to what extent, if any, additional restrictions would enhance investor protection.

Some commenters, suggesting that advertising restrictions are unnecessary because sales must occur through an intermediary's platform,[1460] recommended allowing the issuer more leeway to publicize its business or offering on its own Web site or social media platform so long as the specific terms of the offering could be found only through the intermediary's platform,[1461] and recommended allowing advertising notices to have a section for supplemental information highlighting certain intangible purposes such as a particular social cause.[1462] The alternative of relaxing or eliminating restrictions on advertising could enhance capital formation efforts of issuers. However, it might also result in a cost to investors if they make less informed investment decisions based on incomplete or selectively presented information about the offering contained in advertising materials.

f. Compensation of Persons Promoting the Offering

The statute and the final rules prohibit an issuer from compensating, or committing to compensate, directly or indirectly, any person to promote the issuer's offering through communication channels provided by the intermediary unless the issuer takes reasonable steps to ensure that such person clearly discloses the receipt of such compensation (both past and prospective) each time a promotional communication is made.[1463]

We believe this requirement will benefit the securities-based crowdfunding market by allowing investors to make better informed investment decisions. Although the requirement to take steps to ensure disclosure of compensation paid to persons promoting the offering will impose compliance costs on issuers, we believe that investors will benefit from knowing if the comments about the investment they are considering are being made by a promoter who is compensated by the issuer and therefore may not be providing an independent, disinterested perspective.

The final rules also require that an issuer not compensate or commit to compensate, directly or indirectly, any person to promote its offerings outside of the communication channels provided by the intermediary, unless the promotion is limited to notices that comply with the advertising rules.[1464] We believe this will similarly serve to improve investors' ability to make informed judgments about the information they encounter through various communication channels about the issuer, and thus, to make better informed investment decisions.

g. Oversubscription and Offering Price

The final rules permit an issuer to accept investments in excess of the target offering amount, subject to the $1 million limitation, but require the issuer to disclose the maximum amount the issuer will accept and how shares in oversubscribed offerings will be allocated.[1465] We continue to believe that permitting oversubscriptions will provide flexibility to issuers so that they can raise the amount of capital they deem necessary to finance their businesses. Given the uncertainty on the part of the issuer about potential market demand for the issuer's securities, we believe it is valuable for issuers to have the option to permit oversubscriptions. For example, permitting oversubscriptions will allow an issuer to raise more funds, while lowering compliance costs as a proportion of the amount raised, if the issuer discovers during the offering process that there is greater investor interest in the offering than initially anticipated or if the cost of capital is lower than initially anticipated. As an alternative, we could have limited the maximum oversubscription amount to a certain percentage of the target offering amount, as suggested by one commenter.[1466] However, such a restriction might reduce valuable flexibility and potentially limit capital formation without appreciably enhancing investor protection.

The final rules do not require issuers to set a fixed price, as suggested by one commenter.[1467] While such an alternative might reduce an investor's cost of evaluating the investment, it would reduce flexibility for issuers while providing only limited benefits to investors in light of other disclosures required in the final rules. Further, the required disclosure of the pricing method used and the final prices for the securities before an offering closes,[1468] coupled with the investor's ability to cancel his or her investment commitment,[1469] can mitigate potential concerns that dynamic pricing can be used to provide preferential treatment to certain investors (*e.g.,* when an issuer offers better prices to relatives or insiders). We also believe that the cancellation rights afforded by the rules will help to address the concerns about time pressure on the investment decision because investors will have the opportunity to cancel their investment commitments if they decide to do so.

h. Types of Securities Offered and Valuation

The final rules do not limit the type of securities that may be offered in reliance on Section 4(a)(6). This provision gives issuers the flexibility to offer the types of securities that are most compatible with their desired capital structure and financing needs. Such flexibility may benefit issuers to the extent that capital structure decisions can be relevant for an issuer's firm value.

[1458] *See* Hackers/Founders Letter (supporting the issuer being able to repost the communications elsewhere so long as it first appeared through the intermediary); Joinvestor Letter.

[1459] *See, e.g.,* Commonwealth of Massachusetts Letter; CFIRA Letter 6.

[1460] *See, e.g.,* FundHub Letter 1; Seed&Spark Letter (noting the proposed advertising restrictions will restrict the ability of filmmakers to market and raise money for their films); Arctic Island Letter 5; PeoplePowerFund Letter.

[1461] *See* Fryer Letter.

[1462] *See* RocketHub Letter.

[1463] *See* Section 4A(b)(3). *See also* Rule 205 of Regulation Crowdfunding and Section II.B.5 above.

[1464] *See* Rule 205 of Regulation Crowdfunding. *See also* Section II.B.5 above.

[1465] *See* Rule 201(h) of Regulation Crowdfunding. *See also* Section II.B.6.a above.

[1466] *See* Joinvestor Letter; RFPIA Letter.

[1467] *See* RocketHub Letter.

[1468] *See* Rule 201(l) of Regulation Crowdfunding.

[1469] *See* Rule 201(j) of Regulation Crowdfunding.

The final rules do not prescribe a method for valuing the securities but instead require issuers to describe the terms of the securities and the valuation method in their offering materials. The required disclosure of valuation method is intended to facilitate informed investment decisions. As an alternative, as suggested by commenters, we could have prescribed the use of particular valuation standards,[1470] required issuers to base the valuation of their securities on the price at which the issuer previously sold securities,[1471] or considered other standards designed to ensure that securities are fairly valued and that approaches to valuation that put investors at a disadvantage are prohibited.[1472] If we required a specific valuation methodology, such as one of the suggested alternatives, and it were appropriate for a particular issuer, it could mitigate the likelihood of inaccurate valuations and result in more informed decisions by investors. However, specific valuation requirements that do not accommodate inherent differences among companies, particularly in light of the uncertainty related to the valuation of early-stage companies, might result in inaccurate valuations and less informed investor decisions. Also, potential additional calculations and analysis that might be required to implement a prescribed valuation methodology could impose additional costs on issuers, compared to letting issuers select a valuation method that fits the particular circumstances of their offering.

i. Restrictions on Resales

The statute and the final rules include restrictions on the transfer of securities for one year, subject to limited exceptions (*e.g.,* for transfers to the issuer of the securities, in a registered offering, to an accredited investor or to certain family members).[1473] As we discussed in the proposal, we believe that including such proposed restrictions is important for investor protection. By restricting the transfer of securities for a one-year period, the final rules give investors in a business a defined period to observe the performance of the business and to potentially obtain more information about the potential success or failure of the business before trading occurs. The final rules permit transfers to trusts controlled by, or held for the benefit of, covered family members.[1474] In a change from the proposed rules, the restrictions apply to any purchasers and not only to the initial purchasers, consistent with the suggestions of commenters.[1475] This change addresses the possibility of the initial purchaser selling securities to an eligible purchaser and such eligible purchaser reselling them to the public within the first year, resulting in the securities becoming widely traded within the first year.

We recognize that resale restrictions will impose costs. The one-year restriction on transfers of securities purchased in a transaction conducted in reliance on Section 4(a)(6) may impede price discovery, raise capital costs to issuers and limit investor participation, particularly among investors who are unable or unwilling to risk locking up their investments for this period. The illiquidity cost resulting from the resale restriction may be mitigated, in part, by provisions that allow investors to transfer the securities within one year of issuance by reselling the securities to accredited investors, back to the issuer or in a registered offering or transferring them to certain family members or trusts of those family members. The effect of resale restrictions on the extent to which investors make informed investment decisions is unclear. While resale restrictions may disincentivize investors from continuing to gather and analyze information about the issuer after investing while the resale restrictions are in effect, resale restrictions may also strengthen the incentive to conduct due diligence on the issuer and gather and analyze information before the initial investment. Nevertheless, at the investment amounts involved in these transactions, a typical purchaser's incentives to gather and analyze information before or after investing likely will remain limited, regardless of the presence of resale restrictions.

4. Intermediary Requirements

The statute and the final rules require that offerings in reliance on Section 4(a)(6) be conducted through an intermediary that is a registered broker-dealer or registered funding portal. The use of a registered intermediary to match issuers and investors will cause issuers to incur certain transaction costs associated with the intermediation activity[1476] but also will provide centralized venues for crowdfunding activities that are expected to lower investor and issuer search costs. As discussed earlier, existing lending-based, reward-based, and donation-based crowdfunding platforms already engage in a large volume of transactions in North America,[1477] demonstrating that the use of platforms for crowdfunding may be familiar to investors and issuers.

We believe that existing non-securities-based crowdfunding platforms will initially be the primary funding portals in the securities-based crowdfunding market. The entry of registered broker-dealers and new funding portals in the securities-based crowdfunding market will increase competition among existing non-securities-based crowdfunding intermediaries and potentially lower the cost of intermediation to issuers. One commenter stated that it has ''a serious concern with Broker/Dealers having an unfair advantage in the market, by already being regulated and registered with the Commission as well as FINRA. Therefore, they may be able to service the market well ahead of Portals.'' [1478]

We acknowledge that, to the extent that it may take less time and cost for registered broker-dealers to comply with the requirements of Regulation Crowdfunding as compared to funding portals, registered broker-dealers may be at a competitive advantage compared to new entities that seek to register as funding portals and enter the crowdfunding market. However, as we discuss below, the registration requirements for funding portals are tailored to the more limited scope of funding portal activities and are thus expected to result in a lower compliance cost for these entities. Further, the effective dates of the final rules are expected to provide time for funding portals to register and comply with the other requirements of Regulation Crowdfunding before crowdfunding offerings can occur.[1479] We recognize, however, that registered broker-dealers can retain a competitive advantage relative to funding portals due to their

[1470] *See, e.g.,* 11 Wells Letter; Active Agenda Letter; Borrell Letter; Ellenbogen Letter; Greer Letter; Mountain Hardwear Letter; Moyer Letter; NaviGantt Letter; Vidal Letter.

[1471] *See, e.g.,* Public Startup Letter 3; Wefunder Letter.

[1472] *See* Consumer Federation Letter.

[1473] *See* Section 4A(e). *See also* Rule 501(a) of Regulation Crowdfunding.

[1474] *See* Rule 501(a)(4) of Regulation Crowdfunding.

[1475] *See* CrowdCheck Letter 3; Moskowitz Letter.

[1476] *See* Section III.B.3.a above for a discussion of intermediary fees.

[1477] *See* Section III.A.3 above.

[1478] *See* RocketHub Letter. Several other commenters expressed concern about funding portals being at a competitive disadvantage to registered broker-dealers. *See, e.g.,* Joinvestor Letter; City First Letter; Seed&Spark Letter; Guzik Letter 1.

[1479] The time period between the effective date of the final rules pertaining to funding portal registration as compared to the later effective date for rules governing crowdfunding offerings is expected to mitigate some of these effects. *See also* Section II.C.2.a above.

ability to engage in a wider range of activities in the securities-based crowdfunding market.[1480] In this regard we note that the final rules permit funding portals to compensate a registered broker-dealer and to receive compensation from a registered broker-dealer for services in connection with the funding portal's offer or sale of securities in reliance on Section 4(a)(6),[1481] which may enable funding portals to partly mitigate the impact of restrictions on funding portal activities in the statute and final rules. Moreover, even if funding portals remain at a competitive disadvantage to registered broker-dealers in the securities-based crowdfunding market, overall the expected participation of multiple registered broker-dealers as intermediaries in offerings in reliance on Section 4(a)(6) may nevertheless result in a considerable level of competition in the securities-based crowdfunding marketplace.

Both existing non-securities-based crowdfunding platforms and registered broker-dealers will need to invest resources to comply with the requirements of the statute and final rules. In addition, registered broker-dealers will need to develop Internet-based crowdfunding platforms while existing non-securities-based crowdfunding platforms will need to register as funding portals or broker-dealers and modify their existing platforms to conform to the requirements of the statute and the final rules. Although the eventual extent of broker-dealer involvement in the securities-based crowdfunding market is difficult to estimate, we believe that some broker-dealers may acquire or form partnerships with funding portals to obtain access to a new and diverse investor base. In addition, some existing non-securities-based crowdfunding platforms may eventually form partnerships with registered broker-dealers or funding portals. It is challenging to exactly predict the future number of persons (or entities) who will register as either broker-dealers or funding portals to act as intermediaries in securities-based crowdfunding transactions. For purposes of the PRA,[1482] we estimate that intermediaries will number approximately 110, including approximately 10 intermediaries that will register as broker-dealers in order to engage in securities-based crowdfunding; approximately 50 intermediaries that are already registered as broker-dealers and that will choose to serve as crowdfunding intermediaries; and approximately 50 intermediaries that are not already registered as broker-dealers and that will register as funding portals.[1483] It is possible that the actual number of participants will deviate significantly from these estimates, and it is likely that there will be significant competition between existing crowdfunding venues and new entrants that may result in further changes in the number and types of intermediaries as the market develops and matures. It also is likely that there will be significant developments in the types and ranges of crowdfunding products and services offered by intermediaries to potential issuers and investors, particularly as competitors gain additional experience in this new marketplace. Moreover, the business models of successful crowdfunding intermediaries are likely to change over time as they grow in size or market share or if they are forced to differentiate from other market participants in order to maintain their position in the market.

As a result of the uncertainty over how the market may develop, any estimates of the potential number of market participants, their services or fees charged are subject to significant estimation error. While we recognize that there are benefits as well as costs associated with the statutory requirements and the final rules pertaining to intermediaries, there are significant limitations to our ability to estimate these potential benefits and costs.

The statute requires that the offer or sale of securities in reliance on Securities Act Section 4(a)(6) be conducted through a broker-dealer or a funding portal that complies with the requirements of Securities Act Section 4A(a).[1484] Among other things, the intermediary must register with the Commission as a broker-dealer or a funding portal, and it also must register with a registered national securities association.[1485] The final rules implement these statutory requirements, including by requiring an intermediary to be a member of FINRA or any other applicable registered national securities association.

While the benefits and costs are described in further detail below, the following tables summarize the estimated direct costs to intermediaries, including broker-dealers and funding portals. Some of the direct costs of the rules will be incurred by all intermediaries, while others are specific to whether the intermediary is a new entrant (registering as a broker-dealer or a funding portal) or is already registered as a broker-dealer.

Although we have attempted to estimate the direct costs of the statute and the final rules on intermediaries, we recognize that some costs can vary significantly across intermediaries, and within categories of intermediaries. For example, some intermediaries may choose to leverage existing platforms or systems and so may not need to incur significant additional expenses to develop a platform or comply with specific requirements of Regulation Crowdfunding. In the Proposing Release we provided cost estimates for the various intermediary requirements and requested comment on our estimates. Several commenters discussed the estimates of the costs associated with intermediaries or provided cost estimates of their own.[1486] Below we discuss the comments received on each of these costs and any revisions to our estimates made in response.

[1480] *See also* note 607.

[1481] *See* Rule 402(b)(7) and Rule 402(b)(8) of Regulation Crowdfunding. *See also* Section II.D.3.g.

[1482] *See* Section IV.B.2 and Section IV.B.3 below.

[1483] These estimates are based, in part, on recent indications of interest, which may change as the market develops. According to FINRA, as of October 3, 2013, approximately 36 entities have submitted the voluntary Interim Form for Funding Portals to FINRA to indicate their intention to act as funding portals under Title III of the JOBS Act. *See* Press Release, Financial Industry Regulatory Authority, FINRA Issues Voluntary Interim Form for Crowdfunding Portals (Jan. 10, 2013), *available at http://www.finra.org/Newsroom/NewsReleases/2013/P197636*; Financial Industry Regulatory Authority, *Crowdfunding Portals, available at http://www.finra.org/industry/issues/crowdfunding*. Based on these recent indications of interest, we expect that the number of funding portals that will ultimately register with the Commission will be approximately 50.

We note that these estimates are the same as the estimates of potential crowdfunding intermediaries set forth in the Proposing Release. We did not receive comments about these estimates.

[1484] *See* Section 4(a)(6)(C).

[1485] *See* Section 4A(a)(2).

[1486] *See, e.g.*, ASSOB Letter (suggesting that the cost to establish a funding portal would run at least $480,000); Arctic Island Letter 8 (referring to the cost of establishing and managing escrow accounts); CapSchedule Letter (citing costs of managing securityholder records); Joinvestor Letter (suggesting in reference to records to be kept by funding portals that ''[u]nder the expectation that crowdfunding portals will be online operations and will almost certainly retain records through digital methods, the burden of collection should be minimal'' but not providing a specific estimate of the cost of compliance). Various commenters expressed concern with the cost imposed on intermediaries. *See, e.g.*, Heritage Letter (suggesting that the ''costs incurred by the intermediary in dealing with an issuer, doing the required due diligence and background screening, establishing a Web page describing the offering and so on do not vary linearly with the offering size''); Seed&Spark Letter; SBEC Letter (suggesting that there will be ''extensive staff, technology and operational costs'' in addition to the compliance costs estimated in the Proposing Release).

We estimate that the cost for an entity to register as a broker-dealer and become a member of a national securities association in order to engage in crowdfunding pursuant to Section 4(a)(6) will be approximately $275,000, with an ongoing annual cost of approximately $50,000 to maintain this registration and membership.[1487] In addition, we estimate that the cost to comply with the various requirements that apply to registered broker-dealers engaging in transactions pursuant to Section 4(a)(6) for these new registrants will be approximately $245,000 initially and approximately $180,000 in each year thereafter. In making this estimate, we assume that broker-dealers acting as intermediaries in transactions pursuant to Section 4(a)(6) will provide a full range of brokerage services in connection with these transactions, including certain services such as providing investment advice and recommendations, soliciting investors, and managing and handling customer funds and securities, that funding portals cannot provide.[1488]

If instead an entity were to register as a funding portal and become a funding portal member of a national securities association, we estimate the initial registration and membership cost will be approximately $100,000, with an ongoing cost of approximately $10,000 in each year thereafter to maintain this registration and membership.[1489] We estimate that the initial cost for a registered funding portal to comply with the requirements of the final rules will be approximately $67,000, with an ongoing cost of approximately $40,000 in each year thereafter.

Finally, we estimate that the incremental initial cost for an intermediary that is already registered as a broker-dealer to comply with the requirements of the final rules will be approximately $45,000, with an ongoing cost of approximately $30,000 in each year thereafter.

These estimated costs are consistent with those set forth in the Proposing Release and are exclusive of the cost of establishing and maintaining a platform and related functionality. For purposes of the PRA, we estimate that for the average intermediary, the mid-range initial external platform development cost will be approximately $425,000 and the ongoing cost will be approximately $85,000 per year.[1490] However, we anticipate considerable variation among intermediaries depending on whether they already have in place platforms and systems that can be adapted to meet the requirements of the final rules. We expect that intermediaries (whether broker-dealers or funding portals) that already have in place platforms and related systems that will need only to tailor their existing platform and systems to comply with the requirements of Regulation Crowdfunding, resulting in a lower initial cost on average of $250,000. We expect the ongoing cost to remain approximately $85,000 per year for an intermediary that already has in place a platform and related systems. Commenters did not provide estimates of the cost of establishing a platform or tailoring an existing platform to comply with the requirements of Title III. One commenter suggested that the cost of operating a funding portal and regulatory compliance would be at least $480,000 per year but did not break out this estimate into separate cost components.[1491]

ESTIMATED COSTS OF FINAL RULES FOR INTERMEDIARIES THAT REGISTER AS BROKER-DEALERS

	Estimated costs	
	Initial cost (year 1)	Ongoing cost per year
Form BD Registration and National Securities Association Membership	$275,000	$50,000
Complying with Requirements to Act as an Intermediary in, and to Engage in Broker-Dealer Activities Related to, Transactions pursuant to Section 4(a)(6)[1492]	245,000	180,000
Platform Development[1493]	425,000	85,000
Total	945,000	315,000

[1487] We recognize that the cost of registering and becoming a member of a national securities association varies significantly among broker-dealers, depending on facts and circumstances. The cost can vary, among other factors, based on the number of associated persons of the broker-dealer entity and their licensing requirements, the scope of the brokerage activities, and the means by which the broker-dealer administers the registration process (*e.g.*, it may choose to hire outside counsel to assist with the process). We also recognize that the time required for a broker-dealer to become a member of a national securities association varies and can take six months to one year. We estimate the range of this cost to be between $50,000 and $500,000, and so we have chosen the average amount of $275,000 for purposes of this analysis.

[1488] Among other things, a broker-dealer providing recommendations and investment advice is required to comply with FINRA rules on suitability. *See* FINRA Rule 2111. A broker-dealer soliciting through advertisements is required to comply with FINRA rules relating to communications with the public. *See* FINRA Rule 2210. Broker-dealers handling customer funds and securities also are required to maintain net capital, segregate customer funds and comply with Exchange Act Rule 15c2–4. *See* Exchange Act Rules 15c3–1, 15c3–3 and 15c2–4 [17 CFR 240.15c3–1, 15c3–3 and 15c2–4].

[1489] In making these estimates, we assume that the membership process will take approximately sixty days and that there will be no related licensing requirement for associated persons of the funding portal. In the Proposing Release, we estimated that the membership process will take approximately one month. While it does not affect our estimate of direct costs, we note that a longer membership process can result in incremental indirect costs to funding portals (*e.g.*, opportunity costs due to not being able to serve as an intermediary in crowdfunding offerings while registration requirements are not met and competitive costs due to requiring additional time to register compared to registered broker-dealers. The time period between the effective date of the final rules pertaining to funding portal registration as compared to the later effective date for rules governing crowdfunding offerings is expected to mitigate these effects.

We also only include domestic entities in these estimates, which do not need to comply with the requirements in Regulation Crowdfunding that apply to nonresident funding portals. Nonresident funding portals are subject to an additional cost of completing Schedule C to Form Funding Portal, hiring and maintaining an agent for service of process and providing the required opinion of counsel. *See* Section IV.C.2.a. below (discussing burden estimates of these additional requirements for purposes of the PRA).

[1490] These estimates are based on intermediaries that use a third party to develop the platform. Intermediaries that develop the platform in-house may incur lower costs. For purposes of the PRA, we estimate that intermediaries that develop the platform in-house instead of using a third-party provider will spend an average of 1,500 hours for initial planning, programming and implementation and 300 hours per year in ongoing internal burden. For purposes of the PRA we estimate that approximately half of the intermediaries will use a third party to develop the platform and the other half will develop their platforms in-house. *See* Section IV.C.2.b below.

[1491] *See* ASSOB Letter.

[1492] As discussed above, these costs include, among others, the costs to the broker-dealer of having associated persons who have licensing requirements, suitability requirements, requirements relating to advertisements, net capital requirements, and compliance with Exchange Act Rule 15c2–4 (17 CFR 240.15c2–4), as well as the costs of complying with Subpart C of Regulation Crowdfunding. *See* Section IV.C.2 below for further detail on our estimates, for PRA purposes, of the costs associated with the requirements under Subpart C.

[1493] *See* Section IV.C.2.b below for further detail on our estimates, for PRA purposes, of the costs of developing a platform.

ESTIMATED COSTS OF FINAL RULES FOR INTERMEDIARIES THAT REGISTER AS FUNDING PORTALS

	Estimated costs	
	Initial cost (year 1)	Ongoing cost per year
Form Funding Portal Registration and National Securities Association Membership [1494]	$100,000	$10,000
Complying with Requirements to Act as an Intermediary [1495] in Transactions pursuant to Section 4(a)(6)	67,000	40,000
Platform Development [1496]	425,000	85,000
Total	592,000	135,000

ESTIMATED INCREMENTAL COSTS OF FINAL RULES FOR INTERMEDIARIES ALREADY REGISTERED AS BROKER-DEALERS

	Estimated costs	
	Initial cost (year 1)	Ongoing cost per year
Complying with Requirements to Act as an Intermediary in Transactions pursuant to Section 4(a)(6) [1497]	$45,000	$30,000
Platform Development [1498]	425,000	85,000
Total	470,000	115,000

Commenters suggested that funding portals should not be required to register with the Commission or become FINRA members (or members of any other registered national securities association), because unlike broker-dealers, they serve only as an ''information delivery service.'' [1499] One commenter stated that the Commission's estimates in initial costs of registration as a funding portal and for ongoing expenses create a significant burden given that potential funding portals operate on modest budgets and with thin margins.[1500] As we note above, however, registration is a statutory requirement under Securities Act Section 4A(a)(1).[1501] While the registration requirements will necessarily impose costs on intermediaries, we believe they also will be effective in providing investor protection for the crowdfunding market while taking into account the more limited activities of funding portals. Among other things, in addition to the Commission's oversight and rulemaking functions with regard to broker-dealers, FINRA currently is responsible for conducting most broker-dealer examinations, mandating certain disclosures by its members, writing rules governing the conduct of its members and associated persons, and informing and educating the investing public. Similarly, we believe that in addition to the benefits of the Commission's oversight with regard to funding portals, the regulatory framework that a registered national securities association—initially FINRA—will be required to create for funding portals will play an important role in the oversight of these entities.

The estimated costs in the tables above reflect the direct costs that intermediaries will incur in connection with registering as a broker-dealer on Form BD or as a funding portal on Form Funding Portal, submitting amendments to registrations and withdrawing registrations. For the purposes of the PRA, we estimate that approximately 50 intermediaries will be broker-dealers that have already registered with the Commission [1502] and, as such, these broker-dealers will not incur additional SEC registration costs associated with the final rules. Additionally, intermediaries that are not otherwise registered with FINRA or any other registered national securities association will need to register, and the estimated cost for such registration is included in the tables above. We anticipate that the cost for a funding portal to become a member of a registered national securities association will be lower than the cost for a broker-dealer to do so because of the more limited nature of a funding portal's permissible activities and the streamlined set of rules that an association is likely to impose on funding portals. In this regard, we note that FINRA has solicited public comment on a set of proposed rules and related forms for registered funding portals that become FINRA members pursuant to the crowdfunding provisions of the JOBS Act.[1503]

The final rules also require that an intermediary execute transactions exclusively through its online platform. This requirement may lower the potential for abusive sales practices. However, it may also prevent investors who lack Internet access from investing through crowdfunding, as suggested by one commenter.[1504] We believe that the use of an online platform will enhance the ability of issuers and investors to communicate transparently as compared to the alternative of allowing transactions to occur offline. This requirement also is expected to help issuers gain exposure to a wide range of investors, who also may benefit from

[1494] As described above, this estimate reflects a streamlined process of becoming a member of a national securities association, which we assume will take approximately sixty days and not involve application or licensing of associated persons.

[1495] This includes the costs of complying with the requirements of Subparts C and D of Regulation Crowdfunding. *See* Section IV.C.2 below for further detail on our estimates, for PRA purposes, of these costs.

[1496] *See* Section IV.C.2.b below for further detail on our estimates, for PRA purposes, of the costs of developing a platform.

[1497] This includes the incremental costs of complying with the requirements of Subpart C of Regulation Crowdfunding, but it excludes any registration or membership requirements. *See* Section IV.C.2 below for further detail on our estimates, for PRA purposes, of these costs.

[1498] *See* Section IV.C.2.b below for further detail on our estimates, for PRA purposes, of the costs of developing a platform.

[1499] *See* Perfect Circle Letter.

[1500] *See* Seed&Spark Letter.

[1501] *See* Section II.C.2.a above.

[1502] *See* Section IV.C.2 below.

[1503] *See* Proposed Funding Portal Rules, *available at http://www.finra.org/sites/default/files/NoticeAttachment/p369763.pdf. See also FINRA Requests Comment on Proposed Funding Portal Rules and Related Forms,* FINRA Regulatory Notice 13–34, *available* at *http://www.finra.org/sites/default/files/NoticeDocument/p370743.pdf.* (''The rule is based on the current NASD Rule 1010 Series membership rules that apply to broker-dealers. However, the process for funding portals is simplified to reflect the limited nature of their business.'')

[1504] *See, e.g.,* Projecteureka Letter.

having numerous investment opportunities aggregated in one place, resulting in lower search costs or burdens related to identifying suitable investment opportunities.

The final rules further require that an issuer conduct an offering or concurrent offerings in reliance on Section 4(a)(6) using a single intermediary.[1505] We recognize that this requirement may impose costs by limiting the set of investors, as well as communication about a transaction, to the extent that some investors do not use a specific crowdfunding platform.[1506] However, it may also enhance communication between issuers and investors, as suggested by some commenters,[1507] and enable investors to access investor discussions about a particular transaction on a single platform. This requirement may also reduce the risk of issuers circumventing the aggregate offering limit.

Some commenters suggested that the statutory and rule requirements for establishing a funding portal and ongoing maintenance and compliance expenses create a significant burden on funding portals.[1508] Among other concerns, commenters highlighted potential liability for intermediaries [1509] under Securities Act Section 4A(c) and the cost of conducting background checks [1510] pursuant to Rule 301(c) as particularly burdensome for funding portals. We are mindful of the potentially significant costs as a percentage of offering size incurred by intermediaries, especially funding portals, in securities-based crowdfunding offerings. However, intermediary requirements are designed to provide a measure of investor protection from the risk of fraud in small offerings by relatively unknown issuers. Concentration of certain due diligence tasks at the intermediary level may yield efficiency gains relative to having each small investor incur the cost to perform such tasks. In addition, although funding portals may be subject to issuer liability, the changes we have implemented in the final rules will give them greater ability to control which issuers conduct offerings on their platforms and thus to mitigate to some degree the risks of liability arising from such offerings.

a. Disclosure and Dissemination Requirements

The statute and final rules include disclosure and dissemination provisions designed to provide information to security-based crowdfunding investors. These provisions, together with the issuer disclosure provisions discussed above, are expected to limit information asymmetries and promote the efficient allocation of capital amongst crowdfunding offerings. These provisions also will provide information intended to ensure that investors are aware of the risks associated with their investment, which can enhance investor protection. As discussed above, many of the costs and benefits of these provisions are difficult to quantify or estimate with any degree of certainty, especially considering that securities-based crowdfunding will constitute a new method for raising capital in the United States. Although we are not able to quantify the direct costs specifically associated with each of these requirements, these costs are reflected in our general estimates of the initial and ongoing costs for intermediaries to register, comply with their obligations under the final rules and develop a crowdfunding platform, as reflected in the tables above.

The final rules prohibit an intermediary or its associated persons from accepting an investment commitment until the investor has opened an account with the intermediary and the intermediary has obtained the investor's consent to electronic delivery of materials.[1511] This requirement will help ensure that certain basic information about the investor is on file with the intermediary and that all investors are on notice of the primary method of delivery for communications from the intermediary. To the extent that an intermediary uses a third party to establish account opening functionality, the costs relevant to this requirement will be incorporated into the cost to develop the platform.[1512]

The statute requires intermediaries to provide disclosures related to risks and other investor education materials. The final rules implement this statutory mandate by requiring intermediaries to deliver educational materials that explain how the offering process works and the risks associated with investing in crowdfunding securities.[1513] The educational requirements will help make investors aware of the limits and risks associated with purchasing crowdfunding securities and facilitate the selection of investments suited to their level of risk tolerance. They also may help ensure that offerings proceed more efficiently as investors will be better informed by the time they decide to make their investment commitments and receive required notices. However, we recognize that the effectiveness of the educational materials in enhancing investor protection will vary depending upon the quality of the educational materials and the education and experience of retail investors.[1514] In addition, materials that highlight the risks of securities-based crowdfunding can discourage investor participation, which may limit potential capital formation.

Under the final rules, the educational materials can be in any electronic format, including video format, and the intermediary will have the flexibility to determine how best to communicate the contents of the educational material. Accordingly, the cost for intermediaries to develop educational materials is expected to vary widely. For purposes of the PRA, we estimate that the initial cost for an intermediary using a third-party firm to develop and produce educational materials will be approximately $10,000 to $30,000 and the ongoing cost will be approximately $5,000 to $15,000 per year.[1515]

The final rules also require that intermediaries obtain representations from investors about their review of the investor education materials and their understanding of the risks.[1516] This requirement is expected to improve investors' understanding of investments in securities-based crowdfunding offerings. The direct costs of this requirement to an intermediary are reflected in the tables above as part of the costs of developing a crowdfunding platform, and we believe that the

[1505] *See* Instruction 1 to Rule 100(a)(3) of Regulation Crowdfunding. *See also* Section II.A.3.

[1506] *See, e.g.,* Graves Letter.

[1507] *See, e.g.,* CFA Institute Letter; RocketHub Letter.

[1508] *See, e.g.,* ASSOB Letter (suggesting that the cost to establish a funding portal could be at least $480,000).

[1509] *See, e.g.,* ABA Letter; AngelList Letter; BetterInvesting Letter; CFIRA Letter 10; City First Letter; EarlyShares Letter; EMKF Letter; FSI Letter; Graves Letter; Guzik Letter 1; IAC Recommendation; Inkshares Letter; Milken Institute Letter; PPA Letter; RocketHub Letter; SBA Office of Advocacy Letter; SBEC Letter; SeedInvest Letter 3; Seyfarth Letter; StartupValley Letter; Wefunder Letter; Winters Letter. *See also* Section II.E.5.

[1510] *See, e.g.,* RocketHub Letter; Anonymous Letter 4; Zhang Letter. *See also* Section II.C.3.c above.

[1511] *See* Rule 302(a) of Regulation Crowdfunding.

[1512] *See also* Section IV.C.2.d below.

[1513] *See* Rule 302(b) of Regulation Crowdfunding.

[1514] *See* Jennifer E. Bethel and Allen Ferrell, *Policy Issues Raised by Structured Products,* Harv. L. & Econ. Discussion Paper No. 560, 2007, available at *http://papers.ssrn.com/sol3/papers.cfm?abstract_id=941720.*

[1515] For the purposes of the PRA, we estimate that development of educational materials in-house will be associated with an average initial burden of approximately 20 hours and an average annual burden of approximately 10 hours. *See* Section IV.C.2.e below.

[1516] *See* Rule 303(b)(2) of Regulation Crowdfunding.

ongoing burden to comply will be minimal after the intermediary has systems in place to obtain such representations. This requirement also may limit capital formation to the extent that it deters investors from making investment commitments or otherwise participating in offerings made in reliance on Section 4(a)(6).

Under the final rules, an intermediary must clearly disclose the manner in which the intermediary is compensated in connection with offers and sales of securities in reliance on Section 4(a)(6).[1517] As explained above, we believe that investors will benefit by having information about how intermediaries are compensated, such as through compensation arrangements with affiliates. We believe that the costs of complying with this requirement generally will be included in the overall cost for intermediaries to develop their platforms, as it will entail adding an item of disclosure to the functionality of their platforms.[1518] While the requirement to disclose compensation arrangements may give rise to indirect costs due to the intermediary's competitors learning about the compensation arrangements, we do not expect such indirect costs to be significant since the intermediary's competitors can generally infer information about the intermediary's compensation arrangements from other sources.

The statute and the final rules further require that intermediaries make available certain issuer-provided information.[1519] We recognize that requiring intermediaries to provide prospective investors with information about the issuer will impose costs. We expect that intermediaries will incur costs to develop the functionality that will allow the uploading and downloading of issuer information. We believe that the direct costs of complying with this requirement will be included in the overall cost to intermediaries to develop their platforms and that this requirement will impose only nominal incremental costs on intermediaries on an ongoing basis, primarily because the functionality necessary to upload the required issuer disclosure information is a standard feature offered on many Web sites and would not require frequent updates.[1520]

The issuer disclosure requirements are expected to benefit investors by enabling them to better evaluate the issuer and the offering. Requiring intermediaries to make the issuer information publicly available and easily accessible on their platforms will reduce information asymmetries between issuers and investors and will enhance both transparency and efficiency of the crowdfunding market. Greater accessibility of issuer information may reduce incremental costs to investors of locating issuer information and may increase their willingness to participate in a securities-based crowdfunding offering, thereby enhancing capital formation.

The final rules also require an intermediary to provide communication channels on its platform, meeting certain conditions, which will allow investors who have opened accounts with intermediaries and representatives of the issuer to interact and exchange comments about the issuer's offering on that intermediary's platform, and which will be publicly available for viewing (*i.e.*, by those who may not have opened accounts with the intermediary).[1521]

Compared with the alternative of not requiring intermediaries to provide communication channels, we believe this requirement will allow investors, particularly those who may be less familiar with online social media, to participate in online discussions about ongoing offerings without having to actively search for such discussions on external Web sites. Moreover, the requirement that promoters be clearly identified on these channels will enhance transparency, allowing those investors that draw information from an intermediary's online platform to make potentially better informed investment decisions. The direct costs of this requirement are reflected in the tables above as part of costs of developing a crowdfunding platform, and we believe that once the platform has been set up, the ongoing burden to comply will be minimal. We recognize, however, that this requirement will not assure that participants in online discussions on the intermediary's online platform convey accurate or relevant information in their postings, and it will not preclude investors from participating in discussions on external Web sites or other external social media.

The final rules also require intermediaries, upon receipt of an investment commitment from an investor, promptly to provide or send to the investor a notification of that investment commitment.[1522] This requirement will provide investors with key information about their investment commitments, including notice of the opportunity, as relevant, to cancel their investment commitments. Investors will benefit from these requirements because they will be provided with additional information with which to evaluate their investment commitments, their securities transactions and the intermediaries that are effecting those transactions. The direct costs of these requirements are reflected in the tables above as part of the costs of developing a crowdfunding platform.[1523]

The final rules implement the statutory requirement for intermediaries to allow investors to cancel their commitments to invest, by requiring investors to have until 48 hours prior to the deadline identified in the issuer's offering materials to cancel their investment commitments.[1524] If an issuer reaches its target offering amount prior to the target offering deadline, the final rules permit early closing of the offering under certain conditions, including a requirement that the intermediary send notices to investors informing them of the closing and the deadline for the opportunity to cancel.[1525] The final rules also set forth notice requirements and requirements related to the intermediary directing payments in the event of cancellations and material changes to offerings.[1526] Additionally, the final rules impose specific obligations on intermediaries related to informing investors about their right to cancel an investment commitment.[1527]

We believe that investors will benefit from receiving these notices because the notifications and accompanying information will keep investors informed about the status of the offering and thereby facilitate better investment decisions. This approach also will benefit investors by providing them with a specified period of time to review and assess information and communications about the issuer.

We recognize that allowing investors to cancel their investment commitments up to 48 hours prior to the deadline identified in the issuer's offering materials may impose a cost on issuers who, because of investors cancelling commitments late in the offering period, may fall below the target offering amount and so decide to cancel the offering or to extend the offering period. Accordingly, we recognize that this requirement may reduce the overall amount of capital raised in offerings in

[1517] *See* Rule 302(d) of Regulation Crowdfunding.

[1518] *See also* Section IV.C.2.f below.

[1519] *See* Rule 303(a) of Regulation Crowdfunding.

[1520] *See also* Section IV.C.2.g below.

[1521] *See* Rule 303(c) of Regulation Crowdfunding.

[1522] *See* Rule 303(d) of Regulation Crowdfunding.

[1523] *See also* Section IV.C.2.h below.

[1524] *See* Rule 304(a) of Regulation Crowdfunding.

[1525] *See* Rule 304(b) of Regulation Crowdfunding.

[1526] *See* Rule 304(c) and Rule 304(d) of Regulation Crowdfunding.

[1527] *See* Rule 302(b) of Regulation Crowdfunding.

reliance on Section 4(a)(6) and thus have an adverse effect on capital formation. Intermediaries are expected to incur direct costs in developing and maintaining systems to send the relevant notices to investors. These costs are reflected in the tables above as part of the cost of developing a crowdfunding platform.[1528]

b. Measures To Reduce the Risk of Fraud

The statute and final rules require intermediaries to have a reasonable basis for believing that an issuer seeking to offer and sell securities in reliance on Section 4(a)(6) through the intermediary's platform complies with the requirements in the final rules [1529] and has established means to keep accurate records of holders of the securities.[1530] Under the final rules, an intermediary must deny access to an issuer if it has a reasonable basis for believing that the issuer or the offering presents the potential for fraud or otherwise raises concerns about investor protection [1531] or that the issuer or any of its officers, directors (or any person occupying a similar status or performing a similar function) or 20 Percent Beneficial Owners was subject to a disqualification under the final rules.[1532] The intermediary also must conduct a background and securities enforcement check on each of these persons.[1533] We believe that these requirements will increase investor protection in connection with the offering.[1534]

As noted above, the specific costs and benefits of these provisions are difficult to quantify or estimate with any degree of certainty. However, we have attempted to reflect the direct costs of these provisions in the tables above as part of our general estimates for the cost of complying with requirements to act as an intermediary in transactions pursuant to Section 4(a)(6). For purposes of the PRA, the cost for an intermediary to fulfill the required background checks and securities enforcement regulatory history checks is estimated to be approximately $13,818 to $34,546 in the first year and approximately the same in subsequent years.[1535]

Each of these requirements is intended to help reduce the risk of fraud in securities-based crowdfunding. As a result of these requirements, investors will be able to rely on the efforts of the intermediary that conducted a background and securities enforcement check, solving a collective action problem that would be prohibitively costly if left to individual investors. To the extent that these checks help prevent fraudulent activity, they may increase investor willingness to participate in crowdfunding offerings, thereby facilitating capital formation. We anticipate that most intermediaries will employ third parties to perform these background checks.

We received several suggestions from commenters aimed at reducing or scaling the costs of the proposed requirements. One commenter suggested that the checks be required only after an issuer has met its target offering amount, so as to prevent unnecessary expense to the intermediary.[1536] Requiring a background check only after an issuer has reached its target may reduce the total cost of performing background checks for intermediaries; however, it also may result in intermediaries having to cancel offerings by issuers who fail the background checks, resulting in additional transactional and reputational costs for the intermediary. Overall, relative to this alternative, we believe that an intermediary performing a background check on an issuer prior to the securities offering will improve investor confidence in using a given intermediary.

While intermediaries are required to take certain steps to reduce the risk of fraud, the final rules provide intermediaries with the flexibility to decide the specific steps to take, consistent with some of the commenters' suggestions.[1537] We believe this may reduce intermediary costs relative to establishing a more stringent or more specific standard for intermediaries. For example, deeming an intermediary to have satisfied the Rule 301(b) requirement if the issuer has engaged the services of a transfer agent that is registered under Section 17A of the Exchange Act will reduce the intermediary cost while at the same time potentially improving investor protection.[1538] In addition, intermediaries may rely on the representations of the issuer unless they have reason to question the reliability of those representations. Overall, a more rigorous review requirement represents a tradeoff between enhanced investor confidence in the portal and higher compliance costs for intermediaries. We recognize that permitting an intermediary to rely on an issuer's representations unless the intermediary has reason to question the reliability of the representations can potentially lessen the incentive for an intermediary to thoroughly investigate the issuers and securities to be offered on its platform. Such an outcome may result in higher levels of fraud compared to a requirement that intermediaries perform an independent investigation to ensure that the issuer complied with all the requirements. A higher level of fraud will negatively affect both investors in crowdfunding offerings and non-fraudulent issuers. While we recognize this potential adverse effect, we note that intermediaries may be subject to liability as ''issuers,'' and this liability, together with potential reputational harm, is expected to provide significant incentives for intermediaries to monitor and investigate the offerings on their platforms. We also note that the communication channels provided on these platforms can provide a potential source of information for intermediaries, further facilitating their evaluation of prospective issuers.

c. Other Limitations on Intermediaries

The statute and final rules place certain limitations on intermediaries. These limitations are expected to increase investor protection in the securities-based crowdfunding market.

The final rules require an intermediary before accepting an investment commitment to have a reasonable basis for believing that an investor has not exceeded the final rules' investment limits but permit an intermediary to rely on investor representations concerning compliance unless the intermediary has reason to question the reliability of the representations.[1539] While we realize that investors may make inaccurate representations, we believe that this provision represents a reasonable approach to implement the statutory requirement, appropriately considering the need for investors to adhere to investment limitations while mitigating the costs incurred by intermediaries.

[1528] *See also* Section IV.C.2.h below.

[1529] *See* Rule 301(a) of Regulation Crowdfunding.

[1530] *See* Rule 301(b) of Regulation Crowdfunding.

[1531] *See* Rule 301(c)(2) of Regulation Crowdfunding.

[1532] *See* Rule 301(c)(1) of Regulation Crowdfunding.

[1533] *Id.*

[1534] *See also* Section II.C.3 above.

[1535] *See* Section IV.C.2.c below.

[1536] Anonymous Letter 4.

[1537] *See, e.g.*, StartupValley Letter; Vann Letter.

[1538] We note that while for purposes of this provision, the issuer is not required to continue to engage the services of a registered transfer agent on an ongoing basis, since the use of a registered transfer agent is a condition for the Section 12(g) exemption, issuers with a large number of shareholders of record are expected to have an incentive to continue to engage the services of a registered transfer agent. *See* Section III.B.8. below.

[1539] *See* Rule 303(b)(1) of Regulation Crowdfunding. *See also* Section II.C.5.b above.

The cost to update the required functionality for processing issuer disclosure and investor acknowledgment information is reflected in the tables above as part of the costs to develop a crowdfunding platform, and we believe that the ongoing burden to comply would be minimal.

Under the final rules, intermediaries must require any person, when posting a comment in the communication channels, to clearly disclose with each posting whether he or she is a founder or an employee of an issuer engaging in promotional activities on behalf of the issuer or a compensated promoter.[1540] We believe that these disclosure requirements will benefit investors by promoting a transparent information sharing process. We further believe that intermediaries are in an appropriate position to take such steps as part of designing communication channels on their platform.

Under the final rules, intermediaries will incur direct costs in complying with the requirements to disclose compensation to promoters, and certain additional costs from time to time to ensure continued compliance. These costs are reflected in the table above as part of the costs of complying with the requirements to act as an intermediary in a Section 4(a)(6) transaction. In addition, if this requirement discourages the use of promoters by issuers, it may limit the investor pool for an offering made in reliance on Section 4(a)(6), thus limiting the ability of an issuer to raise capital.[1541]

The statute prohibits the directors, officers or partners of an intermediary, or any person occupying a similar status or performing a similar function, from having any financial interest in an issuer that uses the services of the intermediary. The final rules implement this statutory requirement. In a change from the proposed rules, the final rules provide exceptions to the prohibition on an intermediary having a financial interest in a crowdfunding issuer. The intermediary may hold a financial interest in the crowdfunding issuer if the financial interest represents compensation for the services provided to or for the benefit of the issuer in connection with the offer or sale of securities in a crowdfunding offering and consists of securities of the same class and having the same terms, conditions and rights as the securities being offered or sold in the crowdfunding offering through the intermediary's platform. By not extending the prohibition from having any financial interest in an issuer to intermediaries in all instances, the final rules allow for more flexibility in the payment arrangements between issuers and intermediaries. This additional option by which the issuer may pay an intermediary for its services may be beneficial for issuers by allowing them to use more of the capital raised in an offering for future investments rather than paying a portion of it as a fee to the intermediaries. It also allows funding portals to share in the upside of successful issuers, generating potentially larger revenue than the offering fee. While allowing intermediaries to have a financial interest in issuers can align incentives between intermediaries and investors,[1542] it can alternatively lead to potential conflicts of interest between intermediaries and investors.[1543] While we believe that such conflicts of interest are possible and may reduce investor protection, they will be significantly mitigated by the requirement that an intermediary's financial interest in an issuer consist of securities of the same class and having the same terms, conditions and rights as the securities being offered or sold in the crowdfunding offering through the intermediary's platform. Such limitations on an intermediary's financial interest, combined with reputational concerns and the accompanying disclosure requirements, will likely curb the incentives of intermediaries to act in a way that harms the interests of crowdfunding investors.

The statute requires that intermediaries ensure that all offering proceeds are provided to the issuer only when the aggregate capital raised from all investors is equal to or greater than a target offering amount.[1544] The final rules implement this requirement by requiring intermediaries that are registered as broker-dealers to comply with the existing requirements of Exchange Act Rule 15c2–4 and by requiring intermediaries that are registered funding portals to direct investors to transmit the funds or other consideration directly to a qualified third party that has agreed in writing to hold the funds for the benefit of the investors and the issuer and to promptly transmit or return the funds to the persons entitled to such funds.[1545] Based on several commenters' suggestions,[1546] we modified the proposed definition of qualified third parties in Rule 303(e) also to include registered broker-dealers that carry customer or broker or dealer accounts and hold funds or securities for those persons and credit unions insured by the NCUA.[1547] The final rules also require a funding portal to direct the qualified third party to transmit funds to the issuer once the target offering amount is reached and the cancellation period has elapsed; to return funds to an investor when an investment commitment has been cancelled; and to return funds to investors when the offering has not been completed.

These requirements will benefit investors and issuers by helping ensure that funds are appropriately refunded or transmitted in accordance with the terms of the offering. In particular, the requirement that the account in which funds are deposited be exclusively for the benefit of investors and the issuer will help prevent the intermediary or other parties from claiming or otherwise unlawfully appropriating funds from that account. Expanding the definition of ''qualified third parties'' will increase the number of third parties available to hold funds in an escrow or in an account for the benefit of investors and the issuer, potentially reducing the cost of the service due to increased competition. We do not expect any significant costs due to this change from the proposed rules because credit unions insured by the NCUA offer similar protections to banks while registered broker-dealers that carry customer or broker or dealer accounts and hold funds or securities for those persons are subject to various regulatory obligations, which are designed to provide protection of investor funds through the imposition of capital and other requirements.[1548]

Under the statute, intermediaries may not compensate promoters, finders or lead generators for providing broker-dealers or funding portals with the personally identifiable information of any potential investor. The final rules implement this statutory requirement by prohibiting an intermediary from

[1540] *See* Rule 303(c)(4) of Regulation Crowdfunding. *See also* Section II.C.5.c above.

[1541] *See* Rule 300(b) of Regulation Crowdfunding and Section II.C.2.b.

[1542] *See, e.g.*, AngelList Letter (''So long as the program was consistently applied without judgment by the intermediary, the net effect would purely be to align the interests of the intermediary with the investor.''). *See also* EMKF Letter; Hackers/Founders Letter; Heritage Letter; Milken Institute Letter; RoC Letter; RocketHub Letter; Thomas Letter 1.

[1543] *See* Jacobson Letter.

[1544] *See* Section 4A(a)(7).

[1545] *See* Rule 303(e) of Regulation Crowdfunding.

[1546] *See, e.g.*, Growthfountain Letter; Vann Letter; Ex24 Letter; FOLIOfn Letter.

[1547] *See* Rule 303(e) of Regulation Crowdfunding. *See also* Section II.C.5.b above.

[1548] *See* note 868.

compensating any person for providing the personally identifiable information of any crowdfunding investor to intermediaries.[1549] Investors will benefit from the privacy protection provided by this prohibition. Intermediaries will incur a cost because the rule will not allow them to use personally identifiable information to target and seek out specific investors, thus reducing the potential investor pool for certain offerings. However, subject to this restriction, the final rules permit an intermediary to compensate a person for directing issuers or investors to the intermediary's platform in certain situations.[1550] This provision will provide intermediaries with an alternative means to attract more investors to their crowdfunding platforms, thereby mitigating some of the costs associated with the restriction on paying for personally identifiable information.

5. Additional Funding Portal Requirements

Under the final rules, a funding portal must register with the Commission by filing a complete Form Funding Portal with information concerning the funding portal's operation.[1551] The final rules also include the statutory requirement that a funding portal be a member of a registered national securities association. In the table above, we estimate the costs that intermediaries will incur related to registering as a funding portal on Form Funding Portal and becoming a member of a national securities association to be approximately $100,000 in the initial year and $10,000 thereafter.

The requirement that funding portals register with the Commission and become a member of a national securities association will benefit investors by providing regulatory oversight for these new entities, which will help to reduce the risk for fraud. Although there are costs associated with this requirement, we believe that the protections deriving from this requirement will benefit investors, issuers and potentially intermediaries by helping to create a marketplace in which investors are more willing to participate and issuers are more comfortable using this method of capital formation.

The final rules also require that funding portals use Form Funding Portal to provide updates whenever information on file becomes inaccurate for any reason, to register successor funding portals and to withdraw from funding portal registration. Although funding portals would incur time and compliance costs to update Form Funding Portal, we expect funding portals will have experience with the filing process for Form Funding Portal from their registration and, as a result, will be familiar with the filing process by the time they update the form. In the tables above, this cost is reflected in the $10,000 annual compliance cost associated with registering on Form Funding Portal and becoming a member of a registered national securities association.

The final rules allow nonresident funding portals to register with the Commission, provided that certain conditions are met.[1552] The final rules require a nonresident funding portal to appoint an agent for service of process in the United States and to certify both that it can, as a matter of law, and will provide the Commission and any national securities association of which it becomes a member with prompt access to its books and records and submit to onsite inspection and examination by the Commission and the national securities association. The funding portal also must provide an opinion of counsel attesting to the funding portal's ability to comply with these requirements under home country law. As discussed above, the final rules condition nonresident funding portal registration on the presence of an information sharing arrangement between the Commission and the regulator in the funding portal's jurisdiction.[1553] This provision is expected to facilitate Commission oversight of registered nonresident funding portals, with the potential benefit of stronger protection of investors in offerings conducted on such portals. However, it may limit the ability of some nonresident funding portals to register, potentially resulting in adverse competitive effects on nonresident portals in jurisdictions without an information sharing agreement.

Compared to the alternative of not allowing nonresident entities to operate as funding portals in the U.S. crowdfunding market, the final rules may increase competition among crowdfunding intermediaries, which in turn may reduce the fees that intermediaries charge to issuers. Lower costs of raising capital can also attract more potential issuers to the crowdfunding market, thus enhancing capital formation. Due to lack of data, we are not able to estimate the magnitude of these potential effects.

Although the requirements with respect to the appointment of an agent for service of process, a certification and a legal opinion will impose costs on nonresident funding portals, these requirements are expected to enhance investor protection by requiring steps designed to ensure that the books and records of funding portals that are not based in the United States, or that are subject to laws other than those of the United States, nevertheless are accessible to the Commission and other relevant regulators for purposes of conducting examinations of, and enforcing U.S. laws and regulations against these entities. For PRA purposes, we estimate that nonresident intermediaries will face an additional cost for outside professional services of $25,179 per intermediary to retain an agent for service of process and provide an opinion of counsel to register as a nonresident funding portal.[1554]

The statute also provides an exemption from broker-dealer registration for funding portals. The final rules implement the statutory requirement by stating that a registered funding portal is exempt from the broker-dealer registration requirements of Exchange Act Section 15(a)(1) in connection with its activities as a funding portal.[1555] We believe this approach of exempting funding portals from broker-dealer registration and its accompanying regulations will benefit the market and its participants. The activities of funding portals will be more limited than those of broker-dealers. Thus, the final rules require funding portals to comply with registration requirements that are more appropriate for their limited, permissible activities, rather than the more extensive and higher cost requirements that accompany broker-dealer registration. Lower registration costs for funding portals may translate into lower fees charged to issuers that use these portals, thus possibly benefiting issuers of crowdfunding securities and potentially increasing capital formation. Due to lack of data, we are unable to quantify these potential benefits.

[1549] *See* Rule 305(a) of Regulation Crowdfunding.

[1550] *See* Rule 305(b).

[1551] *See* Rule 400(a) of Regulation Crowdfunding.

[1552] *See* Rule 400(f) of Regulation Crowdfunding.

[1553] *See* Rule 400(f) of Regulation Crowdfunding.

[1554] For the purposes of the PRA, we estimate that entities that register as nonresident funding portals also will incur an additional internal burden of half an hour to complete Schedule C, half an hour to hire an agent for the service of process, and one hour to provide an opinion of counsel. *See* Section IV.C.2.a.

[1555] *See* Rule 401 of Regulation Crowdfunding.

a. Safe Harbor for Certain Activities

Exchange Act Section 3(a)(80) prohibits funding portals from (1) offering investment advice or recommendations, (2) soliciting purchases, sales or offers to buy securities offered or displayed on the funding portal's platform, (3) compensating employees, agents or other such persons for solicitation or based on the sale of securities displayed or referenced on the funding portal's platform, or (4) holding, managing, possessing or otherwise handling investor funds or securities. The final rules give funding portals, their associated persons, affiliates and business associates, a measure of clarity on activities that are permissible without violating these statutory prohibitions, while also helping to protect investors from activities that create potential conflicts of interest.[1556] Thus, compared with the alternative that we could have chosen, that of not providing the safe harbor, the safe harbor provisions in the final rules may facilitate regulatory compliance for funding portals, potentially with corresponding benefits for both issuers and investors. Some safe harbor provisions have additional benefits and costs, which we discuss below. Other safe harbor provisions may facilitate the implementation of other provisions of the final rules in instances where the crowdfunding intermediary is a funding portal, in which case the benefits and costs of such safe harbor provisions will be inseparable from the benefits and costs of the other provisions of the final rules as applied to instances where the crowdfunding intermediary is a funding portal.

The safe harbor for a funding portal to provide communication channels on its platform [1557] will facilitate the realization of the benefits of the provision in the final rules that requires the intermediary to provide communication channels on its platform [1558] in instances where the crowdfunding intermediary is a funding portal. The provision of communication channels by the funding portal has the potential to attract a greater number of investors to crowdfunding transactions through funding portals than otherwise would be the case, thereby encouraging capital formation. The provision of communication channels may enhance information sharing among investors, although the relevance and accuracy of the information shared by investors on these communication channels will likely vary from offering to offering.

In a change from the proposal, the final rules include a conditional safe harbor that will permit funding portals, consistent with the prohibitions under Exchange Act Section 3(a)(80), to determine whether and under what circumstances to allow an issuer to offer and sell securities in reliance on Section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) through their platforms.[1559] Allowing funding portals to decide which securities to offer through their platforms will potentially decrease compliance costs for funding portals because limiting the offerings available on their platform can help decrease the risk of statutory liability under Section 4A(c) of the Securities Act, consistent with the suggestions of some commenters.[1560] The ability to determine which issuers may offer and sell securities through their platforms may also make it easier for funding portals to bar potentially fraudulent offerings from their platforms, thereby potentially enhancing investor protection, consistent with the suggestions of various commenters,[1561] as well as screen out offerings by issuers that are unprepared or not ''crowdfund-ready.'' [1562] A reduction in the prevalence of potentially fraudulent offerings, in turn, may increase investor confidence and facilitate capital formation in the securities-based crowdfunding market. However, we recognize that, depending on the funding portal, the ability to exercise discretion with respect to which offerings to include on the platform may result in the exclusion of some issuers that do not pose a risk of fraud, potentially limiting capital formation and investor access to crowdfunding investment opportunities in those instances. This concern is expected to be mitigated, in part, by the reputational incentives of intermediaries and competition within the crowdfunding market. We also recognize that, while funding portals remain subject to more limitations concerning their activities in the crowdfunding market relative to registered broker-dealers, the ability to exercise discretion with respect to which offerings to include on their platforms is expected to partly mitigate the competitive disadvantage of funding portals relative to registered brokers, as suggested by several commenters.[1563]

The final rules also allow a funding portal to highlight particular issuers or offerings of securities made in reliance on Section 4(a)(6) on its platform based on objective criteria, for example: (1) The type of securities being offered (*e.g.*, common stock, preferred stock or debt securities); (2) the geographic location of the issuer; (3) the industry or business segment of the issuer; (4) the number or amount of investment commitments made; (5) the progress in meeting the target offering amount or, if applicable, the maximum offering amount, and (6) the minimum or maximum investment amount.[1564] The final rules require that these criteria be objective and reasonably designed to highlight a broad selection of issuers and offerings and be applied consistently to all potential issuers and offerings. They also specify that such criteria may not be related to the advisability of investing in the issuer or offering and may not give the impression of an investment recommendation.[1565] Under the final rules, funding portals may provide search functions or other tools on its platform that users may use to search, sort or categorize available offerings according to objective criteria.[1566]

A funding portal may choose to categorize offerings into general subject areas or provide search functions that, for example, allowing an investor to sort through offerings based on a combination of different objective criteria. We believe that these safe harbor provisions will benefit investors by facilitating investor access to information about offerings characterized by certain broad, objective criteria, to the extent that funding portals provide such features and tools in reliance on the final rules. By enabling issuers to utilize technology to lower the costs of each investor to search for information about a particular category of offerings, these provisions also may enhance efficiency. To the extent that the availability of these features and tools encourages investor participation in crowdfunding offerings, these provisions may have a beneficial effect on capital formation in the crowdfunding market.

The final rules prohibit a funding portal from receiving any special or additional compensation for

[1556] *See* Rule 402 of Regulation Crowdfunding.

[1557] *See* Rule 402(b)(4) of Regulation Crowdfunding.

[1558] *See* Rule 303(c) of Regulation Crowdfunding.

[1559] *See* Rule 402(b)(1) of Regulation Crowdfunding.

[1560] *See e.g.*, CrowdCheck 2 Letter; Milken Institute Letter; RocketHub Letter. *See also* Section II.D.3.a.

[1561] *See e.g.*, ABA Letter; CrowdCheck 2 Letter; Graves Letter; Seyfarth Letter.

[1562] *See* EMKF Letter; SBEC Letter.

[1563] *See e.g.*, BetterInvesting Letter; EMKF Letter; SBA Office of Advocacy Letter; ABA Letter; CfPA Letter; CrowdCheck 2 Letter; Graves Letter; Seyfarth Letter; IAC Recommendation; CFIRA Letter 12.

[1564] *See* Rule 402(b)(2) of Regulation Crowdfunding.

[1565] *Id.*

[1566] *See* Rule 402(b)(3) Regulation Crowdfunding.

highlighting (or offering to highlight) one or more issuers or offerings on its platform.[1567] This prohibition is expected to benefit investors by helping prevent conflicts of interest and incentives for funding portals to favor certain issuers over others. The final rules also make clear that such objective criteria may not include the advisability of investing in the issuer or its offering or an assessment of any characteristic of the issuer, its business plan, its management, or risks associated with an investment.[1568]

Under the final rules, funding portals are permitted to provide advice to an issuer on the structure and content of its offerings, including assistance to the issuer in preparing offering documentation.[1569] This will allow issuers to obtain guidance that may not typically be available to them and thereby help to lower funding costs. Many potential issuers seeking to offer and sell crowdfunding securities are unlikely to be familiar with how to structure offerings so as to raise capital in the most cost effective manner, and they may not have the capital, knowledge or resources to hire outside advisors. Given that an issuer will be required to conduct its securities-based crowdfunding offerings through an intermediary, we believe that permitting funding portals to provide these services to issuers will lower overall transaction costs for issuers, as they will not need to engage additional parties to provide these services. This effect will in turn help enhance market efficiency.

The final rules also provide a safe harbor for a funding portal to compensate a third party for referring a person to the funding portal in certain circumstances.[1570] This enables funding portals to realize the benefits of the provision in the final rules that permits an intermediary to compensate a person for directing issuers or investors to the intermediary's platform in certain circumstances.[1571] This provision is expected to benefit intermediaries by providing them with a means to attract more investors to their crowdfunding platforms, thereby encouraging capital formation. Investors also will benefit from the condition of this safe harbor prohibiting transaction-based compensation (other than to registered broker-dealers), which is expected to reduce the incentive for abusive practices.

The final rules also provide a safe harbor for a funding portal to pay or offer to pay compensation to a registered broker-dealer for services provided in connection with the offer or sale of securities in reliance on Section 4(a)(6), subject to conditions set forth in the rule.[1572] Similarly, a funding portal can, subject to certain conditions, receive compensation from a registered broker-dealer for services provided in connection with the offer or sale of securities by the funding portal in reliance on Section 4(a)(6).[1573] We note that some commenters expressed concern that such relationships between funding portals and broker-dealers could create conflicts of interest.[1574] However, funding portals are expected to benefit from being able to enter into these types of arrangements with registered broker-dealers who can provide services that the funding portals otherwise are prohibited from providing, such as engaging a broker-dealer to serve as a qualified third party for the transmission of investor funds. Broker-dealers also will benefit from the additional business that funding portals may be able to attract through the funding portals' platforms, as well as from services, such as those related to technology, that funding portals can provide. We anticipate that these types of service arrangements will ultimately benefit investors.

The final rules permit a funding portal to advertise its existence and identify one or more issuers or offerings available through its platform subject to certain conditions.[1575] This provision will benefit funding portals by allowing them to potentially attract more investors to their crowdfunding platforms. This provision also may enhance market efficiency as investors become more aware of available offerings through advertisements by funding portals and are thus able to better match their investments with projects that are better suited to their risk preferences and investment strategies. The conditions on advertising by funding portals in the final rules aim to consider informational benefits and investor protection concerns. For instance, while a funding portal advertising its existence may also identify one or more issuers or offerings available on its platform, it must do so on the basis of objective criteria that are reasonably designed to identify a broad selection of issuers and offerings and are applied consistently to all potential issuers and offerings. In addition, advertisements sent by a funding portal must not suggest that it is a recommendation to purchase a security or advice as to the advisability in investing in any security.[1576] While we believe these conditions are appropriate to protect the integrity of the crowdfunding market, we recognize that they may impose costs on funding portals. For example these conditions may limit the utility of advertising for the funding portal while the prohibition on special or additional compensation for identifying the offering in an advertisement may reduce the funding portal's revenue.

As discussed above, the final rules require an intermediary to deny access to its platform to an issuer that the intermediary has a reasonable basis for believing presents the potential for fraud or otherwise raises concerns about investor protection.[1577] The final rules also provide a conditional safe harbor to intermediaries that are funding portals to deny access to the platform or cancel an offering in such instances.[1578] These provisions are expected to enhance investor protection by giving funding portals greater ability to deny potentially fraudulent offerings. Funding portals are expected to benefit from the ability to deny access to certain issuers to protect the integrity of the offering process and the market reputation of their crowdfunding platforms, without fear of violating the statutory prohibition on providing investment advice.

The final rules specify that a funding portal may accept, on behalf of an issuer, investment commitments for crowdfunding offerings from investors.[1579] Under the final rules funding portals also can direct investors where to transmit funds or remit payment in connection with the purchase of securities offered and sold in reliance on Section 4(a)(6).[1580] Similarly, a funding portal can direct a qualified third party to release proceeds of a successful offering to the issuer upon completion of the offering or to return investor proceeds when an investment commitment or offering is

[1567] *See* Rule 402(b)(2) of Regulation Crowdfunding.

[1568] *See* Rule 402(b)(2) and Rule 402(b)(3) of Regulation Crowdfunding.

[1569] *See* Rule 402(b)(5) of Regulation Crowdfunding.

[1570] *See* Rule 402(b)(6) of Regulation Crowdfunding.

[1571] *See* Rule 305(b) of Regulation Crowdfunding.

[1572] *See* Rule 402(b)(7) of Regulation Crowdfunding.

[1573] *See* Rule 402(b)(8) of Regulation Crowdfunding.

[1574] *See e.g.,* Commonwealth of Massachusetts Letter; RocketHub Letter.

[1575] *See* Rule 402(b)(9) of Regulation Crowdfunding.

[1576] *See* Section II.D.3.h.

[1577] *See* Rule 301(c) of Regulation Crowdfunding.

[1578] *See* Rule 402(b)(10) of Regulation Crowdfunding.

[1579] *See* Rule 402(b)(11) of Regulation Crowdfunding.

[1580] *See* Rule 402(b)(12) of Regulation Crowdfunding.

cancelled.[1581] These provisions will facilitate the implementation of the requirements of the final rules regarding the maintenance and transmission of investor funds [1582] for intermediaries that are funding portals and give both funding portals and entities with which they do business a measure of legal certainty that funding portals accepting investment commitments for crowdfunding offerings and providing direction for funds to and from qualified third parties in compliance with the final rules will not be in violation of the statutory prohibitions on holding, managing, possessing or otherwise handling investor funds or securities. While we agree with the commenter that stated that the requirement to use a qualified third party to handle customer funds creates an additional cost,[1583] Section 3(a)(80)(D) of the Exchange Act explicitly prohibits funding portals from handling customer funds and securities.

b. Compliance Requirements

The final rules require that a funding portal implement written policies and procedures, reasonably designed to achieve compliance with the federal securities laws and the rules and regulations thereunder, relating to its business as a funding portal.[1584] This requirement will provide a benefit to investors and funding portals alike, as written policies and procedures will enhance compliance with the final rules. Funding portals will incur costs associated with the requirement to develop their own procedures and implement written policies and procedures, as well as to update and enforce them. These costs are reflected in the tables above as part of the costs to comply with requirements to act as an intermediary in transactions pursuant to Section 4(a)(6).

In contrast to the proposal, the final rules do not impose anti-money laundering (AML) obligations for funding portals. Some commenters generally suggested that since funding portals are prohibited from handling customer funds and securities, they should not be required to comply with AML provisions.[1585] As noted above, we believe it would be appropriate to work with other regulators to develop consistent and effective AML obligations for funding portals.[1586] By not imposing AML requirements in the final rules, we may avoid the possibility of conflicting or overlapping requirements. Registered broker-dealers that serve as intermediaries in securities-based crowdfunding transactions continue to have AML obligations, as do certain other parties involved in transactions conducted pursuant to Section 4(a)(6), such as a bank acting as a qualified third party to hold investor funds.[1587] To the extent that this difference in compliance obligations between funding portals and registered broker-dealers affects compliance costs and persists in the future, it may place funding portals at a relative competitive advantage. If this difference in compliance obligations between funding portals and registered broker-dealers persists in the future, it may also potentially expose investors in those securities-based crowdfunding offerings for which the intermediary is a funding portal to additional risks.

Additionally, the statute requires that intermediaries take such steps to protect the privacy of information collected from investors as we determine appropriate. In the final rules, we implement this statutory provision by requiring a funding portal to comply with Regulation S–P, S–ID and Regulation S–AM, as they apply to broker-dealers.[1588] We recognize that compliance with these privacy requirements will impose costs on funding portals. However, we believe that requiring a funding portal to comply with privacy obligations will help protect the personally identifiable information of investors, consistent with how it is required to be protected by other financial intermediaries. These privacy protections can give investors the confidence to participate in offerings made in reliance on Section 4(a)(6), which will facilitate capital formation and benefit the markets generally. As an alternative, we could have developed a more limited privacy regime applicable only to funding portals. Such an alternative would result in inconsistent treatment of funding portals and broker-dealers with respect to privacy obligations and could reduce the willingness of investors to participate in securities-based crowdfunding offerings. This alternative might also affect competition between funding portals and registered broker-dealers in the market for securities-based crowdfunding offerings.

As a condition to exempting funding portals from the requirement to register as broker-dealers under Exchange Act Section 15(a)(1), Exchange Act Section 3(h)(1)(A) requires that registered funding portals remain subject to, among other things, the Commission's examination authority. Under the final rules, a funding portal is required to permit the examination and inspection of all its business and business operations relating to its activities as a funding portal, such as its premises, systems, platforms and records, by Commission representatives and by representatives of the registered national securities association of which it becomes a member.[1589] Although funding portals will face time and compliance costs in submitting to Commission and registered national securities association examinations, inspections or investigations, and potentially responding to any issues identified, funding portals, investors and issuers will benefit from the enhanced compliance with legal obligations due to this oversight, as well as the sanctions or other disciplinary actions that may follow upon findings of violations through such inspections, examinations or investigations.

Further, the final rules require a registered funding portal to maintain and preserve certain books and records relating to its business for a period of not less than five years and in an easily-accessible place for the first two years.[1590] Recordkeeping requirements can assist registrants with compliance. They are a well-established and important element of the approach to broker-dealer regulation, as well as the regulation of investment advisers and others, and are designed to maintain the effectiveness of our inspection program for regulated entities, facilitating our review of their compliance with statutory mandates and with our rules. These requirements will enable the Commission and registered national securities organizations to more effectively gather information about the activities in which a funding portal has been engaged to discern whether the funding portal and the other parties are in compliance with the requirements of Regulation Crowdfunding and other relevant regulatory requirements. Standardized recordkeeping practices for intermediaries will enable regulators to perform more efficient, targeted inspections and examinations and thereby increase the likelihood of

[1581] *See* Rule 402(b)(13) of Regulation Crowdfunding.

[1582] *See* Rule 303(e) of Regulation Crowdfunding.

[1583] *See* Stephenson, *et al.,* Letter.

[1584] *See* Rule 403(a) of Regulation Crowdfunding.

[1585] *See, e.g.,* PeoplePowerFund Letter; Public Startup Letter 3; RFPIA Letter.

[1586] *See* Section II.D.4.b.

[1587] *Id.*

[1588] *See* Rule 403(b) of Regulation Crowdfunding.

[1589] *See* Rule 403(c) of Regulation Crowdfunding.

[1590] *See* Rule 404(a) of Regulation Crowdfunding. We note that registered broker-dealers already are required to comply with Exchange Act Rules 17a–3 and 17a–4 pertaining to books and records (17 CFR 240.17a–3 and 17a–4). Thus, all intermediaries, whether registered as broker-dealers or as funding portals, are required to make and preserve books and records.

identifying improper conduct at earlier stages of the inspection or examination, which ultimately will benefit investors and the marketplace as a whole. To the extent that these requirements result in better regulatory oversight, they may increase investor confidence in funding portals and may also benefit funding portals by promoting issuer reliance on funding portals in crowdfunding offerings.

Funding portals may incur costs in establishing the systems necessary to comply with the books and records requirements. We note that the records required to be made and preserved under the final rules are those that would ordinarily be made and preserved in the ordinary course of business by a regulated broker-dealer engaging in these activities. Entities that newly register as broker-dealers will be subject to the recordkeeping requirements of Rules 17a–3 and 17a–4. While these costs will constitute part of the cost of compliance for entities that choose to become intermediaries in crowdfunding transactions by registering as broker-dealers, the cost of broker-dealer compliance with recordkeeping requirements of Rules 17a–3 and 17a–4 is not by itself a result of the final rule. Entities solely intending to serve as intermediaries in crowdfunding transactions for which the cost of compliance with broker-dealer recordkeeping requirements is too high may elect to register as funding portals. Funding portals will be required to make and keep records related to their activities to facilitate transactions in reliance on Section 4(a)(6), which we estimate for the purposes of the PRA to result in an initial burden of 325 hours and an initial cost of $5,350 per funding portal. We estimate that ongoing recordkeeping burden and cost will be similar to the initial burden and cost.[1591] We also note that some commenters stated that the cost burden for a funding portal to maintain the proposed books and records would not be significant.[1592] We recognize that there may be a slight competitive advantage for funding portals over broker-dealers to the extent that the recordkeeping rule for funding portals is less burdensome for than the requirements applicable to broker-dealers. At the same time, we believe that the recordkeeping rule for funding portals is consistent with the narrow range of their permitted activities.

6. Insignificant Deviations

We are providing a safe harbor for issuers for certain insignificant deviations from a term, condition or requirement of Regulation Crowdfunding.[1593] This safe harbor will provide that insignificant deviations from a term, condition or requirement of Regulation Crowdfunding will not result in a loss of the exemption, so long as the issuer relying on the exemption can show that: (1) The failure to comply was insignificant with respect to the offering as a whole; (2) the issuer made a good faith and reasonable attempt to comply with all applicable terms, conditions and requirements of Regulation Crowdfunding; and (3) the issuer did not know of the failure to comply, where the failure to comply with a term, condition or requirement was the result of the failure of the intermediary to comply with the requirements of Section 4A(a) and the related rules, or such failure by the intermediary occurred solely in offerings other than the issuer's offering.

The safe harbor is expected to decrease the costs incurred by issuers compared to the alternative of not providing a safe harbor. In the absence of a safe harbor, issuers might be hesitant to participate in this new marketplace for fear of inadvertently violating an applicable regulatory requirement, thereby reducing the benefits of Regulation Crowdfunding on efficiency, competition and capital formation. We recognize that providing a safe harbor can impose costs on investors, intermediaries and regulators, compared with the alternative of not providing a safe harbor, to the extent that issuers lessen the vigor with which they develop and implement systems and controls to achieve compliance with the requirements of Regulation Crowdfunding, which may result in a decrease in investor protection. Accordingly, we have designed the conditions of the safe harbor—specifically, the issuer must show that the failure to comply was insignificant with respect to the offering as a whole; it made a good faith and reasonable attempt to comply; and it did not know of the failure or such failure occurred solely in offerings other than the issuer's offering—to lessen the potential impact on investor protection.

Several commenters suggested that the safe harbor for insignificant deviations should not apply with respect to state regulatory enforcement actions.[1594] Adopting such an alternative could have significantly undermined the utility of the Section 4(a)(6) exemption by subjecting issuers to loss of state law preemption [1595] and potential state enforcement action for insignificant deviations from Regulation Crowdfunding's requirements.

7. Relationship With State Law

Section 305 of the JOBS Act amended Securities Act Section 18(b)(4) [1596] to preempt the ability of states to regulate certain aspects of crowdfunding conducted pursuant to Section 4(a)(6). This statutory amendment will benefit issuers by preempting any registration requirements in states in which they offer or sell securities in reliance on Section 4(a)(6), thereby reducing the costs for these transactions. It also can benefit investors because these cost savings ultimately may be passed on to investors. Absent preemption of state registration requirements, an offering made through the Internet in reliance on Section 4(a)(6) and the final rules could result in an issuer potentially violating state securities laws. Some evidence in donation-based and reward-based crowdfunding campaigns suggests that contributions are not exclusively local.[1597] The statutory preemption of state registration requirements will reduce issuer uncertainty about the necessity of state registration. On the other hand, state registration requirements may provide an additional layer of investor protection, and their preemption will remove a potential layer of review that may help to deter fraud. This potential cost of state law preemption, however, may be offset by some of the statutory and final rule requirements that are designed to protect investors, such as public disclosure,[1598] investment limits,[1599] the use of a registered intermediary,[1600] provisions regarding measures to reduce the risk of fraud,[1601] and disqualification provisions.[1602] The requirement in the final rules that issuers file information on EDGAR also helps to ensure that information about

[1591] *See* Section IV.C.2.n.

[1592] *See* CFIRA Letter 1; Joinvestor Letter.

[1593] *See* Rule 502(a) of Regulation Crowdfunding.

[1594] *See, e.g.,* Commonwealth of Massachusetts Letter; NASAA Letter.

[1595] *See* Section III.B.7.

[1596] 15 U.S.C. 77r(b)(4).

[1597] For example, in crowdfunding campaigns for early stage musical projects, the average distance between artist-entrepreneurs and contributors was 3,000 miles. *See* Ajay Agrawal, Christian Catalini and Avi Goldfarb, *The Geography of Crowdfunding,* NET Institute Working Paper No. 10–08 (Oct. 29, 2010), *available at http://ssrn.com/abstract=1692661.*

[1598] *See* Rule 201 of Regulation Crowdfunding.

[1599] *See* Rule 100(a)(2) of Regulation Crowdfunding.

[1600] *See* Rule 100(a)(3) of Regulation Crowdfunding.

[1601] *See* Rule 301 of Regulation Crowdfunding.

[1602] *See* Rule 503 of Regulation Crowdfunding.

issuers is available to individual state regulators, which retain the authority to bring enforcement actions for fraud.

8. Exemption From Section 12(g)

Rule 12g–6 provides that securities issued pursuant to an offering made under Section 4(a)(6) are exempted from the record holder count under Section 12(g) provided the issuer is current in its ongoing annual reports required pursuant to Rule 202 of Regulation Crowdfunding, has total assets as of the end of its last fiscal year not in excess of $25 million, and has engaged the services of a transfer agent registered with the Commission pursuant to Section 17A of the Exchange Act. The issuer size test is broadly consistent with some commenters' suggestions.[1603]

An issuer that exceeds the $25 million total asset threshold in addition to exceeding the thresholds in Section 12(g) will be granted a two-year transition period before it is required to register its class of securities pursuant to Section 12(g), provided it timely files all its ongoing reports due pursuant to Rule 202 of Regulation Crowdfunding during such period.[1604] Section 12(g) registration will be required only if, on the last day of the fiscal year in which the company exceeded the $25 million total asset threshold, the company has total assets of more than $10 million and the class of equity securities is held by more than 2,000 persons or 500 persons who are not accredited investors.[1605] In such circumstances, an issuer that exceeds the thresholds in Section 12(g) and has total assets of $25 million or more is required to begin reporting under the Exchange Act the fiscal year immediately following the end of the two-year transition period.[1606] An issuer entering Exchange Act reporting will be considered an ''emerging growth company'' to the extent the issuer otherwise qualifies for such status.

The conditional 12(g) exemption will defer the more extensive Exchange Act reporting requirements until the issuer either sells securities in a registered transaction or registers a class of securities under the Exchange Act. Consequently, smaller issuers will not be required to become an Exchange Act reporting company as a result of a Section 4(a)(6) offering. These offerings may have a large number of investors due to the limits on the amount each investor may invest and the absence of investor eligibility restrictions, or as a result of secondary market transactions in crowdfunding securities after the expiration of resale restrictions. Given the $1 million offering limitation, the potential cost of becoming an Exchange Act reporting company could have made many offerings in reliance on Section 4(a)(6) prohibitively costly.

The condition that the issuer remain current in its ongoing reporting, as suggested by one commenter,[1607] is intended to provide sufficient disclosure to help investors make informed decisions. We believe that the ongoing disclosures required of crowdfunding issuers in the final rules accomplish this objective and provide an appropriate consideration of investor protection and capital formation. This condition is expected to increase the level of investor protection by strengthening the incentives of securities-based crowdfunding issuers that exceed the Section 12(g) thresholds related to issuer size and the number of shareholders of record to comply with the ongoing reporting requirements of Regulation Crowdfunding. The extent of additional investor protection benefits from this condition is difficult to estimate, given a separate provision in the final rules that conditions the use of the Section 4(a)(6) exemption for future offerings on compliance with Regulation Crowdfunding's ongoing reporting requirements.

The issuer size limit condition is designed to be broadly consistent with the crowdfunding exemption being tailored to facilitate small company capital formation and the likely small size of a typical issuer in the crowdfunding market. This condition is expected to strengthen investor protection by reducing the likelihood that an issuer will grow and accumulate a significant number of investors as a result of multiple offerings in reliance on Section 4(a)(6) while remaining permanently exempt from the more extensive reporting requirements of the Exchange Act that would otherwise be required pursuant to Section 12(g) (unless the issuer registers a class of securities). The size limit condition will require larger issuers to provide investors with the more extensive disclosures required by the Exchange Act for reporting companies. However, we recognize that this condition also may subject crowdfunding issuers that are larger than the size threshold or that have a higher rate of growth, and are thus more likely to exceed the size threshold in the future, to the costs of Section 12(g) registration and Exchange Act reporting, potentially placing them at a competitive disadvantage to issuers that are close to but below the size threshold. It may also discourage some high-growth issuers from relying on Section 4(a)(6) or may lead issuers approaching the size threshold to divest assets to remain under the threshold, potentially resulting in inefficient investment decisions.

While the condition requiring an issuer to use a registered transfer agent to rely on the exemption will impose costs on issuers,[1608] it is designed to provide investor protection benefits by introducing a regulated entity with experience in maintaining accurate shareholder records, thus helping to ensure that security holder records and secondary trades will be handled accurately.

9. Disqualification

The statute and the final rules impose disqualification provisions under which an issuer is not eligible to offer securities pursuant to Section 4(a)(6) and an intermediary is not eligible to effect or participate in transactions pursuant to Section 4(a)(6).[1609] The disqualification provisions for issuers are substantially similar to those imposed under Rule 262 of Regulation A and Rule 506 of Regulation D,[1610] while the disqualification provisions for intermediaries under Section 3(a)(39), which is an established standard for broker-dealers, are substantially similar to the provisions of Rule 262.

a. Issuers

The final rules are expected to induce issuers to implement measures to restrict bad actor participation in offerings made in reliance on Section 4(a)(6). This will help reduce the potential for fraud in the market for such offerings, which in turn may reduce the cost of raising capital to issuers that rely on Section 4(a)(6), to the extent that disqualification standards lower the risk premium associated with the presence of bad

[1603] *See, e.g.,* ABA Letter ($25 million); PeoplePowerFund Letter.

[1604] *Id.*

[1605] 15 U.S.C. 78*l*(g).

[1606] 17 CFR 240.12g–6.

[1607] *See* Joinvestor Letter.

[1608] *See* STA Letter (stating that strong competition in the registered transfer agent industry may result in monthly fees of $75–$300 for transfer agent services, depending on a number of factors). *See also* CapSchedule Letter (stating that there exist cost-effective ways to keep records of security holders, such as ''Software-As-A-Service'' products, that costs $0 to set up initial records regardless of the number of investors, then pricing from $5 per month for up to 100 investors, $15 per month up to 1,000 investors and $25 per month for over 1,000 investors).

[1609] *See* Section 302(d) of the JOBS Act and Rule 503 of Regulation Crowdfunding. *See also* discussion in Section II.E.6 above.

[1610] *See Disqualification Adopting Release,* note 1182. *See also Regulation A Adopting Release,* note 506.

actors in securities offerings. In addition, the requirement that issuers determine whether any covered persons are subject to disqualification may obviate the need for investors to do their own investigations and eliminate redundancies that may exist in otherwise separate investigations. This is expected to help reduce information-gathering costs to investors, to the extent that issuers are at an advantage in accessing much of the relevant information and to the extent that issuers can do so at a lower cost than investors.

The final rules will, however, impose costs on some issuers, other covered persons and investors. If issuers are disqualified from relying on Section 4(a)(6) to make their offerings, they may experience increased costs in raising capital through alternative methods that do not require bad actor disqualification, if available, or they may be precluded from raising capital altogether. This can result in negative effects on capital formation. In addition, issuers may incur costs in connection with internal personnel changes that issuers may make to avoid the participation of those covered persons who are subject to disqualifying events. Issuers also may incur costs associated with restructuring share ownership positions to avoid having 20 Percent Beneficial Owners who are subject to disqualifying events. Finally, issuers may incur costs in connection with seeking waivers of disqualification from the Commission or determinations by other authorities that existing orders do not give rise to disqualification.

The final rules provide a reasonable care exception whereby an issuer will not lose the benefit of the Section 4(a)(6) exemption if it is able to show that it did not know, and in the exercise of reasonable care could not have known, of the existence of a disqualification.[1611] A reasonable care exception may encourage capital formation by eliminating any hesitation issuers may otherwise experience under a strict liability standard. However, such an exception also may encourage issuers to take fewer steps to inquire about the existence of a disqualification than they would if a strict liability standard applied, increasing the potential for fraud in the market for offerings made in reliance on Section 4(a)(6). Nevertheless, some issuers, in exercising reasonable care, may incur costs associated with conducting and documenting their factual inquiry into possible disqualifications. The lack of specificity in the rule, while providing flexibility to the issuer to tailor its factual inquiry as appropriate to a particular offering, may increase these costs because uncertainty can drive issuers to do more than necessary under the rule.

The requirement under the final rules that issuers disclose matters that would have triggered disqualification, had they occurred after the effective date of Regulation Crowdfunding,[1612] also will impose costs and benefits. The disclosure requirement will reduce costs associated with covered persons who would be disqualified under the final rules but for the fact that the disqualifying event occurred prior to the effective date of the rules. However, this approach will allow the participation of past bad actors, whose disqualifying events occurred prior to the effective date of the final rules, which can expose investors to the risks that arise when bad actors are associated with an offering. Nevertheless, investors will benefit by having access to such information that can inform their investment decisions. Issuers also may incur costs associated with the factual inquiry, preparing the required disclosure and making any internal or share ownership changes to avoid the participation of covered persons that trigger the disclosure requirement. Disclosure of triggering events also may make it more difficult for issuers to attract investors, and issuers may experience some or all of the impact of disqualification as a result.

We believe the inclusion of Commission cease-and-desist orders in the list of disqualifying events will not impose a significant, incremental cost on issuers and other covered persons because many of these actors may already be subject to disqualifying orders issued by the states, federal banking regulators and the National Credit Union Administration.[1613]

Under the final rules, orders issued by the CFTC will trigger disqualification to the same extent as orders of the regulators enumerated in Section 302(d)(2)(B)(i) of the JOBS Act (*e.g.,* state securities, insurance and banking regulators, federal banking agencies and the National Credit Union Administration). We believe that including orders of the CFTC will result in the similar treatment, for disqualification purposes, of comparable sanctions. In this regard, we note that the conduct that will typically give rise to CFTC sanctions is similar to the type of conduct that will result in disqualification if it were the subject of sanctions by another financial services industry regulator. This is likely to enable the disqualification rules to more effectively screen out bad actors.

As discussed above, the baseline for our economic analysis of Regulation Crowdfunding, including the baseline for our consideration of the effects of the final rules on efficiency, competition and capital formation, is the situation in existence today, in which startups and small businesses seeking to raise capital through securities offerings must register the offer and sale of securities under the Securities Act unless they can comply with an existing exemption from registration under the federal securities laws. Relative to the current baseline, we believe that the disqualification provisions will not impose significant incremental costs on issuers and other covered persons because the final rules are substantially similar to the disqualification provisions under existing exemptions.

As an alternative, we could have specified that pre-existing events are subject to the disqualification rules, as suggested by some commenters.[1614] As another alternative, we could have expanded the list of covered persons to include transfer agents and lawyers, as suggested by one commenter.[1615] By expanding the range and categories of potentially disqualified persons, both of these alternatives could have the benefit of strengthening investor protection. At the same time, they would increase the compliance costs for issuers and disqualified persons described above. Overall, we believe that preserving consistency with the disqualification criteria of Rule 262 and Rule 506, as we do in the final rules, can potentially yield compliance cost savings for issuers that undertake multiple types of exempt offerings while still maintaining appropriate investor protections.

b. Intermediaries

With regard to intermediaries, the final rules apply the disqualification provisions under Section 3(a)(39) of the Exchange Act, rather than a standard based on Rule 262.[1616] The Section 3(a)(39) standard is an established one among broker-dealers and their regulators, and we believe that, despite the differences, Section 3(a)(39) and Rule 262 are substantially similar with

[1611] *See* Rule 503(b)(4) of Regulation Crowdfunding. *See also* Section II.E.6.a.iii.

[1612] *See* Rule 201(u) of Regulation Crowdfunding. *See also* Section II.E.6.a.v.

[1613] *See Disqualification Adopting Release,* note 1182.

[1614] *See, e.g.,* Guzik Letter 1; NASAA Letter.

[1615] *See* Brown J. Letter (also recommending the Commission adopt similar bad actor provisions under Rule 504).

[1616] *See* Rule 503(d) of Regulation Crowdfunding.

regard to the persons and events they cover, their scope and their purpose.[1617] We believe that imposing any new or different standard, including one based on Rule 262, for those intermediaries that engage in crowdfunding transactions would likely create confusion and unnecessary burdens, as currently-registered broker-dealers and their associated persons would become subject to two distinct standards for disqualification. Moreover, adopting a more stringent disqualification standard may reduce the number of intermediaries eligible under the final rules and decrease competition among intermediaries in the securities-based crowdfunding market. By contrast, consistent standards for all broker-dealers and funding portals will assist a registered national securities association in monitoring compliance and enforcing its rules.

The final rules implement the statutory requirement for intermediaries by providing that a person subject to a statutory disqualification, as defined in Exchange Act Section 3(a)(39), may not act as, or be an associated person of, an intermediary in a transaction involving the offer or sale of securities in reliance on Section 4(a)(6) unless so permitted by Commission rule or order. While this requirement will potentially reduce the number of intermediaries for Section 4(a)(6) transactions, we expect that it will strengthen investor protection by preventing bad actors from entering the securities-based crowdfunding market, thereby reducing the potential for fraud and other abuse.

As discussed above, the baseline for our economic analysis of Regulation Crowdfunding, including the baseline for our consideration of the effects of the final rules on efficiency, competition and capital formation, is the situation in existence today, in which intermediaries intending to facilitate securities transactions are required to register with the Commission as broker-dealers under Exchange Act Section 15(a). Relative to this baseline, we believe that the disqualification provisions will not impose significant incremental costs to broker-dealers because the final rules include the same disqualification provisions that are already imposed on broker-dealers.

IV. Paperwork Reduction Act

A. Background

Certain provisions of the final rules contain ''collection of information'' requirements within the meaning of the Paperwork Reduction Act of 1995 (''PRA'').[1618] We published a notice requesting comment on the collection of information requirements in the Proposing Release, and we submitted the proposal to the Office of Management and Budget (''OMB'') for review in accordance with the PRA.[1619]

In the Proposing Release, we solicited comment on the assumptions and estimates in our PRA analysis. We received no comments on our estimates of and assumptions about the number of issuers and intermediaries that will participate in securities-based crowdfunding transactions or the size and frequency of those transactions. We received several comments on our estimates of the time and expense required of issuers to meet their filing obligations.[1620] We also received several comments on our estimates of the costs incurred by intermediaries.[1621] One commenter recommended a lessened paperwork burden in general.[1622] These comments are discussed in further detail below, and where appropriate, we have revised our burden estimates in response to commenters' suggestions and to reflect changes in the final rules, as adopted.

The titles for the collections of information are:

(1) ''Form ID'' (OMB Control Number 3235–0328);

(2) ''Form C'' (OMB Control Number 3235–0716) (a new collection of information);

(3) ''Form BD'' (OMB Control Number 3235–0012); and

(4) ''Crowdfunding Rules 300–304—Intermediaries'' (OMB Control Number 3235–0726) [1623] (a new collection of information) and

(5) ''Crowdfunding Rules 400–404—Funding Portals'' (OMB Control Number 3235–0727) [1624] (a new collection of information).

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. We applied for OMB control numbers for the new collections of information in accordance with 44 U.S.C. 3507(j) and 5 CFR 1320.13, and as of the date of this release, OMB has assigned a control number to each new collection as specified above. Responses to these new collections of information will be mandatory for issuers raising capital under Regulation Crowdfunding and intermediaries participating in offerings under Regulation Crowdfunding.

The hours and costs associated with preparing disclosure, filing forms, and retaining records constitute reporting and cost burdens imposed by the collections of information. In deriving estimates of these hours and costs, we recognize that the burdens likely will vary among individual issuers and intermediaries based on a number of factors, including the stage of development of the business, the amount of capital an issuer seeks to raise, the number of offerings an intermediary hosts on its platform, and the number of years since inception of the business. We believe that some issuers and intermediaries will experience costs in excess of the average and some issuers and intermediaries may experience less than the average costs.

B. Estimate of Issuers and Intermediaries

1. Issuers

The number, type and size of the issuers that will participate in securities-based crowdfunding transactions are uncertain, but data on current market practices may help identify the number and characteristics of potential issuers that may offer and sell securities in reliance on Section 4(a)(6).[1625] While it is not possible to predict the number of future offerings made in reliance on Section 4(a)(6), particularly because rules governing securities-based crowdfunding are not yet in effect, for purposes of this analysis, we estimate that approximately 1,900 issuers will seek to offer and sell securities in reliance on Section 4(a)(6) per year. We base this estimate on the average number of issuers (excluding issuers that are pooled investment vehicles) per year that conducted a new Regulation D offering of up to $1 million from 2009 to 2014 and had no revenues or less than $1 million in revenues.[1626] We

[1617] *See* discussion in Section II.E.6.b above.

[1618] 44 U.S.C. 3501 *et seq.*

[1619] 44 U.S.C. 3507(d); 5 CFR 1320.11.

[1620] *See, e.g.,* Angel Letter 1; Heritage Letter; SeedInvest Letter 1.

[1621] *See, e.g.,* Arctic Island Letter 8; CapSchedule Letter; Heritage Letter; Joinvestor Letter; SBEC Letter; Seed & Spark Letter; STA Letter.

[1622] Peers Letter.

[1623] This includes burdens for compliance with privacy rules (Reg. S–P, Reg. S–AM and Reg S–ID) as required by Rule 403(b).

[1624] This includes burdens for Form Funding Portal.

[1625] *See* Section III.A.5.a for a discussion of the data regarding current market practices.

[1626] *Id.* This estimate differs from our estimate in the proposal. It uses more recent data than the proposal and is based on the average number of issuers per year rather than the average number of unique issuers. According to filings made with the Commission, an average of approximately 4,559 issuers per year conducted new Regulation D offerings of up to $1 million from 2009 to 2014. 22%, or 1,003, of those issuers reported having no revenues. (0.22 × 4,559 = 1,003). 19%, or 866, of

believe those issuers will be similar in size to the potential issuers that may participate in securities-based crowdfunding, and we assume that each issuer will conduct one offering per year.

We received no comments on our estimate of the number of issuers expected to participate in securities-based crowdfunding transactions or the number of offerings in reliance on Section 4(a)(6) we expect those issuers to conduct. In developing the estimate for the number of issuers in the final rule, we refined the methodology used in the Proposing Release and applied that methodology to more recent data, resulting in an updated estimate that we believe is reasonable and appropriate.

2. Intermediaries That Are Registered Brokers

The final rules require intermediaries to register with us as either a broker-dealer or as a funding portal. Consistent with the Proposing Release, we estimate that the collection of information requirements in the final rules will apply to approximately 10 intermediaries per year that are not currently registered with the Commission and that will choose to register as brokers, rather than as funding portals, to act as intermediaries for offerings made in reliance on Section 4(a)(6). However, we believe that, given the cost that an unregistered entity will incur to register as a broker compared with the lower cost of becoming a funding portal, unregistered entities that choose to act as crowdfunding intermediaries will generally be more likely to register as funding portals than as brokers.

Consistent with the Proposing Release, we further estimate that approximately 50 intermediaries per year that are already registered as brokers with the Commission will choose to add to their current service offerings by also serving as crowdfunding intermediaries. These entities will not have to file a new application for registration with us, and if currently doing business with the public, they will already be members of FINRA (the applicable national securities association registered under Exchange Act Section 15A). We note, however, that given the nascent nature of the equity-based crowdfunding market, we do not have any data or other evidence indicating the number of currently-registered brokers that will be interested in becoming crowdfunding intermediaries. Therefore, we recognize that the number of brokers per year that may engage in crowdfunding activities could differ significantly from our current estimate. We received no comments on our estimates of the number of broker-dealers that will act as intermediaries.

3. Funding Portals

Consistent with the Proposing Release, we estimate that on average approximately 50 intermediaries per year that are *not* already registered as brokers will choose to be registered as funding portals during the first three years following effectiveness of the final rules. This estimate assumes that, upon effectiveness of the final rules, about 15% of the approximately 200 U.S.-based crowdfunding portals [1627] currently in existence will participate in securities-based crowdfunding and that the number of crowdfunding portals will grow at 60% per year over the next three years.[1628] Therefore, we estimate that an average of approximately 50 respondents will be registered as funding portals annually.[1629] Of those 50 funding portals, we estimate that two will be nonresident funding portals. These estimates are based in part on indications of interest expressed in responses to FINRA's voluntary interim form for funding portals. We received no comments on our estimates on the number of funding portals that will act as intermediaries

C. Estimate of Burdens

1. Issuers

a. Form C: Offering Statement and Progress Update

Under the final rules, an issuer conducting a transaction in reliance on Section 4(a)(6) will be required to file with us specified disclosures on a Form C: Offering Statement.[1630] An issuer also will be required to file with us amendments to Form C to disclose any material change in the offer terms or disclosure previously provided to investors.[1631] Form C is similar to the Form 1–A offering statement under Regulation A, but it requires fewer disclosure items (*e.g.,* it does not require disclosure about the plan of distribution, the compensation of officers and directors, litigation or a discussion of federal tax aspects). We note that offerings made in reliance on Regulation A allow issuers to offer up to $50 million, involve review by SEC staff and, in the case of Tier 1 offerings, require filings at the state level.[1632] In light of these factors, we expect that issuers seeking to raise capital pursuant to a Regulation A offering generally will be at a more advanced stage of development than issuers likely to raise capital pursuant to Section 4(a)(6), so the complexity of the required disclosure and, in turn, the burden of compliance with the requirements of Form C will be significantly less than for Form 1–A.[1633] In the Proposing Release we estimated that the burden to prepare and file Form C would be approximately 60 hours per issuer, which represented approximately 10% of the burden to prepare then-existing Form 1–A.[1634] We estimated that 75% of the burden, or 45 hours, would be carried internally and the remaining 25% of the burden would be carried by outside professionals at a cost of $6,000 per issuer.

As discussed in more detail in the Economic Analysis, above, we received a number of comments concerning the burdens and costs of the proposed rules.[1635] Many of these commenters

those issuers reported having less than $1 million in revenues. (0.19 × 4,559 = 866). Therefore, the average number of issuers per year is 1,003 + 866 = 1,869, or approximately 1,900 issuers.

[1627] This estimate is based in part on an industry estimate that, as of April 2012, there were approximately 200 non-securities-based crowdfunding portals operating in the United States. *See* Massolution 2012 at 16. We did not receive comment on these estimates and therefore continue to believe our estimates in the Proposing Release are appropriate. *See also* Massolution 2015 at 84 (estimating that, as of December 2014, there were approximately 375 crowdfunding portals operating in North America, not just the United States).

[1628] A worldwide survey of crowdfunding portals indicated that, in 2011, approximately 14.8% of the surveyed crowdfunding portals (mostly based in Europe) participated in ''equity-based'' crowdfunding. *Id.* Also, the total number of crowdfunding portals worldwide grew by an estimated 60% from 2011 to 2012. *Id.* at 13. We did not receive comment on these estimates and therefore continue to believe our estimates in the Proposing Release are appropriate. *See also* Massolution 2015 at 82–83 (estimating that, as of December 2014, there were approximately 1250 crowdfunding portals worldwide compared to 813 worldwide in 2012, which represents an increase of approximately 54%).

[1629] 200 U.S.-based crowdfunding portals × 15% (estimated percentage of crowdfunding portals that will participate in securities-based crowdfunding) = 30 funding portals that will participate in securities-based crowdfunding. Assuming 60% growth over three years, the number of registered funding portals will be 30 during the first year, 48 during the second year and 77 during the third year. The average number of registered funding portals over three years is (30 + 48 + 77)/3 = 52 funding portals (or approximately 50 funding portals per year).

[1630] *See* Rule 203(a)(1) of Regulation Crowdfunding.

[1631] *See* Rule 203(a)(2) of Regulation Crowdfunding.

[1632] *See* Rule 256 of Regulation A; *Regulation A Adopting Release,* note 506.

[1633] We currently estimate the average burden per response for preparing and filing a Form 1–A to be approximately 750 hours.

[1634] *See* Proposing Release at 78 FR 66540.

[1635] *See* Section III.B.3.a.

provided monetary estimates without distinguishing between internal burden hours and outside professional costs. Some commenters suggested that the Proposing Release underestimated the time and expense that would be required to prepare and file Form C.[1636] In contrast, one commenter stated that it was a third-party service provider that could prepare Form C at much lower costs than those estimated by the Commission.[1637] Another commenter suggested that the cost of preparing and filing these forms and the associated compliance costs would range from $3,000 to $9,000.[1638] Additionally, we received a number of comments about the costs of the audit and review of financial statements, as proposed. We believe that these costs would be a component of the outside professional costs associated with Form C. In the Economic Analysis, we have set forth our monetized estimates of the various cost components, grouped into categories based on the size of the offering. Our Form C estimates range from $2,500 for the smallest offerings (up to $100,000); to a range of $2,500 to $5,000 for somewhat larger offerings (more than $100,000 but not more than $500,000) and a range of $5,000 and $20,000 for the largest offerings (more than $500,000). Additionally, our estimates of the cost of financial statement review or audit range from $0 for the smallest offerings; to between $1,500 and $18,000 for larger offerings and for first-time crowdfunding issuers conducting offerings between $500,000 and $1,000,000; and $2,500 to $30,000 for other issuers that are conducting an offering in the largest offering amount category. Accordingly, in our Economic Analysis we estimate a cost range estimate for Form C and the financial statement review of: $2,500 for the smallest offerings, $4,000 to $23,000 for the larger offerings, $6,500 to $38,000 for first-time crowdfunding issuers conducting offerings between $500,000 and $1,000,000, and $7,500 to $50,000 for other issuers conducting an offering in the largest offering amount category. For purposes of the PRA, however, we must provide a single estimate, comprised of both burden hours and outside professional costs, for an average issuer.

Based on these comments and our Economic Analysis, we have revised our estimate of the burden associated with the preparation and filing of Form C. We acknowledge that a number of commenters suggested that we underestimated the burdens of the proposed rule, but believe that changes in the final rule, particularly with respect to the financial statement requirements for first-time crowdfunding issuers, may mitigate the impact of those costs. Accordingly, we estimate that the average total burden to prepare and file the Form C, including any amendment to disclose any material change, will be approximately 100 hours, which, while higher than our proposed estimate, is still substantially less than the burden to prepare a Form 1–A for an offering under Regulation A, as recently amended. We continue to estimate that 75 percent of the burden of preparation will be carried by the issuer internally and that 25 percent will be carried by outside professionals [1639] retained by the issuer at an average cost of $400 per hour.[1640] This reflects 75 internal burden hours per issuer and $10,000 in external professional costs. While for PRA purposes, we must present this estimate in terms of hours and costs, we believe that this estimate is consistent with the monetary ranges that we set forth in the Economic Analysis.

Under the final rules, the issuer also will be required to file with us regular updates on the progress of the issuer in meeting the target offering amount.[1641] In a change from the proposal, the rules permit issuers to satisfy the progress update requirement by relying on the relevant intermediary to make publicly available on the intermediary's platform frequent updates about the issuer's progress toward meeting the target offering amount. Nevertheless, an issuer relying on the intermediary's reports of progress must still file a progress update at the end of the offering to disclose the total amount of securities sold in the offering. The issuer is required to make the filing under cover of a Form C–U: Progress Update. Form C–U is similar to a Form D Notice of Exempt Offering of Securities under Regulation D.[1642] Form C–U will require significantly less disclosure than the Form D, however, as it will require disclosure only of the issuer's progress in meeting the target offering amount, rather than compensation and use of proceeds disclosures or other information about the issuer and the offering. Thus, the complexity of the required disclosure and the burden to prepare and file Form C–U will be significantly less than for Form D. We continue to estimate that the burden to prepare and file each progress update will be 0.50 hours. In light of the change from the proposal, we expect most issuers will rely on the relevant intermediary to provide interim progress updates and therefore will be required to file an average of one progress update during each offering rather than the two progress updates that we estimated in the Proposing Release.[1643] As in the Proposing Release, we estimate that the entirety of this burden will be borne internally by the registrant.

Overall, we estimate that compliance with the requirements of a Form C filed in connection with offerings made in reliance on Section 4(a)(6) will require 190,000 burden hours (1,900 offering statements × 100 hours/offering statement) in aggregate each year, which corresponds to 142,500 hours carried by the issuer internally (1,900 offering statements × 100 hours/offering statement × 0.75) and costs of $19,000,000 (1,900 offering statements × 100 hours/offering statement × 0.25 × $400) for the services of outside professionals. We also estimate that compliance with the requirements of Form C–U filed during an offering will require 950 burden hours (1,900 offering statements × 1 progress update per offering × 0.50 hours per progress update) in aggregate each year.

b. Form C–AR: Annual Report

Under the final rules, unless the reporting has been terminated, any

[1636] *See, e.g.,* Heritage Letter (stating that the costs to prepare the required disclosures will likely exceed $10,500, except in cases of start-ups with no operating history); NSBA Letter (stating that issuers and intermediaries will likely incur higher attorney and accounting fees and financial and administrative burdens than estimated in the proposed rules but without providing estimates); SeedInvest Letter 2 (estimating upfront compliance costs to be ''potentially hundreds of hours [in internal company time] and $20,000 to $50,000 [in outside professional costs]'').

[1637] FundHub Letter 2 (stating that the commenter will prepare Form C and all disclosure documents, do all bad actor checks, verify investor status and perform all other necessary compliance measures for a $100,000 offering for $2,500 total, and that, in most cases, its services and associated legal fees will cost an issuer between $2,500 and $5,000 for an offering up to $500,000 and between $5,000 and $10,000 for an offering between $500,000 and $1,000,000).

[1638] *See* StartEngine Letter 2.

[1639] For example, an issuer could retain an outside professional to assist in the preparation of the financial statements, but could decide to address the remaining disclosure requirements internally.

[1640] We estimate the average external cost of preparing Form C to be 0.25 × 100 hours × $400 per hour = $10,000.

We recognize that the costs of retaining outside professionals may vary depending on the nature of the professional services, but for purposes of this PRA analysis, we estimate that such costs would be an average of $400 per hour. This is the rate we typically estimate for outside legal services used in connection with public company reporting.

[1641] *See* Rule 203(a)(3) of Regulation Crowdfunding.

[1642] We currently estimate the burden per response for preparing and filing a Form D to be 4.00 hours.

[1643] *See* Rule 203(a)(3) of Regulation Crowdfunding.

issuer that sells securities in a transaction made pursuant to Section 4(a)(6) will be required to file annually with us an annual report on Form C–AR: Annual Report.[1644] Form C–AR will require disclosure substantially similar to the disclosure provided in the Form C: Offering Statement, except that offering-specific disclosure will not be required and the issuer may be able to update disclosure previously provided in the Form C. In addition, in a change from the proposal, instead of requiring financial statements in the annual report that meet the highest standard of review previously provided (either reviewed or audited), the final rules require financial statements of the issuer certified by the principal executive officer of the issuer to be true and complete in all material respects.[1645] Therefore, we estimate that the burden to prepare and file Form C–AR will be less than that required to prepare and file Form C.

As discussed in the Economic Analysis, we received some comments on the costs of Form C–AR.[1646] One commenter that submitted comments concerning both Form C and Form C–AR provided several cost estimates or ranges for Form C–AR that varied but were ranges or amounts that were lower than the commenter's estimates for Form C.[1647] Our analysis of the cost of Form C–AR in our Economic Analysis reflects these comments, and in that analysis, we estimate that the cost of Form C–AR represents two-thirds of the cost of Form C (exclusive of the financial statement review).

Additionally, in light of the change to the final rules for Form C–AR to require financial statements that are certified by the principal executive officer of the issuer to be true and complete in all material respects, rather than requiring financial statements that meet the highest level of review previously provided, we estimate that for Form C–AR there will be a further reduction of PRA burden compared with the burden of Form C. Accordingly, we estimate that compliance with Form C–AR will be approximately one-half of the burden of Form C, resulting in a burden of 50 hours per response. We further estimate that 75 percent of the burden of preparation will be carried by the issuer internally and that 25 percent will be carried by outside professionals[1648] retained by the issuer at an average cost of $400 per hour.[1649]

We estimate that compliance with the requirements of Form C–AR in the first year after issuers sell securities pursuant to Section 4(a)(6) will require 95,000 burden hours (1,900 issuers × 50 hours/issuer) in the aggregate, which corresponds to 71,250 hours carried by the issuer internally (1,900 issuers × 50 hours/issuer × 0.75) and costs of $9,500,000 (1,900 issuers × 50 hours/issuer × 0.25 × $400) for the services of outside professionals.

c. Form C–TR: Termination of Reporting

Under the final rules, any issuer terminating its annual reporting obligations will be required to file a notice under cover of Form C–TR: Termination of Reporting to notify investors and the Commission that it no longer will file and provide annual reports pursuant to the requirements of Regulation Crowdfunding.[1650] We estimate that eight percent of the issuers that sell securities pursuant to Section 4(a)(6) will file a notice under cover of Form C–TR during the first year.[1651] The Form C–TR will be similar to the Form 15 that issuers file to provide notice of termination of the registration of a class of securities under Exchange Act Section 12(g) or to provide notice of the suspension of the duty to file reports required by Exchange Act Sections 13(a) or 15(d).[1652] Therefore, we estimate that compliance with the Form C–TR will result in a similar burden as compliance with Form 15, that is, a burden of 1.50 hours per response. We estimate that compliance with Form C–TR will result in a burden of 228 hours (1,900 issuers × 0.08 issuers filing Form C–TR × 1.50 hours/issuer) in the aggregate during the first year for issuers terminating their reporting obligations. As in the Proposing Release, we estimate that the entirety of this burden will be borne internally by the registrant. We received no comments on our estimates with respect to Form C–TR and continue to believe that these estimates are reasonable.

d. Form ID Filings

Under the final rules, an issuer will be required to file specified disclosures with us on EDGAR.[1653] We anticipate that the majority of first-time issuers seeking to offer and sell securities in reliance on Section 4(a)(6) will not previously have filed an electronic submission with us and so will need to file a Form ID. Form ID is the application form for access codes to permit filing on EDGAR. The final rules will not change the form itself, but we anticipate that the number of Form ID filings will increase due to new issuers seeking to offer and sell securities in reliance on Section 4(a)(6). One commenter stated that it would take approximately 70 minutes to complete a Form ID, considerably more time than the estimated 0.15 hours.[1654] However, the information required by Form ID is very limited, primarily the name and address of the filer, so we continue to believe the estimated 0.15 hours per response is appropriate. For purposes of this PRA analysis, we estimate that all of the issuers who will seek to offer and sell securities in reliance on Section 4(a)(6) will not have filed an electronic submission with us previously and will, therefore, be required to file a Form ID. As noted above, we estimate that approximately 1,900 issuers per year will seek to offer and sell securities in reliance on Section 4(a)(6), which will correspond to 1,900 additional Form ID filings. As a result, we estimate the additional annual burden associated with this form will be approximately 285 hours (1,900 filings × 0.15 hours/filing).[1655]

2. Brokers and Funding Portals

Below, we discuss our estimates of the internal burdens and professional costs associated with the collections of information required under the final rules as they relate to intermediaries. Where relevant, we discuss any comments received on these estimates and any changes to estimates, including changes made in response to comments on them.

a. Registration Requirements

(1) Time Burden

The final rules will require intermediaries to register with us as either a broker or as a funding portal. As noted above, we believe that some intermediaries for transactions made in

[1644] *See* Rule 202 of Regulation Crowdfunding.

[1645] *See* Rule 202(a) of Regulation Crowdfunding. However, issuers that have available financial statements that have been reviewed or audited by an independent certified public accountant because they prepare them for other purposes shall provide them and will not be required to have the principal executive officer certification. *Id.*

[1646] *See* Section III.B.3.a.

[1647] *See* SeedInvest Letter 1; SeedInvest Letter 4.

[1648] *See* note 1639.

[1649] *See* note 1640.

[1650] *See* Rule 203(b)(2) of Regulation Crowdfunding.

[1651] For purposes of this PRA analysis, we estimate that eight percent of issuers will not survive past their first year, based on a recent study that found that of a random sample of 4,022 new high-technology businesses started in 2004, 92.3% survived past their first year. *See* Kauffman Firm Survey, note 1302 at 13.

[1652] We currently estimate the burden per response for preparing and filing a Form 15 to be 1.50 hours.

[1653] *See* Rules 201–203 of Regulation Crowdfunding.

[1654] Angel Letter 1.

[1655] We currently estimate the burden per response for preparing and filing with Form ID to be 0.15 hours.

reliance on Section 4(a)(6) and Regulation Crowdfunding will already be registered as brokers. Therefore, this registration requirement will impose no new requirement on these entities and no additional burden for purposes of this PRA analysis. Entities that are not already registered as brokers may decide to register either as brokers or as funding portals and to become members of a registered national securities association (if they are not already a member) pursuant to the final rules. We estimate that each year, on average, approximately 10 entities may decide to be registered as brokers and approximately 50 entities may decide to be registered as funding portals by filing Form Funding Portal.[1656] In addition, we estimate that of those 50 entities that register as funding portals, two will be nonresident funding portals and subject to the additional requirements under Rule 400(f) of completing Schedule C (including the required certifications), requirements related to the agent for service of process in the United States, and obtaining an opinion of counsel.

We estimate the burden for registering with the Commission as a broker based upon the existing burdens for completing and filing Form BD, currently estimated as 2.75 hours.[1657] Consequently, we estimate that the total annual burden hours required for all crowdfunding intermediaries, including brokers and funding portals, to register with us under the final rules will be approximately 165 hours (2.75 hours/respondent × (10 brokers + 50 funding portals)). In addition, those entities that register as nonresident funding portals will face an additional burden of half an hour to complete Schedule C and make the required certifications, half an hour to document the appointment of an agent for the service of process, and one hour to obtain an opinion of counsel. Consequently, we estimate that, of the 50 registered funding portals, two will each face an additional burden of two hours to register, for a total additional annual burden of four hours.

We have taken into consideration that brokers that register to engage in crowdfunding transactions conducted in reliance on Section 4(a)(6) may eventually decide to withdraw their registration. Withdrawal requires an entity to complete and file with us a Form BDW.[1658] We further estimate that approximately 430 broker-dealers withdraw from Commission registration annually [1659] and, therefore, file a Form BDW. Of them, we estimate that approximately one broker who had registered in order to facilitate crowdfunding offerings made in reliance on Section 4(a)(6) will decide to withdraw in each year following adoption of the rules.[1660] Therefore, the one broker-dealer that withdraws from registration by filing Form BDW will incur an aggregate annual reporting burden of approximately 0.25 hours (0.25 hours/respondent × 1 broker). Similarly, we estimate that approximately five funding portals will choose to withdraw from registration each year [1661] and that each withdrawal, as with Form BDW, will take approximately 0.25 hours. This will result in an aggregate annual reporting burden of approximately 1.25 hours (0.25 hours/respondent × 5 funding portals).

In the Proposing Release, we also included an estimate of PRA burdens and costs for newly-registered intermediaries to become members of FINRA or any other registered national securities association. Specifically, the Proposing Release included a discussion of an estimate of the paperwork burdens and costs that would be incurred by an intermediary to register with a national securities association as well as an estimate of the ongoing fees (*e.g.,* FINRA annual assessment fees) that would be incurred by an intermediary to remain registered with a national securities association. However, after further consideration, we do not believe the hour burdens and costs associated with FINRA's membership constitute paperwork burdens and costs attributable to the Commission's rules. Accordingly, we are not providing estimates of burdens and costs resulting from membership in a registered national securities association in this PRA analysis. We have, however, considered the costs of such membership, both initial and ongoing, in our Economic Analysis above.[1662]

Once registered, a broker must promptly file an amended Form BD when information originally reported on Form BD changes or becomes inaccurate. Similarly, a registered funding portal must file amendments relating to changes in information filed in a Form Funding Portal filing.[1663] Based on the number of amended Forms BD that we received from October 1, 2011 through September 15, 2015, we estimate that the total number of amendments that we will receive on Form BD from the 10 brokers that register under Regulation Crowdfunding will be approximately 32.[1664] Therefore,

[1656] As noted above, funding portals will have to complete and file Form ID in order to obtain access codes to file on EDGAR. Based on our estimates, 50 funding portals per year will newly register through EDGAR, which will correspond to 50 additional Form ID filings. As a result, we estimate the additional annual burden associated with this form will be approximately 7.5 hours (50 filings × 0.15 hours/filing).

[1657] While it is likely that the time necessary to complete Form BD varies depending on the nature and complexity of the entity's securities business, we currently estimate the average time necessary for a broker-dealer to complete and file an application for broker-dealer registration on Form BD to be approximately 2.75 hours. We also estimate that the time burden to register as a funding portal on Form Funding Portal will be, for purposes of this PRA analysis, the same as the time required to complete and file Form BD because the information required for that form is similar.

[1658] The time necessary to complete Form BDW varies depending on the nature and complexity of the applicant's securities business. We currently estimate that it takes a broker-dealer approximately 0.25 burden hours to complete and file a Form BDW to withdraw from Commission registration, as required by Exchange Act Rule 15b6–1 (17 CFR 240.15b6–1).

[1659] This estimate is based on Form BDW data collected over the past five years and may be high as a result of the impact of the financial crisis on broker-dealers. For the past five fiscal years (from 10/1 through 9/30), the number of broker-dealers that withdrew from registration was as follows: 524 in 2011 and 428 in 2012, 434 in 2013, 454 in 2014 and 306 by September 15, 2015. We thus estimate the number of broker-dealers that withdraw from the Commission annually to be 430 ((524+428+434+454+306)/5).

[1660] As of September 2015, there were 4,213 broker-dealers registered with the Commission. An average of 430 broker-dealers per year withdraw from registration, or 10% of the number of registered broker-dealers (430 withdrawing broker-dealers/4,213 registered broker-dealers). We assume that the same percentage of broker-dealers that withdraw from registration will apply to the population of registered broker-dealers participating in offerings in reliance on Section 4(a)(6). Of our estimate of 10 registered broker-dealers per year registering to participate in crowdfunding transactions in reliance on Section 4(a)(6), we estimate that approximately one broker-dealer per year (10 registered broker-dealers × 0.10) will withdraw from registration.

[1661] We estimate that the percentage of registered funding portals participating in crowdfunding transactions in reliance on Section 4(a)(6) that will withdraw from registration annually would be the same as the percentage of broker dealers that withdraw from registration annually because of the similarity of these entities' businesses. Of our estimate of 50 registered funding portals participating in crowdfunding transactions in reliance on Section 4(a)(6), we estimate that approximately five funding portals per year (50 registered funding portals × 0.10) will withdraw from registration. For funding portals, a decision to withdraw registration will be required to be reported to us in the same way as an amendment; however, for brokers, withdrawal requires the filing of Form BDW.

[1662] *See* Section III.B.4.

[1663] We currently estimate that the average time necessary to complete an amended Form BD to be approximately 20 minutes, or 0.33 hours. We estimate that an amendment to Form Funding Portal will take the same amount of time as an amendment to Form BD because the forms are similar.

[1664] We received 15,491, 13,271, 12,902, 14,330 and 10,848 amended Forms BD during the fiscal years ending 2011, 2012, 2013, 2014 and 2015, respectively, reflecting an average of 13,368 amendment filings per year (15,491 + 13,271+12,902+ 14,330+10,848)/5 years). As of September 15, 2015, there were 4,213 broker-dealers registered with the Commission. Therefore,

we estimate that the total additional annual burden hours necessary for broker-dealers to complete and file amended Forms BD will be approximately 10.6 hours (32 amended Forms BD per year × 0.33 hours). Using the same ratios, we estimate that the total annual burden hours for funding portals to complete and file amended Forms Funding Portal will be approximately 52.8 hours (50 funding portals × 3.2 amendments per year × 0.33 hours per amendment).

(2) Cost

We estimate that two intermediaries will face a cost per intermediary of $25,179 to retain an agent for service of process and provide an opinion of counsel to register as a nonresident funding portal.[1665]

b. Development of Intermediary Platform

(1) Time Burden

The final rules envision that intermediaries will develop electronic platforms to offer securities to the public in reliance on Section 4(a)(6). We anticipate that an intermediary's platform will incorporate related systems functionality to comply with our final rules (including the collection of information associated with, for example, the requirements of Rules 302, 303 and 304) as well as execute other platform capabilities and system operations. The estimated time burdens and costs for platform development discussed in this section include the estimated time burdens and costs for the functionalities that will allow funding portals to comply with their disclosure, communication channel, and investor notification requirements.[1666]

Intermediaries that develop their platforms in-house will incur an initial time burden associated with setting up their systems. Based on our discussions with potential intermediaries prior to the publication of our proposed rules, we estimate that intermediaries creating the initial platform in-house will typically have a team of approximately four to six developers that will work on all aspects of platform development, including, but not limited to, front-end programming, data management, systems analysis, communication channels, document delivery, and Internet security.[1667] We estimate, based on our discussions with potential intermediaries prior to the publication of our proposed rules, that in developing a platform in-house, intermediaries will spend an average of 1,500 hours for planning, programming, and implementation.[1668]

It is difficult to estimate the number of intermediaries that will develop their initial platforms in-house, but assuming that half of the 110 newly-registered intermediaries [1669] do so, the total initial time burden on those intermediaries will be 82,500 hours (55 intermediaries × 1,500 hours = 82,500 hours).

We estimate that annually updating the features and functionality of an intermediary's platform will require approximately 20% of the hours required to initially develop the platform, for an average burden of 300 hours per year. If we assume that half of the 110 crowdfunding intermediaries update their systems accordingly each year, the total ongoing time burden will be 16,500 hours per year (55 intermediaries × 300 hours = 16,500 hours).

(2) Cost

There will be a cost associated with developing a platform for an intermediary that hires a third-party to develop its platform rather than developing it in-house. Based on our discussions with potential intermediaries prior to the publication of our proposed rules, we estimate that it will cost an intermediary approximately $250,000 to $600,000 [1670] to build a new Internet-based crowdfunding portal and all of its basic functionality.[1671] Assuming that half of the 110 newly-registered intermediaries hire outside developers to build or to tailor their platforms, the total initial cost will range from $13,750,000 to $33,000,000 (55 intermediaries × $250,000 = $13,750,000; 55 intermediaries × $600,000 = $33,000,000). For purposes of this PRA analysis, we estimate the cost to be $23,375,000 (the average of $13,750,000 and $33,000,000).

We estimate that it will typically cost an intermediary approximately one-fifth of the initial development cost per year to use a third-party developer to provide annual maintenance on an Internet-based crowdfunding portal, including updating and basic functionality, or $85,000 per year on average.[1672] If we assume that half of the 110 crowdfunding intermediaries updated their systems accordingly, the total ongoing cost will be $4,675,000 per year (55 intermediaries × $85,000 = $4,675,000).

c. Measures To Reduce the Risk of Fraud

(1) Time Burden

The final rules will require intermediaries to have a reasonable basis for believing that an issuer seeking to offer and sell securities in reliance on Section 4(a)(6) through the intermediary's platform complies with the requirements in Section 4A(b) and the related requirements in Regulation Crowdfunding.[1673] The final rules will also require intermediaries to have a reasonable basis for believing that an issuer has established means to keep accurate records of the holders of the securities it will offer and sell through the intermediary's platform.[1674] For both requirements, an intermediary may reasonably rely on the representations of the issuer, unless the intermediary has reason to question the reliability of those representations. For the purposes

we estimate that there are approximately 3.17 amendments (13,368 amended Forms BD/4,213 broker-dealers) per registered broker-dealer per year. We therefore estimate that the 10 broker-dealers who register under Regulation Crowdfunding will file, on aggregate, approximately 32 amendments per year.

[1665] We have altered our cost estimates slightly from the Proposing Release (from $25,130 to $25,179) and note that the amended estimates are consistent with our recent estimates of what it would cost other types of nonresident entities to retain an agent for service of process and provide an opinion of counsel. *See* Registration Process for Security-Based Swap Dealers and Major Security-Based Swap Participants, Exchange Act Release No. 34–75611, 80 FR 48964, 48994 (Aug. 14, 2015). We inadvertently included the costs to non-resident funding portals of completing Schedule C in the Proposing Release. We anticipate, however, that nonresident funding portals will incur a time burden rather than a cost burden to complete Schedule C.

[1666] *See* Sections IV.C.2.g. and IV.C.2.h.

[1667] *See* Sections IV.C.2.g. and IV.C.2.h.

[1668] This average takes into account intermediaries that will develop a brand new platform and those that will modify an existing platform to function in accordance with Regulation Crowdfunding.

[1669] As discussed above, we anticipate that 10 intermediaries will newly register as brokers, 50 intermediaries will be brokers that are already registered, and 50 intermediaries will register as funding portals.

[1670] *See, e.g.,* ASSOB Letter (suggesting that the cost to establish a funding portal would run at least $480,000, which is within the range of our estimate).

[1671] We anticipate that some percentage of intermediaries will already have in place platforms and related systems that will need to be tailored to comply with the requirements of Title III of the JOBS Act and Regulation Crowdfunding. We anticipate that these intermediaries will hire outside developers to tailor their platforms. We estimate an average cost of approximately $250,000 in the first year in order to tailor the current systems for an intermediary that already has in place a platform and related systems. Thus, this amount is already covered in our range of costs above—$250,000 to $600,000.

[1672] Our estimate of the average initial external cost per intermediary to develop a crowdfunding platform is the average of the cited range of $250,000 to $600,000, or $425,000 (($250,000 + $600,000)/2). One-fifth of the cost of $425,000 is $85,000.

[1673] *See* Rule 301(a) of Regulation Crowdfunding.

[1674] *See* Rule 301(b) of Regulation Crowdfunding.

of this PRA analysis, we expect that 100% of intermediaries will rely on the representations of issuers. Based on our industry knowledge and discussions with participants prior to the publication of our proposed rules, we calculate that this requirement will impose a time burden in the first year of five hours per intermediary to establish standard representations it will request from issuers, and six minutes per intermediary per issuer to obtain the issuer representation, which is consistent with estimates we have used for other regulated entities to obtain similar documentation, such as consents, from customers.

Based on our estimate that there will be approximately 1,900 offerings per year, that each issuer will conduct one offering per year, and that there will be 110 intermediaries, we estimate that each intermediary will facilitate an average of approximately 17 offerings per year (1,900 offerings/(10 newly registered broker-dealers + 50 previously registered broker-dealers + 50 funding portals)). Therefore, we estimate that the total initial burden hours will be approximately 740 hours ((5 hours/intermediary × (10 newly-registered broker-dealers + 50 previously-registered broker-dealers + 50 funding portals)) + (0.1 hours/issuer × 17 offerings × 110 intermediaries).

We believe that the ongoing time burdens for this requirement will be approximately one hour per intermediary per year to review and confirm that the standard representations it requests from issuers remain appropriate, and six minutes (0.1 hours) per intermediary per issuer to obtain an issuer's representation. Therefore, we estimate that the ongoing total burden hours necessary for intermediaries to rely on the representations of the issuers will be approximately 300 hours per year ((1 hour/intermediary × (10 newly-registered broker-dealers + 50 previously-registered broker-dealers + 50 funding portals)) + (0.1 hours/issuer × 17 offerings × 110 intermediaries).

(2) Cost

The final rules will require intermediaries to conduct a background and securities enforcement regulatory history check on each issuer and each officer, director or 20 Percent Beneficial Owner of an issuer to determine whether the issuer or such person is subject to a disqualification. We anticipate that most intermediaries will employ third parties to perform background and securities enforcement regulatory history checks in light of the costs of developing an in-house capability to conduct such checks. Therefore, for the purposes of this PRA analysis, we assume that 100% of intermediaries will use these third-party service providers.

The cost for a third party to perform a background check is estimated to be between $200 and $500, depending on the nature and extent of the information provided.[1675] We recognize that some issuers will require more than one background check (*e.g.,* for officers or directors of the issuer), and we estimate that intermediaries will perform four background checks per issuer, on average. We base this number on the assumption that most crowdfunding issuers will be startups and small businesses with small management teams and few owners. Assuming an average of approximately 1,900 offerings made in reliance on Section 4(a)(6) per year, the total estimated initial cost for all intermediaries to fulfill the required background and securities enforcement regulatory history checks will range from approximately $1,520,000 to $3,800,000 per year,[1676] or approximately $13,818 to $34,546 per intermediary per year.[1677] For purposes of this PRA analysis, we average this cost to $24,182 per intermediary per year.

One commenter noted, as a general matter, that the ''costs incurred by the intermediary in dealing with an issuer, doing the required due diligence and background screening, establishing a Web page describing the offering and so on do not vary linearly with the offering size. As a percentage of the offering amount, they will be disproportionately high for smaller offerings.'' [1678] This commenter did not, however, question our underlying assumptions or our estimates of these costs. For purposes of this PRA analysis and as discussed above, we believe that these cost estimates are reasonable. We also believe that intermediaries are in a better position to make their own business decisions as to whether such costs would be disproportionately high for smaller offerings.[1679]

We believe that, on an ongoing basis, intermediaries will continue to use third-party services to conduct background and securities enforcement regulatory history checks. We also believe that the total estimated ongoing cost for all intermediaries to fulfill the required background and securities enforcement regulatory history checks will be the same as the estimated initial cost, or on average $24,182 per intermediary per year.

d. Account Opening: Accounts and Electronic Delivery

The final rules provide that no intermediary or associated person of an intermediary may accept an investment commitment in a transaction involving the offer or sale of securities made in reliance on Section 4(a)(6) until an investor has opened an account with the intermediary and consented to electronic delivery of materials.[1680] This requirement will impose certain information gathering and recordkeeping burdens on intermediaries. For the purposes of this PRA analysis, we expect that the functionality required to allow an investor to open an account with an intermediary and obtain consents will result in an initial time burden of approximately 10 hours per intermediary in the first year. Therefore, we estimate that the total initial burden hours resulting from this functionality will be approximately 1,100 hours (10 hours/intermediary × (10 newly-registered broker-dealers + 50 previously-registered broker-dealers + 50 funding portals)).

We believe that the ongoing time burdens for this requirement will be significantly less than the initial time burden, and thus we estimate approximately two hours per intermediary per year to review and assess the related processes. Therefore, we estimate that the ongoing total burden hours necessary for this functionality will be approximately 220 hours per year (2 hours/intermediary × (10 newly-registered broker-dealers + 50 previously-registered broker-dealers + 50 funding portals)).

[1675] *See, e.g.,* A Matter of Fact, *Background Check FAQ: Frequently Asked Questions, available at http://www.amof.info/faq.htm* (Matter of Fact is a background check provider accredited by the National Association of Professional Background Screeners and the Background Screening Credentialing Council. This source states that the cost for a comprehensive background check is $200 to $500).

[1676] 1,900 securities-based offerings made in reliance on Section 4(a)(6) per year × ($200 to $500 per background and securities enforcement regulatory history check) × 4 checks per offering = $1,520,000 to $3,800,000 per year.

[1677] $1,520,000/110 intermediaries = approximately $13,818 per intermediary; $3,800,000/110 intermediaries = approximately $34,546 per intermediary.

[1678] Heritage Letter.

[1679] As noted above, we agree with the commenter's suggestion that there is likely to be a fixed component to these costs that reflects a certain necessary level of due diligence and background screening, which will result in these costs, as a percentage of offering size, being higher for smaller offerings.

[1680] *See* Rule 302(a) of Regulation Crowdfunding.

e. Account Opening: Educational Materials

(1) Time Burden

The final rules require intermediaries to provide educational materials to investors,[1681] about the risks and costs of investing in securities offered and sold in reliance on Section 4(a)(6). Because the intermediary will determine what electronic format will prove most effective in communicating the requisite contents of the educational material, the expected costs for intermediaries to develop the educational material are expected to vary widely and are difficult to estimate. For the purposes of this PRA analysis, we assume that half of the intermediaries will develop their educational materials in-house, potentially including online presentations and written documents, and that the other half will employ third parties to produce educational materials, such as professional-quality online video presentations. We estimate that to develop their educational materials in-house, each intermediary will incur an initial time burden of approximately 20 hours. Therefore, the total initial burden will be approximately 1,100 hours (55 intermediaries × 20 hours/intermediary).[1682]

Assuming that half of the intermediaries will develop their educational materials in-house, we also expect that these intermediaries will update their educational materials in-house, as needed. We estimate that to update their educational materials in-house, each intermediary will incur an ongoing time burden of approximately 10 hours per year. Therefore, the total ongoing burden will be approximately 550 hours per year (55 intermediaries × 10 hours/intermediary).

(2) Cost

As stated above, for the purposes of this PRA analysis, we assume that half of the intermediaries will employ third-party firms to produce educational materials, such as professional-quality online video presentations, instead of developing materials in-house. Public sources indicate that the typical cost to produce a professional corporate training video ranges from approximately $1,000 to $3,000 per production minute.[1683] Based on discussions with industry participants prior to the publication of our proposed rules, we assume that, on average, each intermediary will produce a series of short educational videos that will cover all of the requirements of the final rules and that the video material will be 10 minutes long in total. Based on this assumption, we estimate that the average initial cost for an intermediary to develop and produce educational materials will range from approximately $10,000 to $30,000. The total initial cost across all intermediaries estimated to employ a third party per year will be $550,000 to $1,650,000.[1684] For purposes of this PRA analysis, we average the cost to $20,000 per intermediary per year. We note that the estimated initial cost may be significantly lower, because not all intermediaries that outsource the development of educational materials may choose to produce professional-quality online video presentations; others may produce videos of shorter length or use other types of educational materials.

We estimate that, on an ongoing basis, when using a third-party company to update their video educational materials, each intermediary will spend approximately half of the initial average cost. We estimate, therefore, that the average ongoing annual cost for an intermediary to update its video educational materials will range from approximately $5,000 to $15,000 and that the total ongoing annual cost across all intermediaries will range from approximately $275,000 to $825,000 per year.[1685] For purposes of this PRA analysis, we average the cost to $10,000 per intermediary per year.

f. Account Opening: Promoters

The final rules require an intermediary, at the account opening stage, to disclose to users of its platform that any person who receives compensation to promote an issuer's offering, or who is a founder or employee of an issuer engaging in promotional activities on behalf of the issuer, must clearly disclose the receipt of compensation and his or her engagement in promotional activities on the platform.[1686] We expect that this requirement will result in an estimated time burden of five hours per intermediary in the first year, to prepare this particular disclosure and incorporate it into the account opening process. Therefore, we estimate that the total initial burden hours necessary for intermediaries to comply with this requirement will be approximately 550 hours (5 hours/intermediary × (10 newly-registered broker-dealers + 50 previously-registered broker-dealers + 50 funding portals)).

We believe that the ongoing time burdens for this requirement will be approximately one hour per intermediary per year to review and check that the disclosures remain appropriate. Therefore, we estimate that the ongoing total burden hours necessary for intermediaries to comply with this requirement will be approximately 110 hours per year (1 hour/intermediary × (10 newly-registered broker-dealers + 50 previously-registered broker-dealers + 50 funding portals)).

g. Issuer Disclosures To Be Made Available

(1) Time Burden

The final rules require an intermediary to make publicly available on its platform the information that an issuer of crowdfunding securities is required to provide to investors, in a manner that reasonably permits a person accessing the platform to save, download or otherwise store the information, until the offer and sale of securities is completed or cancelled.[1687]

For purposes of the PRA, our estimate of the hourly burdens related to the public availability of the issuer information is included in our estimate of the hourly burdens associated with overall platform development, discussed above in Section IV.C.2.b. We note that the platform functionality will include not only the ability to display, upload and download issuer information as required under the final rules, but also the ability to provide users with required online disclosures

We recognize that, over time, intermediaries may need to update their systems that allow issuer information to be uploaded to their platforms. We do not expect a significant ongoing burden related to the requirement for providing issuer disclosures, primarily because the functionality required for required issuer disclosure information to be uploaded is a standard feature offered

[1681] *See* Rule 302(b) of Regulation Crowdfunding.

[1682] In the Proposing Release we did not take into account in our estimated time burden and cost calculations our assumption that half of the intermediaries would develop educational materials in-house. Therefore, we have re-calculated the estimated total initial and ongoing time burdens and costs for the development of in-house materials in this release based on 55 (rather than 110) intermediaries.

[1683] *See, e.g.,* Lee W. Frederiksen, *What Is the Cost of Video Production for the Web?,* Hinge Marketing, *available at http://www.hingemarketing.com/library/article/what-is-the-cost-of-video-production-for-the-web.*

[1684] 55 intermediaries × $10,000 production cost = $550,000. 55 intermediaries × $30,000 production cost = $1,650,000.

[1685] $550,000 total cost × 0.50 = $275,000. $1,650,000 total cost × 0.50 = $825,000.

[1686] *See* Rule 302(c) of Regulation Crowdfunding.

[1687] *See* Rule 303(a) of Regulation Crowdfunding.

on many Web sites and will not require frequent or significant updates.

(2) Cost

We do not expect a significant ongoing cost for providing issuer disclosures, primarily because the functionality required to upload required issuer disclosure information is a standard feature offered on many Web sites and will not require frequent updates. To the extent an intermediary uses a third party to develop the functionality for this requirement, the initial costs relevant to this requirement will be incorporated into the cost of hiring a third party to develop the platform, discussed above in subsection IV.C.2.b.2.

h. Other Disclosures to Investors

(1) Time Burden

Intermediaries will be required to implement and maintain systems to comply with the information disclosure, communication channels, and investor notification requirements of Regulation Crowdfunding, including providing disclosure about compensation at account opening, obtaining investor acknowledgments to confirm investor qualifications and review of educational materials, providing investor questionnaires, maintaining communication channels with third parties and among investors, notifying investors of investment commitments, confirming completed transactions and confirming or reconfirming offering cancellations.

For purposes of the PRA analysis, our estimate of the hourly burdens related to these information disclosure, communication channel and investor notification requirements of Regulation Crowdfunding is included in our estimate of the hourly burdens associated with overall platform development, discussed above in Section IV.C.2.b. Based on our discussions with industry participants, we expect that these functionalities will generally be part of the overall platform development process and costs. We discuss the burdens of platform development above, and note that these will include developing the functionality that will allow intermediaries to comply with disclosure and notification requirements.[1688]

We do not expect a significant ongoing burden for providing disclosures, as required by the final rules, because the functionality required to provide information and communication channels will likely not require frequent updates. We incorporate the total burden to update the required functionality for processing investor disclosures and investor acknowledgment information in the total burden estimates relating to platform development discussed above.[1689]

(2) Cost

We recognize that some intermediaries may implement the required functionality for processing investor disclosures and investor acknowledgments by using a third-party developer. The total cost for issuers to use third-party developers to add the required functionality for processing investor disclosures and investor acknowledgments, as well as to update the required functionality for processing investor disclosures and investor acknowledgments, is incorporated into our discussion of the total cost estimates relating to platform development in Section IV.C.2.b.

We also do not expect there to be a significant ongoing cost for developing the functionality to process these disclosures and acknowledgments, primarily because this functionality will likely not require frequent updates by third-party developers.

i. Maintenance and Transmission of Funds

The final rules contain requirements related to the maintenance and transmission of funds. A registered broker will be required to comply with the requirements of Rule 15c2–4 of the Exchange Act (Transmission or Maintenance of Payments Received in Connection with Underwritings).[1690] A registered funding portal will be required to enter into a written agreement with a qualified third party that has agreed in writing to hold the client funds.[1691] It also will be required to send directions to the qualified third party depending on whether an investing target is met or if an investment commitment or offering is cancelled. For purposes of the PRA, we are providing an estimate for the hour burden that a funding portal will incur to enter into a written agreement with the qualified third party on an initial basis, and to review and update that agreement on an ongoing basis.

Based on discussion with industry participants, we estimate that funding portals will incur an initial burden of approximately 20 hours each to comply with these requirements, for a total burden of 1,000 hours (20 hours per funding portal × 50 funding portals). We expect that the burden associated with the Web site functionality required to send directions to third parties will be included as part of the platform development discussed above.[1692]

We expect that, on an ongoing basis, a registered funding portal will have to periodically review and update its written agreement with the qualified third party to hold its client funds. A registered funding portal will also be required to send directions on an ongoing basis to a qualified third party depending on whether an investing target is met or an investment commitment or offering is cancelled. Based on discussion with industry participants, we estimate that funding portals will incur an ongoing annual burden of approximately 5 hours each to comply with these requirements, or 250 hours total (5 hours per funding portal × 50 funding portals).

j. Compliance: Policies and Procedures

The final rules require a funding portal to implement written policies and procedures reasonably designed to achieve compliance with the federal securities laws and the rules and regulations thereunder, relating to its business as a funding portal. We anticipate that funding portals will comply with this requirement by using internal personnel and internal information technology resources integrated into their platforms. Based on discussion with industry participants, we estimate that a funding portal will spend approximately 40 hours to establish written policies and procedures to achieve compliance with these requirements. This will result in a total aggregate initial recordkeeping burden of 2,000 hours (40 hours × 50 funding portals).

We estimate that, on an ongoing basis, funding portals will spend approximately 5 hours per year updating, as necessary, the policies and procedures required by the final rules. This will result in an aggregate ongoing recordkeeping burden of 250 hours (5 hours × 50 funding portals).

k. Compliance: Privacy

Funding portals will be required to comply with the Privacy Rules as they

[1688] *See* Section IV.C.2.b.1.

[1689] *See* Section IV.C.2.b.1.

[1690] *See* Rule 303(e)(1) of Regulation Crowdfunding. *See also* 17 CFR 240.15c2–4. For purposes of this PRA discussion, any burdens associated with Rule 15c2–4, as well as for any other rule to which brokers are subject regardless of whether they engage in transactions pursuant to Section 4(a)(6), are not addressed here; rather, they are included in any OMB approvals for the relevant rules.

[1691] *See* Rule 303(e)(2) of Regulation Crowdfunding.

[1692] *See* Section IV.C.2.b.

apply to broker-dealers, including Regulation S–P, S–AM and S–ID.[1693]

Under Rule 403(b), a funding portal will be required to comply with Regulation S–P, which will require the funding portal to provide notice to investors about its privacy policies and practices; describe the conditions under which a broker may disclose nonpublic personal information about investors to nonaffiliated third parties; and provide a method for investors to prevent a funding portal from disclosing that information to most nonaffiliated third parties by ''opting out'' of that disclosure, subject to certain exceptions. For funding portals, we expect that the privacy and opt-out notices will be delivered electronically, thereby reducing the delivery burden as compared to paper delivery.

We estimate that under the final rules all 50 funding portals will be subject to the requirements of Regulation S–P pursuant to Rule 403(b). In developing an estimate of the burden relating to the Regulation S–P requirements under Rule 403(b), we have considered: (1) The minimal recordkeeping burden imposed by Regulation S–P; [1694] (2) the summary fashion in which information must be provided to investors in the privacy and opt-out notices required by Regulation S–P; [1695] and (3) the availability of the model privacy form and online model privacy form builder. Given these considerations, we estimate that each funding portal will spend, on an ongoing basis, an average of approximately 12 hours per year complying with the information collection requirement of Regulation S–P, for a total of approximately 600 annual burden-hours (12 hours/respondent × 50 funding portals).

Funding portals will be required to comply with Regulation S–AM, which will require funding portals to provide notice to each affected individual informing the individual of his or her right to prohibit such marketing before a receiving affiliate may make marketing solicitations based on the communication of certain consumer financial information from the broker. Based on our discussions with industry participants, we estimate that approximately 20 funding portals will have affiliations that will subject them to the requirements of Regulation S–AM under the final rules, and that they will incur an average one-time burden of one hour to review affiliate marketing practices, for a total of 20 burden hours (1 hour/respondent × 20 funding portals).

We estimate that these 20 funding portals will be required to provide notice and opt-out opportunities to consumers pursuant to the requirements of Regulation S–AM, as imposed by Rule 403(b), and that they will incur an average initial burden of 18 hours to do so, for a total estimated initial burden of 360 hours (18 hours/respondent × 20 funding portals). We also estimate that funding portals will incur an ongoing burden related to Regulation S–AM's requirements for providing notice and opt-out opportunities of approximately four hours per respondent per year. This burden will cover the creation and delivery of notices to new investors and the recording of any opt-outs that are received on an ongoing basis, for a total of approximately 80 annual burden-hours (4 hours/respondent × 20 funding portals).

Funding portals will be required to comply with rule S–ID, which will require funding portals to develop and implement a written identity theft prevention program that is designed to detect, prevent and mitigate identity theft in connection with certain existing accounts or the opening of new accounts. We estimate that the initial burden for funding portals to comply with the applicable portions of Regulation S–ID, as imposed by Rule 403(b), will be (1) 25 hours to develop and obtain board approval of a program; (2) four hours to train staff; and (3) two hours to conduct an initial assessment of relevant accounts, for a total of 31 hours per funding portal. We estimate that all 50 funding portals will incur these initial burdens, resulting in an aggregate time burden of 1,550 hours ((25 + 4 + 2 hours/respondent) × 50 funding portals).

With respect to the requirements of Rule 403(b) relating to Regulation S–ID, we estimate that the ongoing burden per year will include: (1) Two hours to periodically review and update the program, review and preserve contracts with service providers and review and preserve any documentation received from service providers; (2) four hours to prepare and present an annual report to a compliance director; and (3) two hours to conduct periodic assessments to determine if the entity offers or maintains covered accounts, for a total of eight hours, of which we estimate 7 seven hours will be spent by internal counsel and 1 one hour will be spent by a compliance director. We estimate that all 50 funding portals will incur these ongoing burdens, for a total ongoing burden 400 hours (8 hours/respondent × 50 funding portals).

l. Records to be Made and Kept by Funding Portals

(1) Time Burden

All funding portals will be required to make and keep records related to their activities to facilitate transactions in reliance on Section 4(a)(6) and the related rules.[1696] These books and records requirements are based generally on Exchange Act Rules 17a–3 and 17a–4, which apply to broker-dealers. To estimate the initial burden for funding portals, we base our analysis upon the current annual burdens of Rules 17a–3 and 17a–4.

We currently estimate the annual recordkeeping burden for broker-dealer compliance with Rule 17a–3 to be 394.16 hours per respondent, and the most recently approved annual recordkeeping burden for broker-dealer compliance with Rule 17a–4 to be 249 hours per respondent.

Given the more limited scope of a funding portal's business as compared to that of a broker, the more targeted scope of the books and records rules, and the fact that funding portals will be required to make, deliver and store records electronically, we expect the burden of the final rules will likely be less than that of Rules 17a–3 and 17a–4. For the purposes of the PRA, we assume that the recordkeeping burden, on average, for a funding portal to comply with the final rules will be 50% of the burdens of a broker-dealer to comply with Rules 17a–3 and 17a–4. Therefore, we estimate the initial burden to be approximately 325 hours per respondent,[1697] or 16,250 hours total (325 hours/respondent × 50 respondents). We expect the ongoing recordkeeping burden for funding portals will be the same as the initial burden because the requirements regarding maintaining such records will be consistent each year.

(2) Cost

We currently estimate the annual recordkeeping cost for broker-dealer compliance with Rule 17a–3 to be $5,706.67 per respondent. These ongoing recordkeeping costs reflect the costs of systems and equipment

[1693] *See* Rule 403(b) of Regulation Crowdfunding.

[1694] Regulation S–P has no recordkeeping requirement, and records relating to customer communications already must be made and retained by broker-dealers pursuant to other Commission rules. The estimates of the burdens relating to recordkeeping requirements for funding portals are discussed below in Section IV.C.2.l.

[1695] The model privacy form adopted by the Commission and the other agencies in 2009, designed to serve as both a privacy notice and an opt-out notice, is only two pages.

[1696] *See* Rule 404 of Regulation Crowdfunding.

[1697] 394.16 hours (recordkeeping burden for Rule 17a–3) + 249 hours (recordkeeping burden for Rule 17a–4) = 643.16 hours. 638.16 hours/2 = 321.58 hours.

development. We currently estimate the annual recordkeeping cost for broker-dealer compliance with Rule 17a–4 to be $5,000 per respondent.

Given the more limited scope of a funding portal's business as compared to that of a broker, the more targeted scope of the books and records rules, and the fact that funding portals will be required to make, deliver and store records electronically, we expect the annual recordkeeping cost of the final rule requirements will likely be less than that of Rules 17a–3 and 17a–4. For purposes of the PRA, we assume that the annual recordkeeping cost on average for a funding portal to comply with the requirements that records be made and kept will be about 50% less than burdens of a broker-dealer to comply with Rules 17a–3 and 17a–4. We expect the initial recordkeeping cost for funding portals, therefore, to be approximately $5,350 per respondent,[1698] or $267,500 total ($5,350 per respondent × 50 respondents). We expect the ongoing recordkeeping cost burden for funding portals will be the same as the initial burden because the requirements regarding maintaining such records will be consistent each year.

One commenter stated that ''[u]nder the expectation that crowdfunding portals will be online operations and will almost certainly retain records through digital methods, the burden of collection should be minimal.'' [1699] We agree that digital recordkeeping can help to minimize costs, and our estimates reflect this assessment.

D. Collections of Information are Mandatory

The collections of information required under Rules 201 through 203 will be mandatory for all issuers. The collections of information required under Rules 300 through 304 will be mandatory for all intermediaries. The collections of information required under Rules 400 through 404 will be mandatory for all funding portals.

E. Confidentiality

Responses on Form C, Form C–A, Form C–U, Form C–AR and Form C–TR will not be kept confidential. Responses on Form ID will be kept confidential by the Commission, subject to a request under the Freedom of Information Act.[1700] Responses on Forms BD and Forms Funding Portal will not be kept confidential.

F. Retention Period of Recordkeeping Requirements

Issuers are not subject to recordkeeping requirements under Regulation Crowdfunding. Intermediaries that are brokers will be required to retain records and information relating to Regulation Crowdfunding for the required retention periods specified in Exchange Act Rule 17a–4. Intermediaries that are funding portals will be required to retain records and information under Regulation Crowdfunding for the required retention periods specified in Rule 404.[1701]

V. Final Regulatory Flexibility Act Analysis

The Commission has prepared the following Final Regulatory Flexibility Analysis (''FRFA''), in accordance with the provisions of the Regulatory Flexibility Act,[1702] regarding Regulation Crowdfunding. It relates to the rules for securities-based crowdfunding being adopted today. An Initial Regulatory Flexibility Analysis (''IRFA'') was prepared in accordance with the Regulatory Flexibility Act and included in the Proposing Release.

A. Need for the Rule

The regulation is designed to implement the requirements of Title III of the JOBS Act. Title III added Securities Act Section 4(a)(6), which provides a new exemption from the registration requirements of Securities Act Section 5 for securities-based crowdfunding transactions, provided the transactions are conducted in the manner set forth in new Securities Act Section 4A. Section 4A includes requirements for issuers that offer or sell securities in reliance on the crowdfunding exemption, as well as for persons acting as intermediaries in those transactions. The rules prescribe requirements governing the offer and sale of securities in reliance on Section 4(a)(6) and provide a framework for the regulation of registered funding portals and brokers that act as intermediaries in the offer and sale of securities in reliance on Section 4(a)(6).

As discussed above, the crowdfunding provisions of the JOBS Act, which we implement through this regulation, are intended to help alleviate the funding gap and accompanying regulatory concerns faced by small businesses by making relatively low dollar offerings of securities less costly and by providing crowdfunding platforms a means by which to facilitate the offer and sale of securities without registering as brokers, with a framework for regulatory oversight to protect investors.

B. Significant Issues Raised by Public Comments

In the Proposing Release, we requested comment on every aspect of the IRFA, including the number of small entities that would be affected by the proposed amendments, the existence or nature of the potential impact of the proposals on small entities discussed in the analysis, and how to quantify the impact of the proposed rules.

Some commenters expressed concern that the IRFA did not comply with the Regulatory Flexibility Act because it did not, in their view, adequately describe the costs of the proposed rule on small entities, and did not set forth significant alternatives which accomplish the rule's objectives and which minimize the significant economic impact of the proposal on small entities.[1703] These commenters recommended that the Commission republish for public comment a supplemental IRFA to address these concerns. One commenter stated that the IRFA did not set forth significant alternatives which accomplish the Commission's stated objectives because the IRFA only considered alternatives related to exempting small business from the proposed rules.[1704] One commenter believed that the Commission should exercise its discretion and eliminate the need for two years of audited financial statements,[1705] whereas another commenter viewed the audit requirement as a ''heavy-handed'' regulatory approach.[1706]

Commenters suggested several alternatives which in their view could reduce costs while accomplishing the rule's objectives.[1707] Commenters suggested that the Commission use its discretion to raise the threshold amount above which issuers would be required to provide audited financial statements,[1708] with one commenter specifically recommending a threshold of $900,000.[1709] One commenter also suggested that the Commission adopt a ''question and answer'' format for nonfinancial disclosures similar to the

[1698] $5,706.67 (recordkeeping cost for Rule 17a–3) + $5,000 (recordkeeping cost for Rule 17a–4) = $10,706.67. $10,706.67/2 = $5,353.34.

[1699] Joinvestor Letter.

[1700] 5 U.S.C. 552. The Commission's regulations that implement the Freedom of Information Act are at 17 CFR 200.80 *et seq.*

[1701] *See* Rule 404 of Regulation Crowdfunding.

[1702] 5 U.S.C. 603.

[1703] *See* SBA Office of Advocacy Letter; NAHB Letter; Graves Letter.

[1704] *See* SBA Office of Advocacy Letter.

[1705] *See* Guzik Letter.

[1706] *See* Rockethub Letter.

[1707] *See* Graves Letter; SBA Office of Advocacy Letter.

[1708] *Id.*

[1709] *See* Graves Letter.

format used in Regulation A offerings.[1710] This same commenter also recommended that the Commission could develop ''standard, boilerplate disclosures'' for some of the ''more complicated'' nonfinancial disclosures such as risk factors. This commenter stated that the nonfinancial disclosures are not required under the JOBS Act and encouraged the Commission to develop alternatives that would be less burdensome for small issuers. One commenter recommended that the Commission revise the ongoing financial reporting requirements for small issuers to require the disclosure of reviewed rather than audited financial statements, even if such issuers were previously required to disclose audited financial statements pursuant to Section 4A(b)(1)(D).[1711] This commenter also supported a requirement that issuers submit annually an updated statement of financial condition, similar in nature to an abbreviated management's discussion and analysis of financial condition and results of operations.[1712] This commenter also suggested that issuers with total revenue below $5 million should be permitted to use either cash-based or accrual-based methods of accounting, so that businesses using cash accounting will not be required to create two sets of accounting records in order to access crowdfunding.[1713]

One commenter suggested that smaller entities tend to be more volatile and more illiquid than larger entities.[1714] This commenter explained that this illiquidity needs to be considered when crafting regulations for small entity intermediaries and small entity issuers. This commenter also stated that, regardless of whether an intermediary has internal compliance personnel, or uses a third party, these compliance costs ultimately will have to be borne by the investors and issuers using the intermediary service. Another commenter expressed concern that the statutory liability standard of Section 4A(c) will be particularly burdensome for funding portals and noted that the IRFA does not account for the large expense statutory liability will impose on intermediaries.[1715] Similarly, one commenter thought it was appropriate to apply the same level of liability that is reserved for issuers to broker-dealers, but not funding portals.[1716] This commenter urged the Commission to either eliminate liability for funding portals, or create regulatory alternatives for funding portals such as allowing them to limit the offerings on their platforms.[1717] One commenter stated that the IRFA did not account for the cost of prohibiting funding portals from limiting the offerings on their platforms on the basis of subjective factors and suggested that the Commission create a safe harbor for funding portals that allows them to limit such offerings.[1718]

C. Small Entities Subject to the Rules

For purposes of the Regulatory Flexibility Act, under our rules, an issuer (other than an investment company) is a ''small business'' or ''small organization'' if it has total assets of $5 million or less as of the end of its most recently completed fiscal year and is engaged or proposing to engage in an offering of securities which does not exceed $5 million.[1719] We believe that many issuers seeking to offer and sell securities in reliance on Section 4(a)(6) will be at a very early stage of their business development and will likely have total assets of $5 million or less. Also, to qualify for the exemption under Section 4(a)(6), the amount raised by an issuer must not exceed $1 million in a 12-month period. Therefore, we estimate that all issuers who offer or sell securities in reliance on the exemption will be classified as a ''small business'' or ''small organization.''

For purposes of the Regulatory Flexibility Act when used with reference to a broker or dealer, the Commission has defined the term ''small entity'' to mean a broker-dealer that: (1) Had total capital (net worth plus subordinated liabilities) of less than $500,000 on the date in the prior fiscal year as of which its audited financial statements were prepared pursuant to Rule 17a–5(d) or, if not required to file such statements, a broker or dealer that had total capital (net worth plus subordinated debt) of less than $500,000 on the last business day of the preceding fiscal year (or in the time that it has been in business if shorter); and (2) is not affiliated with any person (other than a natural person) that is not a small business or small organization as defined in this release.'' [1720] Currently, based on FOCUS Report [1721] data, there are 871 broker-dealers that are classified as ''small'' entities for purposes of the Regulatory Flexibility Act.[1722] Because of some overlap in permitted functions of funding portals and brokers, we look to the definition of a small broker-dealer to quantify the estimated numbers of small funding portals that will likely register under the new regulation. Based on discussions with industry participants prior to the publication of the proposed rules, we estimate that, of the anticipated 50 funding portals we expect to register under the new regulation, 30 will be classified as ''small'' entities for purposes of the Regulatory Flexibility Act.

D. Projected Reporting, Recordkeeping and Other Compliance Requirements

As discussed above, the final rules include reporting, recordkeeping and other compliance requirements. In particular, the final rules impose certain disclosure requirements on issuers offering and selling securities in a transaction relying on the exemption provided by Section 4(a)(6). The final rules require that issuers relying on the exemption provided by Section 4(a)(6) file with the Commission certain specified information about the issuer and the offering, including information about the issuer's contact information; directors, officers and certain beneficial owners; business and business plan; current number of employees; financial condition; target offering amount and the deadline to reach the target offering amount; use of proceeds from the offering and price or method for calculating the price of the securities being offered; ownership and capital structure; material factors that make an investment in the issuer speculative or risky; indebtedness; description of other offerings of securities; and transactions with related parties. Issuers also will be required to file updates with the Commission to describe the progress of the issuer in meeting the target offering amount, unless the issuer relies on the

[1710] *See* SBA Office of Advocacy Letter.

[1711] *See* Graves Letter.

[1712] *See Id.*

[1713] *See Id.*

[1714] *See* RocketHub Letter.

[1715] *See* SBA Office of Advocacy Letter (stating that the liability standard is especially burdensome for funding portals because broker-dealers already have procedures in place for conducting due diligence on issuers in order to meet FINRA requirements, and funding portals will have to establish these procedures anew).

[1716] *See* Graves Letter (stating that the Commission should recognize the difference in the ability of funding portals and registered broker-dealers to use discretion in selecting or curating offerings, and apply liability to each as appropriate).

[1717] *Id.* (suggesting that funding portals should be allowed the discretion to exclude offerings from their platforms if they deem them to be overly risky, or if they view the offerings as having shortcomings that could be detrimental to investors).

[1718] *See* SBA Office of Advocacy Letter.

[1719] 17 CFR 230.157.

[1720] 17 CFR 240.0–10(c).

[1721] FOCUS Reports, or ''Financial and Operational Combined Uniform Single'' Reports, are monthly, quarterly, and annual reports that broker-dealers generally are required to file with the Commission and/or self-regulatory organizations pursuant to Exchange Act Rule 17a–5 (17 CFR 240.17a–5).

[1722] *See* 17 CFR 240.0–10(a).

intermediary to include this information on its platform, and to disclose the total amount of securities sold in the offering. In addition, any issuer that sells securities in reliance on Section 4(a)(6) also will be required to file with the Commission an annual report to update the previously provided disclosure about the issuer's contact information; directors, officers and certain beneficial owners; business and business plan; current number of employees; financial condition; ownership and capital structure; material factors that make an investment in the issuer speculative or risky; indebtedness; description of other offerings of securities; and transactions with related parties.

Intermediaries will be required to register with the Commission as either brokers or as funding portals. Intermediaries also will be required to provide quarterly reports to the Commission. Funding portals will be required to make and keep certain records in accordance with the rules. Registered broker-dealers are already required to make and keep certain records in accordance with existing Exchange Act Rules 17a–3 and 17a–4. In addition, the final rules impose specific compliance requirements on intermediaries, such as the maintenance of written policies and procedures.

In adopting this regulation, we took into account that the regulation, as mandated by the JOBS Act, aimed to address difficulties encountered by small entities. Accordingly, we designed the final rules for intermediaries, to the extent possible in light of investor protection concerns, with the needs and constraints of small entities in mind, including small intermediaries. We believe that the reporting, recordkeeping and other compliance requirements of the final rules applicable to intermediaries will impact, in particular, small entities that decide to register as funding portals. We believe that most of these requirements will be performed by internal compliance personnel of the broker or funding portal, but we expect that at least some funding portals may decide to hire outside counsel and third-party service providers to assist in meeting the compliance requirements. Given the statutory limitations on crowdfunding, we believe that the potential impact of the final rules on larger brokers and funding portals will be proportionally less than on small brokers and small intermediaries.

E. Agency Action To Minimize Effect on Small Entities

In response to comments, the final rules include a number of changes from the proposal, many of which were made to minimize the effect of the rules on small entities. These changes are outlined in detail above in the discussions of the rules adopted.

1. Issuers

To address commenters' concerns about the cost of the rules to small issuers, we have considered the alternatives suggested by commenters and are adopting final rules which implement certain alternatives we believe will minimize the cost of the final rules to small issuers while also preserving necessary investor protection measures.

First, the final rules include an accommodation for issuers conducting an offering for the first time in reliance on Regulation Crowdfunding. Under the final rules, issuers conducting an offering of more than $500,000 but not more than $1,000,000 that have not previously sold securities in reliance on Section 4(a)(6) will not be required to provide audited financial statements, unless audited financial statements are otherwise available. Instead, the final rules permit these issuers to provide reviewed financial statements. As discussed above, this is a change from the proposal that is responsive to concerns raised by many commenters about the expense of obtaining audited financial statements, especially for start-up issuers without a track record of successfully raising capital.[1723] We believe that requiring reviewed financial statements for issuers using Regulation Crowdfunding for the first time to raise more than $500,000 but not more than $1 million, rather than audited financial statements, will minimize costs for issuers while providing sufficient investor protection by maintaining the benefit of an independent review.

As suggested by one commenter,[1724] and as discussed above, the final Form C includes an optional question-and-answer format that issuers may elect to use to provide the disclosures that are not required to be filed in XML format. Issuers opting to use this format would prepare their disclosures by answering the questions provided and filing that disclosure as an exhibit to the Form C. Given our expectation that issuers engaged in offerings in reliance on Section 4(a)(6) will encompass a wide variety of industries at different stages of business development, we do not believe it would be practical or useful to develop standard, predetermined disclosure, as suggested by one commenter, for such a variety of issuers. Also, as discussed above, we do not believe that financial statements prepared in accordance with other comprehensive bases of accounting, such as cash or accrual-based accounting, as suggested by one commenter, provide investors with a fair representation of a company's financial position and results of operations, and it may be difficult for investors to determine whether the issuer complied with such basis. Although we acknowledge, as some commenters observed, that other bases of accounting may be less expensive than U.S. GAAP, we believe the benefit of a single standard that will facilitate comparison among securities-based crowdfunding issuers justifies any incremental expenses associated with U.S. GAAP. We also note that financial statements prepared in accordance with U.S. GAAP are generally self-scaling to the size and complexity of the issuer, which we expect to reduce the burden of preparing financial statements for many early stage issuers, including small issuers.

The final rules also maintain the progress update requirement, but with a significant modification from the proposed rule which is intended to reduce duplicative disclosure and minimize the burden on small issuers. The final rules will require an issuer to file a Form C–U at the end of the offering to disclosure the total amount of securities sold in the offering, but the rules permit issuers to satisfy the 50% and 100% progress update requirements by relying on the relevant intermediary to make publicly available on the intermediary's platform frequent updates about the issuer's progress toward meeting the target offering amount.

With respect to ongoing reporting requirements, rather than requiring an issuer to provide financial statements in the annual report that meet the highest standard previously provided, as proposed, the final rules require financial statements of the issuer certified by the principal executive officer of the issuer to be true and complete in all material respects. We expect that reducing the required level of public accountant involvement will minimize the costs and burdens for all issuers, including small issuers, associated with preparing reviewed and audited financial statements on an ongoing basis.

In addition, the final rules provide for termination of the ongoing reporting obligation in two additional circumstances: (1) The issuer has filed at least one annual report and has fewer than 300 holders of record, or (2) the

[1723] *See, e.g.,* SBA Office of Advocacy Letter.

[1724] *Id.*

issuer has filed the annual reports for at least the three most recent years and has total assets not exceeding $10,000,000. We believe the addition of these termination events should help reduce related costs for issuers that may not have achieved a level of financial success that would sustain an ongoing reporting obligation.

Overall, we considered whether to establish different compliance or reporting requirements or timetables or to clarify, consolidate or simplify compliance and reporting requirements for small issuers. As noted above, we have made significant revisions to the final rules to address commenters' concerns about compliance and reporting burdens faced by issuers, especially small issuers. With respect to using performance rather than design standards, we used performance standards to the extent appropriate under the statute. For example, issuers have the flexibility to customize the presentation of certain disclosures in their offering statements.[1725] We also considered whether there should be an exemption from coverage of the rule, or any part of the rule, for small issuers. However, because the rules have been designed to implement crowdfunding, which focuses on capital formation by issuers that are small entities, while at the same time provide appropriate investor protections, we do not believe that small issuers should be exempt, in whole or in part, from the proposed rules.

2. Intermediaries

In response to comments, we have made a number of changes from the proposal with respect to intermediaries that will help to alleviate the compliance burdens faced by small entities. Most significantly, and in response to commenters' concerns about the application of Section 4A(c) liability,[1726] as discussed above, Rule 402(b)(1) has been modified from the proposal to include a safe harbor that provides a funding portal the ability to determine whether and under what terms to allow an issuer to offer and sell securities in reliance on Section 4(a)(6) of the Securities Act through its platform; provided that a funding portal otherwise complies with Regulation Crowdfunding. This change is expected to allow intermediaries, including small entities, to reduce their exposure to such liability by denying access to issuers that present risk of fraud or other investor protection concerns. In addition, in a change from the proposed rules, we are not requiring a fidelity bond for intermediaries and also are expanding the definition of qualified third party. These changes should reduce costs for all intermediaries, including small entities.

The final rules have been tailored to the more limited role intermediaries will play in offerings made pursuant to Securities Act Section 4(a)(6) (as compared to the wide range of services that a traditional broker-dealer may provide). Registered brokers and funding portals will engage in similar activities related to crowdfunding and must comply with the adopted rules. The effective date for the registration provisions for funding portals will allow funding portals to be in a position to engage in crowdfunding at the same time as registered brokers once the rest of the rules become effective. These effective dates are designed to accommodate competitiveness concerns related to funding portals' and registered broker dealers' abilities to begin crowdfunding concurrently. While registered broker-dealers may perform services that a funding portal is prohibited from performing, the Exchange Act and rules thereunder, as well as SRO rules, already govern those activities. Therefore, we believe that the adopted rules are appropriate and properly tailored for the permissible activities of all brokers and funding portals.

We also considered whether, for small brokers or small funding portals, to establish different compliance, reporting or timing requirements, or whether to clarify, consolidate or simplify those requirements in our rules. While the final rules are based in large part on existing compliance requirements applicable to registered brokers to the extent they are applicable to activities permitted for funding portals, we do not believe we should establish different requirements for small entities (whether registered brokers or funding portals) that engage in crowdfunding because such activities are limited in scope and, as such, the adopted rules are tailored to that more limited activity.

VI. Statutory Authority

We are adopting the rules and forms contained in this document under the authority set forth in the Securities Act (15 U.S.C. 77a *et seq.*), particularly, Sections 4(a)(6), 4A, 19 and 28 thereof; the Exchange Act (15 U.S.C. 78a *et seq.*), particularly, Sections 3(b), 3(h), 10(b), 15, 17, 23(a) and 36 thereof; and Pub. L. 112–106, secs. 301–305, 126 Stat. 306 (2012).

[1725] *See* Section II.B.3.

[1726] *See, e.g.,* SBA Office of Advocacy Letter.

List of Subjects

17 CFR Part 200

Administrative practice and procedure, Authority delegations (Government agencies), Organization and functions (Government agencies). Reporting and recordkeeping requirements.

17 CFR Part 227

Crowdfunding, Funding Portals, Intermediaries, Reporting and recordkeeping requirements, Securities.

17 CFR Parts 232 and 239

Reporting and recordkeeping requirements, Securities.

17 CFR Part 240

Brokers, Confidential business information, Fraud, Reporting and recordkeeping requirements, Securities.

17 CFR Part 249

Brokers, Reporting and recordkeeping requirements, Securities.

17 CFR Part 269

Reporting and recordkeeping requirements, Securities, Trusts and Trustees.

17 CFR Part 270

Confidential business information, Fraud, Investment companies, Life insurance, Reporting and recordkeeping requirements, Securities.

In accordance with the foregoing, 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 A—Organization and Program Management

■ 1. The authority citation for Part 200, Subpart A, continues to read, in part as follows:

Authority: 15 U.S.C. 77c, 77o, 77s, 77z–3, 77sss, 78d, 78d–1, 78d–2, 78o–4, 78w, 78ll(d), 78mm, 80a–37, 80b–11, 7202, and 7211 *et seq.,* unless otherwise noted.

* * * * *

■ 2. Amend § 200.30–1 by:

■ a. Redesignating paragraphs (d), (e), (f), (g), (h), (i), (j) and (k) as paragraphs (e), (f), (g), (h), (i), (j), (k) and (l), respectively; and

■ b. Adding new paragraph (d).

The addition reads as follows:

§ 200.30–1 Delegation of authority to Director of Division of Corporation Finance.

* * * * *

(d) With respect to the Securities Act of 1933 (15 U.S.C. 77a *et seq.*) and

§§ 227.100 through 227.503 of this chapter, to authorize the granting of applications under § 227.503(b)(2) of this chapter upon the showing of good cause that it is not necessary under the circumstances that the exemption under Regulation Crowdfunding be denied.

* * * * *

■ 3. Effective January 29, 2016, part 227 is added to read as follows:

PART 227—REGULATION CROWDFUNDING, GENERAL RULES AND REGULATIONS

Authority: 15 U.S.C. 77d, 77d–1, 77s, 78c, 78o, 78q, 78w, 78mm, and Pub. L. 112–106, secs. 301–305, 126 Stat. 306 (2012).

§ 227.400 Registration of funding portals.

(a) *Registration.* A funding portal must register with the Commission, by filing a complete Form Funding Portal (§ 249.2000 of this chapter) in accordance with the instructions on the form, and become a member of a national securities association registered under section 15A of the Exchange Act (15 U.S.C. 78*o*–3). The registration will be effective the later of:

(1) Thirty calendar days after the date that the registration is received by the Commission; or

(2) The date the funding portal is approved for membership by a national securities association registered under section 15A of the Exchange Act (15 U.S.C. 78*o*–3).

(b) *Amendments to registration.* A funding portal must file an amendment to Form Funding Portal (§ 249.2000 of this chapter) within 30 days of any of the information previously submitted on Form Funding Portal becoming inaccurate for any reason.

(c) *Successor registration.* (1) If a funding portal succeeds to and continues the business of a registered funding portal, the registration of the predecessor will remain effective as the registration of the successor if the successor, within 30 days after such succession, files a registration on Form Funding Portal (§ 249.2000 of this chapter) and the predecessor files a withdrawal on Form Funding Portal; *provided, however,* that the registration of the predecessor funding portal will be deemed withdrawn 45 days after registration on Form Funding Portal is filed by the successor.

(2) Notwithstanding paragraph (c)(1) of this section, if a funding portal succeeds to and continues the business of a registered funding portal and the succession is based solely on a change of the predecessor's date or state of incorporation, form of organization, or composition of a partnership, the successor may, within 30 days after the succession, amend the registration of the predecessor on Form Funding Portal (§ 249.2000 of this chapter) to reflect these changes.

(d) *Withdrawal.* A funding portal must promptly file a withdrawal of registration on Form Funding Portal (§ 249.2000 of this chapter) in accordance with the instructions on the form upon ceasing to operate as a funding portal. Withdrawal will be effective on the later of 30 days after receipt by the Commission (after the funding portal is no longer operational), or within such longer period of time as to which the funding portal consents or which the Commission by order may determine as necessary or appropriate in the public interest or for the protection of investors.

(e) *Applications and reports.* The applications and reports provided for in this section shall be considered filed when a complete Form Funding Portal (§ 249.2000 of this chapter) is submitted with the Commission. Duplicate originals of the applications and reports provided for in this section must be filed with surveillance personnel designated by any registered national securities association of which the funding portal is a member.

(f) *Nonresident funding portals.* Registration pursuant to this section by a nonresident funding portal shall be conditioned upon there being an information sharing arrangement in place between the Commission and the competent regulator in the jurisdiction under the laws of which the nonresident funding portal is organized or where it has its principal place of business, that is applicable to the nonresident funding portal.

(1) *Definition.* For purposes of this section, the term *nonresident funding portal* shall mean a funding portal incorporated in or organized under the laws of a jurisdiction outside of the United States or its territories, or having its principal place of business in any place not in the United States or its territories.

(2) *Power of attorney.* (i) Each nonresident funding portal registered or applying for registration pursuant to this section shall obtain a written consent and power of attorney appointing an agent in the United States, other than the Commission or a Commission member, official or employee, upon whom may be served any process, pleadings or other papers in any action under the federal securities laws. This consent and power of attorney must be signed by the nonresident funding portal and the named agent(s) for service of process.

(ii) Each nonresident funding portal registered or applying for registration pursuant to this section shall, at the time of filing its application on Form Funding Portal (§ 249.2000 of this chapter), furnish to the Commission the name and address of its United States agent for service of process on Schedule C to the Form.

(iii) Any change of a nonresident funding portal's agent for service of process and any change of name or address of a nonresident funding portal's existing agent for service of process shall be communicated promptly to the Commission through amendment of the Schedule C to Form Funding Portal (§ 249.2000 of this chapter).

(iv) Each nonresident funding portal must promptly appoint a successor agent for service of process if the nonresident funding portal discharges its identified agent for service of process or if its agent for service of process is unwilling or unable to accept service on behalf of the nonresident funding portal.

(v) Each nonresident funding portal must maintain, as part of its books and records, the written consent and power of attorney identified in paragraph (f)(2)(i) of this section for at least three years after the agreement is terminated.

(3) *Access to books and records; inspections and examinations*—(i) *Certification and opinion of counsel.* Any nonresident funding portal applying for registration pursuant to this section shall:

(A) Certify on Schedule C to Form Funding Portal (§ 249.2000 of this chapter) that the nonresident funding portal can, as a matter of law, and will provide the Commission and any registered national securities association of which it becomes a member with prompt access to the books and records of such nonresident funding portal and can, as a matter of law, and will submit to onsite inspection and examination by the Commission and any registered national securities association of which it becomes a member; and

(B) Provide an opinion of counsel that the nonresident funding portal can, as a matter of law, provide the Commission and any registered national securities association of which it becomes a member with prompt access to the books and records of such nonresident funding portal and can, as a matter of law, submit to onsite inspection and examination by the Commission and any registered national securities association of which it becomes a member.

(ii) *Amendments.* The nonresident funding portal shall re-certify, on Schedule C to Form Funding Portal

(§ 249.2000 of this chapter), within 90 days after any changes in the legal or regulatory framework that would impact the nonresident funding portal's ability to provide, or the manner in which it provides, the Commission, or any registered national securities association of which it is a member, with prompt access to its books and records or that would impact the Commission's or such registered national securities association's ability to inspect and examine the nonresident funding portal. The re-certification shall be accompanied by a revised opinion of counsel describing how, as a matter of law, the nonresident funding portal can continue to meet its obligations under paragraphs (f)(3)(i)(A) and (B) of this section.

■ 4. Effective May 16, 2016, part 227 is revised to read as follows:

PART 227—REGULATION CROWDFUNDING, GENERAL RULES AND REGULATIONS

Subpart A—General

Sec.

227.100 Crowdfunding exemption and requirements.

Subpart B—Requirements for Issuers

227.201 Disclosure requirements.
227.202 Ongoing reporting requirements.
227.203 Filing requirements and form.
227.204 Advertising.
227.205 Promoter compensation.

Subpart C—Requirements for Intermediaries

227.300 Intermediaries.
227.301 Measures to reduce risk of fraud.
227.302 Account opening.
227.303 Requirements with respect to transactions.
227.304 Completion of offerings, cancellations and reconfirmations.
227.305 Payments to third parties.

Subpart D—Funding Portal Regulation

227.400 Registration of funding portals.
227.401 Exemption.
227.402 Conditional safe harbor.
227.403 Compliance.
227.404 Records to be made and kept by funding portals.

Subpart E—Miscellaneous Provisions

227.501 Restrictions on resales.
227.502 Insignificant deviations from a term, condition or requirement of this part (Regulation Crowdfunding).
227.503 Disqualification provisions.

Authority: 15 U.S.C. 77d, 77d–1, 77s, 78c, 78o, 78q, 78w, 78mm, and Pub. L. 112–106, secs. 301–305, 126 Stat. 306 (2012).

Subpart A—General

§ 227.100 Crowdfunding exemption and requirements.

(a) *Exemption.* An issuer may offer or sell securities in reliance on section 4(a)(6) of the Securities Act of 1933 (the ''Securities Act'') (15 U.S.C. 77d(a)(6)), provided that:

(1) The aggregate amount of securities sold to all investors by the issuer in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) during the 12-month period preceding the date of such offer or sale, including the securities offered in such transaction, shall not exceed $1,000,000;

(2) The aggregate amount of securities sold to any investor across all issuers in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) during the 12-month period preceding the date of such transaction, including the securities sold to such investor in such transaction, shall not exceed:

(i) The greater of $2,000 or 5 percent of the lesser of the investor's annual income or net worth if either the investor's annual income or net worth is less than $100,000; or

(ii) 10 percent of the lesser of the investor's annual income or net worth, not to exceed an amount sold of $100,000, if both the investor's annual income and net worth are equal to or more than $100,000;

Instruction 1 to paragraph (a)(2). To determine the investment limit for a natural person, the person's annual income and net worth shall be calculated as those values are calculated for purposes of determining accredited investor status in accordance with § 230.501 of this chapter.

Instruction 2 to paragraph (a)(2). A person's annual income and net worth may be calculated jointly with that person's spouse; however, when such a joint calculation is used, the aggregate investment of the investor spouses may not exceed the limit that would apply to an individual investor at that income or net worth level.

Instruction 3 to paragraph (a)(2). An issuer offering and selling securities in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) may rely on the efforts of an intermediary required by § 227.303(b) to ensure that the aggregate amount of securities purchased by an investor in offerings pursuant to section 4(a)(6) of the Securities Act will not cause the investor to exceed the limit set forth in section 4(a)(6) of the Securities Act and § 227.100(a)(2), *provided that* the issuer does not know that the investor has exceeded the investor limits or would exceed the investor limits as a result of purchasing securities in the issuer's offering.

(3) The transaction is conducted through an intermediary that complies with the requirements in section 4A(a) of the Securities Act (15 U.S.C. 77d–1(a)) and the related requirements in this part, and the transaction is conducted exclusively through the intermediary's platform; and

Instruction to paragraph (a)(3). An issuer shall not conduct an offering or concurrent offerings in reliance on section 4(a)(6) of the Securities Act of 1933 (15 U.S.C. 77d(a)(6)) using more than one intermediary.

(4) The issuer complies with the requirements in section 4A(b) of the Securities Act (15 U.S.C. 77d–1(b)) and the related requirements in this part; *provided, however,* that the failure to comply with §§ 227.202, 227.203(a)(3) and 227.203(b) shall not prevent an issuer from relying on the exemption provided by section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)).

(b) *Applicability.* The crowdfunding exemption shall not apply to transactions involving the offer or sale of securities by any issuer that:

(1) Is not organized under, and subject to, the laws of a State or territory of the United States or the District of Columbia;

(2) Is subject to the requirement to file reports pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 (the ''Exchange Act'') (15 U.S.C. 78m or 78o(d));

(3) Is an investment company, as defined in section 3 of the Investment Company Act of 1940 (15 U.S.C. 80a-3), or is excluded from the definition of investment company by section 3(b) or section 3(c) of that Act (15 U.S.C. 80a–3(b) or 80a–3(c));

(4) Is not eligible to offer or sell securities in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) as a result of a disqualification as specified in § 227.503(a);

(5) Has sold securities in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) and has not filed with the Commission and provided to investors, to the extent required, the ongoing annual reports required by this part during the two years immediately preceding the filing of the required offering statement; or

Instruction to paragraph (b)(5). An issuer delinquent in its ongoing reports can again rely on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) once it has filed with the Commission and provided to investors both of the annual reports required during the two years

immediately preceding the filing of the required offering statement.

(6) Has no specific business plan or has indicated that its business plan is to engage in a merger or acquisition with an unidentified company or companies.

(c) *Issuer.* For purposes of § 227.201(r), calculating aggregate amounts offered and sold in § 227.100(a) and § 227.201(t), and determining whether an issuer has previously sold securities in § 227.201(t)(3), *issuer* includes all entities controlled by or under common control with the issuer and any predecessors of the issuer.

Instruction to paragraph (c). The term *control* means the possession, direct or indirect, of the power to direct or cause the direction of the management and policies of the entity, whether through the ownership of voting securities, by contract or otherwise.

(d) *Investor.* For purposes of this part, *investor* means any investor or any potential investor, as the context requires.

Subpart B—Requirements for Issuers

§ 227.201 Disclosure requirements.

An issuer offering or selling securities in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) and in accordance with section 4A of the Securities Act (15 U.S.C. 77d–1) and this part must file with the Commission and provide to investors and the relevant intermediary the following information:

(a) The name, legal status (including its form of organization, jurisdiction in which it is organized and date of organization), physical address and Web site of the issuer;

(b) The names of the directors and officers (and any persons occupying a similar status or performing a similar function) of the issuer, all positions and offices with the issuer held by such persons, the period of time in which such persons served in the position or office and their business experience during the past three years, including:

(1) Each person's principal occupation and employment, including whether any officer is employed by another employer; and

(2) The name and principal business of any corporation or other organization in which such occupation and employment took place.

Instruction to paragraph (b). For purposes of this paragraph (b), the term *officer* means a president, vice president, secretary, treasurer or principal financial officer, comptroller or principal accounting officer, and any person routinely performing similar functions.

(c) The name of each person, as of the most recent practicable date but no earlier than 120 days prior to the date the offering statement or report is filed, who is a beneficial owner of 20 percent or more of the issuer's outstanding voting equity securities, calculated on the basis of voting power;

(d) A description of the business of the issuer and the anticipated business plan of the issuer;

(e) The current number of employees of the issuer;

(f) A discussion of the material factors that make an investment in the issuer speculative or risky;

(g) The target offering amount and the deadline to reach the target offering amount, including a statement that if the sum of the investment commitments does not equal or exceed the target offering amount at the offering deadline, no securities will be sold in the offering, investment commitments will be cancelled and committed funds will be returned;

(h) Whether the issuer will accept investments in excess of the target offering amount and, if so, the maximum amount that the issuer will accept and how oversubscriptions will be allocated, such as on a pro-rata, first come-first served, or other basis;

(i) A description of the purpose and intended use of the offering proceeds;

Instruction to paragraph (i). An issuer must provide a reasonably detailed description of any intended use of proceeds, such that investors are provided with enough information to understand how the offering proceeds will be used. If an issuer has identified a range of possible uses, the issuer should identify and describe each probable use and the factors the issuer may consider in allocating proceeds among the potential uses. If the issuer will accept proceeds in excess of the target offering amount, the issuer must describe the purpose, method for allocating oversubscriptions, and intended use of the excess proceeds with similar specificity.

(j) A description of the process to complete the transaction or cancel an investment commitment, including a statement that:

(1) Investors may cancel an investment commitment until 48 hours prior to the deadline identified in the issuer's offering materials;

(2) The intermediary will notify investors when the target offering amount has been met;

(3) If an issuer reaches the target offering amount prior to the deadline identified in its offering materials, it may close the offering early if it provides notice about the new offering deadline at least five business days prior to such new offering deadline (absent a material change that would require an extension of the offering and reconfirmation of the investment commitment); and

(4) If an investor does not cancel an investment commitment before the 48-hour period prior to the offering deadline, the funds will be released to the issuer upon closing of the offering and the investor will receive securities in exchange for his or her investment;

(k) A statement that if an investor does not reconfirm his or her investment commitment after a material change is made to the offering, the investor's investment commitment will be cancelled and the committed funds will be returned;

(l) The price to the public of the securities or the method for determining the price, provided that, prior to any sale of securities, each investor shall be provided in writing the final price and all required disclosures;

(m) A description of the ownership and capital structure of the issuer, including:

(1) The terms of the securities being offered and each other class of security of the issuer, including the number of securities being offered and/or outstanding, whether or not such securities have voting rights, any limitations on such voting rights, how the terms of the securities being offered may be modified and a summary of the differences between such securities and each other class of security of the issuer, and how the rights of the securities being offered may be materially limited, diluted or qualified by the rights of any other class of security of the issuer;

(2) A description of how the exercise of rights held by the principal shareholders of the issuer could affect the purchasers of the securities being offered;

(3) The name and ownership level of each person, as of the most recent practicable date but no earlier than 120 days prior to the date the offering statement or report is filed, who is the beneficial owner of 20 percent or more of the issuer's outstanding voting equity securities, calculated on the basis of voting power;

(4) How the securities being offered are being valued, and examples of methods for how such securities may be valued by the issuer in the future, including during subsequent corporate actions;

(5) The risks to purchasers of the securities relating to minority ownership in the issuer and the risks associated with corporate actions including additional issuances of

securities, issuer repurchases of securities, a sale of the issuer or of assets of the issuer or transactions with related parties; and

(6) A description of the restrictions on transfer of the securities, as set forth in § 227.501;

(n) The name, SEC file number and Central Registration Depository (CRD) number (as applicable) of the intermediary through which the offering is being conducted;

(o) A description of the intermediary's financial interests in the issuer's transaction and in the issuer, including:

(1) The amount of compensation to be paid to the intermediary, whether as a dollar amount or a percentage of the offering amount, or a good faith estimate if the exact amount is not available at the time of the filing, for conducting the offering, including the amount of referral and any other fees associated with the offering, and

(2) Any other direct or indirect interest in the issuer held by the intermediary, or any arrangement for the intermediary to acquire such an interest;

(p) A description of the material terms of any indebtedness of the issuer, including the amount, interest rate, maturity date and any other material terms;

(q) A description of exempt offerings conducted within the past three years;

Instruction to paragraph (q). In providing a description of any prior exempt offerings, disclose:

(1) The date of the offering;

(2) The offering exemption relied upon;

(3) The type of securities offered; and

(4) The amount of securities sold and the use of proceeds;

(r) A description of any transaction since the beginning of the issuer's last fiscal year, or any currently proposed transaction, to which the issuer was or is to be a party and the amount involved exceeds five percent of the aggregate amount of capital raised by the issuer in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) during the preceding 12-month period, inclusive of the amount the issuer seeks to raise in the current offering under section 4(a)(6) of the Securities Act, in which any of the following persons had or is to have a direct or indirect material interest:

(1) Any director or officer of the issuer;

(2) Any person who is, as of the most recent practicable date but no earlier than 120 days prior to the date the offering statement or report is filed, the beneficial owner of 20 percent or more of the issuer's outstanding voting equity securities, calculated on the basis of voting power;

(3) If the issuer was incorporated or organized within the past three years, any promoter of the issuer; or

(4) Any member of the family of any of the foregoing persons, which includes a child, stepchild, grandchild, parent, stepparent, grandparent, spouse or spousal equivalent, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law, and shall include adoptive relationships. The term *spousal equivalent* means a cohabitant occupying a relationship generally equivalent to that of a spouse.

Instruction 1 to paragraph (r). For each transaction identified, disclose the name of the specified person and state his or her relationship to the issuer, and the nature and, where practicable, the approximate amount of his or her interest in the transaction. The amount of such interest shall be computed without regard to the amount of the profit or loss involved in the transaction. Where it is not practicable to state the approximate amount of the interest, the approximate amount involved in the transaction shall be disclosed.

Instruction 2 to paragraph (r). For purposes of paragraph (r), a transaction includes, but is not limited to, any financial transaction, arrangement or relationship (including any indebtedness or guarantee of indebtedness) or any series of similar transactions, arrangements or relationships.

(s) A discussion of the issuer's financial condition, including, to the extent material, liquidity, capital resources and historical results of operations;

Instruction 1 to paragraph (s). The discussion must cover each period for which financial statements of the issuer are provided. An issuer also must include a discussion of any material changes or trends known to management in the financial condition and results of operations of the issuer subsequent to the period for which financial statements are provided.

Instruction 2 to paragraph (s). For issuers with no prior operating history, the discussion should focus on financial milestones and operational, liquidity and other challenges. For issuers with an operating history, the discussion should focus on whether historical results and cash flows are representative of what investors should expect in the future. Issuers should take into account the proceeds of the offering and any other known or pending sources of capital. Issuers also should discuss how the proceeds from the offering will affect the issuer's liquidity, whether receiving these funds and any other additional funds is necessary to the viability of the business, and how quickly the issuer anticipates using its available cash. In addition, issuers should describe the other available sources of capital to the business, such as lines of credit or required contributions by shareholders.

Instruction 3 to paragraph (s). References to the issuer in this paragraph and its instructions refer to the issuer and its predecessors, if any.

(t) For offerings that, together with all other amounts sold under section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) within the preceding 12-month period, have, in the aggregate, the following target offering amounts:

(1) $100,000 or less, the amount of total income, taxable income and total tax, or the equivalent line items, as reported on the federal income tax returns filed by the issuer for the most recently completed year (if any), which shall be certified by the principal executive officer of the issuer to reflect accurately the information reported on the issuer's federal income tax returns, and financial statements of the issuer, which shall be certified by the principal executive officer of the issuer to be true and complete in all material respects. If financial statements of the issuer are available that have either been reviewed or audited by a public accountant that is independent of the issuer, the issuer must provide those financial statements instead and need not include the information reported on the federal income tax returns or the certifications of the principal executive officer;

(2) More than $100,000, but not more than $500,000, financial statements of the issuer reviewed by a public accountant that is independent of the issuer. If financial statements of the issuer are available that have been audited by a public accountant that is independent of the issuer, the issuer must provide those financial statements instead and need not include the reviewed financial statements; and

(3) More than $500,000, financial statements of the issuer audited by a public accountant that is independent of the issuer; *provided, however,* that for issuers that have not previously sold securities in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)), offerings that have a target offering amount of more than $500,000, but not more than $1,000,000, financial statements of the issuer reviewed by a public accountant that is independent of the issuer. If financial statements of the issuer are available that have been

audited by a public accountant that is independent of the issuer, the issuer must provide those financial statements instead and need not include the reviewed financial statements.

Instruction 1 to paragraph (t). To determine the financial statements required under this paragraph (t), an issuer must aggregate amounts sold in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) within the preceding 12-month period and the offering amount in the offering for which disclosure is being provided. If the issuer will accept proceeds in excess of the target offering amount, the issuer must include the maximum offering amount that the issuer will accept in the calculation to determine the financial statements required under this paragraph (t).

Instruction 2 to paragraph (t). An issuer may voluntarily meet the requirements of this paragraph (t) for a higher aggregate target offering amount.

Instruction 3 to paragraph (t). The financial statements must be prepared in accordance with U.S. generally accepted accounting principles and include balance sheets, statements of comprehensive income, statements of cash flows, statements of changes in stockholders' equity and notes to the financial statements. If the financial statements are not audited, they must be labeled as ''unaudited.'' The financial statements must cover the two most recently completed fiscal years or the period(s) since inception, if shorter.

Instruction 4 to paragraph (t). For an offering conducted in the first 120 days of a fiscal year, the financial statements provided may be for the two fiscal years prior to the issuer's most recently completed fiscal year; however, financial statements for the two most recently completed fiscal years must be provided if they are otherwise available. If more than 120 days have passed since the end of the issuer's most recently completed fiscal year, the financial statements provided must be for the issuer's two most recently completed fiscal years. If the 120th day falls on a Saturday, Sunday, or holiday, the next business day shall be considered the 120th day for purposes of determining the age of the financial statements.

Instruction 5 to paragraph (t). An issuer may elect to delay complying with any new or revised financial accounting standard that applies to companies that are not issuers (as defined under section 2(a) of the Sarbanes-Oxley Act of 2002 (15 U.S.C. 7201(a)) until the date that such companies are required to comply with such new or revised accounting standard. Issuers electing this accommodation must disclose it at the time the issuer files its offering statement and apply the election to all standards. Issuers electing not to use this accommodation must forgo this accommodation for all financial accounting standards and may not elect to rely on this accommodation in any future filings.

Instruction 6 to paragraph (t). An issuer required to provide information from a tax return under paragraph (t)(1) of this section before filing a tax return with the U.S. Internal Revenue Service for the most recently completed fiscal year may provide information from its tax return for the prior year (if any), provided that the issuer provides information from the tax return for the most recently completed fiscal year when it is filed with the U.S. Internal Revenue Service (if the tax return is filed during the offering period). An issuer that requested an extension from the U.S. Internal Revenue Service would not be required to provide information from the tax return until the date the return is filed, if filed during the offering period. If an issuer has not yet filed a tax return and is not required to file a tax return before the end of the offering period, then the tax return information does not need to be provided.

Instruction 7 to paragraph (t). An issuer providing financial statements that are not audited or reviewed and tax information as specified under paragraph (t)(1) of this section must have its principal executive officer provide the following certification:

I, [identify the certifying individual], certify that:

(1) the financial statements of [identify the issuer] included in this Form are true and complete in all material respects; and

(2) the tax return information of [identify the issuer] included in this Form reflects accurately the information reported on the tax return for [identify the issuer] filed for the fiscal year ended [date of most recent tax return].

[Signature and title].

Instruction 8 to paragraph (t). Financial statement reviews shall be conducted in accordance with the Statements on Standards for Accounting and Review Services issued by the Accounting and Review Services Committee of the American Institute of Certified Public Accountants. A signed review report must accompany the reviewed financial statements, and an issuer must notify the public accountant of the issuer's intended use of the review report in the offering. An issuer will not be in compliance with the requirement to provide reviewed financial statements if the review report includes modifications.

Instruction 9 to paragraph (t). Financial statement audits shall be conducted in accordance with either auditing standards issued by the American Institute of Certified Public Accountants (referred to as U.S. Generally Accepted Auditing Standards) or the standards of the Public Company Accounting Oversight Board. A signed audit report must accompany audited financial statements, and an issuer must notify the public accountant of the issuer's intended use of the audit report in the offering. An issuer will not be in compliance with the requirement to provide audited financial statements if the audit report includes a qualified opinion, an adverse opinion, or a disclaimer of opinion.

Instruction 10 to paragraph (t). To qualify as a public accountant that is independent of the issuer for purposes of this part, the accountant must satisfy the independence standards of either:

(i) 17 CFR 210.2–01 of this chapter, or

(ii) The American Institute of Certified Public Accountants. The public accountant that audits or reviews the financial statements provided by an issuer must be:

(A) Duly registered and in good standing as a certified public accountant under the laws of the place of his or her residence or principal office; or

(B) In good standing and entitled to practice as a public accountant under the laws of his or her place of residence or principal office.

Instruction 11 to paragraph (t). Except as set forth in § 227.100(c), references to the issuer in this paragraph (t) and its instructions (2) through (10) refer to the issuer and its predecessors, if any.

(u) Any matters that would have triggered disqualification under § 227.503(a) but occurred before May 16, 2016. The failure to provide such disclosure shall not prevent an issuer from continuing to rely on the exemption provided by section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) if the issuer establishes that it did not know and, in the exercise of reasonable care, could not have known of the existence of the undisclosed matter or matters;

Instruction to paragraph (u). An issuer will not be able to establish that it could not have known of a disqualification unless it has made factual inquiry into whether any disqualifications exist. The nature and scope of the factual inquiry will vary based on the facts and circumstances concerning, among other things, the issuer and the other offering participants.

(v) Updates regarding the progress of the issuer in meeting the target offering amount, to be provided in accordance with § 227.203;

(w) Where on the issuer's Web site investors will be able to find the issuer's annual report, and the date by which such report will be available on the issuer's Web site;

(x) Whether the issuer or any of its predecessors previously failed to comply with the ongoing reporting requirements of § 227.202; and

(y) Any material information necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

Instruction to § 227.201. If disclosure provided pursuant to any paragraph of this section also satisfies the requirements of one or more other paragraphs of this section, it is not necessary to repeat the disclosure. Instead of repeating information, an issuer may include a cross-reference to disclosure contained elsewhere in the offering statement or report, including to information in the financial statements.

§ 227.202 Ongoing reporting requirements.

(a) An issuer that has offered and sold securities in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) and in accordance with section 4A of the Securities Act (15 U.S.C. 77d–1) and this part must file with the Commission and post on the issuer's Web site an annual report along with the financial statements of the issuer certified by the principal executive officer of the issuer to be true and complete in all material respects and a description of the financial condition of the issuer as described in § 227.201(s). If, however, an issuer has available financial statements that have either been reviewed or audited by a public accountant that is independent of the issuer, those financial statements must be provided and the certification by the principal executive officer will not be required. The annual report also must include the disclosure required by paragraphs (a), (b), (c), (d), (e), (f), (m), (p), (q), (r), and (x) of § 227.201. The report must be filed in accordance with the requirements of § 227.203 and Form C (§ 239.900 of this chapter) and no later than 120 days after the end of the fiscal year covered by the report.

Instruction 1 to paragraph (a). Instructions (3), (8), (9), (10), and (11) to paragraph (t) of § 227.201 shall apply for purposes of this section.

Instruction 2 to paragraph (a). An issuer providing financial statements that are not audited or reviewed must have its principal executive officer provide the following certification:

I, [identify the certifying individual], certify that the financial statements of [identify the issuer] included in this Form are true and complete in all material respects.

[Signature and title].

(b) An issuer must continue to comply with the ongoing reporting requirements until one of the following occurs:

(1) The issuer is required to file reports under section 13(a) or section 15(d) of the Exchange Act (15 U.S.C. 78m(a) or 78o(d));

(2) The issuer has filed, since its most recent sale of securities pursuant to this part, at least one annual report pursuant to this section and has fewer than 300 holders of record;

(3) The issuer has filed, since its most recent sale of securities pursuant to this part, the annual reports required pursuant to this section for at least the three most recent years and has total assets that do not exceed $10,000,000;

(4) The issuer or another party repurchases all of the securities issued in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)), including any payment in full of debt securities or any complete redemption of redeemable securities; or

(5) The issuer liquidates or dissolves its business in accordance with state law.

§ 227.203 Filing requirements and form.

(a) *Form C—Offering statement and amendments* (§ 239.900 of this chapter).

(1) *Offering statement.* An issuer offering or selling securities in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) and in accordance with section 4A of the Securities Act (15 U.S.C. 77d-1) and this part must file with the Commission and provide to investors and the relevant intermediary a Form C: Offering Statement (Form C) (§ 239.900 of this chapter) prior to the commencement of the offering of securities. The Form C must include the information required by § 227.201.

(2) *Amendments to offering statement.* An issuer must file with the Commission and provide to investors and the relevant intermediary an amendment to the offering statement filed on Form C (§ 239.900 of this chapter) to disclose any material changes, additions or updates to information that it provides to investors through the intermediary's platform, for any offering that has not yet been completed or terminated. The amendment must be filed on Form C: Amendment (Form C/A) (§ 239.900 of this chapter), and if the amendment reflects material changes, additions or updates, the issuer shall check the box indicating that investors must reconfirm an investment commitment within five business days or the investor's commitment will be considered cancelled.

(3) *Progress updates.* (i) An issuer must file with the Commission and provide to investors and the relevant intermediary a Form C: Progress Update (Form C–U) (§ 239.900 of this chapter) to disclose its progress in meeting the target offering amount no later than five business days after each of the dates when the issuer reaches 50 percent and 100 percent of the target offering amount.

(ii) If the issuer will accept proceeds in excess of the target offering amount, the issuer must file with the Commission and provide to investors and the relevant intermediary, no later than five business days after the offering deadline, a final Form C–U (§ 239.900 of this chapter) to disclose the total amount of securities sold in the offering.

(iii) The requirements of paragraphs (a)(3)(i) and (ii) of this section shall not apply to an issuer if the relevant intermediary makes publicly available on the intermediary's platform frequent updates regarding the progress of the issuer in meeting the target offering amount; however, the issuer must still file a Form C–U (§ 239.900 of this chapter) to disclose the total amount of securities sold in the offering no later than five business days after the offering deadline.

Instruction to paragraph (a)(3). If multiple Forms C–U (§ 239.900 of this chapter) are triggered within the same five business day period, the issuer may consolidate such progress updates into one Form C–U, so long as the Form C–U discloses the most recent threshold that was met and the Form C–U is filed with the Commission and provided to investors and the relevant intermediary by the day on which the first progress update is due.

Instruction 1 to paragraph (a). An issuer would satisfy the requirement to provide to the relevant intermediary the information required by this paragraph (a) if it provides to the relevant intermediary a copy of the disclosures filed with the Commission.

Instruction 2 to paragraph (a). An issuer would satisfy the requirement to provide to investors the information required by this paragraph (a) if the issuer refers investors to the information on the intermediary's platform by means of a posting on the issuer's Web site or by email.

(b) *Form C: Annual report and termination of reporting* (§ 239.900 of this chapter). (1) *Annual reports.* An

issuer that has sold securities in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) and in accordance with section 4A of the Securities Act (15 U.S.C. 77d–1) and this part must file an annual report on Form C: Annual Report (Form C–AR) (§ 239.900 of this chapter) with the Commission no later than 120 days after the end of the fiscal year covered by the report. The annual report shall include the information required by § 227.202(a).

(2) *Amendments to annual report.* An issuer must file with the Commission an amendment to the annual report filed on Form C: Annual Report (Form C–AR) (§ 239.900 of this chapter) to make a material change to the previously filed annual report as soon as practicable after discovery of the need for the material change. The amendment must be filed on Form C: Amendment to Annual Report (Form C–AR/A) (§ 239.900 of this chapter).

(3) *Termination of reporting.* An issuer eligible to terminate its obligation to file annual reports with the Commission pursuant to § 227.202(b) must file with the Commission, within five business days from the date on which the issuer becomes eligible to terminate its reporting obligation, Form C: Termination of Reporting (Form C–TR) (§ 239.900 of this chapter) to advise investors that the issuer will cease reporting pursuant to this part.

§ 227.204 Advertising.

(a) An issuer may not, directly or indirectly, advertise the terms of an offering made in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)), except for notices that meet the requirements of paragraph (b) of this section.

Instruction to paragraph (a). For purposes of this paragraph (a), *issuer* includes persons acting on behalf of the issuer.

(b) A notice may advertise any of the terms of an issuer's offering made in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) if it directs investors to the intermediary's platform and includes no more than the following information:

(1) A statement that the issuer is conducting an offering pursuant to section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)), the name of the intermediary through which the offering is being conducted and a link directing the potential investor to the intermediary's platform;

(2) The terms of the offering; and

(3) Factual information about the legal identity and business location of the issuer, limited to the name of the issuer of the security, the address, phone number and Web site of the issuer, the email address of a representative of the issuer and a brief description of the business of the issuer.

(c) Notwithstanding the prohibition on advertising any of the terms of the offering, an issuer, and persons acting on behalf of the issuer, may communicate with investors and potential investors about the terms of the offering through communication channels provided by the intermediary on the intermediary's platform, provided that an issuer identifies itself as the issuer in all communications. Persons acting on behalf of the issuer must identify their affiliation with the issuer in all communications on the intermediary's platform.

Instruction to § 227.204. For purposes of this section, *terms of the offering* means the amount of securities offered, the nature of the securities, the price of the securities and the closing date of the offering period.

§ 227.205 Promoter compensation.

(a) An issuer, or person acting on behalf of the issuer, shall be permitted to compensate or commit to compensate, directly or indirectly, any person to promote the issuer's offerings made in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) through communication channels provided by an intermediary on the intermediary's platform, but only if the issuer or person acting on behalf of the issuer, takes reasonable steps to ensure that the person promoting the offering clearly discloses the receipt, past or prospective, of such compensation with any such communication.

Instruction to paragraph (a). The disclosure required by this paragraph is required, with each communication, for persons engaging in promotional activities on behalf of the issuer through the communication channels provided by the intermediary, regardless of whether or not the compensation they receive is specifically for the promotional activities. This includes persons hired specifically to promote the offering as well as to persons who are otherwise employed by the issuer or who undertake promotional activities on behalf of the issuer.

(b) Other than as set forth in paragraph (a) of this section, an issuer or person acting on behalf of the issuer shall not compensate or commit to compensate, directly or indirectly, any person to promote the issuer's offerings made in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)), unless such promotion is limited to notices permitted by, and in compliance with, § 227.204.

Subpart C—Requirements for Intermediaries

§ 227.300 Intermediaries.

(a) *Requirements.* A person acting as an intermediary in a transaction involving the offer or sale of securities in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) must:

(1) Be registered with the Commission as a broker under section 15(b) of the Exchange Act (15 U.S.C. 78*o*(b)) or as a funding portal in accordance with the requirements of § 227.400; and

(2) Be a member a national securities association registered under section 15A of the Exchange Act (15 U.S.C. 78*o*–3).

(b) *Financial interests.* Any director, officer or partner of an intermediary, or any person occupying a similar status or performing a similar function, may not have a financial interest in an issuer that is offering or selling securities in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) through the intermediary's platform, or receive a financial interest in an issuer as compensation for the services provided to or for the benefit of the issuer in connection with the offer or sale of such securities. An intermediary may not have a financial interest in an issuer that is offering or selling securities in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) through the intermediary's platform unless:

(1) The intermediary receives the financial interest from the issuer as compensation for the services provided to, or for the benefit of, the issuer in connection with the offer or sale of the securities being offered or sold in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) through the intermediary's platform; and

(2) the financial interest consists of securities of the same class and having the same terms, conditions and rights as the securities being offered or sold in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) through the intermediary's platform. For purposes of this paragraph, a *financial interest in an issuer* means a direct or indirect ownership of, or economic interest in, any class of the issuer's securities.

(c) *Definitions.* For purposes of this part:

(1) *Associated person of a funding portal* or *person associated with a funding portal* means any partner, officer, director or manager of a funding portal (or any person occupying a similar status or performing similar functions), any person directly or

indirectly controlling or controlled by such funding portal, or any employee of a funding portal, except that any person associated with a funding portal whose functions are solely clerical or ministerial shall not be included in the meaning of such term for purposes of section 15(b) of the Exchange Act (15 U.S.C. 78*o*(b)) (other than paragraphs (4) and (6) of section 15(b) of the Exchange Act).

(2) *Funding portal* means a broker acting as an intermediary in a transaction involving the offer or sale of securities in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)), that does not:

(i) Offer investment advice or recommendations;

(ii) Solicit purchases, sales or offers to buy the securities displayed on its platform;

(iii) Compensate employees, agents, or other persons for such solicitation or based on the sale of securities displayed or referenced on its platform; or

(iv) Hold, manage, possess, or otherwise handle investor funds or securities.

(3) *Intermediary* means a broker registered under section 15(b) of the Exchange Act (15 U.S.C. 78*o*(b)) or a funding portal registered under § 227.400 and includes, where relevant, an associated person of the registered broker or registered funding portal.

(4) *Platform* means a program or application accessible via the Internet or other similar electronic communication medium through which a registered broker or a registered funding portal acts as an intermediary in a transaction involving the offer or sale of securities in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)).

Instruction to paragraph (c)(4). An intermediary through which a crowdfunding transaction is conducted may engage in back office or other administrative functions other than on the intermediary's platform.

§ 227.301 Measures to reduce risk of fraud.

An intermediary in a transaction involving the offer or sale of securities in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) must:

(a) Have a reasonable basis for believing that an issuer seeking to offer and sell securities in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) through the intermediary's platform complies with the requirements in section 4A(b) of the Act (15 U.S.C. 77d–1(b)) and the related requirements in this part. In satisfying this requirement, an intermediary may rely on the representations of the issuer concerning compliance with these requirements unless the intermediary has reason to question the reliability of those representations;

(b) Have a reasonable basis for believing that the issuer has established means to keep accurate records of the holders of the securities it would offer and sell through the intermediary's platform, provided that an intermediary may rely on the representations of the issuer concerning its means of recordkeeping unless the intermediary has reason to question the reliability of those representations. An intermediary will be deemed to have satisfied this requirement if the issuer has engaged the services of a transfer agent that is registered under Section 17A of the Exchange Act (15 U.S.C. 78q–1(c)).

(c) Deny access to its platform to an issuer if the intermediary:

(1) Has a reasonable basis for believing that the issuer or any of its officers, directors (or any person occupying a similar status or performing a similar function) or beneficial owners of 20 percent or more of the issuer's outstanding voting equity securities, calculated on the basis of voting power, is subject to a disqualification under § 227.503. In satisfying this requirement, an intermediary must, at a minimum, conduct a background and securities enforcement regulatory history check on each issuer whose securities are to be offered by the intermediary and on each officer, director or beneficial owner of 20 percent or more of the issuer's outstanding voting equity securities, calculated on the basis of voting power.

(2) Has a reasonable basis for believing that the issuer or the offering presents the potential for fraud or otherwise raises concerns about investor protection. In satisfying this requirement, an intermediary must deny access if it reasonably believes that it is unable to adequately or effectively assess the risk of fraud of the issuer or its potential offering. In addition, if an intermediary becomes aware of information after it has granted access that causes it to reasonably believe that the issuer or the offering presents the potential for fraud or otherwise raises concerns about investor protection, the intermediary must promptly remove the offering from its platform, cancel the offering, and return (or, for funding portals, direct the return of) any funds that have been committed by investors in the offering.

§ 227.302 Account opening.

(a) *Accounts and electronic delivery.*

(1) No intermediary or associated person of an intermediary may accept an investment commitment in a transaction involving the offer or sale of securities in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) until the investor has opened an account with the intermediary and the intermediary has obtained from the investor consent to electronic delivery of materials.

(2) An intermediary must provide all information that is required to be provided by the intermediary under subpart C of this part (§§ 227.300 through 227.305), including, but not limited to, educational materials, notices and confirmations, through electronic means. Unless otherwise indicated in the relevant rule of subpart C of this part, in satisfying this requirement, an intermediary must provide the information through an electronic message that contains the information, through an electronic message that includes a specific link to the information as posted on intermediary's platform, or through an electronic message that provides notice of what the information is and that it is located on the intermediary's platform or on the issuer's Web site. Electronic messages include, but are not limited to, email, social media messages, instant messages or other electronic media messages.

(b) *Educational materials.* (1) In connection with establishing an account for an investor, an intermediary must deliver educational materials to such investor that explain in plain language and are otherwise designed to communicate effectively and accurately:

(i) The process for the offer, purchase and issuance of securities through the intermediary and the risks associated with purchasing securities offered and sold in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6));

(ii) The types of securities offered and sold in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) available for purchase on the intermediary's platform and the risks associated with each type of security, including the risk of having limited voting power as a result of dilution;

(iii) The restrictions on the resale of a security offered and sold in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6));

(iv) The types of information that an issuer is required to provide under § 227.202, the frequency of the delivery of that information and the possibility that those obligations may terminate in the future;

(v) The limitations on the amounts an investor may invest pursuant to § 227.100(a)(2);

(vi) The limitations on an investor's right to cancel an investment commitment and the circumstances in which an investment commitment may be cancelled by the issuer;

(vii) The need for the investor to consider whether investing in a security offered and sold in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) is appropriate for that investor;

(viii) That following completion of an offering conducted through the intermediary, there may or may not be any ongoing relationship between the issuer and intermediary; and

(ix) That under certain circumstances an issuer may cease to publish annual reports and, therefore, an investor may not continually have current financial information about the issuer.

(2) An intermediary must make the most current version of its educational material available on its platform at all times and, if at any time, the intermediary makes a material revision to its educational materials, it must make the revised educational materials available to all investors before accepting any additional investment commitments or effecting any further transactions in securities offered and sold in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)).

(c) *Promoters.* In connection with establishing an account for an investor, an intermediary must inform the investor that any person who promotes an issuer's offering for compensation, whether past or prospective, or who is a founder or an employee of an issuer that engages in promotional activities on behalf of the issuer on the intermediary's platform, must clearly disclose in all communications on the intermediary's platform, respectively, the receipt of the compensation and that he or she is engaging in promotional activities on behalf of the issuer.

(d) *Compensation disclosure.* When establishing an account for an investor, an intermediary must clearly disclose the manner in which the intermediary is compensated in connection with offerings and sales of securities in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)).

§ 227.303 Requirements with respect to transactions.

(a) *Issuer information.* An intermediary in a transaction involving the offer or sale of securities in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) must make available to the Commission and to investors any information required to be provided by the issuer of the securities under §§ 227.201 and 227.203(a).

(1) This information must be made publicly available on the intermediary's platform, in a manner that reasonably permits a person accessing the platform to save, download, or otherwise store the information;

(2) This information must be made publicly available on the intermediary's platform for a minimum of 21 days before any securities are sold in the offering, during which time the intermediary may accept investment commitments;

(3) This information, including any additional information provided by the issuer, must remain publicly available on the intermediary's platform until the offer and sale of securities in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) is completed or cancelled; and

(4) An intermediary may not require any person to establish an account with the intermediary to access this information.

(b) *Investor qualification.* Each time before accepting any investment commitment (including any additional investment commitment from the same person), an intermediary must:

(1) Have a reasonable basis for believing that the investor satisfies the investment limitations established by section 4(a)(6)(B) of the Act (15 U.S.C. 77d(a)(6)(B)) and this part. An intermediary may rely on an investor's representations concerning compliance with the investment limitation requirements concerning the investor's annual income, net worth, and the amount of the investor's other investments made pursuant to section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) unless the intermediary has reason to question the reliability of the representation.

(2) Obtain from the investor:

(i) A representation that the investor has reviewed the intermediary's educational materials delivered pursuant to § 227.302(b), understands that the entire amount of his or her investment may be lost, and is in a financial condition to bear the loss of the investment; and

(ii) A questionnaire completed by the investor demonstrating the investor's understanding that:

(A) There are restrictions on the investor's ability to cancel an investment commitment and obtain a return of his or her investment;

(B) It may be difficult for the investor to resell securities acquired in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)); and

(C) Investing in securities offered and sold in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) involves risk, and the investor should not invest any funds in an offering made in reliance on section 4(a)(6) of the Securities Act unless he or she can afford to lose the entire amount of his or her investment.

(c) *Communication channels.* An intermediary must provide on its platform communication channels by which persons can communicate with one another and with representatives of the issuer about offerings made available on the intermediary's platform, provided:

(1) If the intermediary is a funding portal, it does not participate in these communications other than to establish guidelines for communication and remove abusive or potentially fraudulent communications;

(2) The intermediary permits public access to view the discussions made in the communication channels;

(3) The intermediary restricts posting of comments in the communication channels to those persons who have opened an account with the intermediary on its platform; and

(4) The intermediary requires that any person posting a comment in the communication channels clearly and prominently disclose with each posting whether he or she is a founder or an employee of an issuer engaging in promotional activities on behalf of the issuer, or is otherwise compensated, whether in the past or prospectively, to promote the issuer's offering.

(d) *Notice of investment commitment.* An intermediary must promptly, upon receipt of an investment commitment from an investor, give or send to the investor a notification disclosing:

(1) The dollar amount of the investment commitment;

(2) The price of the securities, if known;

(3) The name of the issuer; and

(4) The date and time by which the investor may cancel the investment commitment.

(e) *Maintenance and transmission of funds.* (1) An intermediary that is a registered broker must comply with the requirements of 17 CFR 240.15c2–4.

(2) An intermediary that is a funding portal must direct investors to transmit the money or other consideration directly to a qualified third party that has agreed in writing to hold the funds for the benefit of, and to promptly transmit or return the funds to, the persons entitled thereto in accordance with paragraph (e)(3) of this section. For purposes of this subpart C (§§ 227.300 through 227.305), a qualified third party means a:

(i) Registered broker or dealer that carries customer or broker or dealer

accounts and holds funds or securities for those persons; or

(ii) Bank or credit union (where such credit union is insured by National Credit Union Administration) that has agreed in writing either to hold the funds in escrow for the persons who have the beneficial interests therein and to transmit or return such funds directly to the persons entitled thereto when so directed by the funding portal as described in paragraph (e)(3) of this section, or to maintain a bank or credit union account (or accounts) for the exclusive benefit of investors and the issuer.

(3) A funding portal that is an intermediary in a transaction involving the offer or sale of securities in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) shall promptly direct the qualified third party to:

(i) Transmit funds from the qualified third party to the issuer when the aggregate amount of investment commitments from all investors is equal to or greater than the target amount of the offering and the cancellation period as set forth in § 227.304 has elapsed, *provided that* in no event may the funding portal direct this transmission of funds earlier than 21 days after the date on which the intermediary makes publicly available on its platform the information required to be provided by the issuer under §§ 227.201 and 227.203(a);

(ii) Return funds to an investor when an investment commitment has been cancelled in accordance with § 227.304 (including for failure to obtain effective reconfirmation as required under § 227.304(c)); and

(iii) Return funds to investors when an issuer does not complete the offering.

(f) *Confirmation of transaction.* (1) An intermediary must, at or before the completion of a transaction in a security in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)), give or send to each investor a notification disclosing:

(i) The date of the transaction;

(ii) The type of security that the investor is purchasing;

(iii) The identity, price, and number of securities purchased by the investor, as well as the number of securities sold by the issuer in the transaction and the price(s) at which the securities were sold;

(iv) If a debt security, the interest rate and the yield to maturity calculated from the price paid and the maturity date;

(v) If a callable security, the first date that the security can be called by the issuer; and

(vi) The source, form and amount of any remuneration received or to be received by the intermediary in connection with the transaction, including any remuneration received or to be received by the intermediary from persons other than the issuer.

(2) An intermediary satisfying the requirements of paragraph (f)(1) of this section is exempt from the requirements of § 240.10b–10 of this chapter with respect to a transaction in a security offered and sold in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)).

§ 227.304 Completion of offerings, cancellations and reconfirmations.

(a) *Generally.* An investor may cancel an investment commitment for any reason until 48 hours prior to the deadline identified in the issuer's offering materials. During the 48 hours prior to such deadline, an investment commitment may not be cancelled except as provided in paragraph (c) of this section.

(b) *Early completion of offering.* If an issuer reaches the target offering amount prior to the deadline identified in its offering materials pursuant to § 227.201(g), the issuer may close the offering on a date earlier than the deadline identified in its offering materials pursuant to § 227.201(g), *provided that:*

(1) The offering remains open for a minimum of 21 days pursuant to § 227.303(a);

(2) The intermediary provides notice to any potential investors, and gives or sends notice to investors that have made investment commitments in the offering, of:

(i) The new, anticipated deadline of the offering;

(ii) The right of investors to cancel investment commitments for any reason until 48 hours prior to the new offering deadline; and

(iii) Whether the issuer will continue to accept investment commitments during the 48-hour period prior to the new offering deadline.

(3) The new offering deadline is scheduled for and occurs at least five business days after the notice required in paragraph (b)(2) of this section is provided; and

(4) At the time of the new offering deadline, the issuer continues to meet or exceed the target offering amount.

(c) *Cancellations and reconfirmations based on material changes.* (1) If there is a material change to the terms of an offering or to the information provided by the issuer, the intermediary must give or send to any investor who has made an investment commitment notice of the material change and that the investor's investment commitment will be cancelled unless the investor reconfirms his or her investment commitment within five business days of receipt of the notice. If the investor fails to reconfirm his or her investment within those five business days, the intermediary within five business days thereafter must:

(i) Give or send the investor a notification disclosing that the commitment was cancelled, the reason for the cancellation and the refund amount that the investor is expected to receive; and

(ii) Direct the refund of investor funds.

(2) If material changes to the offering or to the information provided by the issuer regarding the offering occur within five business days of the maximum number of days that an offering is to remain open, the offering must be extended to allow for a period of five business days for the investor to reconfirm his or her investment.

(d) *Return of funds if offering is not completed.* If an issuer does not complete an offering, an intermediary must within five business days:

(1) Give or send each investor a notification of the cancellation, disclosing the reason for the cancellation, and the refund amount that the investor is expected to receive;

(2) Direct the refund of investor funds; and

(3) Prevent investors from making investment commitments with respect to that offering on its platform.

§ 227.305 Payments to third parties.

(a) *Prohibition on payments for personally identifiable information.* An intermediary may not compensate any person for providing the intermediary with the personally identifiable information of any investor or potential investor in securities offered and sold in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)).

(b) For purposes of this rule, personally identifiable information means information that can be used to distinguish or trace an individual's identity, either alone or when combined with other personal or identifying information that is linked or linkable to a specific individual.

Subpart D—Funding Portal Regulation

§ 227.400 Registration of funding portals.

(a) *Registration.* A funding portal must register with the Commission, by filing a complete Form Funding Portal (§ 249.2000 of this chapter) in accordance with the instructions on the

form, and become a member of a national securities association registered under section 15A of the Exchange Act (15 U.S.C. 78*o*–3). The registration will be effective the later of:

(1) Thirty calendar days after the date that the registration is received by the Commission; or

(2) The date the funding portal is approved for membership by a national securities association registered under section 15A of the Exchange Act (15 U.S.C. 78*o*–3).

(b) *Amendments to registration.* A funding portal must file an amendment to Form Funding Portal (§ 249.2000 of this chapter) within 30 days of any of the information previously submitted on Form Funding Portal becoming inaccurate for any reason.

(c) *Successor registration.* (1) If a funding portal succeeds to and continues the business of a registered funding portal, the registration of the predecessor will remain effective as the registration of the successor if the successor, within 30 days after such succession, files a registration on Form Funding Portal (§ 249.2000 of this chapter) and the predecessor files a withdrawal on Form Funding Portal; *provided, however,* that the registration of the predecessor funding portal will be deemed withdrawn 45 days after registration on Form Funding Portal is filed by the successor.

(2) Notwithstanding paragraph (c)(1) of this section, if a funding portal succeeds to and continues the business of a registered funding portal and the succession is based solely on a change of the predecessor's date or state of incorporation, form of organization, or composition of a partnership, the successor may, within 30 days after the succession, amend the registration of the predecessor on Form Funding Portal (§ 249.2000 of this chapter) to reflect these changes.

(d) *Withdrawal.* A funding portal must promptly file a withdrawal of registration on Form Funding Portal (§ 249.2000 of this chapter) in accordance with the instructions on the form upon ceasing to operate as a funding portal. Withdrawal will be effective on the later of 30 days after receipt by the Commission (after the funding portal is no longer operational), or within such longer period of time as to which the funding portal consents or which the Commission by order may determine as necessary or appropriate in the public interest or for the protection of investors.

(e) *Applications and reports.* The applications and reports provided for in this section shall be considered filed when a complete Form Funding Portal (§ 249.2000 of this chapter) is submitted with the Commission. Duplicate originals of the applications and reports provided for in this section must be filed with surveillance personnel designated by any registered national securities association of which the funding portal is a member.

(f) *Nonresident funding portals.* Registration pursuant to this section by a nonresident funding portal shall be conditioned upon there being an information sharing arrangement in place between the Commission and the competent regulator in the jurisdiction under the laws of which the nonresident funding portal is organized or where it has its principal place of business, that is applicable to the nonresident funding portal.

(1) *Definition.* For purposes of this section, the term *nonresident funding portal* shall mean a funding portal incorporated in or organized under the laws of a jurisdiction outside of the United States or its territories, or having its principal place of business in any place not in the United States or its territories.

(2) *Power of attorney.* (i) Each nonresident funding portal registered or applying for registration pursuant to this section shall obtain a written consent and power of attorney appointing an agent in the United States, other than the Commission or a Commission member, official or employee, upon whom may be served any process, pleadings or other papers in any action under the federal securities laws. This consent and power of attorney must be signed by the nonresident funding portal and the named agent(s) for service of process.

(ii) Each nonresident funding portal registered or applying for registration pursuant to this section shall, at the time of filing its application on Form Funding Portal (§ 249.2000 of this chapter), furnish to the Commission the name and address of its United States agent for service of process on Schedule C to the Form.

(iii) Any change of a nonresident funding portal's agent for service of process and any change of name or address of a nonresident funding portal's existing agent for service of process shall be communicated promptly to the Commission through amendment of the Schedule C to Form Funding Portal (§ 249.2000 of this chapter).

(iv) Each nonresident funding portal must promptly appoint a successor agent for service of process if the nonresident funding portal discharges its identified agent for service of process or if its agent for service of process is unwilling or unable to accept service on behalf of the nonresident funding portal.

(v) Each nonresident funding portal must maintain, as part of its books and records, the written consent and power of attorney identified in paragraph (f)(2)(i) of this section for at least three years after the agreement is terminated.

(3) *Access to books and records; inspections and examinations*—(i) *Certification and opinion of counsel.* Any nonresident funding portal applying for registration pursuant to this section shall:

(A) Certify on Schedule C to Form Funding Portal (§ 249.2000 of this chapter) that the nonresident funding portal can, as a matter of law, and will provide the Commission and any registered national securities association of which it becomes a member with prompt access to the books and records of such nonresident funding portal and can, as a matter of law, and will submit to onsite inspection and examination by the Commission and any registered national securities association of which it becomes a member; and

(B) Provide an opinion of counsel that the nonresident funding portal can, as a matter of law, provide the Commission and any registered national securities association of which it becomes a member with prompt access to the books and records of such nonresident funding portal and can, as a matter of law, submit to onsite inspection and examination by the Commission and any registered national securities association of which it becomes a member.

(ii) *Amendments.* The nonresident funding portal shall re-certify, on Schedule C to Form Funding Portal (§ 249.2000 of this chapter), within 90 days after any changes in the legal or regulatory framework that would impact the nonresident funding portal's ability to provide, or the manner in which it provides, the Commission, or any registered national securities association of which it is a member, with prompt access to its books and records or that would impact the Commission's or such registered national securities association's ability to inspect and examine the nonresident funding portal. The re-certification shall be accompanied by a revised opinion of counsel describing how, as a matter of law, the nonresident funding portal can continue to meet its obligations under paragraphs (f)(3)(i)(A) and (B) of this section.

§ 227.401 Exemption.

A funding portal that is registered with the Commission pursuant to § 227.400 is exempt from the broker

registration requirements of section 15(a)(1) of the Exchange Act (15 U.S.C. 78*o*(a)(1)) in connection with its activities as a funding portal.

§ 227.402 Conditional safe harbor.

(a) *General.* Under section 3(a)(80) of the Exchange Act (15 U.S.C. 78c(a)(80)), a funding portal acting as an intermediary in a transaction involving the offer or sale of securities in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) may not: offer investment advice or recommendations; solicit purchases, sales, or offers to buy the securities offered or displayed on its platform or portal; compensate employees, agents, or other persons for such solicitation or based on the sale of securities displayed or referenced on its platform or portal; hold, manage, possess, or otherwise handle investor funds or securities; or engage in such other activities as the Commission, by rule, determines appropriate. This section is intended to provide clarity with respect to the ability of a funding portal to engage in certain activities, consistent with the prohibitions under section 3(a)(80) of the Exchange Act. No presumption shall arise that a funding portal has violated the prohibitions under section 3(a)(80) of the Exchange Act or this part by reason of the funding portal or its associated persons engaging in activities in connection with the offer or sale of securities in reliance on section 4(a)(6) of the Securities Act that do not meet the conditions specified in paragraph (b) of this section. The antifraud provisions and all other applicable provisions of the federal securities laws continue to apply to the activities described in paragraph (b) of this section.

(b) *Permitted activities.* A funding portal may, consistent with the prohibitions under section 3(a)(80) of the Exchange Act (15 U.S.C. 78c(a)(80)) and this part:

(1) Determine whether and under what terms to allow an issuer to offer and sell securities in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) through its platform; provided that a funding portal otherwise complies with this part;

(2) Apply objective criteria to highlight offerings on the funding portal's platform where:

(i) The criteria are reasonably designed to highlight a broad selection of issuers offering securities through the funding portal's platform, are applied consistently to all issuers and offerings and are clearly displayed on the funding portal's platform;

(ii) The criteria may include, among other things, the type of securities being offered (for example, common stock, preferred stock or debt securities); the geographic location of the issuer; the industry or business segment of the issuer; the number or amount of investment commitments made, progress in meeting the issuer's target offering amount or, if applicable, the maximum offering amount; and the minimum or maximum investment amount; provided that the funding portal may not highlight an issuer or offering based on the advisability of investing in the issuer or its offering; and

(iii) The funding portal does not receive special or additional compensations for highlighting one or more issuers or offerings on its platform;

(3) Provide search functions or other tools that investors can use to search, sort, or categorize the offerings available through the funding portal's platform according to objective criteria where;

(i) The criteria may include, among other things, the type of securities being offered (for example, common stock, preferred stock or debt securities); the geographic location of the issuer; the industry or business segment of the issuer; the number or amount of investment commitments made, progress in meeting the issuer's target offering amount or, if applicable, the maximum offering amount; and the minimum or maximum investment amount; and

(ii) The criteria may not include, among other things, the advisability of investing in the issuer or its offering, or an assessment of any characteristic of the issuer, its business plan, its key management or risks associated with an investment.

(4) Provide communication channels by which investors can communicate with one another and with representatives of the issuer through the funding portal's platform about offerings through the platform, so long as the funding portal (and its associated persons):

(i) Does not participate in these communications, other than to establish guidelines for communication and remove abusive or potentially fraudulent communications;

(ii) Permits public access to view the discussions made in the communication channels;

(iii) Restricts posting of comments in the communication channels to those persons who have opened an account on its platform; and

(iv) Requires that any person posting a comment in the communication channels clearly disclose with each posting whether he or she is a founder or an employee of an issuer engaging in promotional activities on behalf of the issuer, or is otherwise compensated, whether in the past or prospectively, to promote an issuer's offering;

(5) Advise an issuer about the structure or content of the issuer's offering, including assisting the issuer in preparing offering documentation;

(6) Compensate a third party for referring a person to the funding portal, so long as the third party does not provide the funding portal with personally identifiable information of any potential investor, and the compensation, other than that paid to a registered broker or dealer, is not based, directly or indirectly, on the purchase or sale of a security in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) offered on or through the funding portal's platform;

(7) Pay or offer to pay any compensation to a registered broker or dealer for services, including referrals pursuant to paragraph (b)(6) of this section, in connection with the offer or sale of securities by the funding portal in reliance on section 4(a)(6) of the Act(15 U.S.C. 77d(a)(6)), provided that:

(i) Such services are provided pursuant to a written agreement between the funding portal and the registered broker or dealer;

(ii) Such services and compensation are permitted under this part; and

(iii) Such services and compensation comply with the rules of any registered national securities association of which the funding portal is a member;

(8) Receive any compensation from a registered broker or dealer for services provided by the funding portal in connection with the offer or sale of securities by the funding portal in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)), provided that:

(i) Such services are provided pursuant to a written agreement between the funding portal and the registered broker or dealer;

(ii) Such compensation is permitted under this part; and

(iii) Such compensation complies with the rules of any registered national securities association of which the funding portal is a member;

(9) Advertise the existence of the funding portal and identify one or more issuers or offerings available on the portal on the basis of objective criteria, as long as:

(i) The criteria are reasonably designed to identify a broad selection of issuers offering securities through the funding portal's platform, and are applied consistently to all potential issuers and offerings;

(ii) The criteria may include, among other things, the type of securities being offered (for example, common stock, preferred stock or debt securities); the geographic location of the issuer; the industry or business segment of the issuer; the expressed interest by investors, as measured by number or amount of investment commitments made, progress in meeting the issuer's target offering amount or, if applicable, the maximum offering amount; and the minimum or maximum investment amount; and

(iii) The funding portal does not receive special or additional compensation for identifying the issuer or offering in this manner;

(10) Deny access to its platform to, or cancel an offering of an issuer, pursuant to § 227.301(c)(2), if the funding portal has a reasonable basis for believing that the issuer or the offering presents the potential for fraud or otherwise raises concerns about investor protection;

(11) Accept, on behalf of an issuer, an investment commitment for securities offered in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) by that issuer on the funding portal's platform;

(12) Direct investors where to transmit funds or remit payment in connection with the purchase of securities offered and sold in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)); and

(13) Direct a qualified third party, as required by § 227.303(e), to release proceeds to an issuer upon completion of a crowdfunding offering or to return proceeds to investors in the event an investment commitment or an offering is cancelled.

§ 227.403 Compliance.

(a) *Policies and procedures.* A funding portal must implement written policies and procedures reasonably designed to achieve compliance with the federal securities laws and the rules and regulations thereunder relating to its business as a funding portal.

(b) *Privacy.* A funding portal must comply with the requirements of part 248 of this chapter as they apply to brokers.

(c) *Inspections and examinations.* A funding portal shall permit the examination and inspection of all of its business and business operations that relate to its activities as a funding portal, such as its premises, systems, platforms, and records by representatives of the Commission and of the registered national securities association of which it is a member.

§ 227.404 Records to be made and kept by funding portals.

(a) *Generally.* A funding portal shall make and preserve the following records for five years, the first two years in an easily accessible place:

(1) All records related to an investor who purchases or attempts to purchase securities through the funding portal;

(2) All records related to issuers who offer and sell or attempt to offer and sell securities through the funding portal and the control persons of such issuers;

(3) Records of all communications that occur on or through its platform;

(4) All records related to persons that use communication channels provided by a funding portal to promote an issuer's securities or communicate with potential investors;

(5) All records required to demonstrate compliance with the requirements of subparts C (§§ 227.300 through 227.305) and D (§§ 227.400 through 227.404) of this part;

(6) All notices provided by such funding portal to issuers and investors generally through the funding portal's platform or otherwise, including, but not limited to, notices addressing hours of funding portal operations (if any), funding portal malfunctions, changes to funding portal procedures, maintenance of hardware and software, instructions pertaining to access to the funding portal and denials of, or limitations on, access to the funding portal;

(7) All written agreements (or copies thereof) entered into by such funding portal relating to its business as such;

(8) All daily, monthly and quarterly summaries of transactions effected through the funding portal, including:

(i) Issuers for which the target offering amount has been reached and funds distributed; and

(ii) Transaction volume, expressed in:

(A) Number of transactions;

(B) Number of securities involved in a transaction;

(C) Total amounts raised by, and distributed to, issuers; and

(D) Total dollar amounts raised across all issuers, expressed in U.S. dollars; and

(9) A log reflecting the progress of each issuer who offers or sells securities through the funding portal toward meeting the target offering amount.

(b) *Organizational documents.* A funding portal shall make and preserve during the operation of the funding portal and of any successor funding portal, all organizational documents relating to the funding portal, including but not limited to, partnership agreements, articles of incorporation or charter, minute books and stock certificate books (or other similar type documents).

(c) *Format.* The records required to be maintained and preserved pursuant to paragraph (a) of this section must be produced, reproduced, and maintained in the original, non-alterable format in which they were created or as permitted under § 240.17a–4(f) of this chapter.

(d) *Third parties.* The records required to be made and preserved pursuant to this section may be prepared or maintained by a third party on behalf of a funding portal. An agreement with a third party shall not relieve a funding portal from the responsibility to prepare and maintain records as specified in this rule. A funding portal must file with the registered national securities association of which it is a member, a written undertaking in a form acceptable to the registered national securities association, signed by a duly authorized person of the third party, stating in effect that such records are the property of the funding portal and will be surrendered promptly on request of the funding portal. The undertaking shall include the following provision:

> With respect to any books and records maintained or preserved on behalf of [name of funding portal], the undersigned hereby acknowledges that the books and records are the property of [name of funding portal], and hereby undertakes to permit examination of such books and records at any time, or from time to time, during business hours by representatives of the Securities and Exchange Commission and the registered national securities association of which the funding portal is a member, and to promptly furnish to the Commission, its representatives, and the registered national securities association of which the funding portal is a member, a true, correct, complete and current hard copy of any, all, or any part of, such books and records.

(e) *Review of records.* All records of a funding portal are subject at any time, or from time to time, to reasonable periodic, special, or other examination by the representatives of the Commission and the registered national securities association of which a funding portal is a member. Every funding portal shall furnish promptly to the Commission, its representatives, and the registered national securities association of which the funding portal is a member true, correct, complete and current copies of such records of the funding portal that are requested by the representatives of the Commission and the registered national securities association.

(f) *Financial recordkeeping and reporting of currency and foreign transactions.* A funding portal that is subject to the requirements of the Currency and Foreign Transactions Reporting Act of 1970 (15 U.S.C. 5311

et seq.) shall comply with the reporting, recordkeeping and record retention requirements of 31 CFR chapter X. Where 31 CFR chapter X and § 227.404(a) and (b) require the same records or reports to be preserved for different periods of time, such records or reports shall be preserved for the longer period of time.

Subpart E—Miscellaneous Provisions

§ 227.501 Restrictions on resales.

(a) Securities issued in a transaction exempt from registration pursuant to section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) and in accordance with section 4A of the Securities Act (15 U.S.C. 77d–1) and this part may not be transferred by any purchaser of such securities during the one-year period beginning when the securities were issued in a transaction exempt from registration pursuant to section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)), unless such securities are transferred:

(1) To the issuer of the securities;

(2) To an accredited investor;

(3) As part of an offering registered with the Commission; or

(4) To a member of the family of the purchaser or the equivalent, to a trust controlled by the purchaser, to a trust created for the benefit of a member of the family of the purchaser or the equivalent, or in connection with the death or divorce of the purchaser or other similar circumstance.

(b) For purposes of this § 227.501, the term *accredited investor* shall mean any person who comes within any of the categories set forth in § 230.501(a) of this chapter, or who the seller reasonably believes comes within any of such categories, at the time of the sale of the securities to that person.

(c) For purposes of this section, the term *member of the family of the purchaser or the equivalent* includes a child, stepchild, grandchild, parent, stepparent, grandparent, spouse or spousal equivalent, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law of the purchaser, and shall include adoptive relationships. For purposes of this paragraph (c), the term *spousal equivalent* means a cohabitant occupying a relationship generally equivalent to that of a spouse.

§ 227.502 Insignificant deviations from a term, condition or requirement of this part (Regulation Crowdfunding).

(a) A failure to comply with a term, condition, or requirement of this part will not result in the loss of the exemption from the requirements of Section 5 of the Securities Act (15 U.S.C. 77e) for any offer or sale to a particular individual or entity, if the issuer relying on the exemption shows:

(1) The failure to comply was insignificant with respect to the offering as a whole;

(2) The issuer made a good faith and reasonable attempt to comply with all applicable terms, conditions and requirements of this part; and

(3) The issuer did not know of such failure where the failure to comply with a term, condition or requirement of this part was the result of the failure of the intermediary to comply with the requirements of section 4A(a) of the Securities Act (15 U.S.C. 77d–1(a)) and the related rules, or such failure by the intermediary occurred solely in offerings other than the issuer's offering.

(b) Paragraph (a) of this section shall not preclude the Commission from bringing an enforcement action seeking any appropriate relief for an issuer's failure to comply with all applicable terms, conditions and requirements of this part.

§ 227.503 Disqualification provisions.

(a) *Disqualification events.* No exemption under this section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) shall be available for a sale of securities if the issuer; any predecessor of the issuer; any affiliated issuer; any director, officer, general partner or managing member of the issuer; any beneficial owner of 20 percent or more of the issuer's outstanding voting equity securities, calculated on the basis of voting power; any promoter connected with the issuer in any capacity at the time of such sale; any person that has been or will be paid (directly or indirectly) remuneration for solicitation of purchasers in connection with such sale of securities; or any general partner, director, officer or managing member of any such solicitor:

(1) Has been convicted, within 10 years before the filing of the offering statement (or five years, in the case of issuers, their predecessors and affiliated issuers), of any felony or misdemeanor:

(i) In connection with the purchase or sale of any security;

(ii) Involving the making of any false filing with the Commission; or

(iii) Arising out of the conduct of the business of an underwriter, broker, dealer, municipal securities dealer, investment adviser, funding portal or paid solicitor of purchasers of securities;

(2) Is subject to any order, judgment or decree of any court of competent jurisdiction, entered within five years before the filing of the information required by section 4A(b) of the Securities Act (15 U.S.C. 77d–1(b)) that, at the time of such filing, restrains or enjoins such person from engaging or continuing to engage in any conduct or practice:

(i) In connection with the purchase or sale of any security;

(ii) Involving the making of any false filing with the Commission; or

(iii) Arising out of the conduct of the business of an underwriter, broker, dealer, municipal securities dealer, investment adviser, funding portal or paid solicitor of purchasers of securities;

(3) Is subject to a final order of a state securities commission (or an agency or officer of a state performing like functions); a state authority that supervises or examines banks, savings associations or credit unions; a state insurance commission (or an agency or officer of a state performing like functions); an appropriate federal banking agency; the U.S. Commodity Futures Trading Commission; or the National Credit Union Administration that:

(i) At the time of the filing of the information required by section 4A(b) of the Securities Act (15 U.S.C. 77d–1(b)), bars the person from:

(A) Association with an entity regulated by such commission, authority, agency or officer;

(B) Engaging in the business of securities, insurance or banking; or

(C) Engaging in savings association or credit union activities; or

(ii) Constitutes a final order based on a violation of any law or regulation that prohibits fraudulent, manipulative or deceptive conduct entered within ten years before such filing of the offering statement;

Instruction to paragraph (a)(3). Final order shall mean a written directive or declaratory statement issued by a federal or state agency, described in § 227.503(a)(3), under applicable statutory authority that provides for notice and an opportunity for hearing, which constitutes a final disposition or action by that federal or state agency.

(4) Is subject to an order of the Commission entered pursuant to section 15(b) or 15B(c) of the Exchange Act (15 U.S.C. 78*o*(b) or 78*o*–4(c)) or Section 203(e) or (f) of the Investment Advisers Act of 1940 (15 U.S.C. 80b–3(e) or (f)) that, at the time of the filing of the information required by section 4A(b) of the Securities Act (15 U.S.C. 77d–1(b)):

(i) Suspends or revokes such person's registration as a broker, dealer, municipal securities dealer, investment adviser or funding portal;

(ii) Places limitations on the activities, functions or operations of such person; or

(iii) Bars such person from being associated with any entity or from participating in the offering of any penny stock;

(5) Is subject to any order of the Commission entered within five years before the filing of the information required by section 4A(b) of the Securities Act (15 U.S.C. 77d–1(b)) that, at the time of such filing, orders the person to cease and desist from committing or causing a violation or future violation of:

(i) Any scienter-based anti-fraud provision of the federal securities laws, including without limitation Section 17(a)(1) of the Securities Act (15 U.S.C. 77q(a)(1)), Section 10(b) of the Exchange Act (15 U.S.C. 78j(b)) and 17 CFR 240.10b–5, section 15(c)(1) of the Exchange Act (15 U.S.C. 78o(c)(1)) and Section 206(1) of the Investment Advisers Act of 1940 (15 U.S.C. 80b–6(1)) or any other rule or regulation thereunder; or

(ii) Section 5 of the Securities Act (15 U.S.C. 77e);

(6) Is suspended or expelled from membership in, or suspended or barred from association with a member of, a registered national securities exchange or a registered national or affiliated securities association for any act or omission to act constituting conduct inconsistent with just and equitable principles of trade;

(7) Has filed (as a registrant or issuer), or was or was named as an underwriter in, any registration statement or Regulation A (17 CFR 230.251 through 230.263) offering statement filed with the Commission that, within five years before the filing of the information required by section 4A(b) of the Securities Act (15 U.S.C. 77d–1(b)), was the subject of a refusal order, stop order, or order suspending the Regulation A exemption, or is, at the time of such filing, the subject of an investigation or proceeding to determine whether a stop order or suspension order should be issued; or

(8) Is subject to a United States Postal Service false representation order entered within five years before the filing of the information required by section 4A(b) of the Securities Act (15 U.S.C. 77d–1(b)), or is, at the time of such filing, subject to a temporary restraining order or preliminary injunction with respect to conduct alleged by the United States Postal Service to constitute a scheme or device for obtaining money or property through the mail by means of false representations.

(b) *Transition, waivers, reasonable care exception.* Paragraph (a) of this section shall not apply:

(1) With respect to any conviction, order, judgment, decree, suspension, expulsion or bar that occurred or was issued before May 16, 2016;

(2) Upon a showing of good cause and without prejudice to any other action by the Commission, if the Commission determines that it is not necessary under the circumstances that an exemption be denied;

(3) If, before the filing of the information required by section 4A(b) of the Securities Act (15 U.S.C. 77d–1(b)), the court or regulatory authority that entered the relevant order, judgment or decree advises in writing (whether contained in the relevant judgment, order or decree or separately to the Commission or its staff) that disqualification under paragraph (a) of this section should not arise as a consequence of such order, judgment or decree; or

(4) If the issuer establishes that it did not know and, in the exercise of reasonable care, could not have known that a disqualification existed under paragraph (a) of this section.

Instruction to paragraph (b)(4). An issuer will not be able to establish that it has exercised reasonable care unless it has made, in light of the circumstances, factual inquiry into whether any disqualifications exist. The nature and scope of the factual inquiry will vary based on the facts and circumstances concerning, among other things, the issuer and the other offering participants.

(c) *Affiliated issuers.* For purposes of paragraph (a) of this section, events relating to any affiliated issuer that occurred before the affiliation arose will be not considered disqualifying if the affiliated entity is not:

(1) In control of the issuer; or

(2) Under common control with the issuer by a third party that was in control of the affiliated entity at the time of such events.

(d) *Intermediaries.* A person that is subject to a statutory disqualification as defined in section 3(a)(39) of the Exchange Act (15 U.S.C. 78c(a)(39)) may not act as, or be an associated person of, an intermediary in a transaction involving the offer or sale of securities in reliance on section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) unless so permitted pursuant to Commission rule or order.

Instruction to paragraph (d). § 240.17f–2 of this chapter generally requires the fingerprinting of every person who is a partner, director, officer or employee of a broker, subject to certain exceptions.

PART 232—REGULATION S–T—GENERAL RULES AND REGULATIONS FOR ELECTRONIC FILINGS

■ 5. The authority citation for part 232 continues to read, in part, as follows:

Authority: 15 U.S.C. 77c, 77f, 77g, 77h, 77j, 77s(a), 77z-3, 77sss(a), 78c(b), 781, 78m, 78n, 78o(d), 78w(a), 78ll, 80a–6(c), 80a–8, 80a–29, 80a–30, 80a–37, 7201 *et seq.;* and 18 U.S.C. 1350, unless otherwise noted.

* * * * *

■ 6. Amend § 232.101 by:

■ a. In paragraph (a)(1)(xvii) removing ''and'' at the end of the paragraph; and

■ b. In paragraph (a)(1)(xviii) removing the period at the end of the paragraph and adding in its place a semicolon; and

■ c. Adding paragraphs (a)(1)(xix) and (a)(1)(xx).

The addition reads as follows:

§ 232.101 Mandated electronic submissions and exceptions.

(a) * * *

(1) * * *

(xix) Form C (§ 239.900 of this chapter). Exhibits to Form C (§ 239.900 of this chapter) may be filed on EDGAR as PDF documents in the format required by the EDGAR Filer Manual, as defined in Rule 11 of Regulation S–T (§ 232.11 of this chapter). Notwithstanding Rule 104 of Regulation S–T (§ 232.104 of this chapter), the PDF documents filed under this paragraph will be considered as officially filed with the Commission; and

(xx) Form Funding Portal (§ 249.2000 of this chapter). Exhibits and attachments to Form Funding Portal (§ 249.2000 of this chapter) may be filed on EDGAR as PDF documents in the format required by the EDGAR Filer Manual, as defined in Rule 11 of Regulation S–T (§ 232.11 of this chapter). Notwithstanding Rule 104 of Regulation S–T (§ 232.104 of this chapter), the PDF documents filed under this paragraph will be considered as officially filed with the Commission.

* * * * *

PART 239—FORMS PRESCRIBED UNDER THE SECURITIES ACT OF 1933

■ 7. The authority citation for part 239 continues to read, in part, as follows:

Authority: 15 U.S.C. 77c, 77f, 77g, 77h, 77j, 77s, 77z–2, 77z–3, 77sss, 78c, 78l, 78m, 78n, 78o(d), 78o–7 note, 78u–5, 78w(a), 78ll, 78mm, 80a–2(a), 80a–3, 80a–8, 80a–9, 80a–10, 80a–13, 80a–24, 80a–26, 80a–29, 80a–30, and 80a–37, unless otherwise noted.

* * * * *

■ 8. Add § 239.900 to read as follows:

§ 239.900 Form C.

This form shall be used for filings under Regulation Crowdfunding (part 227 of this chapter).

Note: The text of Form C will not appear in the Code of Federal Regulations.

BILLING CODE 8011–01–P

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM C

UNDER THE SECURITIES ACT OF 1933

(Mark one.)

□ **Form C: Offering Statement**
□ **Form C-U: Progress Update:** _____
□ **Form C/A: Amendment to Offering Statement:** _____
□ **Check box if Amendment is material and investors must reconfirm within five business days.**
□ **Form C-AR: Annual Report**
□ **Form C-AR/A: Amendment to Annual Report**
□ **Form C-TR: Termination of Reporting**

Name of issuer: _____
Legal status of issuer:
Form: _____
Jurisdiction of Incorporation/Organization: _____
Date of organization): _____
Physical address of issuer: _____
Website of issuer: _____

Name of intermediary through which the offering will be conducted: _____
CIK number of intermediary: _____
SEC file number of intermediary: _____
CRD number, if applicable, of intermediary: _____

Amount of compensation to be paid to the intermediary, whether as a dollar amount or a percentage of the offering amount, or a good faith estimate if the exact amount is not available at the time of the filing, for conducting the offering, including the amount of referral and any other fees associated with the offering:

_____

Any other direct or indirect interest in the issuer held by the intermediary, or any arrangement for the intermediary to acquire such an interest:

_____

Type of security offered: _____
Target number of securities to be offered: _____
Price (or method for determining price): _____
Target offering amount: _____
Oversubscriptions accepted: □ Yes □ No
If yes, disclose how oversubscriptions will be allocated: □ Pro-rata basis □ First-come, first-served basis
□ Other – provide a description:_____
Maximum offering amount (if different from target offering amount): _____
Deadline to reach the target offering amount: _____

NOTE: If the sum of the investment commitments does not equal or exceed the target offering amount at the offering deadline, no securities will be sold in the offering, investment commitments will be cancelled and committed funds will be returned.

Current number of employees: _____

Total Assets:	Most recent fiscal year-end:	_____	Prior fiscal year-end:	_____
Cash & Cash Equivalents:	Most recent fiscal year-end:	_____	Prior fiscal year-end:	_____
Accounts Receivable:	Most recent fiscal year-end:	_____	Prior fiscal year-end:	_____
Short-term Debt:	Most recent fiscal year-end:	_____	Prior fiscal year-end:	_____
Long-term Debt:	Most recent fiscal year-end:	_____	Prior fiscal year-end:	_____
Revenues/Sales	Most recent fiscal year-end:	_____	Prior fiscal year-end:	_____
Cost of Goods Sold:	Most recent fiscal year-end:	_____	Prior fiscal year-end:	_____
Taxes Paid:	Most recent fiscal year-end:	_____	Prior fiscal year-end:	_____
Net Income:	Most recent fiscal year-end:	_____	Prior fiscal year-end:	_____

Using the list below, select the jurisdictions in which the issuer intends to offer the securities:

[List will include all U.S. jurisdictions, with an option to add and remove them individually, add all and remove all.]

GENERAL INSTRUCTIONS

I. Eligibility Requirements for Use of Form C

This Form shall be used for the offering statement, and any related amendments and progress reports, required to be filed by any issuer offering or selling securities in reliance on the exemption in Securities Act Section 4(a)(6) and in accordance with Section 4A and Regulation Crowdfunding (§ 227.100 *et seq.*). This Form also shall be used for an annual report required pursuant to Rule 202 of Regulation Crowdfunding (§ 227.202) and for the termination of reporting required pursuant to Rule 203(b)(2) of Regulation Crowdfunding (§ 227.203(b)(2)). Careful attention should be directed to the terms, conditions and requirements of the exemption.

II. Preparation and Filing of Form C

Information on the cover page will be generated based on the information provided in XML format. Other than the cover page, this Form is not to be used as a blank form to be filled in, but only as a guide in the preparation of Form C. General information regarding the preparation, format and how to file this Form is contained in Regulation S-T (§ 232 *et seq.*).

III. Information to be Included in the Form

Item 1. Offering Statement Disclosure Requirements

An issuer filing this Form for an offering in reliance on Section 4(a)(6) of the Securities Act and pursuant to Regulation Crowdfunding (§ 227.100 *et seq.*) must file the Form prior to the commencement of the offering and include the information required by Rule 201 of Regulation Crowdfunding (§ 227.201).

An issuer must include in the XML-based portion of this Form: the information required by paragraphs (a), (e), (g), (h), (l), (n), and (o) of Rule 201 of Regulation Crowdfunding (§ 227.201(a), (e), (g), (h), (l), (n), and (o)); selected financial data for the prior two fiscal years (including total assets, cash and cash equivalents, accounts receivable, short-term debt, long-term debt, revenues/sales, cost of goods sold, taxes paid and net income); the jurisdictions in which the issuer intends to offer the securities; and any information required by Rule 203(a)(3) of Regulation Crowdfunding (§ 227.203(a)(3)).

Other than the information required to be provided in XML format, an issuer may provide the required information in the optional Question and Answer format included herein or in any other format included on the intermediary's platform, by filing such information as an exhibit to this Form, including copies of screen shots of the relevant information, as appropriate and necessary.

If disclosure in response to any paragraph of Rule 201 of Regulation Crowdfunding (§ 227.201) or Rule 203(a)(3) is responsive to one or more other paragraphs of Rule 201 of Regulation Crowdfunding (§ 227.201) or to Rule 203(a)(3) of Regulation Crowdfunding (§ 227.203(a)(3)), issuers are not required to make duplicate disclosures.

Item 2. Legends

(a) An issuer filing this Form for an offering in reliance on Section 4(a)(6) of the Securities Act and pursuant to Regulation Crowdfunding (§ 227.100 *et seq.*) must include the following legends:

> A crowdfunding investment involves risk. You should not invest any funds in this offering unless you can afford to lose your entire investment.
>
> In making an investment decision, investors must rely on their own examination of the issuer and the terms of the offering, including the merits and risks involved. These securities have not been recommended or approved by any federal or state securities commission or regulatory authority. Furthermore, these authorities have not passed upon the accuracy or adequacy of this document.
>
> The U.S. Securities and Exchange Commission does not pass upon the merits of any securities offered or the terms of the offering, nor does it pass upon the accuracy or completeness of any offering document or literature.
>
> These securities are offered under an exemption from registration; however, the U.S. Securities and Exchange Commission has not made an independent determination that these securities are exempt from registration.

(b) An issuer filing this Form for an offering in reliance on Section 4(a)(6) of the Securities Act and pursuant to Regulation Crowdfunding (§ 227.100 *et seq.*) must disclose in the offering statement that it will file a report with the Commission annually and post the report on its website, no later than 120 days after the end of each fiscal year covered by the report. The issuer must also disclose how an issuer may terminate its reporting obligations in the future in accordance with Rule 202(b) of Regulation Crowdfunding (§ 227.202(b)).

Item 3. Annual Report Disclosure Requirements

An issuer filing this Form for an annual report, as required by Regulation Crowdfunding (§ 227.100 *et seq.*), must file the Form no later than 120 days after the issuer's fiscal year end covered by the report and include the information required by Rule 201(a), (b), (c), (d), (e), (f), (m), (p), (q), (r), (s), (t), (x) and (y) of Regulation Crowdfunding (§§ 227.201(a), (b), (c), (d), (e), (f), (m), (p), (q), (r), (s), (t), (x) and (y)). For purposes of paragraph (t), the issuer shall provide financial statements certified by the principal executive officer of the issuer to be true and complete in all material respects. If, however, the issuer has available financial statements prepared in accordance with U.S. generally accepted accounting principles (U.S. GAAP) that have been reviewed or audited by an independent certified public accountant, those financial statements must be provided and the principal executive officer certification will not be required.

An issuer must include in the XML-based portion of this Form: the information required by paragraphs (a), and (e) of Rule 201 of Regulation Crowdfunding (§ 227.201(a) and (e)); and selected financial data for the prior two fiscal years (including total assets, cash and cash equivalents, accounts receivable, short-term debt, long-term debt, revenues/sales, cost of goods sold, taxes paid and net income).

SIGNATURE

Pursuant to the requirements of Sections 4(a)(6) and 4A of the Securities Act of 1933 and Regulation Crowdfunding (§ 227.100 *et seq.*), the issuer certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form C and has duly caused this Form to be signed on its behalf by the duly authorized undersigned.

_____

(Issuer)

By

_____

(Signature and Title)

Pursuant to the requirements of Sections 4(a)(6) and 4A of the Securities Act of 1933 and Regulation Crowdfunding (§ 227.100 *et seq.*), this Form C has been signed by the following persons in the capacities and on the dates indicated.

_____

(Signature)

_____

(Title)

_____

(Date)

Instructions.

1. The form shall be signed by the issuer, its principal executive officer or officers, its principal financial officer, its controller or principal accounting officer and at least a majority of the board of directors or persons performing similar functions.

2. The name of each person signing the form shall be typed or printed beneath the signature.

Intentional misstatements or omissions of facts constitute federal criminal violations. *See* 18 U.S.C. 1001.

OPTIONAL QUESTION & ANSWER FORMAT

FOR AN OFFERING STATEMENT

Respond to each question in each paragraph of this part. Set forth each question and any notes, but not any instructions thereto, in their entirety. If disclosure in response to any question is responsive to one or more other questions, it is not necessary to repeat the disclosure. If a question or series of questions is inapplicable or the response is available elsewhere in the Form, either state that it is inapplicable, include a cross-reference to the responsive disclosure, or omit the question or series of questions.

Be very careful and precise in answering all questions. Give full and complete answers so that they are not misleading under the circumstances involved. Do not discuss any future performance or other anticipated event unless you have a reasonable basis to believe that it will actually occur within the foreseeable future. If any answer requiring significant information is materially inaccurate, incomplete or misleading, the Company, its management and principal shareholders may be liable to investors based on that information.

THE COMPANY

1. Name of issuer: _____

ELIGIBILITY

2. □ Check this box to certify that all of the following statements are true for the issuer:

- Organized under, and subject to, the laws of a State or territory of the United States or the District of Columbia.
- Not subject to the requirement to file reports pursuant to Section 13 or Section 15(d) of the Securities Exchange Act of 1934.
- Not an investment company registered or required to be registered under the Investment Company Act of 1940.
- Not ineligible to rely on this exemption under Section 4(a)(6) of the Securities Act as a result of a disqualification specified in Rule 503(a) of Regulation Crowdfunding. (For more information about these disqualifications, see Question 30 of this Question and Answer format).
- Has filed with the Commission and provided to investors, to the extent required, the ongoing annual reports required by Regulation Crowdfunding during the two years immediately preceding the filing of this offering statement (or for such shorter period that the issuer was required to file such reports).
- Not a development stage company that (a) has no specific business plan or (b) has indicated that its business plan is to engage in a merger or acquisition with an unidentified company or companies.

INSTRUCTION TO QUESTION 2: If any of these statements is not true, then you are NOT eligible to rely on this exemption under Section 4(a)(6) of the Securities Act.

3. Has the issuer or any of its predecessors previously failed to comply with the ongoing reporting requirements of Rule 202 of Regulation Crowdfunding? □ Yes □ No
Explain: _____

DIRECTORS OF THE COMPANY

4. Provide the following information about each director (and any persons occupying a similar status or performing a similar function) of the issuer:

Name: _____ Dates of Board Service: _____
Principal Occupation: _____
Employer: _____ Dates of Service: _____
Employer's principal business: _____

List all positions and offices with the issuer held and the period of time in which the director served in the position or office:

Position: _____ Dates of Service: _____
Position: _____ Dates of Service: _____
Position: _____ Dates of Service: _____

Business Experience: List the employers, titles and dates of positions held during past three years with an indication of job responsibilities:

Employer: _____
Employer's principal business: _____
Title: _____ Dates of Service: _____
Responsibilities: _____

Employer: _____
Employer's principal business: _____
Title: _____ Dates of Service: _____
Responsibilities: _____

Employer: _____
Employer's principal business: _____
Title: _____ Dates of Service: _____
Responsibilities: _____

OFFICERS OF THE COMPANY

5. Provide the following information about each officer (and any persons occupying a similar status or performing a similar function) of the issuer:

Name: _____
Title: _____ Dates of Service: _____
Responsibilities: _____

List any prior positions and offices with the issuer and the period of time in which the officer served in the position or office:

Position: _____ Dates of Service: _____
Responsibilities: _____

Position: _____ Dates of Service: _____
Responsibilities: _____

Position: _____ Dates of Service: _____
Responsibilities: _____

Business Experience: List any other employers, titles and dates of positions held during past three years with an indication of job responsibilities:

Employer: _____
Employer's principal business: _____
Title: _____ Dates of Service: _____
Responsibilities: _____

Employer: _____
Employer's principal business: _____
Title: _____ Dates of Service: _____
Responsibilities: _____

Employer: _____
Employer's principal business: _____
Title: _____ Dates of Service: _____
Responsibilities: _____

INSTRUCTION TO QUESTION 5: For purposes of this Question 5, the term officer means a president, vice president, secretary, treasurer or principal financial officer, comptroller or principal accounting officer, and any person routinely performing similar functions.

PRINCIPAL SECURITY HOLDERS

6. Provide the name and ownership level of each person, as of the most recent practicable date, who is the beneficial owner of 20 percent or more of the issuer's outstanding voting equity securities, calculated on the basis of voting power.

Name of Holder	No. and Class of Securities Now Held	% of Voting Power Prior to Offering
		%
		%
		%
		%

INSTRUCTION TO QUESTION 6: The above information must be provided as of a date that is no more than 120 days prior to the date of filing of this offering statement.

To calculate total voting power, include all securities for which the person directly or indirectly has or shares the voting power, which includes the power to vote or to direct the voting of such securities. If the person has the right to acquire voting power of such securities within 60 days, including through the exercise of any option, warrant or right, the conversion of a security, or other arrangement, or if securities are held by a member of the family, through corporations or partnerships, or otherwise in a manner that would allow a person to direct or control the voting of the securities (or share in such direction or control — as, for example, a co-trustee) they should be included as being "beneficially owned." You should include an explanation of these circumstances in a footnote to the "Number of and Class of Securities Now Held." To calculate outstanding voting equity securities, assume all outstanding options are exercised and all outstanding convertible securities converted.

BUSINESS AND ANTICIPATED BUSINESS PLAN

7. Describe in detail the business of the issuer and the anticipated business plan of the issuer.

RISK FACTORS

A crowdfunding investment involves risk. You should not invest any funds in this offering unless you can afford to lose your entire investment.

In making an investment decision, investors must rely on their own examination of the issuer and the terms of the offering, including the merits and risks involved. These securities have not been recommended or approved by any federal or state securities commission or regulatory authority. Furthermore, these authorities have not passed upon the accuracy or adequacy of this document.

The U.S. Securities and Exchange Commission does not pass upon the merits of any securities offered or the terms of the offering, nor does it pass upon the accuracy or completeness of any offering document or literature.

These securities are offered under an exemption from registration; however, the U.S. Securities and Exchange Commission has not made an independent determination that these securities are exempt from registration.

8. Discuss the material factors that make an investment in the issuer speculative or risky:

(1) _____

(2) _____

(3) _____

(4) _____

(5) _____

(6) _____

(7) _____

(8) _____

(9) _____

(10) _____

INSTRUCTION TO QUESTION 8: Avoid generalized statements and include only those factors that are unique to the issuer. Discussion should be tailored to the issuer's business and the offering and should not repeat the factors addressed in the legends set forth above. No specific number of risk factors is required to be identified. Add additional lines and number as appropriate.

THE OFFERING

9. What is the purpose of this offering?

10. How does the issuer intend to use the proceeds of this offering?

	If Target Offering Amount Sold	**If Maximum Amount Sold**
Total Proceeds	$	$
Less: Offering Expenses		
(A)		
(B)		
(C)		
Net Proceeds	$	$
Use of Net Proceeds		
(A)		
(B)		
(C)		
Total Use of Net Proceeds	$	$

INSTRUCTION TO QUESTION 10: An issuer must provide a reasonably detailed description of any intended use of proceeds, such that investors are provided with an adequate amount of information to understand how the offering proceeds will be used. If an issuer has identified a range of possible uses, the issuer should identify and describe each probable use and the factors the issuer may consider in allocating proceeds among the potential uses. If the issuer will accept proceeds in excess of the target offering amount, the issuer must describe the purpose, method for allocating oversubscriptions, and intended use of the excess proceeds with similar specificity.

11. How will the issuer complete the transaction and deliver securities to the investors?

12. How can an investor cancel an investment commitment?

NOTE: Investors may cancel an investment commitment until 48 hours prior to the deadline identified in these offering materials.

The intermediary will notify investors when the target offering amount has been met.

If the issuer reaches the target offering amount prior to the deadline identified in the offering materials, it may close the offering early if it provides notice about the new offering deadline at least five business days prior to such new offering deadline (absent a material change that would require an extension of the offering and reconfirmation of the investment commitment).

If an investor does not cancel an investment commitment before the 48-hour period prior to the offering deadline, the funds will be released to the issuer upon closing of the offering and the investor will receive securities in exchange for his or her investment.

If an investor does not reconfirm his or her investment commitment after a material change is made to the offering, the investor's investment commitment will be cancelled and the committed funds will be returned.

OWNERSHIP AND CAPITAL STRUCTURE

The Offering

13. Describe the terms of the securities being offered.

14. Do the securities offered have voting rights? □ Yes □ No

15. Are there any limitations on any voting or other rights identified above? □ Yes □ No
Explain: _____

16. How may the terms of the securities being offered be modified?

Restrictions on Transfer of the Securities Being Offered

The securities being offered may not be transferred by any purchaser of such securities during the one-year period beginning when the securities were issued, unless such securities are transferred:

(1) to the issuer;
(2) to an accredited investor;
(3) as part of an offering registered with the U.S. Securities and Exchange Commission; or
(4) to a member of the family of the purchaser or the equivalent, to a trust controlled by the purchaser, to a trust created for the benefit of a member of the family of the purchaser or the equivalent, or in connection with the death or divorce of the purchaser or other similar circumstance.

NOTE: The term "accredited investor" means any person who comes within any of the categories set forth in Rule 501(a) of Regulation D, or who the seller reasonably believes comes within any of such categories, at the time of the sale of the securities to that person.

The term "member of the family of the purchaser or the equivalent" includes a child, stepchild, grandchild, parent, stepparent, grandparent, spouse or spousal equivalent, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law of the purchaser, and includes adoptive relationships. The term "spousal equivalent" means a cohabitant occupying a relationship generally equivalent to that of a spouse.

Description of Issuer's Securities

17. What other securities or classes of securities of the issuer are outstanding? Describe the material terms of any other outstanding securities or classes of securities of the issuer.

Class of Security	Securities (or Amount) Authorized	Securities (or Amount) Outstanding	Voting Rights	Other Rights
Preferred Stock (list each class in order of preference):				
_____			□ Yes □ No	□ Yes □ No Specify: _____
_____			□ Yes □ No	□ Yes □ No Specify: _____
Common Stock:			□ Yes □ No	□ Yes □ No Specify: _____
Debt Securities:			□ Yes □ No	□ Yes □ No Specify: _____
Other:				
_____			□ Yes □ No	□ Yes □ No Specify: _____
_____			□ Yes □ No	□ Yes □ No Specify: _____

Class of Security	Securities Reserved for Issuance upon Exercise or Conversion
Warrants:	
Options:	
Other Rights:	
_____	
_____	

18. How may the rights of the securities being offered be materially limited, diluted or qualified by the rights of any other class of security identified above?

19. Are there any differences not reflected above between the securities being offered and each other class of security of the issuer? □ Yes □ No
Explain: _____

20. How could the exercise of rights held by the principal shareholders identified in Question 6 above affect the purchasers of the securities being offered?

21. How are the securities being offered being valued? Include examples of methods for how such securities may be valued by the issuer in the future, including during subsequent corporate actions.

22. What are the risks to purchasers of the securities relating to minority ownership in the issuer?

23. What are the risks to purchasers associated with corporate actions including:
- additional issuances of securities,
- issuer repurchases of securities,
- a sale of the issuer or of assets of the issuer or
- transactions with related parties?

24. Describe the material terms of any indebtedness of the issuer:

Creditor(s)	Amount Outstanding	Interest Rate	Maturity Date	Other Material Terms
	$_____	_____%		
	$_____	_____%		
	$_____	_____%		

25. What other exempt offerings has the issuer conducted within the past three years?

Date of Offering	Exemption Relied Upon	Securities Offered	Amount Sold	Use of Proceeds
			$_____	
			$_____	
			$_____	

26. Was or is the issuer or any entities controlled by or under common control with the issuer a party to any transaction since the beginning of the issuer's last fiscal year, or any currently proposed transaction, where the amount involved exceeds five percent of the aggregate amount of capital raised by the issuer in reliance on Section 4(a)(6) of the Securities Act during the preceding 12-month period, including the amount the issuer seeks to raise in the current offering, in which any of the following persons had or is to have a direct or indirect material interest:

(1) any director or officer of the issuer;
(2) any person who is, as of the most recent practicable date, the beneficial owner of 20 percent or more of the issuer's outstanding voting equity securities, calculated on the basis of voting power;
(3) if the issuer was incorporated or organized within the past three years, any promoter of the issuer; or
(4) any immediate family member of any of the foregoing persons.

If yes, for each such transaction, disclose the following:

Specified Person	Relationship to Issuer	Nature of Interest in Transaction	Amount of Interest
			$_____

$_____
$_____

INSTRUCTIONS TO QUESTION 26:

The term transaction includes, but is not limited to, any financial transaction, arrangement or relationship (including any indebtedness or guarantee of indebtedness) or any series of similar transactions, arrangements or relationships.

Beneficial ownership for purposes of paragraph (2) shall be determined as of a date that is no more than 120 days prior to the date of filing of this offering statement and using the same calculation described in Question 6 of this Question and Answer format.

The term "member of the family" includes any child, stepchild, grandchild, parent, stepparent, grandparent, spouse or spousal equivalent, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law of the person, and includes adoptive relationships. The term "spousal equivalent" means a cohabitant occupying a relationship generally equivalent to that of a spouse.

Compute the amount of a related party's interest in any transaction without regard to the amount of the profit or loss involved in the transaction. Where it is not practicable to state the approximate amount of the interest, disclose the approximate amount involved in the transaction.

FINANCIAL CONDITION OF THE ISSUER

27. Does the issuer have an operating history? □ Yes □ No

28. Describe the financial condition of the issuer, including, to the extent material, liquidity, capital resources and historical results of operations.

INSTRUCTIONS TO QUESTION 28:

The discussion must cover each year for which financial statements are provided. Include a discussion of any known material changes or trends in the financial condition and results of operations of the issuer during any time period subsequent to the period for which financial statements are provided.

For issuers with no prior operating history, the discussion should focus on financial milestones and operational, liquidity and other challenges.

For issuers with an operating history, the discussion should focus on whether historical results and cash flows are representative of what investors should expect in the future.

Take into account the proceeds of the offering and any other known or pending sources of capital. Discuss how the proceeds from the offering will affect liquidity, whether receiving these funds and any other additional funds is necessary to the viability of the business, and how quickly the issuer anticipates using its available cash. Describe the other available sources of capital to the business, such as lines of credit or required contributions by shareholders.

References to the issuer in this Question 28 and these instructions refer to the issuer and its predecessors, if any.

FINANCIAL INFORMATION

29. Include the financial information specified below covering the two most recently completed fiscal years or the period(s) since inception, if shorter:

Aggregate Offering Amount (defined below):	Financial Information Required:	Financial Statement Requirements:
(a) $100,000 or less:	• The following information or their equivalent line items as reported on the federal income tax return filed by the issuer for the most recently completed year (if any): o Total income o Taxable income; and o Total tax; certified by the principal executive officer of the issuer to reflect accurately the information reported on the issuer's federal income tax returns; and • Financial statements of the issuer and its predecessors, if any.	Financial statements must be **certified** by the principal executive officer of the issuer as set forth below. If financial statements are available that have either been reviewed or audited by a public accountant that is independent of the issuer, the issuer must provide those financial statements instead along with a signed audit or review report and need not include the information reported on the federal income tax returns or the certification of the principal executive officer.
(b) More than $100,000, but not more than $500,000:	• Financial statements of the issuer and its predecessors, if any.	Financial statements must be **reviewed** by a public accountant that is independent of the issuer and must include a signed review report. If financial statements of the issuer are available that have been audited by a public accountant that is independent of the issuer, the issuer must provide those financial statements instead along with a signed audit report and need not include the reviewed financial statements.
(c) More than $500,000:	• Financial statements of the issuer and its predecessors, if any.	If the issuer **has** previously sold securities in reliance on Regulation Crowdfunding: Financial statements must be **audited** by a public accountant that is independent of the issuer and must include a signed audit report. If the issuer **has not** previously sold securities in reliance on Regulation Crowdfunding and it is offering more than $500,000 but not more than

$1,000,000:	
	Financial statements must be **reviewed** by a public accountant that is independent of the issuer and must include a signed review report.
	If financial statements of the issuer are available that have been audited by a public accountant that is independent of the issuer, the issuer must provide those financial statements instead along with a signed audit report and need not include the reviewed financial statements.

INSTRUCTIONS TO QUESTION 29: To determine the financial statements required, the Aggregate Offering Amount for purposes of this Question 29 means the aggregate amounts offered and sold by the issuer, all entities controlled by or under common control with the issuer, and all predecessors of the issuer in reliance on Section 4(a)(6) of the Securities Act within the preceding 12-month period plus the current maximum offering amount provided on the cover of this Form.

To determine whether the issuer has previously sold securities in reliance on Regulation Crowdfunding for purposes of paragraph (c) of this Question 29, "issuer" means the issuer, all entities controlled by or under common control with the issuer, and all predecessors of the issuer.

Financial statements must be prepared in accordance with U.S. generally accepted accounting principles and must include balance sheets, statements of comprehensive income, statements of cash flows, statements of changes in stockholders' equity and notes to the financial statements. If the financial statements are not audited, they shall be labeled as "unaudited."

Issuers offering securities and required to provide the information set forth in row (a) before filing a tax return for the most recently completed fiscal year may provide information from the tax return filed for the prior year (if any), provided that the issuer provides information from the tax return for the most recently completed fiscal year when it is filed, if filed during the offering period. An issuer that requested an extension of the time to file would not be required to provide information from the tax return until the date when the return is filed, if filed during the offering period.

A principal executive officer certifying financial statements as described above must provide the following certification**:

I, [identify the certifying individual], certify that:

(1) the financial statements of [identify the issuer] included in this Form are true and complete in all material respects; and

(2) the tax return information of [identify the issuer] included in this Form reflects accurately the information reported on the tax return for [identify the issuer] filed for the fiscal year ended [date of most recent tax return].

[Signature]
[Title]

** Intentional misstatements or omissions of facts constitute federal criminal violations. *See* 18 U.S.C. 1001.

To qualify as a public accountant that is independent of the issuer for purposes of this Question 29, the accountant must satisfy the independence standards of either:

(i) Rule 2-01 of Regulation S-X or

(ii) the AICPA.

The public accountant that audits or reviews the financial statements provided by an issuer must be (1) duly registered and in good standing as a certified public accountant under the laws of the place of his or her residence or principal office or (2) in good standing and entitled to practice as a public accountant under the laws of his or her place of residence or principal office.

An issuer will not be in compliance with the requirement to provide reviewed financial statement if the issuer received a review report that includes modifications. An issuer will not be in compliance with the requirement to provide audited financial statements if the issuer received a qualified opinion, an adverse opinion, or a disclaimer of opinion.

The issuer must notify the public accountant of the issuer's intended use of the public accountant's audit or review report in the offering.

For an offering conducted in the first 120 days of a fiscal year, the financial statements provided may be for the two fiscal years prior to the issuer's most recently completed fiscal year; however, financial statements for the two most recently completed fiscal years must be provided if they are otherwise available. If more than 120 days have passed since the end of the issuer's most recently completed fiscal year, the financial statements provided must be for the issuer's two most recently completed fiscal years. If the 120th day falls on a Saturday, Sunday, or holiday, the next business day shall be considered the 120th day for purposes of determining the age of the financial statements.

An issuer may elect to delay complying with any new or revised financial accounting standard until the date that a company that is not an issuer (as defined under section 2(a) of the Sarbanes-Oxley Act of 2002 is required to comply with such new or revised accounting standard, if such standard also applies to companies that are not issuers. Issuers electing such extension of time accommodation must disclose it at the time the issuer files its offering statement and apply the election to all standards. Issuers electing not to use this accommodation must forgo this accommodation for all financial accounting standards and may not elect to rely on this accommodation in any future filings

30. With respect to the issuer, any predecessor of the issuer, any affiliated issuer, any director, officer, general partner or managing member of the issuer, any beneficial owner of 20 percent or more of the issuer's outstanding voting equity securities, calculated in the same form as described in Question 6 of this Question and Answer format, any promoter connected with the issuer in any capacity at the time of such sale, any person that has been or will be paid (directly or indirectly) remuneration for solicitation of purchasers in connection with such sale of securities, or any general partner, director, officer or managing member of any such solicitor, prior to **May 16, 2016**:

    (1) Has any such person been convicted, within 10 years (or five years, in the case of issuers, their predecessors and affiliated issuers) before the filing of this offering statement, of any felony or misdemeanor:

        (i) in connection with the purchase or sale of any security? □ Yes □ No

        (ii) involving the making of any false filing with the Commission? □ Yes □ No

(iii) arising out of the conduct of the business of an underwriter, broker, dealer, municipal securities dealer, investment adviser, funding portal or paid solicitor of purchasers of securities? □ Yes □ No

If Yes to any of the above, explain: _____

(2) Is any such person subject to any order, judgment or decree of any court of competent jurisdiction, entered within five years before the filing of the information required by Section 4A(b) of the Securities Act that, at the time of filing of this offering statement, restrains or enjoins such person from engaging or continuing to engage in any conduct or practice:

(i) in connection with the purchase or sale of any security? □ Yes □ No;

(ii) involving the making of any false filing with the Commission? □ Yes □ No

(iii) arising out of the conduct of the business of an underwriter, broker, dealer, municipal securities dealer, investment adviser, funding portal or paid solicitor of purchasers of securities? □ Yes □ No

If Yes to any of the above, explain: _____

(3) Is any such person subject to a final order of a state securities commission (or an agency or officer of a state performing like functions); a state authority that supervises or examines banks, savings associations or credit unions; a state insurance commission (or an agency or officer of a state performing like functions); an appropriate federal banking agency; the U.S. Commodity Futures Trading Commission; or the National Credit Union Administration that:

(i) at the time of the filing of this offering statement bars the person from:

(A) association with an entity regulated by such commission, authority, agency or officer? □ Yes □ No

(B) engaging in the business of securities, insurance or banking? □ Yes □ No

(C) engaging in savings association or credit union activities? □ Yes □ No

(ii) constitutes a final order based on a violation of any law or regulation that prohibits fraudulent, manipulative or deceptive conduct and for which the order was entered within the 10-year period ending on the date of the filing of this offering statement? □ Yes □ No

If Yes to any of the above, explain: _____

(4) Is any such person subject to an order of the Commission entered pursuant to Section 15(b) or 15B(c) of the Exchange Act or Section 203(e) or (f) of the Investment Advisers Act of 1940 that, at the time of the filing of this offering statement:

(i) suspends or revokes such person's registration as a broker, dealer, municipal securities dealer, investment adviser or funding portal? □ Yes □ No

(ii) places limitations on the activities, functions or operations of such person? □ Yes □ No

(iii) bars such person from being associated with any entity or from participating in the offering of any penny stock? □ Yes □ No

If Yes to any of the above, explain: _____

(5) Is any such person subject to any order of the Commission entered within five years before the filing of this offering statement that, at the time of the filing of this offering statement, orders the person to cease and desist from committing or causing a violation or future violation of:

(i) any scienter-based anti-fraud provision of the federal securities laws, including without limitation Section 17(a)(1) of the Securities Act, Section 10(b) of the

Exchange Act, Section 15(c)(1) of the Exchange Act and Section 206(1) of the Investment Advisers Act of 1940 or any other rule or regulation thereunder?
□ Yes □ No

(ii) Section 5 of the Securities Act? □ Yes □ No

If Yes to either of the above, explain: _____

(6) Is any such person suspended or expelled from membership in, or suspended or barred from association with a member of, a registered national securities exchange or a registered national or affiliated securities association for any act or omission to act constituting conduct inconsistent with just and equitable principles of trade?
□ Yes □ No
If Yes, explain: _____

(7) Has any such person filed (as a registrant or issuer), or was any such person or was any such person named as an underwriter in, any registration statement or Regulation A offering statement filed with the Commission that, within five years before the filing of this offering statement, was the subject of a refusal order, stop order, or order suspending the Regulation A exemption, or is any such person, at the time of such filing, the subject of an investigation or proceeding to determine whether a stop order or suspension order should be issued?
□ Yes □ No
If Yes, explain: _____

(8) Is any such person subject to a United States Postal Service false representation order entered within five years before the filing of the information required by Section 4A(b) of the Securities Act, or is any such person, at the time of filing of this offering statement, subject to a temporary restraining order or preliminary injunction with respect to conduct alleged by the United States Postal Service to constitute a scheme or device for obtaining money or property through the mail by means of false representations?
□ Yes □ No
If Yes, explain: _____

If you would have answered "Yes" to any of these questions had the conviction, order, judgment, decree, suspension, expulsion or bar occurred or been issued after May 16, 2016, then you are NOT eligible to rely on this exemption under Section 4(a)(6) of the Securities Act.

INSTRUCTIONS TO QUESTION 30: Final order means a written directive or declaratory statement issued by a federal or state agency, described in Rule 503(a)(3) of Regulation Crowdfunding, under applicable statutory authority that provides for notice and an opportunity for hearing, which constitutes a final disposition or action by that federal or state agency.

No matters are required to be disclosed with respect to events relating to any affiliated issuer that occurred before the affiliation arose if the affiliated entity is not (i) in control of the issuer or (ii) under common control with the issuer by a third party that was in control of the affiliated entity at the time of such events.

OTHER MATERIAL INFORMATION

31. In addition to the information expressly required to be included in this Form, include:
(1) any other material information presented to investors; and
(2) such further material information, if any, as may be necessary to make the required statements, in the light of the circumstances under which they are made, not misleading.

INSTRUCTIONS TO QUESTION 31: If information is presented to investors in a format, media or other means not able to be reflected in text or portable document format, the issuer should include

(a) a description of the material content of such information;
(b) a description of the format in which such disclosure is presented; and
(c) in the case of disclosure in video, audio or other dynamic media or format, a transcript or description of such disclosure.

ONGOING REPORTING

The issuer will file a report electronically with the Securities & Exchange Commission annually and post the report on its website, no later than:

_____

(120 days after the end of each fiscal year covered by the report).

Once posted, the annual report may be found on the issuer's website at:

_____

The issuer must continue to comply with the ongoing reporting requirements until:

(1) the issuer is required to file reports under Section 13(a) or Section 15(d) of the Exchange Act;
(2) the issuer has filed at least one annual report pursuant to Regulation Crowdfunding and has fewer than 300 holders of record and has total assets that do not exceed $10,000,000;
(3) the issuer has filed at least three annual reports pursuant to Regulation Crowdfunding;
(4) the issuer or another party repurchases all of the securities issued in reliance on Section 4(a)(6) of the Securities Act, including any payment in full of debt securities or any complete redemption of redeemable securities; or
(5) the issuer liquidates or dissolves its business in accordance with state law.

BILLING CODE 8011–01–C

* * * * *

PART 240—GENERAL RULES AND REGULATIONS, SECURITIES EXCHANGE ACT OF 1934

■ 9. The authority citation for part 240 continues to read, in part, as follows:

Authority: 15 U.S.C. 77c, 77d, 77g, 77j, 77s, 77z–2, 77z–3, 77eee, 77ggg, 77nnn, 77sss, 77ttt, 78c, 78c–3, 78c–5, 78d, 78e, 78f, 78g, 78i, 78j, 78j–1, 78k, 78k–1, 78l, 78m, 78n, 78n–1,78o, 78o–4, 78o–10, 78p, 78q, 78q–1, 78s, 78u–5, 78w, 78x, 78ll, 78mm, 80a–20, 80a–23, 80a–29, 80a–37, 80b–3, 80b–4, 80b–11, 7201 et. seq., and 8302; 7 U.S.C. 2(c)(2)(E); 12 U.S.C. 5221(e)(3); 18 U.S.C. 1350; and Public Law 111–203, 939A, 124 Stat. 1376, (2010), unless otherwise noted.

■ 10. Add § 240.12g–6 to read as follows:

§ 240.12g–6 Exemption for securities issued pursuant to section 4(a)(6) of the Securities Act of 1933.

(a) For purposes of determining whether an issuer is required to register a security with the Commission pursuant to Section 12(g)(1) of the Act (15 U.S.C. 78l(g)(1)), the definition of held of record shall not include securities issued pursuant to the offering exemption under section 4(a)(6) of the Securities Act (15 U.S.C. 77d(a)(6)) by an issuer that:

(1) Is current in filing its ongoing annual reports required pursuant to § 227.202 of this chapter;

(2) Has total assets not in excess of $25 million as of the end of its most recently completed fiscal year; and

(3) Has engaged a transfer agent registered pursuant to Section 17A(c) of the Act to perform the function of a transfer agent with respect to such securities.

(b) An issuer that would be required to register a class of securities under Section 12(g) of the Act as a result of exceeding the asset threshold in paragraph (a)(2) of this section may continue to exclude the relevant securities from the definition of ''held of record'' for a transition period ending on the penultimate day of the fiscal year two years after the date it became ineligible. The transition period terminates immediately upon the failure of an issuer to timely file any periodic report due pursuant to § 227.202 at which time the issuer must file a registration statement that registers that class of securities under the Act within 120 days.

PART 249—FORMS, SECURITIES EXCHANGE ACT OF 1934

■ 11. The authority citation for part 249 continues to read, in part, as follows:

Authority: 15 U.S.C. 78a *et seq.* and 7201 *et seq.;* 12 U.S.C. 5461 *et seq.;* and 18 U.S.C. 1350, unless otherwise noted.

* * * * *

■ 12. Add subpart U, consisting of § 249.2000 to read as follows:

Subpart U—Forms for Registration of Funding Portals

§ 249.2000 Form Funding Portal.

This form shall be used for filings by funding portals under Regulation Crowdfunding (part 227 of this chapter).

Note: The text of Form Funding Portal will not appear in the Code of Federal Regulations.

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM FUNDING PORTAL

APPLICATION OR AMENDMENT TO APPLICATION FOR REGISTRATION OR WITHDRAWAL FROM REGISTRATION AS FUNDING PORTAL UNDER THE SECURITIES EXCHANGE ACT OF 1934

WARNING: Failure to complete this form truthfully, to keep this form current and to file accurate supplementary information on a timely basis, or the failure to keep accurate books and records or otherwise to comply with the provisions of law applying to the conduct of business as a *funding portal*, would violate the Federal securities laws and may result in disciplinary, administrative, injunctive or criminal action.

Check the appropriate box:
This is:

- ☐ an initial application to register as a *funding portal* with the *SEC*.
- ☐ an amendment to any part of the *funding portal*'s most recent Form Funding Portal, including a *successor* registration.
- ☐ a withdrawal of the *funding portal*'s registration with the *SEC*.

Schedule A must be completed as part of all initial applications. Amendments to Schedule A must be provided on Schedule B. Schedule C must be completed by *nonresident funding portals.* If this is a withdrawal of a *funding portal*'s registration, complete Schedule D.

If this is an amendment to any part of the *funding portal's* most recent Form Funding Portal, provide an explanation describing the amendment: _____

_____

Item 1 – Identifying Information

Exact name, principal business address, mailing address, if different, and contact information of the *funding portal*:

A. Full name of the *funding portal*: _____

B. Name(s)/Website URL(s) under which business is conducted, if different from Item 1A:

_____

C. IRS Empl. Ident. No.: _____

D. If a name and/or website URL in (1A) or (1B) has changed since the *funding portal*'s most recent Form Funding Portal, enter the previous name and/or website URL and specify whether the name change is of the □ *funding portal* name (1A), or □ name/website URL (1B).

Previous name(s) or website URL(s): _____

E. *Funding portal*'s main street address (Do not use a P.O. Box):

_____

_____

F. Mailing address(es) (if different) and office locations (if more than one):

_____

_____

G. Contact Information:
Telephone Number: _____
Fax Number: _____
Email Address: _____

H. Contact Employee Information:
Name: _____
Title: _____
Direct Telephone Number: _____
Fax Number: _____
Direct Email Address: _____

I. Month *applicant*'s fiscal year ends: _____

J. Registrations

Was the *applicant* previously registered on Form Funding Portal as a *funding portal* or with the Commission in any other capacity?

□ Yes SEC File No.: _____
□ No

K. Foreign registrations

(1) Is the *applicant* registered with a *foreign financial regulatory authority*? Answer "no" even if affiliated with a business that is registered with a *foreign financial regulatory authority*.

□ Yes □ No

If "yes," complete Section K.2. below.

(2) List the name, in English, of each *foreign financial regulatory authority* and country with which the *applicant* is registered. A separate entry must be completed for each *foreign financial regulatory authority* with which the *applicant* is registered.

English Name of *Foreign Financial Regulatory Authority*:

_____

Registration Number (if any): _____

Name of Country: _____

Item 2 – Form of Organization

A. Indicate legal status of *applicant*.

☐ Corporation ☐ Limited Liability Company
☐ Sole Proprietorship ☐ Other (please specify) _____
☐ Partnership

B. If other than a sole proprietor, indicate date and place *applicant* obtained its legal status (*i.e.*, state or country where incorporated, where partnership agreement was filed, or where *applicant* entity was formed):

State/Country of formation: _____
Date of formation: _____

Item 3 – Successions

A. Is the *applicant* at the time of this filing succeeding to the business of a currently registered *funding portal*?

□ Yes □ No

Do not report previous successions already reported on Form Funding Portal. If "yes," complete Section 3.B. below.

B. Complete the following information if succeeding to the business of a currently-registered *funding portal*. If the *applicant* acquired more than one *funding portal* in the succession being reported on this Form Funding Portal, a separate entry must be completed for each acquired firm.

Name of Acquired *Funding Portal*:

_____

Acquired *Funding Portal*'s *SEC* File No.: _____

C. Briefly describe details of the succession including any assets or liabilities not assumed by the *successor*.

Item 4 – Control Relationships

In this Item, identify every *person* that, directly or indirectly, *controls* the *applicant*, *controls* management or policies of the *applicant*, or that the *applicant* directly or indirectly *controls*.

_____

_____

If this is an initial application, the *applicant* also must complete Schedule A. Schedule A asks for information about direct owners and executive officers. If this is an amendment updating information reported on the Schedule A filed with the *applicant*'s initial application, the *applicant* must complete Schedule B.

Item 5 – Disclosure Information

In this Item, provide information about the *applicant*'s disciplinary history and the disciplinary history of all *associated persons* or *control affiliates* of the *applicant* (as applicable). This information is used to decide whether to revoke registration, to place limitations on the *applicant*'s activities as a *funding portal*, and to identify potential problem areas on which to focus during examinations. One event may result in the requirement to answer "yes" to more than one of the questions below. Check all answers that apply. Refer to the Explanation of Terms section of Form Funding Portal Instructions for explanation of italicized terms.

If the answer is "yes" to any question in this Item, the *applicant* must complete the appropriate Disclosure Reporting Page ("DRP") (FP) – Criminal, Regulatory Action, Civil Judicial Action, Bankruptcy/SIPC, Bond, or Judgment/Lien, as applicable.

Criminal Disclosure

If the answer is "yes" to any question below, complete a Criminal DRP.

A. In the past ten years, has the *applicant* or any *associated person*:

(1) been convicted of any *felony*, or pled guilty or nolo contendere ("no contest") to any charge of a *felony*, in a domestic, foreign, or military court?

□ Yes □ No

The response to the following question may be limited to charges that are currently pending:

(2) been *charged* with any *felony*?

□ Yes □ No

B. In the past ten years, has the *applicant* or any *associated person*:

(1) been convicted of any *misdemeanor*, or pled guilty or nolo contendere ("no contest"), in a domestic, foreign, or military court to any charge of a *misdemeanor* in a case involving: *investment-related* business, or any fraud, false statements, or omissions, wrongful taking of property, bribery, perjury, forgery, counterfeiting, extortion, or a conspiracy to commit any of these offenses?

□ Yes □ No

The response to the following question may be limited to charges that are currently pending:

(2) been *charged* with a *misdemeanor* listed in Item 5-B(1)?

□ Yes □ No

Regulatory Action Disclosure

If the answer is "yes" to any question below, complete a Regulatory Action DRP.

C. Has the *SEC* or the Commodities Futures Trading Commission ("CFTC") ever:

(1) *found* the *applicant* or any *associated person* to have made a false statement or omission?

□ Yes □ No

(2) *found* the *applicant* or any *associated person* to have been *involved* in a violation of any *SEC* or CFTC regulations or statutes?

□ Yes □ No

(3) *found* the *applicant* or any *associated person* to have been a cause of the denial, suspension, revocation, or restriction of the authorization of an *investment-related* business to operate?

□ Yes □ No

(4) entered an *order* against the *applicant* or any *associated person* in connection with *investment-related* activity?

□ Yes □ No

(5) imposed a civil money penalty on the *applicant* or any *associated person*, or ordered the *applicant* or any *associated person* to cease and desist from any activity?

□ Yes □ No

D. Has any other federal regulatory agency, any state regulatory agency, or any *foreign financial regulatory authority*:

(1) ever *found* the *applicant* or any *associated person* to have made a false statement or omission, or been dishonest, unfair, or unethical?

□ Yes □ No

(2) ever *found* the *applicant* or any *associated person* to have been *involved* in a violation of *investment-related* regulations or statutes?

□ Yes □ No

(3) ever *found* the *applicant* or any *associated person* to have been the cause of a denial, suspension, revocation, or restriction of the authorization of an *investment-related* business to operate?

□ Yes □ No

(4) in the past ten years entered an *order* against the *applicant* or any *associated person* in connection with an *investment-related* activity?

□ Yes □ No

(5) ever denied, suspended, or revoked the registration or license of the *applicant* or that of any *associated person*, or otherwise prevented the *applicant* or any *associated person* of the *applicant*, by *order*, from associating with an *investment-related* business or restricted the activities of the *applicant* or any *associated person*?

□ Yes □ No

E. Has any *self-regulatory organization* or commodities exchange ever:

(1) *found* the *applicant* or any *associated person* to have made a false statement or omission?

□ Yes □ No

(2) *found* the *applicant* or any *associated person* to have been *involved* in a violation of its rules (other than a violation designated as a *minor rule violation* under a plan approved by the *SEC*)?

□ Yes □ No

(3) *found* the *applicant* or any *associated person* to have been the cause of a denial, suspension, revocation or restriction of the authorization of an *investment-related* business to operate?

□ Yes □ No

(4) disciplined the *applicant* or any *associated person* by expelling or suspending the *applicant* or the *associated person* from membership, barring or suspending the *applicant* or *the associated person* from association with other members, or by otherwise restricting the activities of the *applicant* or the *associated person*?

□ Yes □ No

F. Has the *applicant* or any *associated person* ever had an authorization to act as an attorney, accountant, or federal contractor revoked or suspended?

□ Yes □ No

G. Is the *applicant* or any *associated person* currently the subject of any regulatory *proceeding* that could result in a "yes" answer to any part of Item 5-C, 5-D, or 5-E?

□ Yes □ No

Civil Judicial Disclosure

If the answer is "yes" to a question below, complete a Civil Judicial Action DRP.

H. Has any domestic or foreign court:

(1) in the past ten years, *enjoined* the *applicant* or any *associated person* in connection with any *investment-related* activity?

□ Yes □ No

(2) ever *found* that the *applicant* or any *associated person* was *involved* in a violation of *investment-related* statutes or regulations?

□ Yes □ No

(3) ever dismissed, pursuant to a settlement agreement, an *investment- related* civil action brought against the *applicant* or any *associated person* by a state or *foreign financial regulatory authority*?

□ Yes □ No

I. Is the *applicant* or any *associated person* now the subject of any civil *proceeding* that could result in a "yes" answer to any part of Item 5-H(1)-(3)?

□ Yes □ No

Financial Disclosure

If the answer is "yes" to a question below, complete a Bankruptcy/Disclosure, Bond Disclosure or Judgment/Lien DRP, as applicable.

J. In the past ten years, has the *applicant* or a *control affiliate* of the *applicant* ever been a securities firm or a *control affiliate* of a securities firm that:

(1) has been the subject of a bankruptcy petition?

□ Yes □ No

(2) has had a trustee appointed or a direct payment procedure initiated under the Securities Investor Protection Act?

□ Yes □ No

K. Has a bonding company ever denied, paid out on, or revoked a bond for the *applicant*?

□ Yes □ No

L. Does the *applicant* have any unsatisfied judgments or liens against it?

□ Yes □ No

Item 6 – Non-Securities Related Business

Does *applicant* engage in any non-securities related business?

□ Yes □ No

If "yes," briefly describe the non-securities business.

_____

_____

Item 7 – Qualified Third Party Arrangements; Compensation Arrangements

A. Qualified Third Party Arrangements. Complete the following information for each *person* that will hold investor funds in escrow or otherwise pursuant to the requirements of Rule 303(e) of Regulation Crowdfunding (17 CFR 227.303(e)).

Name of *person*: _____

Address: _____

Phone Number: _____

B. Compensation. Please describe any compensation arrangements *funding portal* has with issuers.

_____

EXECUTION

The *funding portal* consents that service of any civil action brought by or notice of any proceeding before the Securities and Exchange Commission or any *self-regulatory organization* in connection with the *funding portal*'s investment-related business may be given by registered or certified mail to the *funding portal*'s contact *person* at the main address, or mailing address, if different, given in Items 1.E., 1.F., and 1.H. If the applicant is a *nonresident funding portal*, it must complete Schedule C to designate a U.S. agent for service of process.

The undersigned represents and warrants that he/she has executed this form on behalf of, and is duly authorized to bind, the *funding portal*. The undersigned and the *funding portal* represent that the information and statements contained herein and other information filed herewith, all of which are made a part hereof, are current, true and complete. The undersigned and the *funding portal* further represent that, if this is an amendment, to the extent that any information previously submitted is not amended, such information is currently accurate and complete.

Date: _____

Full Legal Name of *Funding Portal*: _____

By:_____
(signature)

Title: _____

FORM FUNDING PORTAL
SCHEDULE A

Direct Owners and Executive Officers

1. Complete Schedule A only if submitting an initial application. Schedule A asks for information about the *applicant*'s direct owners and executive officers. Use Schedule B to amend this information.

2. Direct Owners and Executive Officers. List below the names of:

   (a) each Chief Executive Officer, Chief Financial Officer, Chief Operations Officer, Chief Legal Officer, Chief Compliance Officer, director and any other individuals with similar status or functions;

   (b) if *applicant* is organized as a corporation, each shareholder that is a direct owner of 5% or more of a class of the *applicant*'s voting securities, unless *applicant* is a public reporting company (a company subject to Section 13 or 15(d) of the Exchange Act);

   Direct owners include any *person* that owns, beneficially owns, has the right to vote, or has the power to sell or direct the sale of 5% or more of a class of the *applicant*'s voting securities. For purposes of this Schedule, a *person* beneficially owns any securities: (i) owned by his/her child, stepchild, grandchild, parent, stepparent, grandparent, spouse, sibling, mother-in-law, father-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law, sharing the same residence; or (ii) that he/she has the right to acquire, within 60 days, through the exercise of any option, warrant, or right to purchase the security.

   (c) if the *applicant* is organized as a partnership, <u>all</u> general partners and those limited and special partners that have the right to receive upon dissolution, or have contributed, 5% or more of the *applicant*'s capital;

   (d) in the case of a trust, (i) a *person* that directly owns 5% or more of a class of the *applicant*'s voting securities, or that has the right to receive upon dissolution, or has contributed, 5% or more of the *applicant*'s capital, (ii) the trust and (iii) each trustee; and

   (e) if the *applicant* is organized as a limited liability company ("LLC"), (i) those members that have the right to receive upon dissolution, or have contributed, 5% or more of the *applicant*'s capital, and (ii) if managed by elected managers, all elected managers.

3. In the DE/FE/NP column below, enter "DE" if the owner is a domestic entity, "FE" if the owner is an entity incorporated or domiciled in a foreign country, or "NP" if the owner or executive officer is a natural person.

4. Complete the Title or Status column by entering board/management titles; status as partner, trustee, sole proprietor, elected manager, shareholder, or member; and for shareholders or members, the class of securities owned (if more than one is issued).

5. Ownership codes are:

NA - less than 5%
A - 5% but less than 10%
B - 10% but less than 25%
C - 25% but less than 50%
D - 50% but less than 75%
E - 75% or more
G - Other (general partner, trustee, or elected member)

6. Control Person:
(a) In the Control Person column, enter "Yes" if the *person* has *control* as defined in the Glossary of Terms to Form Funding Portal, and enter "No" if the *person* does not have *control*. Note that under this definition, most executive officers and all 25% owners, general partners, elected managers, and trustees are "control persons".

(b) In the PR column, enter "PR" if the owner is a public reporting company under Section 13 or 15(d) of the Exchange Act.

7. Complete each column.

FULL LEGAL NAME (**Natural Persons: Last Name, First Name, Middle Name**)	**DE/FE/NP**	**Title or Status**	**Date Title or Status Acquired**		**Ownership Code**	**Control Person**		***CRD* No.** (**If None: S.S. No. and Date of Birth, IRS Tax No., or IRS Employer ID No.**)
			MM	YYYY		Yes/No	PR	

FORM FUNDING PORTAL
SCHEDULE B

Amendments to Schedule A

1. Use Schedule B only to amend information requested on Schedule A. Refer to Schedule A for specific instructions for completing this Schedule B. Complete each column. File with a completed Execution Page.

2. In the Type of Amendment column, indicate "A" (addition), "D" (deletion), or "C" (change in information about the same *person*).

3. Ownership codes are:

NA - less than 5%	B - 10% but less than 25%	D - 50% but less than 75%
A - 5% but less than 10%	C - 25% but less than 50%	E - 75% or more
	G - Other (general partner, trustee, or elected member)	

4. List below all changes to Schedule A (Direct Owners and Executive Officers):

FULL LEGAL NAME (Natural Persons: Last Name, First Name, Middle	**DE/FE/NP**	**Type of Amendment**	**Title or Status**	**Date Title or Status Acquired**		**Ownership Code**	**Control Person**		***CRD* No. (If None: S.S. No. and Date of Birth, IRS Tax No., or IRS Employer ID No.)**
				MM	YYYY		Yes/No	PR	

FORM FUNDING PORTAL
SCHEDULE C

Nonresident Funding Portals

Service of Process and Certification Regarding Prompt Access to Books and Records and Ability to Submit to Inspections and Examinations

Each *nonresident funding portal applicant* shall use Schedule C of Form Funding Portal to: identify its United States agent for service of process, and certify that it can, as a matter of law and will: (1) provide the Commission and any registered national securities association of which it becomes a member with prompt access to its books and records, and (2) submit to onsite inspection and examination by the Commission and any registered national securities association of which it becomes a member.

A. Agent for Service of Process:

1. Name of United States *person applicant* designates and appoints as agent for service of process:

   _____

2. Address of United States *person applicant* designates and appoints as agent for service of process

   _____

The above identified agent for service of process may be served any process, pleadings, subpoenas, or other papers in:

(a) any investigation or administrative proceeding conducted by the Commission that relates to the *applicant* or about which the *applicant* may have information; and

(b) any civil or criminal suit or action or proceeding under the federal securities laws brought against the *applicant* or to which the *applicant* has been joined as defendant or respondent, in any appropriate court in any place subject to the jurisdiction of any state or of the United States or of any of its territories or possessions or of the District of Columbia. The *applicant* has stipulated and agreed that any such suit, action or administrative proceeding may be commenced by the service of process upon, and that service of an administrative subpoena shall be effected by service upon, the above-named agent for service of process, and that service as aforesaid shall be taken and held in all courts and administrative tribunals to be valid and binding as if personal service thereof had been made.

B. Certification regarding access to records and ability to submit to inspections and examinations:

Applicant can, as a matter of law, and will:

1. provide the Commission and any registered national securities association of which it becomes a member with prompt access to its books and records, and

2. submit to onsite inspection and examination by the Commission and any registered national securities association of which it becomes a member.

Applicant must attach as an exhibit to this Form Funding Portal, Exhibit C, a copy of the opinion of counsel it is required to obtain in accordance with Rule 400(f) of Regulation Crowdfunding, i.e., the opinion of counsel that the nonresident funding portal can, as a matter of law, provide the Commission and any registered national securities association of which the nonresident funding portal becomes a member with prompt access to the books and records of such nonresident funding portal, and that the nonresident funding portal can, as a matter of law, submit to onsite inspection and examination by the Commission and any registered national securities association of which the nonresident funding portal becomes a member.

EXECUTION FOR NON-RESIDENT FUNDING PORTALS

The undersigned represents and warrants that he/she has executed this form on behalf of, and is duly authorized to bind, the *nonresident funding portal*. The undersigned and the *nonresident funding portal* represent that the information and statements contained herein and other information filed herewith, all of which are made a part hereof, are current, true and complete. The undersigned and the *nonresident funding portal* further represent that, if this is an amendment, to the extent that any information previously submitted is not amended, such information is currently accurate and complete.

The undersigned certifies that the *nonresident funding portal* can, as a matter of law, and will provide the Commission and any registered national securities association of which it becomes a member with prompt access to the books and records of such *nonresident funding portal* and can, as a matter of law, and will submit to onsite inspection and examination by the Commission and any registered national securities association of which it becomes a member. Finally, the undersigned authorizes any person having custody or possession of these books and records to make them available to federal regulatory representatives.

Signature: _____

Name and Title: _____

Date: _____

FORM FUNDING PORTAL
SCHEDULE D

If this is a withdrawal of registration:

A. The date the *funding portal* ceased business or withdrew its registration request:
Date (MM/DD/YYYY): _____

B. Location of Books and Records after Registration Withdrawal

Complete the following information for each location at which the *applicant* will keeps books and records after withdrawing its registration.

Name and address of entity where books and records are kept:

_____

_____

_____

(area code)(telephone number) (area code) (fax number)

This is (check one): ☐ one of *applicant*'s branch offices or affiliates.
☐ a third party unaffiliated recordkeeper.
☐ other.

If this address is a private residence, check this box: ☐

Briefly describe the books and records kept at this location.

_____
_____
_____
_____

C. Is the *funding portal* now the subject of or named in any *investment-related*

1. Investigation

□ Yes □ No

2. Investor initiated complaint

□ Yes □ No

3. Private civil litigation

□ Yes □ No

CRIMINAL ACTION DISCLOSURE REPORTING PAGE (FP)

General Instructions

This Disclosure Reporting Page (DRP FP) is an ☐ INITIAL ***OR*** ☐ AMENDED response used to report details for affirmative responses to Items 5-A or 5-B of Form Funding Portal.

Check item(s) being responded to: ☐ 5-A(1) ☐ 5-A(2) ☐ 5-B(1) ☐ 5-B(2)

Use a separate DRP for each event or *proceeding*. The same event or *proceeding* may be reported for more than one *person* or entity using one DRP. File with a completed Execution Page.

Multiple counts of the same charge arising out of the same event(s) should be reported on the same DRP. Unrelated criminal actions, including separate cases arising out of the same event, must be reported on separate DRPs. Use this DRP to report all charges arising out of the same event. One event may result in more than one affirmative answer to the items listed above.

Part 1

Check all that apply:

1. The *person*(s) or entity(ies) for whom this DRP is being filed is (are) the:

   Select only one.

   ☐ *Applicant*
   ☐ *Applicant* and one or more *associated persons*
   ☐ One or more of *applicant*'s *associated persons*

If this DRP is being filed for the *applicant*, and it is an amendment that seeks to remove a DRP concerning the *applicant* from the record, the reason the DRP should be removed is:

☐ The *applicant* is registered or applying for registration, and the event or *proceeding* was resolved in the *applicant*'s favor.
☐ The DRP was filed in error.

If this DRP is being filed for an *associated person*:

This *associated person* is: ☐ a firm ☐ a natural person
The *associated person* is: ☐ registered with the *SEC* ☐ not registered with the *SEC*

Full name of the *associated person* (including, for natural persons, last, first and middle names):

_____

If the *associated person* has a *CRD* number, provide that number. _____

If this is an amendment that seeks to remove a DRP concerning the *associated person*, the reason the DRP should be removed is:

☐ The *associated person* (s) is (are) no longer associated with the *applicant*.
☐ The event or *proceeding* was resolved in the *associated person*'s favor.
☐ The event or *proceeding* occurred more than ten years ago.
☐ The DRP was filed in error. Explain the circumstances:

_____
_____

Part 2

1. If charge(s) were brought against a firm or organization over which the *applicant* or a *associated person* exercise(s)(d) *control*:

   A. Enter the firm or organization's name _____

   B. Was the firm or organization engaged in an *investment-related* business?

   ☐ Yes ☐ No

   C. What was the relationship of the *applicant* with the firm or organization? (In the case of a *associated person*, include any position or title with the firm or organization.)

   _____

2. Court where formal charge(s) were brought in: (include the name of Federal, Military, State or Foreign Court, Location of Court - City or County and State or Country, and Docket/Case number).

   A. Name of Court: _____

   B. Location of Court:

   Street Address: _____
   City or County: _____ State/Country: _____
   Postal Code: _____

   C. Docket/Case Number: _____

3. Event Disclosure Detail (Use this for both organizational and individual charges.)

   A. Date First *Charged* (MM/DD/YYYY): _____ ☐ Exact

   ☐ Explanation

If not exact, provide explanation:

_____

B. Event Disclosure Detail (include charge(s)/charge Description(s), and for each charge provide: (1) number of counts, (2) *felony* or *misdemeanor*, (3) plea for each charge, and (4) product type if charge is *investment-related*).

_____

C. Did any of the charge(s) within the event *involve* a *felony*? ☐ Yes ☐ No

D. Current status of the event? ☐ Pending ☐ On Appeal ☐ Final

E. Event status date (Complete unless status is pending)

(MM/DD/YYYY): _____ ☐ Exact
☐ Explanation

If not exact, provide explanation:

_____

4. Disposition Disclosure Detail: Include for each charge (a) Disposition Type (e.g., convicted, acquitted, dismissed, pretrial, etc.), (b) Date, (c) Sentence/Penalty, (d) Duration (if sentence-suspension, probation, etc.), (e) Start Date of Penalty, (f) Penalty/Fine Amount, and (g) Date Paid.

_____

5. Provide a brief summary of circumstances leading to the charge(s) as well as the disposition. Include the relevant dates when the conduct that was the subject of the charge(s) occurred. (The response must fit within the space provided.)

_____

_____

REGULATORY ACTION DISCLOSURE REPORTING PAGE (FP)

GENERAL INSTRUCTIONS

This Disclosure Reporting Page (DRP FP) is an ☐ INITIAL ***OR*** ☐ AMENDED response used to report details for affirmative responses to Item 5-C, 5-D, 5-E-5-F or 5-G of Form Funding Portal.

Check item(s) being responded to: ☐ 5-C(1) ☐ 5-C(2) ☐ 5-C(3) ☐ 5-C(4)
☐ 5-C(5) ☐ 5-D(1) ☐ 5-D(2) ☐ 5-D(3) ☐ 5-D(4) ☐ 5-D(5)
☐ 5-E(1) ☐ 5-E(2) ☐ 5-E(3) ☐ 5-E(4) ☐ 5-F ☐ 5-G

Use a separate DRP for each event or *proceeding*. An event or *proceeding* may be reported for more than one *person* or entity using one DRP. File with a completed Execution Page.

One event may result in more than one affirmative answer to Items 5-C, 5-D, 5-E, 5- F or 5-G. Use only one DRP to report details related to the same event. If an event gives rise to actions by more than one regulator, provide details for each action on a separate DRP.

Part 1

The *person*(s) or entity(ies) for whom this DRP is being filed is (are) the:

Select only one.

☐ *Applicant* (the *funding portal*)
☐ *Applicant* and one or more of the *applicant*'s *associated person* (s)
☐ One or more of *applicant*'s *associated person* (s)

If this DRP is being filed for the *applicant* and it is an amendment that seeks to remove a DRP concerning the *applicant* from the record, the reason the DRP should be removed is:

☐ The *applicant* is registered or applying for registration, and the event or *proceeding* was resolved in the *applicant*'s favor.
☐ The DRP was filed in error.

If this DRP is being filed for an *associated person*:

This *associated person* is: ☐ a firm
☐ a natural person

The *associated person is*: ☐ registered with the *SEC*
☐ not registered with the *SEC*

Full name of the *associated person* (including, for natural persons, last, first and middle names):

_____

If the *associated person* has a *CRD* number, provide that number. _____

If this is an amendment that seeks to remove a DRP concerning the *associated person*, the reason the DRP should be removed is:

☐ The *associated person* (s) is (are) no longer associated with the *applicant*.
☐ The event or *proceeding* was resolved in the *associated person*'s favor.
☐ The DRP was filed in error. Explain the circumstances:

_____
_____

Part 2

1. Regulatory Action was initiated by:

☐ *SEC* ☐ Other Federal Authority ☐ *SRO*
☐ Foreign Authority ☐ State

(Full name of regulator, *foreign financial regulatory authority*, federal authority, state or *SRO*)

_____
_____
_____

2. Principal Sanction (check appropriate item):

☐ Civil and Administrative Penalty(ies)/Fine(s)

☐ Restitution	☐ Expulsion	☐ Disgorgement
☐ Bar	☐ Revocation	☐ Suspension
☐ Cease and Desist	☐ Injunction	☐ Undertaking
☐ Censure	☐ Prohibition	☐ Other
☐ Denial	☐ Reprimand	

Other Sanctions:

_____
_____
_____

3. Date Initiated (MM/DD/YYYY): _____ ☐ Exact ☐ Explanation

If not exact, provide explanation:

_____
_____
_____
_____

4. Docket/Case Number: _____

5. *Associated person*'s Employing Firm when activity occurred that led to the regulatory action (if applicable):

_____
_____
_____

6. Principal Product Type (check appropriate item):

☐ Annuity(ies) - Fixed	☐ Derivative(s)	☐ Mutual Fund(s)
☐ Annuity(ies) - Variable	☐ Direct Investment(s) - DPP & LP Interest(s)	
☐ Money Market Fund(s)	☐ Equity - OTC	☐ Options
☐ CD(s)	☐ Equity Listed (Common & Preferred Stock)	
☐ Commodity Option(s)	☐ Futures - Commodity	☐ Penny Stock(s)
☐ Debt - Asset Backed	☐ Futures - Financial	☐ Unit Investment Trust(s)
☐ Debt - Corporate	☐ Index Option(s)	☐ Other
☐ Debt - Government	☐ Insurance	☐ No Product
☐ Debt - Municipal	☐ Investment Contract(s)	

Other Product Types:

_____
_____
_____

7. Describe the allegations related to this regulatory action. (The response must fit within the space provided.)

_____
_____
_____

8. Current status? ☐ Pending ☐ On Appeal ☐ Final

9. If on appeal, to whom the regulatory action was appealed (*SEC*, *SRO*, Federal or State Court) and date appeal filed:

_____

_____

If Final or On Appeal, complete all items below. For Pending Actions, complete Item 13 only.

10. How was matter resolved (check appropriate item):

☐ Acceptance, Waiver & Consent (AWC)
☐ Consent
☐ Decision
☐ Decision & *Order* of Offer of Settlement
☐ Dismissed
☐ Withdrawn
☐ Settled
☐ Stipulation and Consent
☐ Vacated
☐ *Order*
☐ Other

11. Resolution Date (MM/DD/YYYY): _____ ☐ Exact ☐ Explanation

If not exact, provide explanation:

_____

_____

12. Resolution Detail:

A. Were any of the following Sanctions Ordered (check all appropriate items)?

☐ Monetary/Fine Amount: $_____
☐ Bar
☐ Revocation/Expulsion/Denial
☐ Disgorgement
☐ Cease & Desist/Injunction
☐ Censure
☐ Suspension

B. Other Sanctions Ordered:

_____

_____

C. Sanction detail: If suspended, *enjoined* or barred, provide duration including start date and capacities affected (General Securities Principal, Financial Operations Principal, etc.). If requalification by exam/retraining was a condition of the sanction, provide length of time given to requalify/retrain, type of exam required and whether condition has been satisfied. If disposition resulted in a fine, penalty, restitution, disgorgement or monetary compensation, provide total amount, portion levied against the *applicant* or an *associated person*, date paid and if any portion of penalty was waived:

_____

_____

13. Provide a brief summary of details related to the action status and (or) disposition, and include relevant terms, conditions and dates.

_____

CIVIL JUDICIAL ACTION DISCLOSURE REPORTING PAGE (FP)

GENERAL INSTRUCTIONS

This Disclosure Reporting Page (DRP FP) is an ☐ INITIAL ***OR*** ☐ AMENDED response used to report details for affirmative responses to Item 5-H or 5-I of Form Funding Portal.

Check item(s) being responded to: ☐ 5-H(1) ☐ 5-H(2) ☐ 5-H(3) ☐ 5-I

Use a separate DRP for each event or *proceeding*. An event or *proceeding* may be reported for more than one *person* or entity using one DRP. File with a completed Execution Page.

One event may result in more than one affirmative answer to Item 5-H or 5-I. Use only one DRP to report details related to the same event. Unrelated civil judicial actions must be reported on separate DRPs.

Part 1

The *person*(s) or entity(ies) for whom this DRP is being filed is (are) the:

Select only one.

☐ *Applicant* (the *funding portal*)
☐ *Applicant* and one or more of the applicant's *associated person* (s)
☐ One or more of the *applicant*'s associated *person* (s)

If this DRP is being filed for the *applicant* and it is an amendment that seeks to remove a DRP concerning the *applicant* from the record, the reason the DRP should be removed is:

☐ The *applicant* is registered or applying for registration, and the event or *proceeding* was resolved in the *applicant*'s favor.
☐ The DRP was filed in error.

If this DRP is being filed for an *associated person*:

This *associated person* is: ☐ a firm ☐ a natural person
The *associated person*: ☐ registered with the *SEC* ☐ not registered with the *SEC*

Full name of the *associated person* (including, for natural persons, last, first and middle names):

_____

If the *associated person* has a *CRD* number, provide that number. _____

If this is an amendment that seeks to remove a DRP concerning the *associated person*, the reason the DRP should be removed is:

☐ The *associated person* (s) is (are) no longer associated with the *applicant*.
☐ The event or *proceeding* was resolved in the *associated person*'s favor.
☐ The DRP was filed in error. Explain the circumstances:

_____

_____

Part 2

1. Court Action initiated by: (Name of regulator, *foreign financial regulatory authority*, *SRO*, commodities exchange, agency, firm, private plaintiff, etc.)

2. Principal Relief Sought (check appropriate item):

☐ Cease and Desist (Private/Civil Complaint)	☐ Disgorgement	☐ Money Damages
☐ Restraining Order	☐ Civil Penalty(ies)/Fine(s)	
☐ Injunction	☐ Restitution	
☐ Other _____		

Other Relief Sought: _____

3. Filing Date of Court Action (MM/DD/YYYY): _____ ☐ Exact ☐ Explanation

If not exact, provide explanation:

_____

4. Principal Product Type (check appropriate item):

☐ Annuity(ies) - Fixed	☐ Derivative(s)	☐ Investment Contract(s)
☐ Annuity(ies) - Variable	☐ Direct Investment(s) – DPP & LP Interest(s)	
☐ Money Market Fund(s)	☐ CD(s)	☐ Equity - OTC
☐ Mutual Fund(s)	☐ Commodity Option(s)	☐ No Product
☐ Equity Listed (Common & Preferred Stock)		☐ Options
☐ Debt - Asset Backed	☐ Futures - Commodity	☐ Penny Stock(s)
☐ Debt - Corporate	☐ Futures - Financial	☐ Unit Investment Trust(s)
☐ Debt - Government	☐ Index Option(s)	☐ Other
☐ Debt - Municipal	☐ Insurance	

Other Product Types:

_____

5. Formal Action was brought in (include the name of the Federal, State, or Foreign Court; Location of Court – City or County and State or Country; and Docket/Case Number

_____

6. *Associated person*'s Employing Firm when activity occurred that led to the civil judicial action (if applicable):

_____

7. Describe the allegations related to this civil action (the response must fit within the space provided):

_____

_____

8. Current status? ☐ Pending ☐ On Appeal ☐ Final

9. If on appeal, court to which the action was appealed (provide name of the court) and Date Appeal Filed (MM/DD/YYYY):

_____

_____

10. If pending, date notice/process was served (MM/DD/YYYY): _____

☐ Exact ☐ Explanation

If not exact, provide explanation:

_____

If Final or On Appeal, complete all items below. For Pending Actions, complete Item 14 only.

11. How was matter resolved (check appropriate item):

☐ Consent ☐ Judgment Rendered ☐ Settled ☐ Dismissed ☐ Opinion
☐ Withdrawn ☐ Other _____

12. Resolution Date (MM/DD/YYYY): _____ ☐ Exact
☐ Explanation

If not exact, provide explanation:

_____

13. Resolution Detail:

A. Were any of the following Sanctions Ordered or Relief Granted (check appropriate items)?

☐ Monetary/Fine Amount: $ _____
☐ Bar
☐ Revocation/Expulsion/Denial
☐ Censure
☐ Suspension
☐ Disgorgement/Restitution
☐ Cease and Desist/Injunction

B. Other Sanctions Ordered:

C. Sanction detail: If suspended, *enjoined* or barred, provide duration including start date and capacities affected (General Securities Principal, Financial Operations Principal, etc.). If requalification by exam/retraining was a condition of the sanction, provide length of time given to requalify/retrain, type of exam required and whether condition has been satisfied. If disposition resulted in a fine, penalty, restitution, disgorgement or monetary compensation, provide total amount, portion levied against the *applicant* or an *associated person*, date paid and if any portion of penalty was waived:

14. Provide a brief summary of circumstances related to the action(s), allegation(s), disposition(s) and/or finding(s) disclosed above.

BANKRUPTCY/SIPC DISCLOSURE REPORTING PAGE (FP)

GENERAL INSTRUCTIONS

This Disclosure Reporting Page (DRP FP) is an ☐ INITIAL ***OR*** ☐ AMENDED response used to report details for affirmative responses to Item 5-J of Form Funding Portal.

Check item(s) being responded to: ☐ 5-J(1) ☐ 5-J(2)

Use a separate DRP for each event or *proceeding*. An event or *proceeding* may be reported for more than one *person* or entity using one DRP. File with a completed Execution Page.

One event may result in more than one affirmative answer to Item 5-J. Use only one DRP to report details related to the same event. Unrelated civil judicial actions must be reported on separate DRPs.

Part 1

1. The *person*(s) or entity(ies) for whom this DRP is being filed is (are) the:

Select only one.

☐ *Applicant*
☐ *Applicant* and one or more *control affiliate*(s)
☐ One or more of *control affiliate*(s)

If this DRP is being filed for a *control affiliate*, give the full name of the *control affiliate* below (for individuals, Last name, First name, Middle name).

If the *control affiliate* is registered with the CRD, provide the CRD number. If not, indicate "non-registered'' by checking the appropriate checkbox.

FP DRP - CONTROL AFFILIATE

_____
Control Affiliate CRD Number

This *control affiliate* is: ☐ a firm ☐ a natural person

Registered: ☐ Yes ☐ No

Full name of the *control affiliate* (including, for natural persons, last, first and middle names):

_____

☐ This is an amendment that seeks to remove a DRP record because the *control affiliate*(s) is (are) no longer associated with the *funding portal*.

2. If the *control affiliate* is registered through the CRD, has the *control affiliate* submitted a DRP (with Form U-4) or BD DRP to the CRD System for the event? If the answer is "Yes,'' no other information on this DRP must be provided.

Yes ☐ No ☐

NOTE: The completion of this Form does not relieve the *control affiliate* of its obligation to update its CRD records.

Part 2

1. Action Type: (check appropriate item)

☐ Bankruptcy ☐ Declaration ☐ Receivership

☐ Compromise ☐ Liquidated ☐ Other_____

2. Action Date (MM/DD/YYYY):_____ ☐ Exact

☐ Explanation

If not exact, provide explanation:_____

3. If the financial action relates to an organization over which the *applicant* or *control affiliate person* exercise(s)(d) *control*, enter organization name and the *applicant*'s or *control affiliate*'s position, title or relationship:

_____

Was the Organization *investment-related*? ☐ Yes ☐ No

4. Court action brought in (Name of Federal, State or Foreign Court), Location of Court (City or County and State or Country), Docket/Case Number and Bankruptcy Chapter Number (if Federal Bankruptcy Filing):

_____

5. Is action currently pending? ☐ Yes ☐ No

6. If not pending, provide Disposition Type: (check appropriate item)

☐ Direct Payment Procedure ☐ Dismissed ☐ Satisfied/Released
☐ Discharged ☐ Dissolved ☐ SIPA Trustee Appointed

☐ Other _____

7. Disposition Date (MM/DD/YYYY): ☐ Exact ☐ Explanation

If not exact, provide explanation: _____

8. Provide a brief summary of events leading to the action, and if not discharged, explain. (The information must fit within the space provided):

_____

9. If a SIPA trustee was appointed or a direct payment procedure was begun, enter the amount paid by you; or the name of trustee:

Currently Open? ☐ Yes ☐ No

Date Direct Payment Initiated/Filed or Trustee Appointed (MM/DD/YYYY):_____

☐ Exact ☐ Explanation

If not exact, provide explanation:_____

10. Provide details to any status disposition. Include details as to creditors, terms, conditions, amounts due and settlement schedule (if applicable):_____

BOND DISCLOSURE REPORTING PAGE (FP)

GENERAL INSTRUCTIONS

This Disclosure Reporting Page (DRP FP) is an ☐ INITIAL ***OR*** ☐ AMENDED response used to report details for affirmative responses to Item 5-K of Form Funding Portal.

Check item(s) being responded to: ☐ 5-K

Use a separate DRP for each event or *proceeding*. An event or *proceeding* may be reported for more than one *person* or entity using one DRP. File with a completed Execution Page.

One event may result in more than one affirmative answer to Item 5-K. Use only one DRP to report details related to the same event. If an event gives rise to actions by more than one regulator, provide details for each action on a separate DRP.

1. Firm Name: (Policy Holder)

_____

2. Bonding Company Name:

_____

3. Disposition Type: (check appropriate item)

☐ Denied ☐ Payout ☐ Revoked

4. Disposition Date (MM/DD/YYYY): ☐ Exact ☐ Explanation

If not exact, provide explanation:

_____

_____

_____

5. If disposition resulted in Payout, list Payout Amount and Date Paid:

_____

_____

_____

6. Summarize the details of circumstances leading to the necessity of the bonding company action:

_____

_____

_____

_____

_____

JUDGMENT / LIEN DISCLOSURE REPORTING PAGE (FP)

GENERAL INSTRUCTIONS

This Disclosure Reporting Page (DRP FP) is an ☐ INITIAL ***OR*** ☐ AMENDED response used to report details for affirmative responses to Item 5-L of Form Funding Portal.

Check item(s) being responded to: ☐ 5-L

Use a separate DRP for each event or *proceeding*. An event or *proceeding* may be reported for more than one *person* or entity using one DRP. File with a completed Execution Page. One event may result in more than one affirmative answer to Item 5-L. Use only one DRP to report details related to the same event. If an event gives rise to actions by more than one regulator, provide details for each action on a separate DRP.

1. Judgment/Lien Amount:_____
2. Judgment/Lien Holder:_____

3. Judgment/Lien Type: (check appropriate item)

☐ Civil ☐ Default ☐ Tax

4. Date Filed (MM/DD/YYYY):_____ ☐ Exact ☐ Explanation

If not exact, provide explanation: _____

5. Is Judgment/Lien outstanding? ☐ Yes ☐ No

If No, provide explanation:_____

If No, how was matter resolved? (check appropriate item)

☐ Discharged ☐ Released ☐ Removed ☐ Satisfied

6. Court where judgment was given:

A. Name of Court _____

B. Location of Court:

Street Address: _____
City or County: _____ State/Country: _____
Postal Code: _____

C. Docket/Case Number _____

7. Provide a brief summary of events leading to the action and any payment schedule details, including current status (if applicable):_____

FORM FUNDING PORTAL INSTRUCTIONS

A. GENERAL INSTRUCTIONS

1. EXPLANATION OF FORM

- This is the form that a *funding portal* must use to register with the Securities and Exchange Commission ("SEC" or "Commission"), to amend its registration and to withdraw from registration.
- The Commission may make publicly accessible all current Forms Funding Portal, including amendments and registration withdrawal requests, which may be searchable by the public, with the exception of certain personally identifiable information or other information with significant potential for misuse (including the contact employee's direct phone number, fax number and e-mail address and any IRS Tax Number, IRS Employer Identification Number, social security number, date of birth, or any other similar information). If the *applicant* submits any attachments to Form Funding Portal in PDF format it is the responsibility of the *applicant* to redact certain personally identifiable information or other information with significant potential for misuse (including the contact employee's direct phone number, fax number and e-mail address and any IRS Tax Number, IRS Employer Identification Number, social security number, date of birth, or any other similar information) from the PDF.

2. WHEN TO FILE FORM FUNDING PORTAL

- A *funding portal*'s registration must become effective before offering or selling any securities in reliance on Section 4(a)(6) through a platform. Under Rule 400, a *funding portal*'s registration will be effective the later of: (1) 30 calendar days after the date a complete Form Funding Portal is received by the Commission or (2) the date the *funding portal* is approved for membership by a national securities association registered under Section 15A of the Securities Exchange Act of 1934 ("Exchange Act").

- A registered *funding portal* must promptly file an amendment to Form Funding Portal when any information previously submitted on Form Funding Portal becomes inaccurate or incomplete for any reason.

- A *successor funding portal* may succeed to the registration of a registered *funding portal* by filing a registration on Form Funding Portal within 30 days after the succession.

- If a *funding portal* succeeds to and continues the business of a registered *funding portal* and the succession is based solely on a change of the predecessor's date or state of incorporation, form of organization, or composition of a partnership or similar reason, the *successor* may, within 30 days of the succession, amend the registration on Form Funding Portal to reflect these changes.

- A *funding portal* must also file a withdrawal on Form Funding Portal (and complete Schedule D) promptly upon ceasing to operate as a *funding portal*. Withdrawal will be effective on the later of 30 days after receipt by the Commission, after the *funding portal* is no longer operational, or within such longer period of time as to which the *funding portal* consents or which the Commission by order may determine as necessary or appropriate in the public interest or for the protection of investors.

- A Form Funding Portal filing will not be considered complete unless it complies with all applicable requirements.

3. ELECTRONIC FILING – The *applicant* must file Form Funding Portal electronically, and must utilize this system to file and amend Form Funding Portal electronically to assure the timely acceptance and processing of those filings.

4. CONTACT EMPLOYEE – The individual listed as the contact employee must be authorized to receive all compliance information, communications, and mailings, and be responsible for disseminating it within the *applicant*'s organization.

5. FEDERAL INFORMATION LAW AND REQUIREMENTS

- The principal purpose of this form is to provide a mechanism by which a *funding portal* can register with the Commission, amend its registration and withdraw from registration. The Commission maintains a file of the information on this form and will make certain information collected through the form publicly available. The SEC will not accept forms that do not include the required information.

- Section 4A(a) of the Securities Act of 1933 [15 U.S.C. §77d-1(a)] and Sections 3(h) and 23(a) the Exchange Act [15 U.S.C. §§78c(h) and 78w(a)] authorize the SEC to collect the information required by Form Funding Portal. The SEC collects the information for regulatory purposes. Filing Form Funding Portal is mandatory for *persons* that are registering as *funding portals* with the SEC.

- Any member of the public may direct to the Commission any comments concerning the accuracy of the burden estimate on this Form and any suggestions for reducing this burden. This collection of information has been reviewed by the Office of Management and Budget in accordance with the clearance requirements of 44 U.S.C. §3507. The information contained in this form is part of a system of records subject to the Privacy Act of 1974, as amended. The Securities and Exchange Commission has published in the Federal Register the Privacy Act Systems of Records Notice for these records.

B. FILING INSTRUCTIONS

1. FORMAT

- All fields requiring a response in Items 1-7 must be completed before the filing will be accepted.

- *Applicant* must complete the execution page certifying that Form Funding Portal and amendments thereto have been executed properly and that the information contained therein is accurate and complete.

- To amend information, the *applicant* must update the appropriate Form Funding Portal pages or Schedules.

- A paper copy, with original manual signatures, of the initial Form Funding Portal filing and amendments to Form Funding Portal and Disclosure Reporting Pages must be retained by the *applicant* and be made available for inspection upon a regulatory request.

2. DISCLOSURE REPORTING PAGES (DRP) – Information concerning the *applicant* or *associated person* that relates to the occurrence of an event reportable under Item 5 must be provided on the *applicant*'s appropriate DRP (FP). If an *associated person* is an individual or organization registered through the CRD, such *associated person* need only complete the *associated person* name and CRD number of the *applicant*'s appropriate DRP. Details for the event must be submitted on the *associated person*'s appropriate DRP or DRP (U-4). If an *associated person* is an individual or organization not registered through the CRD, provide complete answers to all of the questions and complete all fields requiring a response on the *associated person*'s appropriate DRP (FP).

3. DIRECT OWNERS - Amend the Direct Owners and Executive Officers page when changes in ownership occur.

4. NONRESIDENT APPLICANTS – Any *applicant* that is a *nonresident funding portal* must complete Schedule C and attach the opinion of counsel referred to therein.

C. EXPLANATION OF TERMS

1. GENERAL

APPLICANT - The *funding portal* applying on or amending this form.

ASSOCIATED PERSON - Any partner, officer, director or manager of the funding portal (or any person occupying a similar status or performing similar functions), any person directly or indirectly controlling or controlled by the funding portal, or any employee of the funding portal, except that any person associated with a funding portal whose functions are solely clerical or ministerial shall not be included in the meaning of such term for purposes of section 15(b) of the Exchange Act (other than paragraphs (4) and (6) thereof).

CONTROL - The power, directly or indirectly, to direct the management or policies of the *funding portal*, whether through contract, or otherwise. A *person* is presumed to *control* a *funding portal* if that *person*: (1) is a director, general partner or officer exercising executive responsibility (or has a similar status or functions); (2) directly or indirectly has the right to vote 25 percent or more of a class of a voting security or has the power to sell or direct the sale of 25 percent or more of a class of voting securities of the *funding portal*; or (3) in the case of a partnership, has contributed, or has a right to receive, 25 percent or more of the capital of the *funding portal*. (This definition is used solely for the purposes of Form Funding Portal).

CONTROL AFFILIATE – A *person* named in Item 4 or any other individual or organization that directly or indirectly controls, is under common control with, or is controlled by, the *applicant*, including any current employee of the *applicant* except one performing only clerical, administrative, support or similar functions, or who, regardless of title, performs no executive duties or has no senior policy making authority.

FOREIGN FINANCIAL REGULATORY AUTHORITY – Includes (1) a foreign securities authority; (2) other governmental body or foreign equivalent of a *self-regulatory organization* empowered by a foreign government to administer or enforce its laws relating to the regulation of *investment* or *investment-related* activities; and (3) a foreign membership organization, a function of which is to regulate the participation of its members in the activities listed above.

FUNDING PORTAL - A broker acting as an intermediary in a transaction involving the offer or sale of securities offered and sold in reliance on Section 4(a)(6), that does not, directly or indirectly: (1) offer *investment* advice or recommendations; (2) solicit purchases, sales or offers to buy the securities displayed on its platform; (3) compensate employees, agents, or other *persons* for such solicitation or based on the sale of securities displayed or referenced on its platform; or (4) hold, manage, possess, or otherwise handle investor funds or securities.

JURISDICTION – Any state of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, any other territory of the United States, or any subdivision or regulatory body thereof.

NONRESIDENT FUNDING PORTAL – A *funding portal* incorporated in or organized under the laws of a jurisdiction outside of the United States or its territories, or having its principal place of business in any place not in the United States or its territories.

PERSON - An individual, partnership, corporation, trust, or other organization.

SELF-REGULATORY ORGANIZATION ("SRO") – A national securities association registered under Section 15A of the Exchange Act or any national securities exchange or registered clearing agency.

SUCCESSOR –A *funding portal* that assumes or acquires substantially all of the assets and liabilities, and that continues the business of, a registered predecessor *funding portal* that ceases its *funding portal* activities. *See* Rule 400(c) of Regulation Crowdfunding (17 CFR 227.400(c)).

2. FOR THE PURPOSE OF ITEM 5 AND THE CORRESPONDING DISCLOSURE REPORTING PAGES (DRPs) (FP)

CHARGED - Being accused of a crime in a formal complaint, information, or indictment (or equivalent formal charge).

ENJOINED – Includes being subject to a mandatory injunction, prohibitory injunction, preliminary injunction, or temporary restraining order.

FELONY – For *jurisdictions* that do not differentiate between a *felony* and a *misdemeanor*, a *felony* is an offense punishable by a sentence of at least one year imprisonment and/or a fine of at least $1,000. The term also includes a general court martial.

FOUND – Includes adverse final actions, including consent decrees in which the respondent has neither admitted nor denied the findings, but does not include agreements, deficiency letters, examination reports, memoranda of understanding, letters of caution, admonishments, and similar informal resolutions of matters.

INVESTMENT OR INVESTMENT-RELATED – Pertaining to securities, commodities, banking, savings association activities, credit union activities, insurance, or real estate (including, but not limited to, acting as or being associated with a *funding portal* broker-dealer, municipal securities dealer, government securities broker or dealer, issuer, investment company, investment adviser, futures sponsor, bank, security-based swap dealer, major security-based swap participant, savings association, credit union, insurance company, or insurance agency).

INVOLVED – Doing an act or aiding, abetting, counseling, commanding, inducing, conspiring with or failing reasonably to supervise another in doing an act.

MINOR RULE VIOLATION – A violation of a *self-regulatory organization* rule that has been designated as "minor" pursuant to a plan approved by the SEC or Commodity Futures Trading Commission. A rule violation may be designated as "minor" under a plan if the sanction imposed consists of a fine of $2,500 or less and if the sanctioned *person* does not contest the fine. (Check with the appropriate *self-regulatory organization* to determine if a particular rule violation has been designated as "minor" for these purposes).

MISDEMEANOR – For *jurisdictions* that do not differentiate between a *felony* and a *misdemeanor*, a *misdemeanor* is an offense punishable by a sentence of less than one year

imprisonment and/or a fine of less than $1,000. The term also includes a special court martial.

ORDER – A written directive issued pursuant to statutory authority and procedures, including orders of denial, suspension, or revocation; does not include special stipulations, undertakings or agreements relating to payments, limitations on activity or other restrictions unless they are included in an *order*.

PROCEEDING – Includes a formal administrative or civil action initiated by a governmental agency, *self-regulatory organization* or a *foreign financial regulatory authority*; a *felony* criminal indictment or information (or equivalent formal charge); or a *misdemeanor* criminal information (or equivalent formal charge). Does not include other civil litigation, investigations, or arrests or similar charges effected in the absence of a formal criminal indictment or information (or equivalent formal charge).

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PART 269—FORMS PRESCRIBED UNDER THE TRUST INDENTURE ACT OF 1939

■ 13. The authority citation for part 269 continues to read as follows:

Authority: 15 U.S.C. 77ddd(c), 77eee, 77ggg, 77hhh, 77iii, 77jjj, 77sss, and 78*ll*(d), unless otherwise noted.

PART 274—FORMS PRESCRIBED UNDER THE INVESTMENT COMPANY ACT OF 1940

■ 14. The authority citation for part 274 continues to read, in part, as follows:

Authority: 15 U.S.C. 77f, 77g, 77h, 77j, 77s, 78c(b), 78*l,* 78m, 78n, 78*o*(d), 80a–8, 80a–24, 80a–26, and 80a–29, unless otherwise noted.

* * * * *

■ 15. Form ID (referenced in §§ 239.63, 249.446, 269.7 and 274.402) is amended by adding a check box that reads ''Funding Portal'' in alphabetical order in the list of applicants in Part I; and the Instructions to Form ID are amended to include the definition of ''Funding Portal'' in alphabetical order under Part I and reads ''Funding Portal: A broker acting as an intermediary in a transaction involving the offer or sale of securities offered and sold in reliance on Section 4(a)(6) of the Securities Act, that does not: (1) Offer investment advice or recommendations; (2) solicit purchases, sales or offers to buy the securities displayed on its platform; (3) compensate employees, agents, or other persons for such solicitation or based on the sale of securities displayed or referenced on its platform; or (4) hold, manage, possess, or otherwise handle investor funds or securities.''

Note: The amendments to Form ID will not appear in the Code of Federal Regulations.

Dated: October 30, 2015.
By the Commission.

Jill M. Peterson,

Assistant Secretary.

Note: The following Exhibit A will not appear in the Code of Federal Regulations.

Exhibit A

Comment Letters Received Regarding Proposing Release To Implement Regulation Crowdfunding (File No. S7–09–13)

AABOC: Letter from Doby Gavn, President and CEO, African American Business Opportunities Communities, Oct. 26, 2013
ABA: Letter from Catherine T. Dixon, Chair, Federal Regulation of Securities Committee, Business Law Section, American Bar Association
Accredify: Letter from Herwig G. Konings, CEO, Accredify LLC, Nov. 30, 2013
Active Agenda: Letter from Daniel F. Zahlis, Founder, Product Architect, Active Agenda LLC, Jan. 29, 2014
Advanced Hydro: Letter from Dileep Agnihotri, Ph.D., CEO, Advanced Hydro Inc., Oct. 23, 2013
AEO: Letter from Connie E. Evans, President & CEO, Association for Enterprise Opportunity, Feb. 3, 2014
AFL–CIO: Letter from Brandon J. Rees, Acting Director, Office of Investment, AFL–CIO, Feb. 3, 2014
AFR: Letter from Americans for Financial Reform, March 5, 2014
Ahmad: Letter from Mohamed Ahmad, Aug. 21, 2014
AICPA: Letter from The American Institute of Certified Public Accountants, Feb. 3, 2014
Amram 1: Letter from Elan Amram, Feb. 3, 2014
Amram 2: Letter from Elan Amram, Feb. 3, 2014
Angel 1: Letter from James J. Angel, Ph.D., CFA, Visiting Associate Professor, Georgetown University, Feb. 5, 2014
Angel 2: Letter from James J. Angel, Ph.D., CFA, Visiting Associate Professor, Georgetown University, Jul. 1, 2014
AngelList: Letter from Naval Ravikant, CEO, AngelList, Jan. 24, 3014
Anonymous 1: Letter from an anonymous person, Nov. 9, 2013
Anonymous 2: Letter from an anonymous person, Nov. 13, 2013
Anonymous 3: Letter from an anonymous person, Nov. 25, 2013
Anonymous 4: Letter from an anonymous person, Dec. 5, 2013
Anonymous 5: Letter from an anonymous person, Jan. 25, 2014
Anonymous 6: Letter from an anonymous person, Feb. 7, 2014
Arctic Island 1: Letter from Scott Purcell, Founder and CEO, Arctic Island LLC, Nov. 4, 2013
Arctic Island 2: Letter from Scott Purcell, Founder and CEO, Arctic Island LLC, Dec. 4, 2013
Arctic Island 3: Letter from Scott Purcell, Founder and CEO, Arctic Island LLC, Dec. 4, 2013
Arctic Island 4: Letter from Scott Purcell, Founder and CEO, Arctic Island LLC, Dec. 4, 2013
Arctic Island 5: Letter from Scott Purcell, Founder and CEO, Arctic Island LLC, Dec. 6, 2013
Arctic Island 6: Letter from Scott Purcell, Founder and CEO, Arctic Island LLC, Dec. 6, 2013
Arctic Island 7: Letter from Scott Purcell, Founder and CEO, Arctic Island LLC, Dec. 6, 2013
Arctic Island 8: Letter from Scott Purcell, Founder and CEO, Arctic Island LLC, Dec. 31, 2013
ASSOB: Letter from Paul M. Niederer, CEO, ASSOB Equity Funding Platform Australia, Oct. 25, 2013
ASTTC: Letter from Mark C. Healy, President and Chief Executive Officer, American Stock Transfer & Trust Company, Brooklyn, New York, Feb. 3, 2014
AWBC: Letter from Marsha Bailey, Chair, Association of Women's Business Centers, Feb. 3, 2014

BackTrack: Letter from Randy Shain, Founder and EVP, BackTrack Reports, Nov. 12, 2013
Ball: Letter from Robert Ball, Feb. 1, 2014
BCFCU: Letter from Margot Brandenburg, Chair, Brooklyn Cooperative Federal Credit Union, New York, New York, Feb. 3, 2014
Benavente: Letter from Javier E. Benavente, Jan. 16, 2014
Benjamin: Letter from Jordan Benjamin, Nov. 30, 2013
BetterInvesting: Letter from Kamie Zaracki, Chief Executive Officer, et. al., Jul. 29, 2014
Borrell: Letter from Monica L. Borell, Jan. 27, 2014
Brown D.: Letter from Douglas Brown, Start-up business owner, Jan. 29, 2014
Brown J.: Letter from J. Robert Brown, Jr., Professor of Law, University of Denver, Sturm College of Law, Jan. 27, 2014
Bullock: Letter from Leo M. Bullock, IV, Nov. 10, 2013
Bushroe: Letter from Fred Bushroe, Oct. 29, 2013
CalTech Entrepreneurs: Letter from Russell M. Frandsen, Esquire, The Business Legal Group Executive Committee of the Caltech Entrepreneurs Forum, Jan. 29, 2014
Campbell R.: Letter from Rutheford B. Campbell, Jr., Spears-Gilbert Professor of Law, University of Kentucky, Feb. 14, 2014
CAMEO: Letter from Claudia Viek, CEO, California Association for Micro Enterprise Opportunity, Feb. 3, 2014
CapSchedule: Letter from Scott Purcell, CapSchedule.com, LLC, Oct. 23, 2013
CarbonTech: Letter from Robert Shatz, CEO, CarbonTech Global LLC, Oct. 24, 2013
CCI: Letter from Carrie Devorah, The Center For Copyright Integrity, Feb. 3, 2014
CEI: Letter from John Berlau, Senior Fellow, Finance and Access to Capital, Competitive Enterprise Institute, Feb. 3, 2014
CFA Institute: Letter from Kurt N. Schacht, CFA, Managing Director, Standards and Financial Market Integrity, and Linda L. Rittenhouse, Director, Capital Markets, CFA Institute, Feb. 3, 2014
CFIRA 1: Letter from Freeman White, Board Member, et al., CFIRA, Jan. 19, 2014
CFIRA 2: Letter from Kim Wales, Executive Board Member, and Chris Tyrrell, Chairman, CFIRA, Jan. 20, 2014
CFIRA 3: Letter from Kim Wales, Executive Board Member, and Chris Tyrrell, Chairman, CFIRA, Jan. 26, 2014
CFIRA 4: Letter from Kim Wales, Executive Board Member, et al., CFIRA, Jan. 26, 2014
CFIRA 5: Letter from Kim Wales, Founder and CEO, Wales Capital, and Executive Board Member, CFIRA, Jan. 26, 2014
CFIRA 6: Letter from Joy Schoffler, Board Member, et al., CFIRA, Jan. 27, 2014
CFIRA 7: Letter from Mary Juetten, Board Member, et al., CFIRA, Jan. 31, 2014
CFIRA 8: Letter from Jonathan Miller, Board Member, et al., CFIRA
CFIRA 9: Letter from Daryl Bryant, Board Member, et al., CFIRA, Feb. 4, 2014
CFIRA 10: Letter from Robert Carbone, CFIRA Board Member, CrowdBouncer, CEO, New York, New York, Feb. 6, 2014
CFIRA 11: Letter from Chris Tyrell, Chairman, and Kim Wales, Executive Board Member, CFIRA, New York, New York, Feb. 6, 2014
CFIRA 12: Letter from Kim Wales, CEO, Wales Capital, and CFIRA Executive Board Member, and Scott Purcell, CEO, Artic Island, and CFIRA Board Member, Apr. 24, 2014
City First: Letter from John Hamilton, President, City First Enterprises, Washington, District of Columbia, Feb. 3, 2014
Clapman: Letter from Mordechai Clapman, Oct. 25, 2013
ClearTrust: Letter from Kara Kennedy, Executive Director, ClearTrust, LLC, Jan. 20, 2014
Cole A.: Letter from Adam Cole, Nov. 24, 2013
Cole D.: Letter from Don Cole, Oct. 25, 2013
Commonwealth of Massachusetts: Letter from William F. Galvin, Secretary of the Commonwealth of Massachusetts, Feb. 3, 2014
Computershare: Letter from Martin (Jay) J. McHale, Jr., President, US Equity Services, Computershare, Canton, Massachusetts, Feb. 3, 2014
Concerned Capital: Letter from Bruce Dobb, Concerned Capital—A Social Benefit Corp., Feb. 2, 2014
Consumer Federation: Letter from Barbara Roper, Director of Investor Protection, Consumer Federation of America, Feb. 2, 2014
Craw: Letter from Kristopher R. Craw, J.D., Denver, Colorado, Jun. 14, 2014
CSTTC: Letter from Steven G. Nelson, President and Chairman of Continental Stock Transfer Trust Company, Jan. 31, 2014
CST: Letter from Carylyn K. Bell, President, Corporate Stock Transfer, Inc., Jan. 15, 2014
Coombs: Letter from Jason Coombs, Feb. 7, 2014
CfPA: Letter from Charles Sidman, MBA, Ph.D., President and Chair, for the Board of, the Crowdfunding Professional Association, Feb. 3, 2014
CRF: Letter from Frank Altman, President and CEO, Community Reinvestment Fund, USA, Feb. 3, 2014
Cromwell: Letter from David M. Cromwell, Yale School of Management, Adjunct Professor of Entrepreneurship, Oct. 27, 2013
CrowdBouncer: Letter from Robert C. Carbone, Founder & CEO, CrowdBouncer, Inc., Buffalo, New York, Feb. 3, 2014
CrowdCheck 1: Letter from Sara Hanks, CEO, CrowdCheck, Inc., Jan. 9, 2014
CrowdCheck 2: Letter from Andrew D. Stephenson, Research Manager, CrowdCheck, Inc., Jan. 23, 2014
CrowdCheck 3: Letter from Sara Hanks, CEO, CrowdCheck, Inc., Feb. 2, 2014
CrowdCheck 4: Letter from Brian R. Knight, VP, CrowdCheck, Inc., Feb. 2, 2014
CrowdFundConnect: Letter from Randy A. Shipley, CrowdFundConnect Incorporated, Dec. 14, 2013
Crowdpassage 1: Letter from Matthew R. Nutting, Esq., Executive Director, National Legal Director, Crowdpassage.com, Jan. 31, 2014
Crowdpassage 2: Letter from Matthew R. Nutting, Esq., Executive Director, National Legal Director, Crowdpassage.com, Jan. 31, 2014
Crowdpassage 3: Letter from Matthew R. Nutting, Esq., Executive Director, National Legal Director, Crowdpassage.com, Jan. 31, 2014
CrowdStockz: Letter from Frederic C. Schultz, Esq. and Alastair Onglingswan, Esq., Owners of CrowdStockz.com., CrowdStockETFs.com., and CrowdStockFunds.com, Feb. 3, 2014
Crowley: Letter from Vincent Crowley, Nov. 11, 2013
CrwdCorp: Letter from Sean Shepherd, Founder & Chief Executive Officer, CrwdCorp, LLC, Jan. 16, 2014
Cunningham 1: Letter from William Michael Cunningham, Social Investing Advisor, Washington, District of Columbia, Feb. 3, 2014
Cunningham 2: Letter from William Michael Cunningham, M.B.A., M.A., Social Investing Advisor, Washington, District of Columbia, Feb. 3, 2014
dbb*mckennon:* Letter from dbb*mckennon,* Certified Public Accountants, Oct. 1, 2014
DeMarco: Letter from Peter J. DeMarco, Student, Stanford Law School, Nov. 12, 2013
Denlinger 1: Letter from Craig Denlinger, CPA, Denver, Colorado, Feb. 3, 2014
Denlinger 2: Letter from Craig Denlinger, CPA, CrowdfundCPA, Aug. 21, 2014
Doctor: Letter from Roger Doctor, Dec. 10, 2013
Donohue: Letter from Patrick E. Donohue, Minneapolis, Minnesota, Feb. 24, 2014
DreamFunded: Letter from Manny Fernandez, Co-Founder and CEO, *www.DreamFunded.com*, Jan. 8, 2014
Duke: Letter from Heather Duke, Dec. 3, 2013
EarlyShares: Letter from Joanna Schwartz, CEO, EarlyShares.com, Inc., Feb. 3, 2014
Echterling: Letter from Ian Echterling, Entrepreneur Feb. 21, 2014
Ellenbogen: Letter from David M. Ellenbogen, Jan. 27, 2014
EMKF: Letter from Alicia Robb, Ph.D., Senior Fellow, and Dane Stangler, Vice President, Research & Policy, Ewing Marion Kauffman Foundation, Feb. 3, 2014
Empire Stock: Letter from Matthew J. Blevins, Vice President, Empire Stock Transfer Inc., Jan. 15, 2014
EquityNet: Letter from Judd E. Hollas, Founder and CEO, EquityNet, LLC
Equity Stock: Letter from Mohit Bhansali, Chief Operating Officer, Equity Stock Transfer LLC, New York, New York, Feb. 3, 2014
Ex24: Letter from James. P. Lennane, ex24, Inc., Jan. 29, 2014
EY: Letter from Ernst & Young LLP, Feb. 3, 2014
Farnkoff: Letter from Brian Farnkoff, Editor-in-Chief, Journal of Contemporary Health Law and Policy, Feb. 3, 2014
Farese: Letter from Robert L. Farese, Jr., Oct. 30, 2014
FAST: Letter from Salli A. Marinov, President and CEO, First American Stock Transfer, Inc., January 23, 2014
Feinstein: Letter from Todd Feinstein, Feinstein Law, P.A., Feb. 3, 2014
Finkelstein: Letter from Elizabeth R. Makris, Finkelstein Thompson LLP, Jan. 31, 2014
FOLIOfn: Letter from Michael J. Hogan, President & Chief Executive Officer,

FOLIOfn Investments, Inc., McLean, Virginia, Feb. 3, 2014
Frutkin: Letter from Jonathan Frutkin, The Frutkin Law Firm, Jan. 30, 2014
Fryer: Letter from Gregory S. Fryer, Esq., Partner, Verrill Dana, LLP, Portland, Maine, Feb. 5, 2014
FSI: Letter from David T. Bellaire, Esq., Executive Vice President & General Counsel, Financial Services Institute, Feb. 3, 2014
Fund Democracy: Letter from Mercer Bullard, President and Founder, Fund Democracy, Associate Professor, University of Mississippi School of Law, Oxford, Mississippi, Feb. 3, 2014
Funderbuddies: Letter from John Mark Wendler, CPA, Funderbuddies, Nov. 26, 2013
FundHub 1: Letter from Kendall Almerico, Crowdfunding Expert, Attorney and CEO, Fund Hub and ClickStartMe, Jan. 29, 2014
FundHub 2: Letter from Kendall Almerico, Crowdfunding Attorney and CEO of FundHub.Biz, Tampa, Florida, Oct. 8, 2014
Generation Enterprise: Letter from Ubon Isang, Executive, Generation Enterprise Corporation, Oct. 24, 2013
Gibb: Letter from Jeremy Gibb, Nov. 13, 2013
Gill: Letter from Michael D. Gill, III, Esq., Jan. 22, 2014
Gimpelson 1: Letter from Alexander Gimpelson, Chest Nut Hill, Massachusetts, Feb. 3, 2014
Gimpelson 2: Letter from Alexander Gimpelson, Chest Nut Hill, Massachusetts, Feb. 3, 2014
Grassi: Letter from Louis C. Grassi, CPA, CFE, Managing Partner, Grassi and Co., Jan. 20, 2014
Graves: Letter from Sam Graves, Chairman, U.S. House of Representatives, Committee on Small Business, Washington, District of Columbia, Feb. 3, 2014
Greenfield: Letter from Richard D. Greenfield, Esq., Greenfield Goodman LLC, Nov. 10, 2013
Greer: Letter from Diana Greer, Jan. 27, 2014
Growthfountain: Letter from Growthfountain LLC, Jan. 7, 2014
GSJ Advisors: Letter from George Surgeon, President and CEO, GSJ Advisors, Ltd., Feb. 3, 2014
Guzik 1: Letter from Samuel S. Guzik, Guzik and Associates, Los Angeles, California, Feb. 11, 2014
Guzik 2: Letter from Samuel S. Guzik, Guzik and Associates, Los Angeles, Feb. 20, 2014
Guzik 3: Letter from Samuel S. Guzik, Guzik and Associates, Los Angeles, California, Feb. 28, 2014
Hackers/Founders: Letter from Charles Belle, Ken Priore, and Timothy Yim, Hackers/Founders, Feb. 3, 2014
Hakanson: Letter from Sten E. Hakanson, Stillwater, Minnesota, Feb. 28, 2014
Hamilton: Letter from Brenda L. Hamilton, Hamilton & Associates Law Group, P.A., Nov. 8, 2013
Hamman: Letter from Charles J. Hamman, Oct. 24, 2013
Harrison: Letter from Mark Harrison, Ph.D., Jan. 6, 2014
Holland: Letter from Alexandra D. Holland, Ph.D., Founder and CEO, PIARCS, PBC, June 3, 2014
Martin: Letter from Andrew Martin, OFS, CB, Rockville, Maryland, Oct. 18, 2014
MCS: Letter from Andrew M. Hartnett, Missouri Commissioner of Securities, Feb. 3, 2014
Merkley: Letter from Jeffrey A. Merkley, United States Senator, Apr. 29, 2014
Haylock: Letter from Todd Haylock, Dec. 10, 2013
Heritage: Letter from David R. Burton, Senior Fellow in Economic Policy, The Heritage Foundation, Feb. 3, 2014
Hyatt: Letter from Todd R. Hyatt, Nov. 6, 2013
IAC Recommendation: Recommendation of the SEC's Investor Advisory Committee: Crowdfunding Regulations, Apr. 10, 2014
iCrowd: Letter from J. Bradford McGee and John P. Callaghan, Founders, iCrwod, LLC, Jan. 31, 2014
Inkshares: Letter from Adam J. Gomolin, General Counsel, Inkshares, Inc., Feb. 3, 2014
Jacobson: Letter from William A. Jacobson, Clinical Professor of Law, Cornell Law School, and Director, Cornell Securities Law Clinic, Ithaca, New York, Feb. 3, 2014
Jazz: Letter from Jim C. Shaw, Jazz Gas, Jan. 12, 2014
Johnston: Letter from Phil Johnston, Feb. 3, 2014
Joinvestor: Letter from Bryan Healey, CEO, Joinvestor, Jan. 2, 2014
Kelso: Letter from Carl Kelso, Jan. 7, 2014
Kickstarter Coaching: Letter from Jay Wittner, President Kickstarter Coaching, Bradenton, Florida, Feb. 3, 2014
Kingonomics: Letter from Rodney S. Sampson, CEO, Kingonomics, Feb. 3, 2014
Kishon: Letter from Mannis Kishon, Dec. 22, 2013
Knudsen: Letter from Michael Knudsen, Jan. 6, 2014
Konecek: Letter from Kathleen Konecek, Nov. 30, 2013
Langrell: Letter from Alex M. Langrell, Camp Pendelton, California, Jan. 21, 2014
Leverage PR: Letter from Joy Schoffler, Principal, Leverage PR, Austin, Texas, Sep. 2, 2014
Loposssa: Letter from Gabriel M. Lopossa, Oct. 30, 2013
Luster: Letter from Louise Luster, Oct. 31, 2013
Mahoney: Letter from Steve Mahoney, Managing Director, Highlands Ranch, Colorado, Jan. 20, 2014
Mantel: Letter from Russ Mantel, Oct. 23, 2013
M.A.V.: Letter from M.A.V., Nov. 3, 2013
Marsala: Letter from Charles E. Marsala -Profitibale Dining LLC, Feb. 15, 2014
McCulley: Letter from Matthew McCulley, Jan. 10, 2014
McGladrey: Letter from McGladrey LLP, Feb. 3, 2014
Meling: Letter from Rosemary Meling, Oct. 30, 2013
Menlo Park: Letter from James O. Mason, Founder/CEO, Menlo Park Social Media Crowdfunding Incubator, Feb. 28, 2014
Miami Nation: Letter from Ben Barnes, Director of Tribal Gaming, Miami Nation Enterprises, Oct. 25, 2013
Milken Institute: Letter from Daniel S. Gorfine, Director, Financial Markets Policy, and Staci Warden, Executive Director, Center for Financial Markets, Milken Institute, Washington, District of Columbia, Feb. 3, 2014
Mlinarich: Letter from Brett A. Mlinarich, Jan. 2, 2014
Mollick: Letter from Ethan R. Mollick, Edward B. and Shirley R. Shils Assistant Professor of Management, Wharton School, University of Pennsylvania, Phildelphia, Pennsylvania, Feb. 5, 2014
Morse: Letter from Matt R. Morse, Sr., Dec. 3, 2013
Moskowitz: Letter from Yonatan Moskowitz, Nov. 13, 2013
Moyer: Letter from Mike Moyer, Adjunct Associate Professor of Entrepreneurship at the University of Chicago Booth School of Business, Adjunct Lecturer of Entrepreneurship at Northwestern University, Jan. 25, 2014
Mountain Hardwear: Letter from Alan A. Tabor, Co-founder, Mountain Hardwear, Jan. 27, 2014
Multistate Tax: Letter from Frank L. Dantonio, Managing Principal, Multistate Tax Service, LLC, Oct. 29, 2013
NAAC: Letter from Faith Bautista, President and CEO, National Asian American Coalition, Oct. 31, 2013
NACVA: Letter from David M. Freedman, Editorial Advisor, The Value Examiner magazine (NACVA), Jan. 16, 2014
NAHB: Letter from David L. Ledford, Senior Vice President, Housing Finance & Regulatory Affairs, National Association of Home Builders, Jan. 31, 2014
NASAA: Letter from Andrea Seidt, President, North American Securities Administrators Association, Inc. (NASAA)
NASE: Letter from Katie Vlietstra, Vice President of Government Relations Public Affairs, The National Association for the Self-Employed, Washington, District of Columbia, Feb. 3, 2014
NaviGantt: Letter from Christopher R. York, CEO, NaviGantt, Jan. 27, 2014
NYSSCPA: Letter from J. Michael Kirkland, President, New York State Society of Certified Public Accountants, Jan. 20, 2014
Nether: Letter from Darrell W. Nether, Nov. 1, 2013
NFIB: Letter from Dan Danner, President and CEO, National Federation of Independent Business, Feb. 3, 2014
NPCM: Letter from Robert C. Guinto, Jr., President, Non Profit Capital management, LLC, Oct. 24, 2013
NSBA: Letter from Todd O. McCracken, President, National Small Business Association, Feb. 3, 2014
Odhner: Letter from Chad E. Odhner, Nov. 25, 2013
ODS: Letter from Faye Morton, General Counsel, Oklahoma Department of Securities, Feb. 3, 2014
Omara: Letter from Sherouk Omara, Nov. 14, 2013
Otherworld: Letter from Mark Henry, Founder, Otherworld Pictures, Apr. 11, 2014
Parsont: Letter from Jason W. Parsont, Feb. 18, 2014
Partners: Letter from Jeannine Jacokes, CEO, Partners for the Common Good, Washington DC, District of Columbia, Feb. 3, 2014

Patel: Letter from Raj Patel, Jan. 17, 2014
PBA: Letter from Graham R. Laub, Chair, and Katayun I. Jaffari, Vice Chair, Securities Regulation Committee of the Business Law Section, Philadelphia Bar Association, Philadelphia, Pennsylvania, Feb. 3, 2014
Peers: Letter from Kit Hayes, Campaign Director, Peers.org, Feb. 7, 2014
Perfect Circle: Letter from Frederick C. Young, Perfect Circle Solutions, Oct. 30, 2013
PeoplePowerFund: Letter from Steve Mayer, PeoplePowerFund.com, Jan. 31, 2014
Phillips: Letter from Everette Phillips, Entrepreneur, Jan. 15, 2014
Pioneer Realty: Letter from Charles E. Williams, MBA, EA, Founder and Managing Director, Pioneer Realty Capital, Jan 15, 2014
Platkin: Letter from Matthew Platkin, Nov. 13, 2013
Powers: Letter from Jordan Berg Powers, Nov. 4, 2013
PPA: Letter from Douglas R. Slain, Managing Partner, Private Placement Advisors LLC
Projectheureka: Letter from Anthony and Erika Endres, Projectheureka LLC, Nov. 17, 2013
Propellr 1: Letter from Todd M. Lippiatt, CEO, Propellr, LLC, Jan. 27, 2014
Propellr 2: Letter from Todd M. Lippiatt, CEO, Propellr, LLC, Jan. 27, 2014
Public Startup 1: Letter from Jason Coombs, Co-Founder and CEO, Public Startup Company, Inc., Dec. 15, 2013
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Ramsey: Letter from Rebecca Ramsey, Oct. 24, 2013
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RFPIA: Letter from T. W. Kennedy, BE, CEO, Regulated Funding Portal Industry Association, Jan. 26, 2014
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RoC: Letter from Sang H. Lee, CEO, Return on Change, Jan. 30, 2014
RocketHub: Letter from Alon Hillel-Tuch and Jed Cohen, RocketHub, New York, New York, Feb. 3, 2014
Rosenthal O.: Letter from Oren Rosenthal, Attorney, Nov. 4, 2013
Sam H.: Letter from Sam H., Oct. 27, 2013
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Saunders: Letter from R. Kevin Saunders, Staff Editor, Vanderbilt Journal of Entertainment Technology Law, Nashville, Tennessee, Feb. 3, 2014
Sawhney: Letter from Sanjay Sawhney, Jan. 27, 2014
SBA Office of Advocacy: Letter from Winslow Sargeant, Ph.D., Chief Counsel for Advocacy, and Dillon Taylor, Assistant Chief Counsel for Advocacy, SBA Office of Advocacy, Jan. 16, 2014
SBEC: Letter from Karen Kerrigan, President & CEO, Small Business & Entrepreneurship Council, Feb. 3, 2014
SBM: Letter from Cassie Mills, Communications Associate, Small Business Majority, Feb. 4, 2014
Schatz: Letter from Jonathan Schatz, Nov. 13, 2013
Schwartz: Letter from Andrew A. Schwartz, Associate Professor of Law, University of Colorado, Boulder, Colorado, Feb. 3, 2014
Scruggs: Letter from Frank Scruggs, Jan. 17, 2014
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SFAA: Letter from Robert. J. Duke, Corporate Counsel, The Surety & Fidelity Association of America, Nov. 19, 2013
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STA: Letter from Charles V. Rossi, Chairman, STA Board Advisory Committee, The Securities Transfer Association, Inc., Dec. 18, 2013
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US Black Chambers: Letter from Ron Busby, President, US Black Chambers, Inc., Washington, District of Columbia, Feb. 3, 2014
U.S. Chamber of Commerce: Letter from Tom Quaadman, Vice President, Center for Capital Markets Competitiveness, U.S. Chamber of Commerce, Feb. 3, 2014
Verinvest: Letter from David Benway, Chief Executive Officer, Verinvest Corporation, Jan. 17, 2014
Vann: Letter from James Vann, Greenfield, Missouri, Apr. 11, 2014
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Wilson: Letter from Margaret A. Wilson, Professor of Technology Commercialization, Austin, Texas, Feb. 3, 2014
Winters: Letter from Dennis Winters, Esq., Jan. 9, 2014
WIPP: Letter from Barbara Kasoff, President, Women Impacting Public Policy, Feb. 3, 2014
Woods: Letter from Thell M. Woods, Jan. 13, 2014
Yudek: Letter from David B. Kopp, CEO, Yudek, Inc. Oct. 29, 2013

Zeman: Letter from Jason Zeman, Nov. 30, 2013

Zhang: Letter from Runan Zhang, Esq., Law Offices of Runan Zhang, Washington, District of Columbia, Feb. 3, 2014

7thenterprise: Letter from Jarone V. Price, CEO, 7thenterprise International Inc., Jan. 22, 2014

11 Wells: Letter from Robert McManus, The 11 Wells Spirits Company, Jan. 28, 2014

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Drug Enforcement Administration

Mark William Andrew Holder, M.D.; Decision and Order; Notice

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 14–13]

Mark William Andrew Holder, M.D.; Decision and Order

On October 9, 2014, Administrative Law Judge Christopher B. McNeil (hereinafter, ALJ) issued the attached Recommended Decision (hereinafter, cited as R.D.). On October 31, 2014, one day after the due date, *see* 21 CFR 1316.66, Respondent filed Exceptions to the Decision.

According to Respondent's counsel, on the day on which his Exceptions were due, her word processing program shut down and while she was able to find a recovered document, ''it was not the most recent version and did not include the final arguments or footnotes.'' Resp. Mot. for the Administrator to Accept and Review the Updated Version of Respondent's Exceptions to the ALJ's Recommendations, at 1. Respondent's counsel represents that she immediately contacted the ALJ's law clerk to request an extension; according to Respondent's counsel, she spoke with the ALJ who stated that she could either submit the document ''as is'' or ''send a motion to the [A]dministrator requesting an extension.'' *Id.* at 1–2.

Respondent's counsel chose to file his Exceptions ''as is.'' *Id.* at 2. However, according to Respondent's counsel, the document contained ''many errors and . . . was incomplete.'' *Id.* Respondent's counsel also represented that on the day before the Exceptions were due, she had to deal with a family medical emergency. *Id.* Accordingly, on November 5, 2015, Respondent's counsel filed the above-referenced motion along with a revised version of his Exceptions. *Id.* at 1. Having considered Respondent's motion, I find that good cause exists to excuse the untimely filing of his Exceptions and consider them in my review of the record.

Having considered the record in its entirety,[1] I adopt the ALJ's findings of facts and conclusions of law except as discussed throughout this decision. I agree with the ALJ's findings that Respondent (1) unlawfully prescribed controlled substances (Percocet and Xanax) to S.S., *see* R.D. at 59; (2) unlawfully obtained and self-administered Adderall, *see id.* at 59; (3) provided inconsistent and misleading accounts of his drug use to DEA Investigators, *see id.* at 61–62, 65–66; (4) materially falsified his application for a DEA registration; *see id.* at 62–63; and (5) failed to unequivocally acknowledge his misconduct in issuing unlawful prescriptions to S.S., *see id.* at 41–42, as well as in materially falsifying his DEA application, *id.* at 66; and (6) failed to produce sufficient evidence of remediation. *Id.* at 66–67. Accordingly, I adopt the ALJ's ultimate conclusions of law that Respondent has materially falsified his application for a DEA registration and committed acts which render his registration inconsistent with the public interest, and that he has failed to rebut the Government's *prima facie* case. *See id.* at 67. I therefore adopt the ALJ's recommendation that I deny Respondent's application. A discussion of Respondent's Exceptions follows.

Respondent's Exceptions

Respondent takes exception to three of the ALJ's enumerated factual findings (numbers 12, 13, and 14) asserting that they are not supported by the record. He also takes exception to five of the ALJ's conclusions of law (numbers 2, 5, 6, 9, and 13).

Exception to Finding of Fact #12

In Finding of Fact number 12, the ALJ found:

> In the course of investigating the circumstances surrounding state medical board action pertaining to Respondent's medical licenses in Florida and Minnesota, DEA Diversion Investigator Virginia McKenna met with or spoke with Respondent on several occasions between July 19, 2012 and August 23, 2013. Throughout this period, Investigator McKenna made repeated requests for Respondent to provide the DEA with copies of monitoring and treatment records reflecting action by the medical boards in Florida and Minnesota. Initially, and for a period extending more than six months, Respondent deferred complying with these requests while assuring Investigator McKenna he would comply. By April 2013, when the records still had not been produced, Investigator McKenna presented Respondent with release forms that would authorize the DEA to receive copies of these reports. Respondent refused to sign the releases, and advised Investigator McKenna that he would not permit the DEA access to the PRN report from Florida, and gave her what appears to be an incomplete set of records reflecting the report from Minnesota.

R.D. at 61.

Respondent asserts that this finding is not supported by the record, because the Diversion Investigator acknowledged in her testimony that she had received duplicate copies of a physician's report prior to obtaining some 82 pages of documents from Respondent, and that ''[i]n order to receive a duplicate copy she must have received a previous copy of the report.'' Exceptions at 2. Respondent argues that the DI's statement that she did not receive '' 'much, if anything' is contradicted by the fact that she acknowledged receipt of 82 pages of information,'' which included ''copies of notes [prepared by his case manager at the Minnesota Health Professionals Services Program (HPSP)], the quarterly reports[,] as well as a toxicology report provided to'' the DI. *Id.* at 2–3.

Respondent also asserts that he provided the results of a chemical assessment, which included the diagnosis, prognosis and recommended treatment, by Ms. Hasper (who he saw outside of the HPSP program), as well as reports from Dr. Albert, a psychologist he saw some fifteen times as part of the HPSP program. *Id.* at 3 (citing Tr. 481). Respondent then argues that the DI ''intentionally mislead [sic] the court when she stated that she did not receive any documentation of diagnosis, treatment and prognosis'' and this calls ''into question the credibility of the rest of her testimony.'' *Id.* at 4.

While Respondent acknowledges that he did not provide his Florida PRN file to the DI, he argues that he ''provide[d] a copy of his HPSP information which reflected the most recent analysis of his treatment, diagnosis and prognosis'' to the DI and that she did not ''articulate what information she was missing from

[1] On November 3, 2014 (which was after the record had closed), Respondent filed a request for me to review an additional document, this being a chemical assessment performed on October 9, 2013 by Ms. Joan Hasper. Resp. Req. for Administrator to Review an Additional Document. Respondent argues that I should review this document because ''[t]here is no way that [he] can prove that he gave [the DI] a copy of the HPSP file without access to the Government's file which would document receipt of the HPSP file,'' and that ''it is necessary in the interest of justice to review the additional assessment which [the DI] testified that she did in fact receive.'' *Id.* at 3. Given that Ms. Hasper did not perform her assessments as part of the HPSP program, it is not clear why this document impeaches the DI's testimony that Respondent refused to provide releases for the records of his treatment which were maintained by the Florida PRN and the HPSP programs.

However, Respondent furthers argues that ''this document shows that [the DI] received diagnosis, prognosis, and treatment [information], it further shows that Dr. Holder provided the necessary release which allowed [the DI] to meet with Ms. Hasper and discuss the process of the evaluation and its contents.'' *Id.* Respondent then acknowledges that ''this document probably should have been included in the evidence introduced at the hearing.'' *Id.*

I agree. This document does not constitute newly discovered evidence and was obviously available to Respondent at the time of the hearing. I therefore decline to consider it. *See Richard A. Herbert*, 76 FR 53942, 53944 (2011); *see also ICC* v. *Brotherhood of Locomotive Engineers*, 482 U.S. 270, 286 (1987).

the HPSP file.'' *Id.* at 4. He then asserts that the DI, ''[a]fter having [his] HPSP file for months, . . . returned to his place of work to request that he sign a release.'' *Id.* Respondent asserts that he ''requested his entire file from HPSP and provided that file to [the DI] in January, four months before her visit to his office.'' *Id.* He then argues that ''[t]here was no reason for him to believe that HPSP records beyond what he provided existed or that signing the release would have provided any additional information than what he had already provided to'' the DI and that ''[t]here was also no reason to believe that providing PRN information would lead to an outcome.'' *Id.*

I do not find Respondent's Exception to establish sufficient reason to reject the ALJ's finding, which was based largely on his assessment of the credibility of the DI and Respondent. As for Respondent's contention that because the DI testified that she received duplicate copies of a physician's report, she must have received the report previously, I do not agree. The DI testified that notwithstanding numerous requests she made of Respondent to provide his HPSP records, including on July 19, 2012 and August 25, 2012, as well as on an unspecified date in November 2012, he did not provide the aforesaid 82 pages, which he represented as being the HPSP records, until the January 4, 2013 meeting. Tr. 464, 469–70, 472–73. Notably, before Government counsel even broached the subject of the January 4, 2013 meeting the DI had with Respondent, Government Counsel asked the DI: ''and did you get the records?'' to which the DI answered: ''I did not.'' *Id.* at 473. Moreover, Respondent did not cross-examine the DI regarding her testimony that she received ''a duplicate copy'' of a quarterly report by Dr. Albert. *Id.* at 488–98. Indeed, the DI's testimony does not suggest that she had previously received the documents but that she received duplicate copies of various documents when on January 4, 2013, Respondent provided these documents to her. *Id.* at 474–75 (testimony of DI that after noting ''three or four pages of notes from'' his case manager, ''the remainder of the information were [sic] duplicate copies of his agreement to work with HPSP, faxes going back and forth showing people submitting quarterly reports but the quarterly reports didn't have a lot of detail. There was a duplicate copy from Dr. Albert on a quarterly report and the third page of that was from a second quarterly report which was almost identical to the first one and then there were a whole bunch of releases that he signed for different entities to receive some of these records'').[2]

As for Respondent's contention that in January 2013, he provided his complete HPSP file, the evidence nonetheless establishes that in August 2013,[3] the DI, who still believed that Respondent had not provided the full file (indeed, he had not provided any material from the Florida PRN program), went to his place of employment and requested that he provide releases so that the DI could directly obtain his records from the HPSP and PRN programs. Tr. 478. Respondent again asserted that he had provided the DI with ''everything.'' *Id.* at 479. However, even after the DI told Respondent that she ''needed to obtain [the records] for [her]self in order to be sure that [she] had everything,'' Respondent declined to execute the releases saying that he wanted to talk to his attorney. *Id.* However, when the DI called him ten days later and asked whether ''he was willing to sign the releases,'' Respondent stated ''that he had already given me all of HPSP's records, that PRN's records were full of inaccuracies, and that it would be inappropriate for me to have that information and to use it at this point.'' *Id.*

It is true that during this phone call, Respondent told the DI that he was going to undergo a chemical assessment by Ms. Hasper, which he did outside of the HSPS, as he had already completed the program. *Id.* at 480–81. Respondent also apparently agreed to release the contents of his file with Dr. Hasper to the DI. *Id.* at 480. However, upon reviewing the file, the DI found that it contained notes from Dr. Albert (the psychologist who treated him under the HPSP program) for Respondent's first two visits (when generally a history and evaluation are completed). *Id.* at 481. According to the DI, she had not previously seen these notes in the documents Respondent submitted. *Id.* at 482.

Thus, contrary to Respondent's Exception that the DI did not ''articulate what she was missing from the HPSP file,'' Exceptions at 4, the DI did identify information that was likely in his HPSP file.[4] And even if this information was not in the file, I find that the rest of the ALJ's factual finding is supported by a preponderance of the evidence. I therefore reject this exception.

Exception to Finding of Fact #13

In Finding of Fact Number 13, the ALJ found:

> In meetings and conversations conducted by DEA Diversion Investigator McKenna . . . Henderson, and . . . Capello, Respondent gave evasive and conflicting answers to questions regarding his history of drug abuse, his use and abuse of marijuana and Adderall, the sources supplying him with controlled substances, his ability to recall the events immediately prior to and after the June 13, 2008 crash, the nature and severity of injuries he and his passenger sustained due to the crash, his use of controlled substances while working at MD Now, and his reasons for answering registration application Question Three in the negative. He provided similarly evasive and conflicting answers to questions presented to him by the medical boards in Florida and Minnesota, particularly minimizing the severity of injuries he and his passenger sustained in the June 13, 2008 crash. Respondent continued providing evasive, inconsistent, and deflecting responses during the evidentiary hearing he requested upon his receipt of the pending DEA Order to Show Cause.

R.D. at 61–62.

In excepting to this finding, Respondent takes issue with the ALJ's credibility findings with respect to multiple witnesses for the Government. These include: (1) The DI whose testimony is discussed above; (2) S.S., who testified, *inter alia*, that Respondent wrote a fraudulent prescription for Adderall in S.S.'s name, which S.S. filled, and after taking some of the pills, then provided to Respondent, as well as that he provided other drugs such as cocaine and marijuana to Respondent; (3) a

[2] As the 82 pages Respondent provided the DI were not submitted as a discrete exhibit (some of the documents may have been submitted as other exhibits), I have no basis to conclude whether the records were complete. However, the quarterly reports submitted as Respondent's Exhibit M (which covered the quarters ending on April 15, 2012 and July 15, 2012) were essentially three page documents, one page being the ''Participant Update,'' the second page being the ''Treatment Provider Report Form,'' and the third page being a letter from the Executive Director of Physicians Serving Physicians attesting to his attendance at various meetings. RX M. As for the Treatment Provider Report Forms, they list the primary and secondary treatment foci, Respondent's symptoms, and then provide a ''diagnostic impression,'' a ''Treatment Plan,'' ''Client/Patient Insight,'' and ''Medications.'' *See* RX M. While it is certainly true that these forms listed Dr. Albert's diagnosis and recommended treatment, given the brevity of the notes, which did not include a discussion of Respondent's history (including his history of substance abuse) and Dr. Albert's initial evaluation of him, it is understandable that the DI did not believe that Respondent had provided his complete HPSP file.

[3] While the record establishes that in April 2013, the DI had a further conversation with Respondent about obtaining his records, including those from the Florida PRN program (which she ''hadn't received anything about''), the record does not establish the precise scope of this conversation. Tr. 478.

[4] As the DI testified, the notes showed that Respondent told Dr. Albert that he had ''used Adderall one time in residency and a total of perhaps five times outside of residency.'' Tr. 482.

paramedic who responded to the scene after Respondent crashed his vehicle; and (4) N.P., a passenger in Respondent's vehicle, who was injured in the crash. Exceptions at 5–14.

As for the DI, Respondent raises a further challenge to her credibility. He notes that during her testimony regarding a meeting (on July 19, 2012) with Respondent and his attorney, during which the allegation that he materially falsified Question Three on his application was raised, the DI testified that:

> He answered on the application no. When I asked him about that, he said that he didn't understand the question, that he wasn't intending to lie, at which time Mr. Harbison interjected, why would he lie when he knew it was public record, but I had no, I don't know why he would or wouldn't do such a thing, so I showed him the application. And then he said that he didn't read the question thoroughly, and that's when I showed him a sample application that I had.

Tr. 463. According to Respondent, the DI later admitted that Respondent's ''application was not presented to him at the meeting.'' Exceptions at 6. Respondent based this on the following colloquy during cross examination:

> Resp. Counsel: And concerning the application, when Mr. Harbison first requested the application, wasn't he told that you all were not able to provide him an application because it was done on the internet?
>
> DI: Yes, ma'am. That was my error. I spoke with . . . the section chief for Registration, and I misunderstood what he said. And I relayed that, my misunderstanding. And that's when they went further and were able to produce it.

Id. at 495.

I do not find this testimony sufficient to support Respondent's contention that the DI gave false testimony in the proceeding. The DI's testimony is simply insufficient to establish that at the July 2012 meeting, she showed the actual application filed by Respondent as opposed to the sample application she referred to in the next sentence. Notably, the DI's testimony that ''so I showed him the application'' does not specify that it was Respondent's actual application which she showed him, and her continuing testimony supports the inference that it was only a sample application.[5] Accordingly, I reject Respondent's challenge to the DI's credibility.

Respondent further argues that the ALJ gave inappropriate weight to the testimony of S.S., who, in Respondent's words, ''was willing to make many exaggerations/false statements against [him] for a get out of jail card.'' Exception at 7. Respondent contends that S.S. gave ''internally conflicting testimony that he provided cocaine 'sporadically' and marijuana 'relatively regularly to Dr. Holder,' '' and ''he used these drugs with Dr. Holder.'' *Id.* at 7–8. According to Respondent, this is so because at the time of his drug use with Respondent, ''he was on probation'' and subject to drug testing, and yet testified that he did not fail any drug tests when he was living in Palm Beach County. *Id.* at 8. Respondent argues that this establishes that S.S.'s testimony is not credible because ''how could he use marijuana and cocaine with [Respondent] and evidence of this drug use never reveal itself on any of his drug tests?'' *Id.*

While S.S. testified that he was on probation during the same time-period in which he testified that he ''used cocaine and marijuana with'' Respondent, *id.* at 198, there is no evidence in the record as to how frequently S.S., who had been on probation for more than two years at this point, *id.* at 212, was subject to drug testing during this period. Moreover, evidence in the record establishes that following the accident, the Palm Beach County Sheriff's office obtained a blood specimen from Respondent which tested positive for Delta-9-Carboxy THC, *see* GX 13, a metabolite of THC, thus establishing that Respondent had used marijuana.

S.S. further testified that in June 2008, he was smoking marijuana with Respondent at the latter's residence, when Respondent told him that he needed a favor—this being for S.S. to come by the office and fill a prescription for Adderall, which S.S. was to then return to Respondent. Tr. 208. On June 11, 2008, Respondent either called or texted S.S., who went to Respondent's clinic, picked up a prescription for 60 tablets of Adderall 30 mg which was written by Respondent and listed S.S. as the patient. *Id.* at 208–09. S.S. then went to a Walgreens pharmacy located next to the clinic, filled the prescription, and after taking some pills for himself, gave the rest of the pills to Respondent. *Id.* at 209–11; *see also* GX 6.

To be sure, as Respondent argues, S.S. gave conflicting testimony as to how many of the Adderall pills he took from the prescription, initially stating that he took one or two pills, which was his ''best recollection,'' before adding that ''[i]t could have been three or four.'' Tr. 213–14. While Respondent argues that S.S. was ''willing to say just about anything,'' Exceptions at 9, the evidence shows that following the accident, the police found in Respondent's car the prescription vial bearing S.S.'s name as the patient and listing the contents as amphetamine 30 mg, along with 41 pink tablets. GX 11, at 1. Moreover, the blood specimen obtained from Respondent following the accident showed that he had ingested amphetamines. GXs 13, 14. Thus, I find no reason to reject the ALJ's finding that S.S. gave credible testimony.[6]

As for N.P.'s testimony, which primarily focused on the scope of the injuries she suffered in the accident, whether she had only minor injuries as Respondent suggests or more serious injuries to include a dislocated elbow, shattered cervical disc, a broken back, and neurologic damage, is of only nominal relevance in resolving whether granting Respondent's application is consistent with the public interest. 21 U.S.C. 823(f). In any event, given that the Government disclosed to Respondent that it intended to elicit testimony from N.P. regarding the injuries she sustained and that the ALJ found her testimony credible, in the absence of medical records refuting her testimony, I find no reason to reject the ALJ's credibility determination.

Finally, Respondent takes exception to the ALJ's factual finding that ''[h]e provided similarly evasive and conflicting answers to questions presented to him by the medical boards in Florida and Minnesota, particularly minimizing the severity of injuries he and his passenger sustained in the June 13, 2008 crash.'' R.D. at 62. As evidence for his finding that Respondent provided evasive and conflicting answers to the questions presented by the Florida Board, the ALJ did not cite any evidence in the record.[7] Moreover,

[5] Indeed, if the DI had Respondent's actual application available to her at the time of the meeting, there would have been no need to then show him a sample application, as the actual application would have included the same question. Also, regarding her testimony at Tr. 463, it is not unusual for a witness to offer an answer, which she subsequently clarifies while reflecting on the question.

[6] As for the discrepancy between the Palm Beach County EMS report which documented that Respondent had a seizure and the testimony of the paramedic that he did not witness Respondent having a seizure upon arriving at the accident scene or while transporting him to the hospital and that the paramedics ''were just following our protocols [by administering Valium] in case he ha[d] a history,'' Tr. 258, it is unclear why this fact is material in assessing the ALJ's finding that Respondent gave inconsistent testimony regarding the circumstances surrounding the accident. However, even if it is material, I do not find adequate justification to reject the ALJ's credibility determination as to the paramedic's testimony.

[7] Later in his decision, the ALJ quoted the following statement in Respondent's Petition for Reinstatement:

> The related criminal matter has been referred for pre-trial intervention and Respondent is currently

other than Respondent's Petition for Reinstatement, the Record does not include any other evidence establishing what statements Respondent made to the Florida Board. Therefore, I do not find this portion of the ALJ's finding to be supported by substantial evidence.

There is, however, substantial evidence that Respondent provided false information on his Minnesota application. Respondent provided a yes answer with the notation to ''Please View Addendum'' to questions regarding: (1) Whether his license to practice medicine in any state had been revoked, suspended, restricted or conditioned; (2) whether he had been notified of any investigation by any state board regarding the practice of medicine; (3) whether any criminal charges had ever been filed against him, regardless of whether they had been expunged; and (4) whether he had ever been charged with DWI or DUI. GX 34, at 6.

In the addendum, Respondent wrote that: ''I had a seizure while driving on June 1, 2008. A collision with a sign post followed. Both the passenger and I were in seatbelts and only suffered minor injuries form [sic] airbag deployment.'' *Id.* at 9. Respondent stated that while he had ''walked out of the car,'' he refused both a neck collar and to lie on a stretcher, after which he was restrained by the police. *Id.* Respondent then asserted that ''[d]uring this restraining process I was tazed 14 times, and received multiple blows to my face, head and back'' and that he was diagnosed with a ''traumatic head injury (bleeding in three distinct lobes of my brain), multiple contusions in lungs bilaterally, 4 fractured bones in [the] maxillary region of face, complete nasal fracture with deviation of the septum, facial lacerations, lacerations in all extremities, right sides [sic] rotator cuff injury and respiratory failure.'' *Id.*

Respondent represented to the Board that ''[n]o controlled substances were found in my possession or in [the] vehicle (via police report).'' *Id.* And he further asserted that ''[n]o charges were filed'' until approximately three months after the incident when he was charged with ''possession of a controlled substance without a prescription (Adderall), fraud to acquire a controlled substance, and driving under the influence (sub therapeutic levels of Adderall in blood).'' *Id.*

The evidence also shows that the Minnesota application's question number 12 specifically included charges of disorderly conduct and required that he disclose any charge regardless of whether it had had been expunged or removed from his record by executive pardon. GX 34, at 6. In his testimony, Respondent admitted that that he had been charged with disorderly conduct on another occasion. Tr. 151–52. Yet he failed to disclose this charge on the Minnesota application. GX 34, at 9. Respondent explained the omission, asserting that while his answer to the application question ''may not have been complete . . . it was truthful,'' and that he was truthful about ''the charges that I thought were actually most important'' and that ''the charges were dismissed.'' Tr. 151–52.

Respondent did acknowledge that the Florida Board of Medicine suspended his license, but that it had been reinstated. GX 34, at 10. He then wrote: ''Admittedly, I did use Adderall as used for ADHD without a prescription while working long hours. I acquired from a colleague who worked in the Urgent Care where I worked.'' *Id.*

As the record shows, several of these statements were false. These include Respondent's statement that no controlled substances were found in his possession or vehicle,[8] as well as that he acquired the Adderall from a colleague.[9]

After the Minnesota Board's Licensure Committee denied his application, *see* GX 35, Respondent sought reconsideration of its decision. In his letter to the Board, Respondent's counsel again asserted that ''[o]ne of the possible reasons that the prosecution decided to dismiss the case was that the original police report showed that there were no drugs or alcohol found in the vehicle'' and ''[t]his obviously negated the charges of DWI and illegal possession of drugs.'' GX 37, at 2 (citing Respondent's Affidavit, at ¶ 5). Respondent's lawyer also asserted that ''[t]he prosecution's dismissal also means that it did not have enough confidence in the charges even to pursue the claim that Dr. Holder somehow had a trace of marijuana in his blood.'' *Id.* Still later in his letter, Respondent's counsel wrote that ''[h]e certainly acknowledges his bad judgment in obtaining the Adderall tablets, but that was an isolated instance of a questionable thought process.'' *Id.* at 5.

In support of his request for reconsideration by the licensure committee, Respondent submitted an affidavit. Therein, Respondent again asserted that ''[t]he original police report showed that no alcohol or illegal drugs were found in my vehicle.'' *Id.* at 11 (¶ 5). He further asserted that he ''definitely did not use or have marijuana as charged in the criminal case'' and ''ha[d] no idea where that claim comes from.'' *Id.*at 12 (¶ 8). While Respondent admitted to having used Adderall the day before the accident, he maintained that this was ''because of a stupid error of judgment'' and that he had obtained the drug ''inappropriately from a friend.'' *Id.* Respondent then asserted that:

> I obtained the Adderall only for the purpose of helping me stay alert during a period when I was working hard for many hours. I definitely do not have a ''drug problem,'' and have never had a history of anything even close to that. I realize and agree that what I did in obtaining the Adderall was wrong. I had never done that before and will never do it again.

complying with the requirements for successfully completing the Circuit Court's requirements to avoid prosecution for those criminal charges. These requirements include successful completion of the Comprehensive Alcoholism Rehabilitation Program (CARP) as ordered by the Court. This is a program providing a continuum of care to individuals affected by alcoholism, drug dependency and co-occurring disorders and PRN is monitoring Respondent's participation in the CARP.

R.D. at 37 (quoting GX 30, at 12). While the record establishes that Respondent did not complete the program because, in his words, the program was taking too long, there is no evidence that Respondent was not ''currently complying'' with the Drug Court program at the time of his petition. The ALJ did not cite this passage as support for his conclusion that Respondent gave evasive and conflicting answers to the questions of the Florida Board, but rather, only as support for his conclusion that although Respondent ''participated in monitoring by PRN and the CARP program . . . [he] has effectively withheld from the Administrator records showing his treatment in Florida for these disorders.'' R.D. at 37.

[8] As for Respondent's assertion that this was per the police report, the Offense Report filed by the Sheriff's Office included the Supplemental Report of a crash scene investigator. See GX 46. In his report, the Investigator documented that another Investigator had conducted an inventory search of Respondent's car and found the aforementioned vial of 41 tablets of Adderall bearing a label which listed the patient as S.S. *Id.* at 6. So too, a further supplemental report prepared by a Detective stated that he learned ''during the at[-]scene investigation,'' that the vial of 41 Adderall tablets was found in Respondent's car and that it listed S.S. as the patient and had been prescribed by Respondent. RX D, at 37 (page 36 of the report).

[9] The record includes the results of a blood test which shows that Respondent's level of amphetamine was 76 ng/ml. GX 14. While there is also testimony by the DI that she read the deposition of the toxicologist who certified the test results taken in the criminal case brought against Respondent, the deposition was not entered into evidence and the DI's testimony does not establish what constitutes a therapeutic level. Tr. 468–69. Of note, the DI testified that Respondent initially claimed that he had taken only one Adderall pill on the night of the accident. *Id.* at 469. The DI testified that based on her reading of the deposition, it was her ''understanding that a therapeutic level is usually obtained from the regular maintenance on a medication'' and that taking one ''pill on the night of the crash would not be sufficient to provide a therapeutic level.'' *Id.* When, in a subsequent interview, the DI raised the issue, Respondent stated that he ''might have taken two that night.'' *Id.*

Id. at 12 (¶ 10).

However, even if it is true that the ''original'' police report did not state that illegal drugs were found in his vehicle, several of the supplemental police reports establish that the Adderall vial was found in his car. Thus, his statement is nonetheless misleading. Moreover, his statement that he did not use marijuana is refuted by the blood test results. As for his statement as to how he obtained the Adderall, while S.S. may have arguably been ''a friend,'' the statement is nonetheless misleading in that Respondent attempted to minimize his culpability as he actually obtained the drug by writing a fraudulent prescription in S.S.'s name. Finally, Respondent's assertion that he did not have a drug problem is amply refuted by the record, which includes the blood test results following the accident, *see* GXs 13 & 14, the testimony of S.S. regarding Respondent's use of marijuana and cocaine, *see* Tr. 196, 198, as well as the evidence showing that while he was subject to the Florida Drug Court program, he tested positive for opiates, missed a drug test, and provided a diluted sample. *See* GX 18, 19, 20. Thus, there is substantial evidence that Respondent made multiple false statements to the Minnesota Board.

In his decision, the ALJ expressed the view ''that Respondent's misrepresentations to these boards calls into question whether the actions taken by these regulators would be the same had they been told the same things [Respondent] reported as true during this administrative process.'' R.D. at 48. Continuing, the ALJ explained that ''[t]he Government's identification of the nature of these misrepresentations accurately reflects the many ways in which the two state medical boards were acting with less than a complete and accurate record due to [Respondent's] duplicity.'' *Id.*

Respondent argues, however, that the Minnesota Board ''had complete information'' and that the Minnesota Board ''conducted [a] hearing[ ] were [sic] [he] was vigorously questioned about his explanation of events.'' [10] Exceptions at 14–15. Respondent argues that while he was granted a restricted license by the Minnesota Board, ''[a] review of those restrictions suggest that they were in response to improprieties with documenting medical visits or charting and drug use.'' *Id.* at 15. Respondent thus contends that ''[t]he fact that [he] was granted a conditional license does not indicate that he was dishonest in these meetings, it simply indicates that he communicated his improprieties to both boards and they were willing to give him a chance to prove his trustworthiness.'' *Id.*

The record thus clearly establishes that Respondent made multiple false statements in both his applications to the Minnesota Board and in his affidavit in support of his request for reconsideration. The record also clearly establishes that on October 20, 2011, Respondent appeared before the Board's ''Licensure Committee and discussed his use of controlled substances that had not been prescribed for him'' and that ''[t]he Committee decided to recommend that Applicant be granted licensure with conditions and restrictions based upon a report of chemical abuse and diversion of controlled substances for his own use.'' GX 39, at 4.

The evidence also includes the minutes of the Licensure Committee meeting. *See* GX 52. However, the minutes are marked as confidential, and in any event, do not offer any detail as to what representations Respondent made to the Board. *Id.* Moreover, there is no verbatim record of the proceeding and the Government did not call as a witness any person (other than Respondent) who either observed or participated in the proceeding and who could have testified as to the representations made by Respondent.[11] While the Government questioned Respondent about his appearance before the Committee and what it had asked him about, the Government did not ask Respondent whether he had made the same false statements and failed to disclose various facts to the Committee as he had in his prior submissions to the Board.[12] Tr. 153–54. The record of this proceeding thus does not establish whether Respondent made additional false statements when he appeared before the Minnesota Board's Licensure Committee.

Finally, Respondent takes exception to the ALJ's adverse credibility finding with respect to his testimony. He maintains, that ''given his limitations in memory, [he] has made every effort to be upfront and honest about his improprieties.'' Exceptions at 9. He argues that ''[o]rdinarily, it would be difficult to remember specific details of occurrences that occurred over six years ago'' and that he ''is not only impacted by the 'normal memory loss' from the passing of time, he experienced a severe brain injury.'' *Id.* at 10. Respondent points to the testimony of a neurologist who treated him after the accident that he suffered '''post-traumatic amnesia,' where he was in a state of confusion and not able to form new memory.'' *Id.* (quoting Tr. 510, 515). He further argues that he ''is trying to understand what happened to him'' and that ''[g]iven his prior experiences with law enforcement he does not necessarily trust law enforcement's explanation of this event'' and ''does not believe that all of his injuries were caused by the accident and he has never wavered from this belief.'' Exceptions at 10.

However, Respondent's neurologist testified only that the injury affected his ability ''to form new memory'' and that it only ''lasted maybe up to, even up to when he left the rehabilitation center.'' Tr. 510. Respondent's neurologist further explained that:

> [W]ith the extent of the injury he suffered, I would expect that he would have trouble recalling events even shortly after, and even a while after, because of his problem with what we call encoding. When someone says something to you, particularly when it comes through what we call short-term memory, there is a spot it goes [to] on your brain that allows you to retain it. In his case, he didn't have the ability to use that spot on his brain.

Id. at 515.

Still later, Respondent's neurologist testified that ''there's a condition'' that is ''very common in people with traumatic brain injury called confabulation.'' *Id.* at 518. He then explained that ''what happens is'' that a person ''pull[s] information from different parts of the brain in a disorganized manner, but the patient attempts to organize it in a way that makes sense to them, but to other people may not be factual.'' *Id.* at 519.

While this testimony may establish that Respondent had issues with his short-term memory, ultimately, it does not persuade me that Respondent's numerous false statements can be explained by his brain injury rather than his intent to deceive the Agency's Investigators, the ALJ, and this Office.

[10] While Respondent argues that both the Florida and Minnesota Boards ''had complete information'' and ''conducted hearings'' during which he ''was vigorously questioned about his explanation of events,'' because I do not find that there is substantial evidence to support the ALJ's finding with respect to the Florida Board, I address this argument only with respect to the Minnesota Board proceeding.

[11] According to a letter from the Board's Complaint Review Unit to the DI regarding a subpoena *duces tecum* which sought ''all records, memorandums, notes of Board Members, and audio or video recordings of [Respondent's] appearance'' before the Licensure Committee, ''Committee meetings are not audio or video-recorded.'' GX 52.

[12] During the colloquy, Respondent stated the Committee ''had a lot of questions,'' but when asked by the Government what the Committee had asked about, he initially answered ''I don't know'' before stating: ''I mean, they were asking me about incidences of the same [as] was described here and much of what was talking about, about the issues that happened in Florida. Etcetera. So forth.'' Tr. 153–54.

Respondent made the false statements to the DIs four years after the accident, and he made the false statements in this proceeding six years after the accident. At no point, however, did the neurologist offer testimony to support the conclusion that Respondent would still be suffering from memory loss and the inability to piece together accurate information years after the accident.

Moreover, even if Respondent's brain injury accounts for the disparity between his testimony and the testimony of the other witnesses (and the various exhibits) regarding the accident, the scope of both his and N.P.'s injuries, and the cause of his extensive injuries, these issues are of only tangential relevance in assessing whether granting his application would be ''consistent with the public interest.'' 21 U.S.C. 823(f). What is relevant is that Respondent materially falsified his application, made false statements to the Agency's Investigators who investigated the application, and gave false testimony in this proceeding.

For example, during the investigation, Respondent provided multiple accounts as to how many Adderall tablets he had taken before the crash, initially telling a DI that he took only one tablet the day before the crash (on July 19, 2012). Tr. 465. However, upon being confronted by the DI during a phone call (on August 25, 2012) that one pill would not provide a therapeutic level, Respondent then asserted that he might have taken two pills. *Id.* at 469. And yet during a subsequent phone conversation (on June 3, 2013) with another Investigator, he then claimed that he took ''between four and six dosage units[,] but more than likely it was five.'' *Id.* at 328.

Likewise, when asked during the July 19, 2012 interview why the police found the Adderall in his car, Respondent asserted that he had no knowledge as to why the drugs were in his car and asserted that the police had planted them. *Id.* at 461. Still later, in the January 4, 2013 interview, Respondent again claimed that ''[h]e did not know where the pill bottle came from,'' and while he admitted to having ''used Adderall on a few different occasions,'' he claimed that ''he obtained it from a colleague.'' *Id.* at 475.

Moreover, when asked at this interview about the Adderall prescription issued in the name of S.S., Respondent initially said that he had met with S.S. but did not document the prescription in S.S.'s medical record ''because it had already been discussed.'' *Id.* at 476–77. Later in the conversation, Respondent then claimed that because ''he had been in a coma'' he did not recall issuing the prescription, only to subsequently revert to his original story that he wrote the prescription but did not do an exam or chart the prescription because it ''was already in the prior record.'' *Id.* at 477.

In the July 19, 2012 interview, Respondent also denied having smoked marijuana, claiming that the blood test result was a false positive. *Id.* at 461–62. Also, during a November 2012 phone conversation, a DI asked Respondent if he had completed the Florida Drug Court Program. *Id.* at 471. Respondent initially ''said that he had completed the program and the charges were dropped.'' *Id.* at 472. However, when confronted by the DI that he had not completed the program, Respondent admitted that ''he withdrew from the program because it was taking too long.'' *Id.*

During the hearing, Respondent testified that the Adderall prescription he wrote (which listed S.S. as the patient but was actually issued to obtain the drugs for his own use) was a refill of a prescription S.S. usually got. R.D. at 28 (quoting Tr. 95). Moreover, while in his testimony Respondent admitted to using Adderall on three or four occasions during the period in which he was working at MD Now (an urgent care clinic), he claimed that he got the drug from a colleague at the clinic, who was a physician's assistant (PA). Tr. 114. He also later testified that ''took no more than four pills . . . when I worked at MD Now,'' and after asserting that this was four pills in total, he then testified that he never took more than one pill at a time.[13] *Id.* at 128. While Respondent testified that the PA's first name was William, he maintained that he did not remember William's last name. *Id.* at 114. Moreover, when asked if he had ever gotten Adderall from anyone other than William, Respondent answered: ''No. Except for when I was in residency.'' *Id.* at 116–17.

Regarding his marijuana use, Respondent admitted that he had used marijuana in college and ''on occasion on vacation.'' *Id.* at 129. When asked to explain the positive test for THC, Respondent claimed it was a false positive and asserted that he had not used marijuana in the period before the accident because he had worked ''twelve days . . . in a row'' and that there was ''no time'' to do so. *Id.* at 131. When then asked how many times he had used marijuana in 2008, Respondent testified that he could not remember, and when asked from whom he got his marijuana, answered: ''I have no idea.'' *Id.*[14]

Still later, when testifying on his own behalf, Respondent testified that while there are ''a lot of things that I'm very unproud of . . . I cannot remember diverting any medications with S.S. I cannot remember and I honestly cannot remember how the medication got into the car, got into my car, but I do admit completely to using Adderall without prescriptions.'' *Id.* at 590–91.

Contrary to his contention, the record amply establishes that Respondent ''has not made every effort to be upfront and honest about his improprieties.'' Exceptions at 9. I thus find Respondent's Exception is well taken only with respect to the ALJ's finding that ''[h]e provided similarly evasive and conflicting answers to questions presented to him by the'' Florida Medical Board, and only to the extent the ALJ's finding suggests that he gave ''evasive and conflicting answers to questions presented to him by the'' Minnesota's Boards Licensure Committee during his appearance before the Committee.[15]

Exception to Finding of Fact #14

In his Finding of Fact Number 14, the ALJ discussed Respondent's evidence of remediation. While the ALJ acknowledged that Respondent successfully completed one year of monitoring under the Minnesota Health Professionals Services Program, that he produced letters of support from patients and professional colleagues, and testified that he had changed his lifestyle, learned from his experiences,

[13] As found above, during interviews with DEA Investigators, Respondent provided three different answers when asked how many Adderall pills he took on the night he crashed his car.

[14] As for the drug test results during the Florida Drug Court matter, Respondent asserted that his positive test for opiates was caused by an antibiotic which ''cross react[s] with opiate derivatives.'' Tr. 135. The State Judge apparently did not agree, as he/she ordered Respondent to write a 500 word essay ''on honesty.'' GX 18. As for the diluted drug test, Respondent testified that because he ''didn't have a car'' and had to walk ''approximately six miles'' in ''Florida's hot sun,'' ''I might have drank too much water before I started on my journey.'' Tr. 136. As for the drug test he missed, Respondent testified that he ''forgot to call for one day and I missed that urine.'' *Id.* While this may be, the State Judge did not find this to be a persuasive excuse and sent him to jail for one day. GX 19.

[15] It is also acknowledged that Respondent asserted that he had a seizure the day before the hearing. To the extent Respondent's argument is that his numerous false statements during this proceeding should be excused because the seizure impacted his recollection of the various events, Exceptions at 23, I reject it as the evidence shows that his false testimony at the hearing was generally consistent with other false statements he made to the DIs, as well as on his Minnesota application and in the affidavit he submitted in support of his request for reconsideration. Notably, Respondent does not claim that he had seizures before his various interactions with the DIs and before he submitted his application and prepared his affidavit.

gotten married and had a daughter, the ALJ ultimately found that Respondent had not presented sufficient ''evidence of remediation to overcome the Government's *prima facie* case.'' R.D. at 62.

As for his reasoning, the ALJ explained that he ''question[ned] the weight that can be attributed to this evidence,'' noting that the monitoring program imposed by the Minnesota Board ''was based on Respondent's material misrepresentation of the nature of the injuries he and his passenger sustained in the June 2008 crash, and his failure to disclose the extent and nature of his history of drug abuse.'' *Id.* As support for his finding, the ALJ also explained that while the Florida Board ''ordered Respondent to participate in monitoring and a five-year period of probation, which Respondent failed to comply with, [he] surrender[ed] his medical license in that state in order to avoid these remedial requirements.'' *Id.*

With respect to the reasons given by ALJ as to why he gave less weight to the Minnesota Board's Order, Respondent argues that the Order ''specifically states that '. . . Respondent was licensed by the board pursuant to a Stipulation . . . based upon his unprofessional conduct, diversion of drugs for his own use, and disciplinary action taken against his license in another state or jurisdiction.' '' Exceptions at 16. As explained previously, while the record establishes that Respondent made false statements to the Minnesota Board and failed to disclose other information in both his application and the affidavit he submitted in support of his request for reconsideration, the record does not establish whether he made the same false statements, as well as withheld material information, when he appeared before the Licensure Committee to discuss his unprofessional conduct and diversion of drugs for his own use. Of note, while once the Government established its *prima facie* case, Respondent bore the burden of production on the issue of whether he had engaged in sufficient remedial measures, the Government retained the burden of proof throughout this proceeding. Thus, because there is no evidence in the record as to what statements Respondent made before the Licensure Committee, the ALJ's conclusion that Respondent's compliance with the Minnesota Board's Order is not entitled to weight cannot be sustained on the basis that he failed to fully and truthfully disclose the nature of his drug abuse and misconduct at the Licensure Committee hearing.[16]

Respondent also takes exception to the ALJ's finding that ''the record establishes that Respondent surrender[ed] his [Florida] medical license . . . in order to avoid the[ ] remedial requirements'' imposed by the Florida Board. Exceptions at 17. While I agree with Respondent that this finding is not supported by substantial evidence, ultimately this finding is of no consequence, because Respondent had the burden of production on the issue of whether he has undertaken sufficient remedial measures to demonstrate that he can be entrusted with a new registration. *See Medicine Shoppe Jonesborough*, 73 FR 364, 387 (2008) (quoting *Samuel S. Jackson*, 72 FR 23848, 23853 (2007)). The fact remains that less than three months after the Florida Board placed him on probation, Respondent withdrew from the practice of medicine in Florida and did not complete the probation ordered by the Board. Regardless of the reason he left the State, I agree with the ALJ that Respondent's interaction with the Florida Board does not support a finding that he has produced sufficient evidence of remediation to rebut the Government's *prima facie* case.

In Finding of Fact number 14, the ALJ did not rely on Respondent's failure to provide the DI with a release for his HPSP file as one of the reasons he discounted the weight to be given to his compliance with the HPSP. However, the ALJ did decline to consider the testimony of Respondent's case manager as to his ''progress in the HPSP'' because it was unclear whether the Government had ever been provided with a complete record of his treatment. R.D. at 24 (citing 21 CFR 1301.15[17]). Respondent takes exception to the ALJ's reasoning, arguing that while he ''did not provide a release . . . he did provide the necessary documents,'' and that other evidence in the record, namely the Minnesota Board's Order of Unconditional License (GX 40), establishes that he ''complied with the Minnesota Medical Board['s] conditions [as] well as the terms and conditions of the HPSP monitoring [p]lan.'' *Id.* at 17.

The Order of Unconditional License does constitute some evidence of Respondent's having undertaken remedial measures. It is also acknowledged that Respondent submitted into evidence various records regarding his treatment with the HPSP. While in his testimony Respondent maintained that he had provided the Agency with the entirety of his HPSP file, even if he had never made a misrepresentation to the Agency, the Investigators were under no obligation to take him at his word that he had provided the entire file to them given his history of abusing controlled substances. As for the records Respondent submitted into evidence, the DI's testimony supports a finding that this is not a complete set of records as it does not include the treatment notes for his first two visits with his psychologist. Tr. 481–82. Absent Respondent's consent to the disclosure of his complete HPSP file, there is no way to assess the adequacy of his remedial measures, as it is unclear what he disclosed to those who evaluated him and whether he disclosed the full extent of his substance abuse to those providers who created his treatment program.[18] I thus reject Respondent's exception to this factual finding.

[16] The Application (GX 34) states that the ''[f]ailure to answer all questions completely and accurately, omission or falsification of material facts . . . may be cause for denial of your application, or disciplinary action if you are subsequently licensed by the Board.'' GX 34, at 1. The Recommended Decision does not, however, cite any authority from Minnesota which discusses the materiality standard employed by the State.

[17] This regulation provides that:

> [t]he Administrator may require an applicant to submit such documents or written statements of fact relevant to the application as he/she deems necessary to determine whether the application should be granted. The failure of the applicant to provide such documents or statements within a reasonable time after being requested to do so shall be deemed to be a waiver by the applicant of an opportunity to present such documents or facts for consideration by the Administrator in granting or denying the application.

21 CFR 1301.15.

[18] While it may appear that this is inconsistent with the discussion of the Government's obligation to show that Respondent continued to make the same false statements and failed to disclose material information when he appeared before the Licensure Committee, the difference is that the Government may have had some means of developing evidence as to the statements he made and did not make when he appeared before the Committee. Indeed, the Government could have questioned Respondent on these issues. However, because the Government repeatedly asked Respondent to provide the complete file, as well as to sign a release so that the Government could obtain the information directly from the HPSP, I agree with the ALJ's ruling declining to consider the testimony of his HPSP case manager regarding his compliance with the HPSP program. R.D. 24–25 (citing 21 CFR 1301.15). Indeed, absent provision of the compete file, it is unclear how the Government could have effectively cross-examined his case manager.

Finally, Respondent provided copies of the releases he had given to the credentialing departments of various insurers, and a local hospital, allowing them to obtain limited information from the HPSP. *See* RXs I, J, K, and L. It is not clear what this proves, and in any event, given the Agency's responsibility to ensure that granting Respondent's application would be consistent with the public interest, 21 U.S.C. 823(f), the Agency was entitled to his complete file.

Exception to the ALJ's Conclusion of Law #2

The ALJ found that the record establishes that Respondent materially falsified his application for a DEA registration because he denied that his medical license had been suspended or restricted and knew this to be a false answer. R.D. at 63. Respondent takes exception to this finding, asserting that he ''did not intent [sic] to provide a false response'' and ''that any false information was due to the fact that he did not read the question correctly.'' Exceptions at 19. Continuing, Respondent argues that ''[i]t would be stupid of [him] to lie about public information and he is not a stupid person.'' *Id.*

The evidence shows that on March 7, 2012, Respondent submitted an application for a DEA registration on which he was required to answer four questions with either a ''yes'' or ''no.'' GX 2, at 1. Question Three asked: ''Has the applicant ever surrendered (for cause) or had a state professional license or controlled substance registration revoked, suspended, denied, restricted or placed on probation, or is any such action pending?'' GX 2, at 3. Respondent answered ''N'' for no, notwithstanding that: (1) On January 26, 2009, the Florida Department of Health had ordered the emergency suspension of his medical license, GX 26, at 10–11; (2) on June 22, 2009, the Florida Board of Medicine had ordered that Respondent's medical license ''be SUSPENDED until such time as he personally appear[ed] before the Board and demonstrate[d] the ability to practice medicine with appropriate skill and safety,'' GX 29, at 1–3; (3) on December 17, 2010, the Florida Board of Medicine granted his petition for reinstatement while placing him on probation for five years, GX 30, at 2–9; and (4) on November 12, 2011, the Minnesota Board of Medicine had grant him a medical license subject to various restrictions and conditions. GX 39. Thus, the evidence clearly shows that Respondent's answer was false.

At the hearing, Respondent did not testify regarding the circumstances surrounding his completion of the application. However, a DI testified that during an interview, Respondent asserted that ''he didn't read the question thoroughly'' and that when she provided a copy of an application to him, ''[h]e went through it and underlined the first word, surrender, and stopped.'' Tr. 463. After the DI underlined the rest of the application, she asked Respondent if when he sat for his Boards, he ''just gloss[ed] over the questions or . . . read them thoroughly in order to answer them?'' *Id.* at 464. Respondent ''said that he didn't gloss over'' the questions. *Id.*

I reject Respondent's contention that he did not intentionally mislead the Agency. Notably, the question is neither lengthy nor ambiguous, and thus, I do not believe his contention that he did not thoroughly read the question. Indeed, even if he had glossed over the question, it is not credible that he did not note that the question asked about other types of state board disciplinary actions, and certainly Respondent was no stranger to state board disciplinary actions.[19] Moreover, as demonstrated by his experience with his Minnesota application, Respondent was obviously aware that providing a truthful answer to question three would likely trigger the Agency's scrutiny into why both Boards imposed sanctions on his licenses and lead to the discovery that he was a drug abuser. Accordingly, I agree with the ALJ's finding that Respondent intentionally and materially falsified his application. This conclusion provides reason alone to deny his application. *See* 21 U.S.C. 824(a)(1); *see also Pamela Monterosso*, 73 FR 11146, 11148 (2008) (holding that ''the various grounds for revocation or suspension of an existing registration that Congress enumerated in section 304(a), 21 U.S.C. 824(a), are also properly considered in deciding whether to grant or deny an application under section 303'') (citations omitted); *Jackson*, 72 FR 23848, 23852 (2007).

Exception to the ALJ's Conclusion of Law #5

In this legal conclusion, the ALJ addressed the application of factor one under the public interest analysis, specifically—''[t]he recommendation of the appropriate State licensing board or professional disciplinary authority.'' 21 U.S.C. 823(f)(1); *see also* R.D. at 46. The ALJ correctly noted that neither the Florida nor Minnesota Board has made a recommendation in this matter (whether to support or oppose Respondent's application), and that Agency precedent holds that even where an applicant possesses the requisite state authority, *see* 21 U.S.C. 802(21), ''the Administrator 'possesses a separate oversight responsibility with respect to the handling of controlled substances' and therefore must make an 'independent determination as to whether the granting of an application would be in the public interest.' '' R.D. at 46–47 (quoting *Mortimer B. Levin*, 55 FR 8209 (1990)). While this should have been the end of his discussion, with the conclusion that the factor neither supported nor refuted a finding that granting his application is consistent with the public interest, the ALJ found that ''the actions of state medical regulators in'' both States ''establish a basis for finding that [Respondent's] application should be denied.'' R.D. at 46. The ALJ then explained:

> My concern with respect to evidence relating to the licensure actions taken by the medical boards in Florida and Minnesota rests not so much with their ultimate decisions, but with the process that led to those decisions being made. The Government is correct, in my view, in proposing that Respondent's misrepresentations to these boards call into question whether the actions taken by these regulators would be the same had they been told the same things [Respondent] reported as true during this administrative process.
>
> The Government's identification of the nature of these misrepresentations accurately reflects the many ways in which the two state medical boards were acting with less than a complete and accurate record due to [Respondent's] duplicity. Those misrepresentations regarding [his] ability to recall what happened immediately preceding the June 2008 crash, his description of his history of abusing marijuana and Adderall, and his description of the nature of his injuries and those of his passenger, all threaten the integrity of the administrative process by which the Florida and Minnesota boards performed their assessments of [Respondent's] fitness to practice medicine in those states. Accordingly, nothing in our

[19] In his Exceptions, Respondent does not dispute whether his false statement was material. It clearly was because the various board orders were imposed based on Respondent's abuse of controlled substances and his unlawful obtaining of controlled substances, and under the public interest standard, the Agency is directed to consider an applicant's compliance with applicable laws related to controlled substances and such other conduct which may threaten public health and safety. 21 U.S.C. 823(f)(4)–(5). Also, the Agency has long held that a practitioner's self-abuse of a controlled substance constitutes actionable misconduct under factor five. *See Tony Bui,* 75 FR 49979, 49989 (2010) (citing cases).

While in his decision, the ALJ correctly noted that ''a false statement is material if it has a natural tendency to influence or was capable of influencing the decision making body to which it is addressed,'' R.D. at 55 (citation omitted), he then explained that '' '[a]nswers to the liability question[s] are always material because DEA relies on the answers to these questions to determine whether it is necessary to conduct an investigation prior to granting an application.' '' *Id.* (quoting Gov. Br. at 29–30 (quoting *Theodore Neujahr,* 65 FR 5680, 5681 (2000))). The latter statement, however, is incorrect. *See Kungys* v. *United States*, 485 U.S. 759, 771 (1988) (''It has never been the test of materiality that the misrepresentation or concealment would more likely than not have produced an erroneous decision, or even that it would more likely than not have triggered an investigation.'') (quoted in *Hoi Y. Kam*, 78 FR 62694, 62696 (2013)). Instead, the test is ''whether the misrepresentation or concealment was predictably capable of affecting, *i.e.*, had a natural tendency to affect, the official decision.' '' *Id.* '' '[T]he ultimate finding of materiality turns on an interpretation of substantive law.' '' *Id.* at 772 (int. quotations and citations omitted).

record supports a finding that the elements of Factor One warrant a conclusion that granting Respondent's application would be consistent with the public interest.

R.D. at 48-49.[20]

Respondent takes exception to the ALJ's conclusion, noting that ''where there is no specific recommendation from the state licensing board for or against an applicant's request for a . . . registration, the factor may not be considered [to] support the denial of'' an application. Exceptions at 20. He then argues that ''the appropriate state licensing board is the Minnesota Medical Board, which has not provided a specific recommendation for or against [Respondent's] request for a DEA registration.'' *Id.*

I agree with Respondent that the appropriate board is Minnesota, because it is the State where Respondent now seeks registration. With respect to the action of the Minnesota Board, I agree that the evidence shows that Respondent made multiple false statements to the Minnesota Board in both his application and his affidavit in support of his request for reconsideration. I also appreciate the ALJ's concern that his misrepresentations ''threaten the integrity of the [State Board's] administrative process.'' I nonetheless respectfully disagree with the ALJ's analysis because it is not supported by the evidence and takes the Agency far beyond the appropriate scope of this factor.

As explained above, the record does not establish whether Respondent continued to make the same false statements before the Licensure Committee as he did in his application and affidavit. However, even if Respondent made the same false statements to the Committee, the ALJ's analysis simply assumes—without any evidence—that the Board would have come to a different result. Notably, it is not even clear why Respondent's misrepresentations regarding [his] ability to recall what happened immediately preceding the June 2008 crash and his description of the nature of his injuries and those of his passenger would have been material to the Board's decision. I therefore conclude that factor one neither supports nor refutes the conclusion that granting Respondent's application would be ''inconsistent with the public interest.'' [21] 21 U.S.C. 823(f).

Exception to Conclusion of Law #6

In this legal conclusion, the ALJ summarized his conclusions regarding the evidence relevant to factor two—Respondent's experience in dispensing controlled substances. Specifically, the ALJ explained that:

> [w]hile there is some evidence that through the course of his education, training, and employment Respondent has acquired sufficient experience to appropriately fulfill those responsibilities attendant to persons authorized to prescribe controlled substances, the preponderant evidence of Respondent's experience in procuring controlled substances creates material questions regarding the benefit Respondent obtained from his positive experiences, where those experiences should have instilled in Respondent a greater sense of responsibility when procuring and using highly addictive controlled substances. If granted the authority to prescribe often-diverted controlled substances, Respondent's experience . . . would, in the event of relapse constitute a threat to the public interest, particularly where Respondent continues to deny having drug abuse problems notwithstanding a history of abuse. While this risk is attenuated during Respondent's sustained period of stable recovery, it is sufficiently present here, given the absence of any on-going monitoring or treatment, to warrant a finding that granting this application is consistent with the public interest.

R.D. at 64.

Respondent takes exception to the ALJ's conclusion contending that the ALJ ''minimize[d] [his] experience and training in dispensing controlled substances and assert[ed] that [he] 'entered the world of drug dealers, using his association with Patient S.S. to acquire cocaine and marijuana on a regular basis.' '' Exceptions at 21 (quoting R.D. at 51). Respondent argues that ''many medical doctors apply for and are granted a DEA . . . Registration while in the last stages of medical residency of [sic] immediately following the completion of their medical residency program'' and ''have less experience that [his] experience at MD Now [but] that experience is not used against them.'' *Id.*

It is true that the ALJ engaged in a lengthy discussion of Respondent's medical career and his experience in prescribing controlled substances therein. For example, the ALJ found that ''[a]fter successfully completing his residency, [Respondent] continued to gain experience in a clinical practice in fields not generally associated with dispensing controlled substances'' and then listed various activities Respondent engaged in in Liberia which do not appear to have involved clinical practice, let alone the dispensing of controlled substances. R.D. at 50. The ALJ then noted that Respondent's ''most significant post-graduate prescribing experience . . . is that which he obtained while working at MD Now [an urgent care clinic] for seven months and while serving in his family medicine residency at the University of Miami from 2004 to 2007.'' *Id.* at 51. The ALJ explained that ''while this experience includes training in critical care and emergency medicine (both of which may emphasize the use of controlled substances), the residency reflects a curriculum that was not concentrated in a practice requiring dispensing of controlled substances, including emphases in infectious diseases, pediatrics, 'wards' medicine, and women's health.'' *Id.* The ALJ thus opined that ''while [Respondent's] experiences as an independent contractor at MD Now and parts of his residence [sic] do suggest experience in dispensing controlled substances, the overall arc of his practice has not been one that would support a finding that his experience in dispensing controlled substances is substantial.'' *Id.*

To be sure, the word ''experience'' connotes that the Agency is authorized to conduct an inquiry into the adequacy of a practitioner's training in prescribing controlled substances as well as his/her ''direct observation of or participation in'' prescribing controlled substances. *See JM Pharmacy Group, d/b/a Farmacia Nueva and Best Pharma Corp.*, 80 FR 28667, 28667 n.2 (2015). However, under 21 U.S.C. 823(f), DEA is directed to register an applicant to dispense controlled substances ''if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he[/she] practices.'' Thus, with the exception of those instances in which a practitioner has been shown to have committed violations of the CSA (and in which a practitioner must produce evidence of the remedial measures he/she has undertaken to rebut the Government's *prima facie* case), in making the public interest determination, DEA does not

[20] There is, of course, a difference between stating that ''the actions of state medical regulators . . . establish a basis for finding that [Respondent's] application should be denied,'' R.D. at 46, and that ''nothing in our record supports a finding [under Factor One] . . . that granting Respondent's application would be consistent with the public interest.'' *Id.* at 49. While the latter statement suggests that he gave no weight to factor one either way, in his conclusion of law, the ALJ explained that ''the circumstances attendant to the action of these boards constitute evidence tending to establish that Respondent's DEA registration would be inconsistent with the public interest under Factor One.'' *Id.* at 63–64.

[21] As for the concerns expressed by both the Government and the ALJ that Respondent made false statements in obtaining his medical licenses which threaten the integrity of the state administrative process, nothing prevents the Government from providing the evidence it obtained in the course of this investigation and proceeding to the respective state boards.

look beyond the State's determination that the practitioner possesses adequate training to prescribe controlled substances.[22]

Here, however, Respondent's experience as a dispenser of controlled substances includes not only the fraudulent June 11, 2008 Adderall prescription listing S.S. as the patient, but also the unlawful prescriptions he issued to S.S. on June 4, 2008 for Percocet (oxycodone) and Xanax (alprazolam), which the ALJ found were ''issued outside the usual course of professional practice and for other than a legitimate medical purpose.'' R.D. at 58–59. Moreover, the evidence shows that Respondent induced S.S. to fill the Adderall prescription as ''a favor'' for his having provided S.S. with the Percocet and Xanax prescriptions. Tr. 207—210–11.

As explained above, the ALJ found that Respondent ''us[ed] his experience and his association with Patient S.S. to acquire cocaine and marijuana on a regular basis.'' R.D. at 51. There is, however, no evidence that Respondent used his registration to trade controlled substance prescriptions for street drugs, and as the Agency has previously explained, ''factor two does not call for an inquiry into a practitioner's life experience generally or even his experience related in any manner to controlled substances, but rather, only his ''experience in dispensing . . . controlled substances.'' *Abbas E. Sina*, 80 FR 53191, 53199 (2015). Nonetheless, the evidence does show that Respondent used his prescription writing authority to induce S.S. to fill the fraudulent Adderall prescription for him. This conduct is relevant in assessing Respondent's experience as a dispenser of controlled substances.[23]

Exception to Conclusion of Law #9

In this conclusion, the ALJ discussed the evidence relevant to factor five—''such other conduct which may threaten public health and safety.'' R.D. at 65; *see also* 21 U.S.C. 823(f)(5). Specifically, the ALJ found that the record establishes:

> that Respondent refused without good cause shown to execute releases granting the DEA access to monitoring reports in Minnesota and Florida; provided misleading accounts of the circumstances surrounding the June 13, 2008 motor vehicle crash in reports tendered to medical boards in Florida and Minnesota and in his accounts of the same to DEA investigators; and provided inconsistent and misleading accounts of his history of drug use to the DEA and to medical boards in Florida and Minnesota.

R.D. at 65–66. For these reasons, the ALJ found that this factor supports the conclusion that granting Respondent's application ''would be inconsistent with the public interest.'' R.D. at 66.

Respondent takes exception to the ALJ's conclusion. According to Respondent, the ALJ's conclusion ''rest [sic] on the testimony of [the DI] and N.P. and ignores the testimony of [Respondent], the undisputed testimony of Dr. Nedd [the neurologist who treated him after the crash] and the fact that . . . the incident which occurred in 2008 occurred over 6 years ago.'' Exceptions at 22–23. Respondent argues that he stipulated to many of the facts outlined in the Government's Pre-Hearing Statements and that at the hearing, he did not dispute paragraphs two through six of the Order to Show Cause. *Id.* at 23. He further argues that he did not mean ''to be evasive,'' but ''simpl[y] . . . cannot remember the details'' of the accident because he ''suffers from post-traumatic amnesia'' and was ''under stress during the weeks prior to the hearing and had to try to gather pieces about a very traumatic incident he does not remember.'' *Id.* Finally, he argues that he had a seizure the day before the hearing and that ''[d]uring the hearing [he] was post-ictal and his emotional defenses and skills'' were compromised. *Id.*

For the reasons explained in my discussion of Respondent's exceptions to the ALJ's factual findings numbers 12 and 13, I reject Respondent's exception to the ALJ's conclusions of law with respect to factor five.[24] Moreover, with respect to factor five, I further find that Respondent made material false statements in this proceeding. These included: (1) When he testified that the Adderall prescription he wrote for S.S. was a refill of a prescription S.S. usually got and that while he had used Adderall, he obtained it from a physician's assistant at the clinic but could not remember the PA's last name; (2) when he testified that he could not ''remember diverting medications with SS'' and could not ''remember how the [Adderall] got into his car,'' (3) when he denied having used marijuana even though he tested positive for the drug following the accident and then asserted that he had ''no idea'' from whom he obtained the marijuana; (4) as well as in his testimony regarding why he tested positive for opiates and provided a diluted sample while subject to the Florida Drug Court program.

Accordingly, I reject Respondent's Exception to factor five and conclude that this factor supports the conclusion that granting Respondent's application would be ''inconsistent with the public interest.'' 21 U.S.C. 823(f)(5); *Hoxie* v. *DEA*, 419 F.3d 477, 483 (6th Cir. 2005); *John* v. *Scalera*, 78 FR 12092, 12100 & n.21 (2013); *Robert F. Hunt*, 75 FR 49995, 5004 (2010); *Rose Mary Jacinta Lewis*, 72 FR 4035, 4042 (2007).

Exception to Conclusion of Law #13

Finally, Respondent takes exception to the ALJ's legal conclusion that he has failed to produce sufficient evidence to rebut the Government's *prima facie* showing that granting his application would be inconsistent with the public interest. In this conclusion, the ALJ found that:

> The record . . . establishes that Respondent has failed to timely provide the DEA with reports of his treatment or monitoring from the Florida Medical Board and PRN and from the Minnesota Board of Medical Practice and HPSP; failed to acknowledge the need to provide forthright, accurate, and complete responses to questions presented regarding his prescription practice and his history of drug

[22] While under 21 CFR 1301.18 an applicant, who seeks to conduct research with respect to a schedule I controlled substance, must submit a research protocol which contains his/her ''[q]ualifications, including a curriculum vitae and an appropriate . . .list of publications,'' the CSA requires that the application ''be referred to the Secretary, who shall determine the qualifications and competency of each practitioner requesting registration, as well as the merits of the research protocol.'' 21 U.S.C. 823(f). *Cf. id.* § 823(g)(1)(A) (''The Attorney General shall register an applicant to dispense narcotic drugs to individuals for maintenance treatment or detoxification treatment . . . if the application is a practitioner who is determined by the Secretary to be qualified (under standards established by the Secretary) to engage in the treatment with respect to which registration is sought[.]''); *id* § 823(g)(2)(B)(i) & (G)(ii)(VII) (authorizing the Secretary to promulgate by regulation criteria for determining that a ''physician has such other training or experience as the Secretary considers to demonstrate the ability of the physician to treat and manage opiate dependent patients'' by prescribing schedule III through V drugs approved for maintenance or detoxification treatment).

[23] Respondent also takes exception to the ALJ's discussion that Respondent continues to deny that he has a drug abuse problem and presents a risk of relapse ''given the absence of any on-going monitoring or treatment, to warrant a finding that [his] experiences in dispensing controlled substances contradicts a finding that granting this application is consistent with the public interest.'' R.D. at 64. I conclude, however, that the issue of whether Respondent presents an unacceptable risk of relapse does not involve his experience in dispensing, but rather, whether he has produced sufficient evidence to rebut the Government's *prima facie* case. Accordingly, Respondent's arguments are addressed in that discussion.

[24] However, for reasons explained previously, I do not adopt the ALJ's conclusion to the extent it states that Respondent provided misleading accounts of the accident and his history of drug use to the Florida Board. Nor do I adopt the ALJ's conclusion to the extent it suggests that Respondent providing misleading statements when he appeared before the Minnesota Board's licensure committee.

abuse; and failed to account for his false statement in making this application[.]

R.D. at 66.

Moreover, earlier in his discussion of Respondent's evidence of remediation, the ALJ explained that:

[t]he most probative evidence of [Respondent's] efforts to address any drug abuse problems he may have had would have come from the reports by monitors in the Florida PRN program and Minnesota's HPSP program. Even as he insists he has and had no drug abuse problem, the evidence of drug abuse associated with the 2008 crash, his abuse of marijuana and cocaine prior to the crash, and his adamant determination to deflect and minimize the adverse impact of his drug use are all both abundant and troubling. [Respondent] has thwarted a complete review of the steps he has taken (or has failed to take) by refusing [the DI's] request for releases that would allow the DEA to see the PRN and HPSP reports. We have what appears to be only part of the report maintained by HPSP, and none of the report by PRN. In the absence of such evidence, I cannot find Respondent has established by at least preponderant evidence that he has accepted responsibility for his wrong-doing and has put in place effective corrective measures that would guard against future misconduct.

R.D. at 57–58.

Respondent nonetheless contends that at the hearing, he ''took full responsibility for his drug use and diversion of controlled substances.'' Exceptions at 25. He also argues that he acknowledged his use of marijuana and his diversion of Adderall in his first meeting with the DIs, and that Minnesota Board's decision to grant him a conditional license ''is evidence of his acknowledgment of his past drug use and diversion of prescription drugs,'' because the Board noted that it ''discussed [with him] his use of controlled substances that had not been prescribed to him.'' *Id.* at 24–25.

I reject Respondent's contention. His assertion that he acknowledged his use of marijuana at his first meeting with the DI is counterfactual, as Respondent asserted that his positive drug test following the accident ''was a false positive'' and that ''he had not used marijuana in a long time.'' Tr. 462. Moreover, while at the hearing, Respondent admitted to facts which establish that the prescriptions he issued to S.S. for Percocet and Xanax were outside of the usual course of professional practice and which lacked a legitimate medical purpose (*see* R.D. at 5–7; Tr. 610–11), he continued to deny that he wrote the Adderall prescription in S.S.'s name for the purpose of obtaining the drugs for his own use and that S.S. had given him the filled prescription.[25] Tr. 612. Moreover, Respondent failed to acknowledge his misconduct in intentionally and materially falsifying his application for his DEA registration. Also, he failed to acknowledge that he made various false statements to the Agency's Investigators.

Accordingly, I reject Respondent's contention that he accepted responsibility for the full extent of the misconduct which has been proven on this record. *See MacKay* v. *DEA*, 664 F.3d 808, 820 (10th Cir. 2011) (''The DEA may properly consider whether a physician admits fault in determining if the physician's registration should be revoked. When faced with evidence that a doctor has a history of distributing controlled substances unlawfully, it is reasonable for the Deputy Administrator to consider whether that doctor will change his . . . behavior in the future. And that consideration is vital to whether continued registration is in the public interest.'') (citing *Hoxie* v. *DEA*, 419 F.3d 477, 483 (6th Cir. 2005)).

This is reason alone to conclude that Respondent has not rebutted the Government's *prima facie* showing that granting his application ''would be inconsistent with the public interest.'' 21 U.S.C. 823(f). Respondent nonetheless argues that he has put on ''uncontested evidence of his efforts to rehabilitate his career.'' Exceptions at 25. He argues that he ''participated in all the required programs[,] treatment plan and drug testing,'' and that he has ''met fully every condition and gained the trust of the Minnesota Medical Board, his employer, his peers, and his patients.'' *Id.* Respondent further argues that ''[t]he fulfillment of these conditions cannot simple [sic] be ignored because [he] did not sign a release for [the DI] to access HPSP directly'' and that he ''provided her with 82 pages of documentation which included the quarterly reports, results of toxicology test [sic], his case manager's notes.'' *Id.* at 26–27. He also argues that ''[t]here is no justification for not considering the Minnesota Board's Order'' and that ''[t]he argument that [he] did not disclose the extent of his drug use and diversion of controlled substances to the Minnesota Medical Board is not supported by either'' the Board's Order granting him a conditional license or the Order which granted him an unconditional license. *Id.* at 27.

The ALJ did, however, consider the Board's Order as evidence in remediation. *See* R.D. at 62 (FoF #14) (''Evidence of remediation in this record takes the form of Respondent's successful completion of a one-year period of monitoring under the auspices of the Minnesota Health Professional Services Program.''). He just found it insufficient to satisfy Respondent's burden of production on the issue of the adequacy of his remedial measures.

As for Respondent's further contention that ''[t]he fulfillment of these conditions cannot simple [sic] be ignored because [he] did not sign a release for [the DI] to access HPSP directly'' and that he ''provided her with 82 pages of documentation which included the quarterly reports, results of toxicology test [sic], his case manager's notes,'' *id.* at 26–27, where, as here, the evidence shows that Respondent has a history of abusing controlled substances, the Agency is not required to take him at his word that he provided his complete HPSP file. Here, while Respondent submitted various documents related to his participation in the HPSP program, there is ample reason to believe that these records are incomplete as they do not appear to include the initial evaluation conducted by Dr. Albert (his psychologist),[26] and thus, it remains unclear what he disclosed to the psychologist regarding his history of substance abuse. Accordingly, I agree with the ALJ's conclusion that Respondent has not produced sufficient evidence of his remedial measures to rebut the Government's *prima facie* case.[27]

[25] As for his contention that the Minnesota Board's decision to grant him a conditional license ''is evidence of his acknowledgement of his past drug use and diversion of prescription drugs,'' while Respondent may have admitted to some misconduct in that proceeding, it is unclear exactly what he admitted to in that proceeding. Also, under Agency precedent, Respondent is required to acknowledge his misconduct with respect to the full extent of the misconduct proved on the record of this proceeding. *See Robert L. Dougherty*, 76 FR 16823, 16834 (2011); *Jeffrey Patrick Gunderson*, 61 FR 26208, 26211 (1996); *Prince George Daniels*, 60 FR 62884, 62887 (1995).

[26] The DI testified that upon receiving a file from Dr. Hasper, it contained notes for Respondent's ''first two visits'' with Dr. Albert, but these notes were not included in the HPSP records that Respondent provided to her. Tr. 481, 497. Notwithstanding that Respondent had the burden of production on the issue of the adequacy of his remedial measures, he did not submit these documents for the record. *See generally* Resp. Exhibits. Moreover, although the Government was eventually provided with these notes, the fact remains that because Respondent would not agree to release his HPSP file and did not submit these documents, it remains unclear whether he fully disclosed his history of substance abuse to his treating professionals.

[27] As previously noted, in his legal conclusions pertaining to factor two, the ALJ explained that if Respondent was ''granted the authority to prescribe often-diverted controlled substances, [his] experience as demonstrated in this record would, in the event of relapse, constitute a threat to the public interest, particularly where Respondent continues to deny having drug abuse problems

Summary

The Government has made out a *prima facie* case to deny Respondent's application based on his material falsification of his DEA application, his diversion of controlled substances to both S.S. and himself, his substance abuse, and the numerous false statements he made to DEA Investigators and in this proceeding. Notably, at most, Respondent has acknowledged his misconduct only with respect to the Percocet and Xanax prescriptions he issued to S.S. While Respondent's failure to acknowledge his misconduct in materially falsifying his application, the circumstances surrounding his issuance of the Adderall prescription, and his false statements to the Investigators, provides reason alone to conclude that he has not rebutted the Government's case, he also failed to produce sufficient evidence in remediation. Because I conclude that Respondent's misconduct is both extensive and egregious, I agree with the ALJ that granting his application ''would be inconsistent with the public interest.'' 21 U.S.C. 823(f). Accordingly, I will adopt the ALJ's recommended order and deny his application.

notwithstanding a history of abuse.'' R.D. at 64. The ALJ then explained that ''[w]hile this risk is attenuated during [his] sustained period of stable recovery, it is sufficiently present here, given the absence of any on-going monitoring or treatment, to warrant a finding that [his] experience in dispensing controlled substances contradicts a finding that granting this application is consistent with the public interest.'' *Id.*

Respondent argues that ''there is nothing in the record which shows [that he] has a risk of relapse.'' Exceptions at 21. He argues that ''[h]e was not diagnosed with a drug problem,'' but ''with authority conflicts'' and that he ''fully shared his history of drug uses with Dr. Albert'' and ''completed his treatment plan.'' *Id.* He then argues that if the Board ''believed that he had a risk of relapse they never would have removed the conditions on his medical license'' and that the Government ''did not provide any evidence, testimonial or otherwise, by any professional, serving those with a history of drug abuse, to contradict'' the conclusions of Dr. Albert and the Board. *Id.* at 22.

I agree that there is no evidence establishing what Respondent's risk of relapse is. I conclude, however, that because Respondent would not provide the Government with a release allowing it to obtain his HPSP file directly from the program so that it could verify whether he actually ''fully shared his history of drug use'' with his treating professional, his evidence as to his rehabilitation is insufficient.

Of further note, as found above, Respondent also unlawfully distributed Percocet (oxycodone) and Xanax (alprazolam) to S.S. *See* 21 U.S.C. 841(a)(1); 21 CFR 1306.04(a). While Respondent admitted to the facts which establish the violation, he has failed to produce any evidence of remedial training he had undertaken in the proper prescribing of controlled substances. Thus, Respondent has failed to produce sufficient evidence of remedial measures with respect to these violations.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 28 CFR 0.100(b), I order that the application of Mark William Andrew Holder, M.D., for a DEA Certificate of Registration be, and it hereby is, denied. This Order is effective immediately.

Dated: November 5, 2015.

Chuck Rosenberg,

Acting Administrator.

Krista Tongring, Esq., for the Government.
Yende Anderson, Esq., for the Respondent.

Recommended Rulings, Findings of Fact, Conclusions of Law, and Decision of the Administrative Law Judge

Nature of the Proceeding

Christopher B. McNeil, Administrative Law Judge. These are proceedings before the Drug Enforcement Administration and the United States Department of Justice, under DEA docket number 2014–13, captioned ''In the Matter of Mark William Andrew Holder, M.D.'' The proceedings are being held pursuant to sections 303 and 304 of the Controlled Substances Act, Title 21 United States Code sections 823 and 824.

On March 7, 2012, Respondent Mark W.A. Holder, M.D., applied for a DEA Certificate of Registration as a practitioner in Controlled Substance Schedules 2, 2N, 3, 3N, 4 and 5, identifying the business location as 2810 Nicollet Avenue South, Minneapolis, Minnesota 55408–3160.[1] After reviewing this application the Drug Enforcement Administrator through her Deputy Assistant Administrator issued an order dated April 11, 2014 extending to Dr. Holder the opportunity to show cause why the Administrator should not deny this application.[2] In the order, the Administrator alleged that Dr. Holder's registration would be inconsistent with the public interest and thus should be denied pursuant to 21 U.S.C. 823(f); and further alleged that Dr. Holder materially falsified a DEA registration application, warranting the denial of the application pursuant to 21 U.S.C. 824(a)(1) and 824(a)(4).[3]

On May 8, 2014, the Office of Administrative Law Judges for the DEA received Respondent's May 6, 2014 request for a hearing to permit him the opportunity to establish why his application should not be denied. The parties presented evidence during a hearing conducted at the DEA Hearing Facility in Arlington, Virginia, on August 4 and 5, 2014.

Summary of the Evidence

Prior to the hearing, the parties entered into stipulations,[4] which will be presented here, along with summaries of testimony taken during two days of hearings conducted in Arlington, Virginia.

In articulating the bases upon which the Administrator proposed to deny Dr. Holder's application for a Certificate of Registration, the Deputy Assistant Administrator identified the following:

(1) The Government alleged improprieties with respect to Dr. Holder's prescription practice as it concerned Patient S.S. on June 4, 2008.[5] The Government alleged Dr. Holder prescribed Percocet and Xanax for this patient under conditions that were outside the usual course of professional practice and for other than a legitimate medical purpose.[6] The Government specifically alleged that Dr. Holder failed to document a complete medical history and physical exam prior to prescribing controlled substances to the patient, failed to determine the nature and intensity of the pain attributed to the patient, failed to determine the patient's true medication history, and failed to provide a legitimate diagnosis to support prescribing controlled substances to this patient, during an office visit on June 4, 2008.[7] The Administrator further alleged that on June 11, 2008, Dr. Holder issued a handwritten prescription to Patient S.S. for Adderall, a Schedule II controlled substance, without creating any written record of diagnosis or treatment for the prescription.[8]

(2) With respect to the prescription for Adderall dated June 11, 2008, the Administrator also alleged that Dr. Holder wrote this prescription in order to illegally obtain the medication for his own use; and that after taking control of the medication, Dr. Holder engaged in behavior resulting in a single-vehicle crash on June 13, 2008 that seriously injured Dr. Holder and his passenger, N.P., while Dr. Holder was under the influence of THC and amphetamines.[9]

(3) The Administrator further alleged that consequent to the crash involving Dr. Holder and his passenger, the Florida Department of Health indefinitely suspended Dr. Holder's

[1] Gov't Ex. Two at 1.
[2] A.L.J. Ex. One at 1.
[3] *Id.*
[4] A.L.J. Ex. 31.
[5] A.L.J. Ex. One at 1.
[6] *Id.* at 1–2 .
[7] *Id.*
[8] *Id.* at 2.
[9] *Id.*

license to practice medicine in that State, and the Minnesota Board of Medical Practice initially recommended the denial of his application to practice in that State, thereafter granting him a restricted, conditional license to practice medicine in Minnesota.[10] The Administrator alleged that despite his history of proceedings before the boards regulating the practice of medicine in Florida and Minnesota, when asked in his DEA application whether he ever had a state professional license suspended, denied, or restricted, Dr. Holder falsely answered in the negative.[11]

(4) The Administrator alleged that in the course of the investigation into whether Dr. Holder's application should be granted, Dr. Holder engaged in evasive conduct, evinced a lack of candor when responding to investigators, has given inconsistent or evasive reports of his past drug use, has refused requests from the DEA investigators seeking records demonstrating compliance with drug treatment programs in Florida and Minnesota, and has tested positive for prohibited controlled substances during periods of court supervision subsequent to the June 13, 2008 motor vehicle crash.[12]

Background

Dr. Holder attended the University of Minnesota and Morehouse School of Medicine, completing his residency from 2004 to 2007 at Jackson Memorial Hospital in Miami, Florida, with a specialty in family medicine.[13] During his residency, he was trained in critical care, emergency medicine, infectious disease, pediatrics, wards medicine, and women's health.[14] Shortly after completing that residency program, Dr. Holder accepted employment as an independent contractor at an urgent care facility called MD Now, which has locations throughout southern Florida.[15] Respondent previously held DEA Certificate of Registration BH9956232, issued on November 21, 2007, with a registered address of 221 164th Street, NE., Suite 329, North Miami Beach, Florida.[16] This registration expired by its own terms on October 31, 2009.[17]

In addition to his experience as an urgent care medical doctor, Dr. Holder has evaluated the Cuban health care system to formulate a *Student National Medical Association* article promoting preventative medicine, and has conducted HIV prevention research and initiated recommended therapy in Accra and Ada, Ghana.[18]

When describing why he wanted to go to medical school, Dr. Holder stated: ''I thought that medicine was a good way to kind of give back to the world. And I think there's a huge need for medicine in this nation and all over the world, and I thought this is a good way to use the energies that I had.'' [19]

Dr. Holder's Prescription Practice Regarding Patient S.S.

In his testimony and through stipulation, Dr. Holder admitted that on June 4, 2008, he saw Patient S.S., a 25 year old male, at MD Now's Royal Palm Beach Facility.[20] This was Dr. Holder's initial encounter with Patient S.S. in a professional capacity, and it was Patient S.S.'s first visit of any kind to MD Now.[21] At this encounter, Dr. Holder prescribed Percocet and Xanax for Patient S.S., allegedly for back pain.[22] Percocet 10/235 is the brand name for oxycodone 10mg/acetaminophen 325 mg and is a Schedule II narcotic controlled substance.[23] Xanax is a brand name for alprazolam, a Schedule IV controlled substance.[24]

Dr. Holder acknowledged that when he issued these prescriptions, he was acting outside the usual course of his professional practice, and that he did so for other than a legitimate medical purpose.[25]

Patient S.S. explained the circumstances under which he obtained these prescriptions from Dr. Holder. Patient S.S. testified that in 2007 and 2008, while he had a legitimate job working part-time in a restaurant and running a mortgage branch location, he also earned money as a drug dealer.[26] He said he was introduced to Dr. Holder by an associate who believed Dr. Holder was a potential client for cocaine and marijuana.[27] He said this introduction occurred six to twelve months before the 2008 vehicle crash, adding that he was able to recall the date of the crash because he received a phone call around 2:00 a.m. on the day of the crash.[28] He described selling marijuana to Dr. Holder once or twice a week during this period, and selling cocaine to Dr. Holder sporadically.[29] He said he would make these transactions either at Dr. Holder's personal residence or at locations that were near to where Dr. Holder was at the time.[30]

According to Patient S.S., he had been experiencing some pain in his back, and on June 4, 2008, he visited Dr. Holder at MD Now to discuss the matter.[31] Patient S.S. stated that during this visit, ''[a] very brief examination was done after I filled out all the intake paperwork, from his front office staff. He came in the room, basic examination. [He] wrote me three prescriptions; one was for Xanax for anxiety, one was for Percocet for pain and one was Naproxen which was also used as an anti-inflammatory.'' [32] He said Dr. Holder took his blood pressure and weight, listened to his breathing, and told him ''he had to make it look like a real examination, so he was going to spend about five to ten minutes with me.'' [33]

Dr. Holder agreed that the records of this encounter indicated his failure to document a complete medical history and physical examination, as well as his failure to determine either the nature or the intensity of the patient's pain.[34] He also acknowledged failing to determine the nature of Patient S.S.'s current and past treatments for the pain.[35]

Dr. Holder did not dispute the Government's claim that while Patient S.S. reported that he currently was taking Percocet, Flexeril, and Xanax, the patient's medical records contained no mention of who had prescribed these medications and no indication that Dr. Holder inquired as to the identity of the treating source or sources who prescribed these medications.[36] He agreed that his brief treatment records for Patient S.S. included a diagnosis of ''disc degeneration,'' despite the complete absence of any indication that he reviewed any imaging studies or prior medical records that would support this diagnosis.[37]

Patient S.S. testified that the only narcotic pills he ever distributed to Dr. Holder were those in the prescription for Adderall written by Dr. Holder.[38] D-amphetamine Salt Combo is the generic substitute for Adderall, the brand name for a stimulant containing a mixture of

[10] *Id.*
[11] *Id.* at 2–3.
[12] *Id.* at 3.
[13] Tr. at 87.
[14] Gov't Ex. 37 at 59.
[15] Tr. at 88–89; A.L.J. Ex. 31 at 1.
[16] A.L.J. Ex. 31 at 1.
[17] *Id.*
[18] Gov't Ex. 37 at 60.
[19] Tr. at 573.
[20] *Id.* at 610; A.L.J. Ex. 31 at 1–2.
[21] Tr. at 610.
[22] *Id.*
[23] A.L.J. Ex. 31 at 2.
[24] *Id.*
[25] Tr. at 610.
[26] *Id.* at 193.
[27] *Id.* at 194.
[28] *Id.* at 195.
[29] *Id.* at 197.
[30] *Id.*
[31] *Id.* at 201, 206.
[32] *Id.* at 201.
[33] *Id.* at 204.
[34] Tr. at 610 and A.L.J. Ex. One at 1.
[35] Tr. at 610 and A.L.J. Ex. One at 2.
[36] Tr. at 610 and A.L.J. Ex. One at 2.
[37] Tr. at 610.
[38] *Id.* at 200.

amphetamine, a Schedule II controlled substance.[39]

Without objection, the Government presented the testimony of Mark Rubenstein, M.D., as an expert medical witness in the standard of care for patients with pain and also as an expert in biomedical engineering.[40] Drawing from his review of the medical records reflecting Dr. Holder's treatment of Patient S.S. on June 4, 2008 and the subsequent prescription of Adderall on June 11, 2008, Dr. Rubenstein prepared a written report, dated May 30, 2014.[41]

In his report, Dr. Rubenstein cited State of Florida Board of Medicine Rule 64B8–9.003, which requires that the medical record contain ''sufficient information to support the diagnosis [and] justify the treatment,'' in opining that ''there is no evidence that the prescription for Adderall is supported by the medical records.'' [42] Further, citing the requirement at Board of Medicine Rule 64B8–9.013 that the prescription of controlled substances for pain must be based on ''a complete history and physical exam'' documenting the ''nature and intensity of the pain, current and past treatments for the pain, effect of pain on physical and psychological functioning, etc.,'' Dr. Rubenstein opined that the prescriptions for Percocet, Flexeril, and Xanax attributed to Dr. Holder were not supported by the medical records reviewed.[43]

Dr. Rubenstein also was present for the direct and cross examination of Dr. Holder in the Government's case in chief. Upon his consideration of the patient records and based on what Dr. Holder testified to during the first day of hearing, Dr. Rubenstein testified that nothing presented during the hearing caused him to change any of the findings set forth in his written report.[44] He added, with respect to Dr. Holder's decision to prescribe Xanax after Patient S.S.'s initial visit on June 4, 2008, that there was a clear risk of drug diversion presented, explaining that, ''in [the] absence of pre-existing history, pre-existing documentation, or objective correlation, you can't just take necessarily the patient at their word in view of the risk of drug dependence, drug addiction, and drug diversion.'' [45] He opined similarly that the history taken and the physical examination reported during the office visit on June 4, 2008, would not support Dr. Holder's prescription for Percocet for Patient S.S.[46] It was Dr. Rubenstein's opinion that Dr. Holder's June 4, 2008 prescriptions for Xanax and Percocet ''cannot be deemed for a legitimate medical purpose''.[47] Similarly, Dr. Rubenstein opined that the June 11, 2008 prescription for Adderall ''was not provided in compliance with Florida Regulations and Rules . . . and cannot be deemed rendered for a legitimate medical purpose in the usual course of professional practice.'' [48]

The Adderall Prescription and Subsequent Automobile Crash

Patient S.S. explained that before June 11, 2008, he and his ex-girlfriend went to Dr. Holder's house on ''multiple occasions'' to drop off marijuana and ''a little bit of cocaine.'' [49] During the hearing, Patient S.S. described one such occasion:

> [A] couple of days prior [to June 11, 2008], we were sitting on his porch and we were actually smoking marijuana and he said, you know, I need a favor. Is there a chance that you can come by my office? I'll have a prescription for Adderall waiting for you. You're going to meet me around back of the office. I'm going to hand you the prescription, you're going to go get them filled. Bring it back here and I'll pay you for it. And he left the money in his car for, to cover my copay.[50]

When asked about why Dr. Holder turned to Patient S.S. for this favor, Patient S.S. testified that Dr. Holder told him that ''since I did you a favor, now you owe me one. And the favor was that I come in, see him, pick up the prescriptions and have them filled . . . and release them to him.'' [51] Patient S.S. said he understood that the ''favor'' Dr. Holder had performed for him was ''[t]he fact that he wrote me prescriptions [for Percocet, Flexeril, and Xanax] without any real background or history . . . aside from what was on the initial patient consultation form.'' [52]

Patient S.S. stated that as requested, he picked up the Adderall prescription, went next door to Walgreens to fill the prescription, then delivered to Dr. Holder the filled prescription, either leaving it in his Cadillac or handing it to him directly (he could not recall with certainty which), after first retaining two tablets for his own use.[53] (Patient S.S. later testified that he may have taken as many as four tablets, but it was not more than four because, as he put it, ''I was mostly using cocaine myself.'' [54])

Dr. Holder agreed that on June 11, 2008, he issued a handwritten prescription to Patient S.S. for 60 tablets of 30 mg Adderall, a Schedule II controlled substance.[55] He agreed that he issued these prescriptions from MD Now's Lake Worth, Florida facility, located at 4570 Lantana Road; and that the facility has no medical records or any other documentation of Patient S.S.'s visit on June 11, nor is there any record of the issuance of this prescription.[56] Dr. Holder did not dispute the Government's assertion that he wrote this prescription without conducting an examination of Patient S.S., acknowledging during the hearing that he wrote the prescription without making a diagnosis for any condition necessitating the prescription, and without documenting the fact that he had prescribed Adderall for Patient S.S.[57]

When asked during the hearing how the police found a bottle of Adderall identified as belonging to Patient S.S. in the car Dr. Holder was driving at the time of the crash, Dr. Holder said simply, ''I can't explain that,'' adding that he might have offered an explanation for it in the past, but ''right now, I'm at the place where I cannot explain how it got there. I do not recall how it got there.'' [58]

When questioned about the presence of the bottle of Adderall found in the Cadillac after the crash, Dr. Holder admitted to DEA Diversion Investigator Virginia McKenna that he used Adderall ''on a few different occasions [and] that he obtained it from a colleague [but] he did not know where the pill bottle came from.'' [59]

According to Investigator McKenna, when she presented a copy of the Adderall prescription for Patient S.S. written by Dr. Holder,

> Initially he said that he did meet with SS and provide him the prescription, but it wasn't documented because it had already been discussed. Later during the conversation, he said he didn't recall giving the prescription, that he had been in a coma, and he did not have a good memory of it. And then later in the conversation, he admitted in fact that he did give the prescription and repeated that it was not documented or charted, no exam, because that was already in the prior record.
>
> * * *

[39] A.L.J. Ex. 31 at 2.
[40] Tr. at 303–04.
[41] Gov't Ex. 42.
[42] *Id.* at 4.
[43] *Id.*
[44] Tr. at 305.
[45] *Id.* at 313.
[46] *Id.* at 315.
[47] Gov't Ex. 42 at 1–4.
[48] *Id.*
[49] Tr. at 207.
[50] *Id.* at 208.
[51] *Id.* at 211.
[52] *Id.*
[53] *Id.* at 209.
[54] *Id.* at 212–13.
[55] *Id.* at 611 and A.L.J. Ex. One at 2.
[56] Tr. at 611 and A.L.J. Ex. One at 2.
[57] Tr. at 611 and A.L.J. Ex. One at 2.
[58] Tr. at 168.
[59] Tr. at 475.

His mother [Dr. Wilhelmina Holder] quite forcefully stated that law enforcement planted it in the car. That's when I turned to Dr. Holder and again asked him, how would law enforcement know to go specifically to that person, knowing that that person received a prescription for Adderall from you just two days prior, to get the bottle to plant. And he said he didn't know, that law enforcement had been looking through his phone and would have found his number.[60]

The passenger in Dr. Holder's car at the time of the crash, N.P., provided details of what took place on June 13, 2008. Because her testimony was internally consistent, consistent with the evidence generally, and not contradicted by any other testimony or evidence, I found her testimony to be credible and gave it great weight.

N.P. testified that she met Dr. Holder in the early morning of June 13, 2008, when Dr. Holder introduced himself to her at a nightclub.[61] Although N.P. left the club as the passenger in another vehicle, she encountered Dr. Holder while in the other vehicle, at which time Dr. Holder caught her attention, and then arranged to follow the car to N.P.'s home.[62] Once at her home, N.P. asked Dr. Holder to take her to a 24-hour Walgreens, and the two then departed in Dr. Holder's Cadillac.[63]

While making the five-minute drive from her home to the drug store, N.P. observed that at first Dr. Holder was driving within the speed limit; but that, while engaged in conversation with her, Dr. Holder missed the turn that would have brought them to the drug store.[64] She said when she brought this to his attention, Dr. Holder ''started moaning and . . . he stiffened up his back. His head was, he threw his head back on the seat and his eyes were rolling back in the back of his head.'' [65] She said Dr. Holder's foot pressed heavily on the accelerator, ''his arms were stretched out holding the steering wheel,'' and the car was increasing in speed.[66]

At this point, N.P. sought to control the vehicle, with one hand reaching for the steering wheel and the other seeking the parking brake.[67] There was, however, neither braking nor any slowing, when the car hit a concrete signage wall and light pole.[68] Upon impact, N.P. thought she ''was actually dead, because I couldn't see anything.'' [69] She then realized the passenger airbag had deployed, and Dr. Holder was slumped over her left shoulder, bleeding profusely.[70]

Taking her own condition into account, N.P. testified that she could hardly breathe and was in ''a lot of pain.'' [71] She had a gash on her left leg, was in great pain, and learned upon being admitted to the hospital that she had a severely dislocated elbow, shattered cervical spinal discs, and a broken back.[72] According to N.P., however, her treatment at the scene had to be interrupted, as the first responders were diverted when it appeared Dr. Holder was yelling at those who had come to his aid.[73] She said that after surgery, she now has limited mobility in her neck, with sustained periodic back pain; and has been told to expect an increase in that pain as she ages.[74]

Also testifying were first responders who encountered Dr. Holder after he crashed his car. Ryan Biramontes is a driver operator and paramedic for the Palm Beach County Fire and Rescue squad, who described responding to a vehicle accident call at approximately 3 a.m. on June 13, 2008.[75] He described encountering N.P., who was crying and reporting that she was in pain.[76] He saw Dr. Holder, who appeared to have sustained a head injury, but was not responding to his name.[77]

Mr. Biramontes reviewed reports of the crash, and described his encounters with Dr. Holder after Dr. Holder got out of the vehicle and in an ''altered'' state began ''screaming and stumbling around.'' [78] He described the steps other responders took to subdue Dr. Holder, generally describing Dr. Holder as ''combative'' and ''resisting.'' [79] Included in the responses by these responders were multiple attempts to subdue Dr. Holder using a Taser, which proved to be less than effective.[80] He said that after repeated efforts by a team of responders, they were able to restrain Dr. Holder, administer Valium, and transport him to the Delray Medical Center for treatment.[81] The toxicology report provided by Delray Center noted that Respondent's blood taken shortly after the accident by law enforcement tested negative for alcohol and positive for the presence of amphetamines and THC, the active ingredient in marijuana.[82] Respondent admitted that he took amphetamines without a valid prescription on or about June 12, 2008.[83]

In addition, the Government presented testimony from Palm Beach County Sheriff's Deputy Jesse McCoy, who gave testimony that was substantially the same as that provided by Mr. Biramontes, in that he observed N.P. having sustained a dislocated elbow and finding Dr. Holder with a bloody face, grunting behind the wheel, refusing to acknowledge the deputy's presence.[84] He added that when members of the Fire Rescue team arrived, he saw the members having trouble restraining Dr. Holder so that he could be taken in to the hospital for treatment.[85]

Also called to the scene of the crash, although later in time, after Dr. Holder had departed for the hospital, was Palm Beach Sheriff's Office Investigator Robert Stephan.[86] Investigator Stephan described the crash scene, noted the condition of the Cadillac's windshield after the crash, and opined that from the spider-webbing fractures and pieces of organic material found on the inside of the driver's side of the windshield, it was likely the driver of the car was not wearing a seatbelt at the time of the crash.[87] He said this was confirmed during his review of the vehicle's on-board Crash Data Retrieval System report.[88]

The Government also presented the testimony of Palm Beach County Deputy Sheriff Judith Little, who testified regarding the condition of Dr. Holder's Cadillac on the morning after the crash. Specifically, Deputy Sheriff Little said she discovered the prescription bottle that had been issued to Patient S.S., located inside the vehicle.[89] She counted the pills inside the vial, and determined there were 41 pills remaining in the 60-pill June 11, 2008 prescription.[90] Palm Beach County Detective Daniel Morgado, too, testified about his review of the crash scene and vehicle in the morning after the crash.[91] He said he received the prescription bottle and determined that Dr. Holder had issued the prescription out of MD Now's office for Patient S.S.[92] There is

[60] Tr. at 476–77.
[61] *Id.* at 52.
[62] *Id.* at 53–54.
[63] *Id.* at 55.
[64] *Id.* at 58.
[65] *Id.* at 58–59.
[66] *Id.* at 59–60.
[67] *Id.* at 60.
[68] *Id.* at 61.
[69] *Id.* at 62.
[70] *Id.*
[71] *Id.*
[72] *Id.* at 62, 66.
[73] *Id.* at 64–65.
[74] *Id.* at 66.
[75] *Id.* at 238.
[76] *Id.*
[77] *Id.* at 239.
[78] *Id.* at 250.
[79] *Id.* at 252.
[80] *Id.* at 254.
[81] *Id.* at 258, 260.
[82] A.L.J. Ex. 31 at 2.
[83] *Id.*
[84] Tr. at 405.
[85] *Id.* at 407.
[86] *Id.* at 270–71.
[87] *Id.* at 286–91.
[88] *Id.* at 279–81.
[89] *Id.* at 396.
[90] *Id.*
[91] *Id.* at 426–28.
[92] *Id.* at 429.

no direct testimony from Dr. Holder accounting for the nineteen Adderall tablets missing from the prescription bottle found in Dr. Holder's Cadillac after the June 13, 2008 crash, although Patient S.S. acknowledged taking no more than four tablets prior to delivering the vial to Dr. Holder.[93]

Respondent subsequently was criminally charged in Palm Beach County with driving under the influence, possession of amphetamines, driving on a suspended license, and obtaining amphetamines by fraud. The State of Florida subsequently issued a nolle prosse for all criminal charges.[94]

Regarding the crash, Dr. Holder presented the testimony of Kester Jimmy Nedd, M.D., who treated Dr. Holder upon his arrival at the hospital.[95] Dr. Nedd is a board certified neurologist and is the Medical Director for Neurological Rehabilitation at Jackson Memorial Hospital.[96] Dr. Nedd testified that from his review of treatment records, he was of the opinion that Dr. Holder ''suffered a severe traumatic brain injury with hemorrhage in the brain'' and that this ''resulted in cognitive impairment.'' [97] He said Dr. Holder suffered from ''post-traumatic amnesia, where he was in a state of confusion and not able to form new memory. This lasted maybe up to, even up to when he left the rehabilitation center,'' at which point Dr. Nedd followed him at the outpatient center.[98]

According to Dr. Nedd, Dr. Holder's ''cognitive symptoms include trouble with judgment, reasoning, [and] executive function.'' [99] Dr. Nedd testified that even after many years, Dr. Holder ''was still having issues,'' [100] explaining that ''for many patients with traumatic brain injury, this could be a life-long issue.'' [101] He added that he ''would expect that [Dr. Holder] would have trouble recalling events'' associated with the 2008 crash.[102] He added that not only might someone with these symptoms have difficulty remembering the events relating to the crash, such a person might also substitute alternative facts for what actually happened, called ''confabulation,'' where ''the patient actually combines many pieces of information and it's not always truthful.'' [103]

The Misrepresentation of Dr. Holder's Record of Suspensions

Dr. Holder acknowledged that on January 26, 2009, the Florida Department of Health issued an Emergency Suspension of his license to practice medicine.[104] He did not dispute that the Departmental action was the result of his illegal and unprofessional conduct surrounding his prescriptions to Patient S.S., as well as his unlawful possession and use of Adderall, and the subsequent traffic crash and DUI arrest.[105] Further, he acknowledged that on June 19, 2009, the Florida Board of Medicine issued a final order indefinitely suspending his medical license in Florida.[106]

Dr. Holder also acknowledged that on March 25, 2011, he applied for a medical license in Minnesota; and that the licensure committee of the Minnesota Board of Medical Practice initially recommended denial of the application for his failure to show good moral character.[107] He further agreed that in November 2011, he was granted a restricted and conditional medical license in Minnesota.[108]

The application for a DEA Certificate of Registration requires applicants to answer the following question: ''[h]as the applicant ever surrendered (for cause) or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?'' [109] Despite holding a restricted and conditional license in Minnesota, and despite having had his Florida license suspended, when asked this question in his application for a DEA Certificate of Registration on March 7, 2012, Dr. Holder answered in the negative.[110]

On July 19, 2012, Diversion Investigators McKenna and Joseph Cappello met with Dr. Holder and Dr. Holder's attorney, Kent G. Harbison, of Fredrikson & Byron, P.A., Minneapolis, Minnesota. Investigator McKenna said she questioned Dr. Holder about this response as part of her investigation, prior to the issuance of the Order to Show Cause. According to Investigator McKenna,

> [Dr. Holder] answered on the application no. When I asked him about that, he said that he didn't understand the question, that he wasn't intending to lie, at which time Mr. Harbison interjected, ''why would he lie when he knew it was public record?'' but I had no, I don't know why he would or wouldn't do such a thing, so I showed him the application. And then he said that he didn't read the question thoroughly, and that's when I showed him a sample application that I had.[111]

According to Investigator McKenna, upon being presented with the sample application, Dr. Holder:

> [W]ent through it and he underlined the first word—''surrendered''—and stopped. I then went on and underlined the rest: ''Revoked, suspended, denied, restricted or placed on probation, or is any other such action pending?''
>
> MR. LAWSON: So in other words, he was trying to tell you that he answered the question properly because he had never surrendered?
>
> MS. MCKENNA: That could have been the suggestion, and I [asked] about his training as a student for medical doctor and sitting for Boards, and I asked him if during those occasions, ''did you just gloss over the questions or did you read them thoroughly in order to answer them?'' And he said he didn't gloss over.[112]

Dr. Holder's Lack of Candor in the Investigative Process

In its Order to Show Cause, the Government averred the existence of multiple instances in which it appeared Dr. Holder had been other than forthright and honest with state regulators and the DEA.[113] These instances included the following:

1. Dr. Holder provided inconsistent statements with respect to the number of doses of Adderall he consumed prior to the automobile crash, and gave inconsistent statements regarding how he obtained the medication, including a claim that the presence of Adderall (in the bottle bearing the prescription he wrote to Patient S.S.) was the product of Florida law enforcement officers planting the bottle in his car, or, alternatively, had been provided by an unnamed colleague at work.[114]

2. Dr. Holder attributed a positive screen for marijuana to be the result of a false positive, rather than to his own use of the drug.[115]

3. Dr. Holder provided evasive answers to DEA agents regarding his past use of controlled substances, and refused multiple requests from the DEA seeking the release of records showing

[93] *Id.* at 212–213.
[94] A.L.J. Ex. 31 at 2.
[95] Tr. at 509.
[96] *Id.* at 508–09.
[97] *Id.* at 510.
[98] *Id.*
[99] *Id.* at 510–11.
[100] *Id.* at 512.
[101] *Id.*
[102] *Id.* at 515–16.
[103] *Id.* at 519.
[104] *Id.* at 614 and A.L.J. Ex. One at 2.
[105] Tr. at 614 and A.L.J. Ex. One at 2.
[106] Tr. at 614 and A.L.J. Ex. One at 2.
[107] Tr. at 614 and A.L.J. Ex. One at 2.
[108] Tr. at 614 and A.L.J. Ex. One at 2.
[109] Gov't Ex. Two at 3.
[110] *Id.*
[111] Tr. at 463.
[112] *Id.* at 463–64.
[113] A.L.J. Ex. One at 3.
[114] *Id.*
[115] *Id.*

his participation in court-ordered monitoring in Florida through the Florida Professional Resource Network, and during regulatory monitoring required in Minnesota by the Minnesota Health Professional Services Program.[116]

4. Records of drug screening results during court-ordered monitoring included positive testing for opiates on one occasion, the submission of a diluted urine sample on another, and skipping a call for random sampling on another occasion.[117]

Diversion Investigator Jack Henderson testified with respect to the process by which his office evaluated Dr. Holder's March 2012 application for a DEA Certificate of Registration in Minnesota. Investigator Henderson is in charge of the diversion control program for the DEA in the Minneapolis/St. Paul District office.[118] After the application was received on March 8, 2012, Investigator Henderson's office began the process of reviewing the responses Dr. Holder provided in his application.[119] By June 3, 2013, Investigator Henderson had determined that it appeared Dr. Holder had provided ''inconsistent and potentially false information'' to the DEA, warranting the issuance of a show cause order regarding the application.[120]

Asked to provide specific instances that gave rise to his determination, Investigator Henderson noted first a discrepancy regarding the number of dosages of Adderall Dr. Holder admitted to consuming on the evening of the crash.[121] Investigator Henderson said he understood Dr. Holder acknowledged taking one unit, but when asked about this on June 3, 2013, ''he told me that he could have taken on that evening between four and six dosage units, but more than likely it was five.'' [122]

Investigator Henderson also identified the business record reflecting the answers provided by Dr. Holder to the questions appearing on the online application Dr. Holder submitted in March 2012.[123]

Also working out of the DEA's Minneapolis/St. Paul district office,[124] Investigator McKenna was the lead investigator responsible for evaluating Dr. Holder's March 2012 application.[125] She explained that a registration specialist in the office initially reviewed Dr. Holder's application, then checked to see if there were any records of board orders regarding Dr. Holder's past history.[126] She said Dr. Holder did not disclose such a history, so when the specialist found evidence that the medical boards in Florida and Minnesota had taken action regarding Dr. Holder's licenses in those states, the file was forwarded to the investigator.[127] Because her testimony was internally consistent, consistent with the evidence generally, and not contradicted by any other reliable testimony or evidence, I found her testimony to be credible and gave it great weight.

The application includes Question Three, which asks ''[h]as the applicant ever surrendered (for cause) or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?'' [128] In his application, Dr. Holder responded in the negative to this question.[129] Investigator McKenna then identified documents establishing that Dr. Holder's medical license had been suspended and was currently on probation in Florida, and was restricted in Minnesota.[130]

Investigator McKenna said that when assigned to review an application, her first task is to check for orders from state boards, apparently replicating the task attributed to the DEA registration specialist.[131] Doing so, Investigator McKenna found the record of disciplinary action taken with respect to Dr. Holder's medical licenses in both Florida and Minnesota.[132] Upon making these findings, she then sought copies of the drug monitoring program reports from Florida (*i.e.*, the Professional Resource Network, or PRN, report), and Minnesota (the Health Professional Services Program, or HPSP, report).[133] She explained that she needed to see the contents of these reports in order to corroborate what Dr. Holder was telling her.[134] She said she specifically wanted to learn what Dr. Holder's diagnoses and prognoses were, and whether there were issues relating to his treatment that were being addressed or had been addressed in the past.[135]

According to Investigator McKenna, Dr. Holder was not forthcoming with securing these reports:

> MR. LAWSON: Okay. And if you can remember, what sort of documents were you focused on collecting before you ever spoke with Dr. Holder?
>
> MS. MCKENNA: The Board orders, of course. And then I wanted to get the law enforcement file, the police reports, any supporting documentation to get a clearer picture of what the allegations were there.
>
> MR. LAWSON: Okay. Now your investigation went on for quite a long time. Is that correct?
>
> MS. MCKENNA: Yes, sir. It did.
>
> MR. LAWSON: All right. Why did it take so long?
>
> MS. MCKENNA: On numerous occasions, I requested the HPSP and PRN records from Dr. Holder in order to afford him the opportunity to present his side, so to speak. On those occasions, I would get, ''I'll get them for you,'' or I would remind him that I was still waiting for them, and I never really received much, if anything.[136]

Investigator McKenna said she asked for these reports during the meeting on July 19, 2012, at which time Dr. Holder told her he ''would look for them.'' [137] He failed to produce the records, and when Investigator McKenna repeated the request during a discussion on August 25, 2012, Dr. Holder again offered to provide them.[138] When that failed, she

> [A]ttempted to subpoena the records and was instructed I would need a court order or a release from Dr. Holder. I then presented him with a release, one each for Florida, one for Minnesota, on August 13th of 2013, I believe it was, and asked him if he would consent to me receiving the records personally.
>
> MR. LAWSON: And was August 13th the date that you actually presented, did you actually go ahead and complete, fill out the release forms?
>
> MS. MCKENNA: Yes, sir. I had the release forms completed. I brought them to him at his place of business, at, Whittier Clinic, and presented them to him personally.[139]

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[116] *Id.*

[117] *Id.*

[118] Tr. at 326.

[119] *Id.* at 326–27.

[120] *Id.* at 327.

[121] *Id.* at 328.

[122] *Id.*

[123] *Id.* at 334–35. Note: The print-out of this document has a caption stating ''DEA Form 224—Completed,'' and was identified by Investigator Henderson as a true copy of Dr. Holder's application. Investigator Henderson acknowledged that the document (shown as Government Exhibit 53) bears a header that reads ''Page 1 of 3,'' but testified that to the best of his recollection, the form consists of two pages, not three, and he provided copies of both pages to Dr. Holder's counsel upon receiving a request for the same in July 2014. Tr. at 332–34.

[124] Tr. at 440.

[125] *Id.* at 442.

[126] *Id.* at 442–43.

[127] *Id.* at 443–44. Upon inquiry, Investigator McKenna also confirmed testimony by Investigator Henderson regarding the printed copy of this application, stating that the document is two pages long, not three, and that there are no questions presented to the applicant other than those shown on pages three and four of Government Exhibit Two. Tr. at 446.

[128] Gov't Ex. Two at 3.

[129] *Id.*

[130] *Id.* at 448 and Gov't Exs. 46 through 50.

[131] Tr. at 453.

[132] *Id.* at 453–54.

[133] *Id.*

[134] *Id.*

[135] *Id.*

[136] *Id.* at 455.

[137] *Id.* at 464.

[138] *Id.* at 469–70.

[139] *Id.* at 455–57.

On August 23, 2013, however, Dr. Holder informed Investigator McKenna that he would not sign the release for either set of records.[140]

In the course of her investigation, Investigator McKenna learned of ''three different occasions where [Dr. Holder] either tested positive for opiates, had a diluted [urine] sample, or missed a testing date.'' [141] When in November 2012 she asked Dr. Holder if he completed the Florida program, Dr. Holder said that he had completed the program.[142] Investigator McKenna then testified: ''I said 'no. In fact, you didn't complete the program.' And that's when he said that he withdrew from the program because it was taking too long.'' [143]

During this conversation, Dr. Holder again stated he would look for records of his participation in PRN and HPSP, but again failed to provide the requested records, a process that repeated itself when Investigator McKenna met with Dr. Holder in person on January 4, 2013.[144] At that meeting, Dr. Holder provided 82 pages of records, the most significant of which were five pages of treatment records written by Marilyn Miller, Dr. Holder's contact at HPSP.[145]

Evidence of Respondent's Acknowledgement of Wrongdoing and Remediation

Testifying on behalf of Dr. Holder, Ms. Miller said she provides case management services at the Health Professionals Services Program (HSPS) in Minnesota.[146] Due to Dr. Holder's failure to supply a release reflecting Ms. Miller's treatment records, it is unclear whether the records of her services have been fully presented in this proceeding.

Pursuant to 21 CFR 1301.15,[147] the Administrator may require an applicant to submit such documents or written statements of fact relevant to the application as the Administrator deems necessary to determine whether the application should be granted. This regulation provides that ''[t]he failure of the applicant to provide such documents or statements within a reasonable time after being requested to do so shall be deemed to be a waiver by the applicant of an opportunity to present such documents or facts for consideration by the Administrator in granting or denying the application.''

The record here establishes that Dr. Holder failed to provide a release that would permit Diversion Investigator McKenna to obtain a complete record of monitoring by HPSP, creating an instance where by operation of this regulation, Dr. Holder has waived the opportunity to present HPSP records for consideration in this application. The Government timely objected to the presentation of Ms. Miller's testimony, based on 21 CFR 1301.15.[148] Finding the objection is well-taken, I limit my use of Ms. Miller's testimony. I do consider as uncontroverted Ms. Miller's description of the purpose of the Minnesota HPSP. The program, according to Ms. Miller, ''is a state program that was created by the Health Licensing Boards in 1994 to monitor health professionals with illnesses that could potentially impair their ability to practice with reasonable skill and safety.'' [149] According to Ms. Miller, under this program (which is not managed by the state medical board), she monitors participants for ''substance problems, psychiatric problems, and medical conditions.'' [150]

I do not consider as substantive evidence Ms. Miller's proffer of facts regarding Dr. Holder's progress in the HPSP program. Although Ms. Miller testified that a substance abuse treatment plan has been established for Dr. Holder, and that Dr. Holder complied with that plan, it is not clear from the record before me that a complete record of treatment has ever been produced for the Administrator's consideration. Ms. Miller testified that while Dr. Holder provided releases authorizing potential employers and credentialing agencies to see the full record of monitoring at HPSP, Dr. Holder did not provide a similar release that would have authorized the DEA to see these records.[151]

The evidence establishes that Dr. Holder requested and received from HPSP a copy of his case file as it existed on September 18, 2012,[152] but it appears this case file has not been provided to the Government and does not appear as part of the record of this proceeding. Given Dr. Holder's explicit determination to withhold from the Administrator the record of his experience at PRN in Florida and his refusal to sign a release allowing the DEA access to the full record of his experience in Minnesota, I give no weight to the balance of Ms. Miller's testimony, including her statement that Dr. Holder has met all of the conditions of monitoring at HPSP.[153]

Further, I note with concern Ms. Miller's testimony that established June 2008 as Dr. Holder's date of sobriety.[154] As the Government brought forward during its examination of Ms. Miller, it appears Ms. Miller used this as Dr. Holder's sobriety date without knowing that Dr. Holder tested positive for unprescribed opiate use while a participant in the Florida PRN program, that he submitted a diluted urine sample while in that program, and that these events arose after June 2008.[155] Accordingly, I give no weight to Ms. Miller's testimony that Dr. Holder has a continuous sobriety date of June 2008.

As of April 2013, Investigator McKenna still did not have records of treatment from PRN, and renewed her request for those and for records not yet provided from HPSP.[156] No records were forthcoming, however, so Investigator McKenna went to see Dr. Holder at his workplace, presenting him with releases allowing the release of PRN and HPSP records.[157] Dr. Holder elected not to sign the releases, telling Investigator McKenna he had given her all of the records and saying that before he approved the releases, he wanted to consult with his sister, who is an attorney.[158] On August 23, 2013, Investigator McKenna called Dr. Holder regarding the releases. She testified that Dr. Holder said ''he had already given me all of HPSP's records, that PRN's records were full of inaccuracies, and that it would be inappropriate for me to have that information and to use it at this point.'' [159] As a result, records of Dr. Holder's participation in and withdrawal from the court-ordered monitoring by PRN in Florida are not available for the Administrator's review.

It bears noting that on the day testimony began in this case, Dr. Holder reported that he experienced a seizure of unknown duration the day before, one that came upon him without advance warning, during which he lost

[140] *Id.* at 479.

[141] *Id.* at 471.

[142] *Id.* at 472.

[143] *Id.* at 472.

[144] *Id.* at 473.

[145] *Id.* at 474.

[146] *Id.* at 532.

[147] 21 CFR 1301.15 Additional information. The Administrator may require an applicant to submit such documents or written statements of fact relevant to the application as he/she deems necessary to determine whether the application should be granted. The failure of the applicant to provide such documents or statements within a reasonable time after being requested to do so shall be deemed to be a waiver by the applicant of an opportunity to present such documents or facts for consideration by the Administrator in granting or denying the application.

[148] Tr. at 520.

[149] *Id.* at 523.

[150] *Id.*

[151] *Id.* at 528.

[152] *Id.* at 535.

[153] *See id.* at 526–27.

[154] *Id.* at 532.

[155] *Id.* at 533.

[156] *Id.* at 478.

[157] *Id.*

[158] *Id.* at 479.

[159] *Id.*

consciousness for a few moments and afterwards had ''a little bit of a headache and [was] a bit confused.'' [160] Dr. Holder explained that he could not anticipate when such a seizure would occur, although he ''attribute[d] a lot of it to like extreme fatigue.'' [161] He said that he has an unrestricted Minnesota driver license, despite the fact that if he were driving when such a seizure occurred, there would be nothing he could do to safely pull over.[162] When asked whether the condition could be controlled by medication, Dr. Holder explained that ''[i]t was recommended by a neurologist that I take medication,'' but Dr. Holder has elected not to follow that recommendation and currently takes no medication for this condition.[163]

Also noteworthy are the impressions created during this administrative proceeding, by the character of Dr. Holder's responses to questions put to him during the evidentiary hearing. In many respects, the material facts presented by the Government in its Order to Show Cause had in one form or another been stipulated to in advance of the hearing, or were not disputed when Dr. Holder was directly questioned about them. In his closing statement, Dr. Holder accurately states that ''at the end of the hearing Dr. Holder . . . acknowledged that there were no factual disputes with respect to paragraph 2–6 of the Government's Notice [sic] to Show Cause.'' [164]

Despite having stipulated to key material facts, however, Dr. Holder frequently proved to be either unable or unwilling to respond directly to questions about the evidence that supported those facts. For example, in advance of the hearing the parties stipulated that on June 4, 2008, Respondent saw Patient S.S., a 25 year old male, at MD Now's Royal Palm Beach facility, and that he prescribed Patient S.S. 30 tablet of Percocet 10/325 and 30 tablets of 2 mg Xanax XR (extended release), later orally changed to 60 tablets Xanax (immediate release).[165]

When the Government presented copies of the prescriptions (Government Exhibit 5) to Dr. Holder, however, and asked that he identify them, Dr. Holder's answers were less than direct.

MR. LAWSON: Dr. Holder would you just take a look at the documents at Exhibit 5? And those are three prescriptions issued to Patient SS, correct?

DR. HOLDER: That's what it appears to be.

MR. LAWSON: And is that your signature on those prescriptions?

DR. HOLDER: That is my signature.

MR. LAWSON: All right. And so you issued those prescriptions to Patient SS on June 4, 2008?

DR. HOLDER: Seems like it.[166]

Similar deflection can be found when Dr. Holder was asked about his decision to prescribe Adderall to Patient S.S. When asked whether there were any factual misstatements appearing in paragraph three in the Order to Show Cause, Dr. Holder answered in the negative.[167] That paragraph alleges on June 11, 2008 Dr. Holder issued a prescription for 60 tablets of 30 mg Adderall to Patient S.S. without conducting an examination, without making a diagnosis for any condition calling for the prescription, and without making any documentation to support the prescription.[168]

When the Government asked Dr. Holder to explain why the June 11, 2008 prescription was hand-written when others in the record were computer-generated, however, Dr. Holder offered a different account of the circumstances leading to the issuance of this prescription:

MR. LAWSON: Okay. And can you tell me why that is a handwritten prescription versus the electronically generated prescriptions in the previous exhibit?

DR. HOLDER: Yes, well what I assume what's going on here is it seems that he came to this visit, which the previous prescriptions were, and if you look, they are dated different dates as well. And then if you look at this one um, which was on 11th, meaning that we, it's not infrequent that people come in after the appointment wanting medications that they usually get and I was refilling those medicines.

MR. LAWSON: Sir, are you saying that the prescription you issued on June 11th to SS was a refill of a prescription he usually gets?

DR. HOLDER: Yes, I am.[169]

Dr. Holder also exhibited a marked tendency not to fully disclose information that may call into question his ability to comply with the law, doing so both in his representations to the Minnesota Board, and in his testimony before me.

In the following exchange, Government's counsel brought to Dr. Holder's attention the answers appearing in Dr. Holder's application for licensure in Minnesota, with respect to criminal convictions. The application question, Question 12, provides as follows:

Have there ever been any criminal charges filed against you? This includes charges of disorderly conduct, assault or battery, or domestic abuse, whether the charges were misdemeanor, gross misdemeanor, or felony. This also includes any offenses which have been expunged or otherwise removed from your record by executive pardon. If so, give particulars, including the date of conduct, state and local jurisdiction in which the charges were filed.[170]

In the space provided, Dr. Holder wrote ''please view addendum.'' [171] The addendum describes charges arising from the June 13, 2008 vehicle crash, but no other criminal charges are reported.[172] When questioned about the true state of his criminal record, Dr. Holder testified as follows:

MR. LAWSON: Okay. And Question 12 asks whether any criminal charges have been filed against you and you circled yes and said, please view addendum, right?

DR. HOLDER: Yes.

MR. LAWSON: And so your addendum is part of your application, correct? Because you had to give an explanation for positive answers?

DR. HOLDER: Yes, it is.

MR. LAWSON: And I guess going back to the last question I asked you about, did you in that addendum disclose every instance in which criminal charges had been filed against you?

DR. HOLDER: I focused specifically on the incidents of June—

ADMIN. JUDGE MCNEIL: You need to answer yes or no to begin that.

DR. HOLDER: Okay. Yes. Well. Yes.

MR. LAWSON: So your addendum discloses every instance in your life in which criminal charges have been filed against you?

DR. HOLDER: In my life. Perhaps there were charges, maybe filed against me another time that I did not mention. So, so maybe it's no. The answer is no.

MR. LAWSON: So the answer then is that you didn't answer that question completely and truthfully on that form? That's a yes or no question, Dr. Holder.

DR. HOLDER: I was—

ADMIN. JUDGE MCNEIL: Answer the question, please. Completely and truthfully. So go to completely first. Did you answer it completely?

MR. LAWSON: Dr. Holder, did you answer, in your addendum did you completely disclose every instance in which criminal charges have been filed against you?

DR. HOLDER: Let me read the question again. What's the question that you are pointing to on the, the Minnesota Board application? Because I'm certain I was truthful.

MR. LAWSON: It is Question 12 on Page 6 of the form. And I will specifically point out to you that it says it includes charges of disorderly conduct, assault or battery, or domestic abuse; whether those charges were misdemeanor, gross misdemeanor or felony

[160] *Id.* at 80–81.

[161] *Id.* at 82.

[162] *Id.*

[163] *Id.* at 83.

[164] Respondent's Written Closing Statement at 11 (citing Tr. at 611–16).

[165] A.L.J. Ex. 31 at 1, Stipulation Three.

[166] Tr. at 92–93.

[167] *Id.* at 611.

[168] A.L.J. Ex. One at 2.

[169] Tr. at 95.

[170] Gov't Ex. 34 at 6.

[171] *Id.*

[172] *Id.* at 9-10.

and includes charges that have been expunged.

DR. HOLDER: And also, it may not have been complete, but it was truthful.

MR. LAWSON: So you were truthful about the charges you chose to disclose?

DR. HOLDER: And the charges that I thought were actually most important.

MR. LAWSON: But you had, in fact, you've been charged with other crimes besides the one stemming from the June 13, 2008 accident, correct?

DR. HOLDER: I think disorderly conduct before.

MR. LAWSON: Right.

DR. HOLDER: But this was, the charges were dismissed.

MR. LAWSON: Right. They were dismissed, but they were charges for disorderly conduct, correct?

DR. HOLDER: I vaguely remember, but you know, I don't know the details about that. Nothing came of that incident.

ADMIN. JUDGE MCNEIL: I'll take that as a yes.[173]

I also note with concern the question of whether Dr. Holder was forthright in his communication with the medical boards in Florida and Minnesota in other respects. In describing his recollection of events immediately before and after the motor vehicle crash on June 13, 2008, Dr. Holder told me he remembered none of the circumstances of the crash.[174] He made no similar claim when describing the crash to the Minnesota Board of Medical Practice.

In his Minnesota application, dated March 18, 2011, Dr. Holder stated that he had a seizure while driving on June 13, 2008; and that ''[a] collision with a sign post followed. Both the passenger and I were in seatbelts and only suffered minor injuries form [sic] airbag deployment.'' [175] During this hearing, however, Palm Beach Sheriff's Office Investigator Robert Stephan credibly testified that the evidence gathered at the scene of the crash established the driver of the Cadillac was not wearing a seatbelt at the time of the crash.[176] Further, passenger N.P. credibly testified that she suffered a serious cut to her leg, dislocation of her elbow, and multiple spinal injuries, and sustained in excess of $100,000 in medical expenses.[177] Dr. Holder indirectly confirmed the severity of N.P.'s injuries, testifying that his insurer, Progressive Auto, paid in excess of $100,000 to settle N.P.'s civil lawsuit against him.[178] Dr. Holder's statement to the Minnesota Board, however, made no mention of these details.[179] Instead, he attributed his injuries to being repeatedly tazed and beaten by seven police officers who responded to the scene of the crash.[180] He also minimized the injuries sustained by his passenger, reporting only that she ''was treated for an elbow injury on scene,'' without disclosing N.P.'s hospitalization and subsequent treatment for orthopedic dislocation and spinal injuries.[181]

Beyond what appears to be Dr. Holder's tendency to minimize the injuries he and N.P. suffered as a result of this crash, there is also the unresolved inconsistency regarding his capacity to describe N.P.'s condition after the crash. During the hearing, Dr. Holder repeatedly testified that he remembered none of the circumstances of the crash,[182] at one point claiming that his knowledge of the events at the time of the crash was based on police reports, not his own independent recollection.[183] Indeed, the thrust of testimony from his treating physician, Dr. Nedd, was that the injuries Dr. Holder sustained in the crash likely impaired his ability to recall what happened at the time of the crash.[184] Dr. Holder's representations to the Florida and Minnesota medical boards, however, do not reflect the presence of any such cognitive impairment, nor do they indicate that his answers were based on his reliance on police reports; to the contrary, his answers appear to reflect descriptions based on his own knowledge and recollection.

Similarly, Dr. Holder's representations to the Minnesota Board differed significantly from what he presented during this administrative hearing with respect to his possession of Adderall at the time of the crash. As noted above, in order to demonstrate that he has accepted responsibility for engaging in the conduct attributed to him in paragraphs two through six in the Order to Show Cause, Dr. Holder ''acknowledged that there were no factual disputes with respect to paragraph 2–6'' of the Order to Show Cause.[185] In paragraph four of that Order, the Administrator alleged that Dr. Holder issued the Adderall prescription to Patient S.S. ''solely in order to illegally obtain amphetamines for [his] own personal use,'' and not for any legitimate medical purpose.[186] On the other hand, Dr. Holder withheld from the Minnesota Board any reference to Patient S.S., nor did he mention taking Adderall on the evening of the crash, averring instead that he ''did use Adderall as used for ADHD without a prescription while working long hours. I acquired from a colleague who worked in the Urgent Care where I worked.'' [187] During the hearing before me, however, when asked whether he had been diagnosed with ADHD, Dr. Holder answered in the negative.[188]

Also of concern was Dr. Holder's account of his use of Adderall on the day of the crash. Initially, Dr. Holder told Diversion Investigator McKenna he had taken one tablet of Adderall on the day before the crash.[189] After receiving the toxicology report from the crash (*i.e.*, the University of Florida Diagnostic Reference Laboratory Report of Dr. Bruce A. Goldberger) [190] and reviewing Dr. Goldberger's deposition from the criminal case involving Dr. Holder, Investigator McKenna returned to the subject with Dr. Holder during an interview on August 25, 2012.[191] At that interview, Dr. Holder said ''he thinks he might have taken two [Adderall doses] that night.'' [192] These accounts, further, are at odds with what Dr. Holder told Diversion Investigator Henderson on June 3, 2013, when ''[Dr. Holder] told me that he could have taken on that evening between four and six dosage units, but more than likely it was five.'' [193]

No disclosure of such use appears in his description of the events as presented to the Minnesota Medical Board.[194] While Dr. Holder does disclose that he was charged with unlawful possession of Adderall, with fraud to acquire a controlled substance, and with driving under a ''sub-therapeutic'' level of Adderall in his blood, he does not acknowledge any misconduct with respect to Adderall.[195] Instead, he reported that he elected not to appear before the Florida Medical Board, asserting that he was not ''physically or legally'' fit to participate in such a hearing; and that as a result, after he refused to appear before the Florida Board, ''they adopted the charges and incorporated the police report as their findings.'' [196]

During the hearing before me, Dr. Holder admitted using Adderall

[173] Tr. at 149–52.

[174] *Id.* at 107.

[175] Gov't Ex. 34 at 9.

[176] Tr. at 279–81, 286–91.

[177] *Id.* at 66–71.

[178] *Id.* at 147.

[179] *Id.*

[180] *Id.*

[181] *Id.*

[182] *Id.* at 107, 118.

[183] *Id.* at 118.

[184] *See id.* at 510–17.

[185] Respondent's Written Closing Statement at 11; A.L.J. Ex. One at 2.

[186] Respondent's Written Closing Statement at 11; A.L.J. Ex. One at 2.

[187] Gov't Ex. 34 at 10.

[188] Tr. at 108.

[189] *Id.* at 464–65.

[190] Gov't Ex. 14.

[191] Tr. at 469.

[192] *Id.*

[193] *Id.* at 328.

[194] Gov't Ex. 34 at 9–10.

[195] *Id.*

[196] *Id.* at 10.

immediately after accompanying Patient S.S. to fill the prescription on June 12, 2008, but did so ''because I wanted to stay alert.'' [197] When asked ''Stay alert for what?'' Dr. Holder responded: ''Seeing patients. I wanted to be alert while I was seeing patients.'' When asked ''[s]o does that indicate to you then that you were in fact working on June 12, 2008 if you were taking Adderall?'' he responded ''If I took it, then I probably was working, yes.'' [198] When asked to identify by name the source of Adderall other than the prescription he wrote for Patient S.S., Dr. Holder testified that he ''would rather not mention his name,'' and then asserted the source was a medical colleague, a physician's assistant, working at MD Now whose first name is William and whose last name Dr. Holder could no longer recall.[199] He acknowledged, however, that he has never disclosed to the management at MD Now that they had an employee who was unlawfully distributing controlled substances.[200]

When describing her interview of Dr. Holder (in the presence of Dr. Holder's attorney) during a meeting at the DEA on July 19, 2012, Diversion Investigator McKenna said that when she asked Dr. Holder about the bottle of Adderall found in his Cadillac immediately after the crash,

> [H]e said he said he had no knowledge of how the bottle got there. He suggested that law enforcement planted it. When I asked how would the police know to go to that particular individual and ask for that particular prescription, he said that the law enforcement was rifling through his cell phone and could have found his phone number in it, that he had a criminal history or criminal record.
>
> MR. LAWSON: Who had a criminal record?
>
> MS. MCKENNA: The patient on the bottle, SS.
>
> MR. LAWSON: So, he denied having any knowledge of how that bottle got in his car?
>
> MS. MCKENNA: He did deny it.[201]

In a similar manner, Dr. Holder gave what appear to be inconsistent accounts to the Minnesota Medical Board and to me during the hearing, with respect to his past use of Adderall. At the outset, Dr. Holder wanted me to know that while he agreed with the written statement submitted to the Minnesota Board, what was written there was not his own work but was instead written by his attorney.[202] Justifying his duplicity, Dr. Holder stated ''like I said before, I did not write this document. I signed it. I read it and signed it. So I can't tell you exactly what, you know, I meant on this document.'' [203]

Dr. Holder then acknowledged that the representation regarding his past use of Adderall appearing in his sworn statement to the Minnesota Board, dated August 8, 2011 was not true.[204] There is, however, no evidence to date that Dr. Holder has ever brought this error to the attention of the Minnesota Board.

In his written statement to the Board, Dr. Holder makes reference to his past use of Adderall. Dr. Holder stated the following:

> It is true that, because of a stupid error of judgment, I did obtain improperly from a friend tablets of Adderall. I obtained Adderall only for the purpose of helping me stay alert during a period when I was working hard for many hours. I definitely do not have a ''drug problem,'' and have never had a history of anything even close to that. I realize and agree that what I did in obtaining the Adderall was wrong. I had never done that before and will never do it again.[205]

When asked if he agreed that his statement that he had never used Adderall before was a lie, Dr. Holder first denied it was a lie, then reiterated that ''I don't understand what this things written [sic]. I have a problem with this because I've got, I'm, like I'm mentioning, this is not written by me.'' [206]

Under questioning by his attorney, Dr. Holder stated he knew diversion of prescription medications would be ''misusing my privilege to practice medicine and serve the community that I wish to serve,'' and said he would never divert medicine, under any circumstances.[207] He said he's a changed man now, living a life that is different than the one he lived in 2008. Elaborating, he stated:

> The way I've lived my life back then is very different from my life now, and I think one of the things that this whole opportunity has made me do, is really kind of surrender my will to my creator and I've always believed in, you know, Jesus Christ growing up, because that's what I learned. So as long as I've known myself, I've actually believed that Jesus was the Lord of all, etc. But I've never really surrendered my will, so being a very strong-willed person, I still kind of would do what I wanted to do, even though I would pray or go to church or whatever. And I think in this case, I've had to completely surrender my will and what I've found from this, is I have actually have reached a place of joy, advancement and completion. And going from the place where I lost everything, you know, with my trust and faith, has propelled me to the place where I am right now.[208]

Dr. Holder explained that he currently works as a doctor practicing urgent care at Whittier Clinic, in a ''family medicine residency.'' [209] He lives with his wife (who attended much of the evidentiary hearing) and the couple's three-month old daughter, spending a lot of time with them and with his parents, who are part of his ''support system.'' [210]

Pursuant to orders from the Florida Board, Dr. Holder participated in monitoring and drug testing by Professional Resource Network, or PRN.[211] According to Dr. Holder, PRN provides monitoring and testing ''to make sure people are providing competent medicine.'' [212] The criminal charges arising from the 2008 crash were reinstated for prosecution, but ultimately those charges were dropped.[213] The Florida Medical Board, however, did not end its inquiry, but instead in June 2009 it issued a final order indefinitely suspending Dr. Holder's license to practice medicine.[214] Dr. Holder testified that after being enrolled in a court-sponsored drug monitoring program in Florida, he left the program, and has never completed it.[215]

Dr. Holder explained that in November 2010 he submitted a petition to the Florida Medical Board, seeking reinstatement of his medical license.[216] Included in that petition is the following description of Dr. Holder's status at the time of the petition, along with the requirements of PRN-based monitoring:

> The related criminal matter has been referred for pre-trial intervention and Respondent is currently complying with the requirements for successfully completing the Circuit Court's requirements to avoid prosecution for those criminal charges. These requirements include successful completion of the Comprehensive Alcoholism Rehabilitation Program (CARP) as ordered by the Court. This is a program providing a continuum of care to individuals affected by alcoholism, drug dependency and co-occurring disorders and PRN is monitoring Respondent's participation in the CARP.[217]

[197] Tr. at 109.

[198] *Id.* at 109–10.

[199] *Id.* at 114–15.

[200] *Id.* at 118.

[201] *Id.* at 460–61.

[202] *Id.* at 176.

[203] *Id.*

[204] *Id.* at 175–77 and Gov't Ex. 37 at 10–13.

[205] Gov't Ex. 37 at 12 (emphasis *sic*).

[206] Tr. at 176–77.

[207] *Id.* at 185.

[208] *Id.* at 186.

[209] *Id.* at 187.

[210] Tr. at 187–88.

[211] *Id.* at 143–44.

[212] *Id.* at 144–45.

[213] *Id.* at 137–38.

[214] *Id.* at 139.

[215] *Id.* at 137.

[216] *Id.* at 146.

[217] *Id.* and Gov't Ex. 30 at 12.

Although from this description it appears Dr. Holder participated in monitoring by PRN and the CARP program, Dr. Holder elected not to complete the course of monitoring and refused to permit access to these records upon request by DEA Diversion Investigator.[218] As a result, although he has been identified as a person affected by alcoholism, drug dependence and co-occurring disorders, Dr. Holder has effectively withheld from the Administrator records showing his treatment in Florida for these disorders.

The record reflects that the Florida Board, presumably having the benefit of PRN's full report of Dr. Holder's incomplete participation in CARP, did not grant Dr. Holder's request for an unconditional medical license.[219] Instead, it required that for one year his practice be under direct supervision by a board certified physician who was to review all of Dr. Holder's prescriptions, and that his license be subject to a five year period of probation.[220]

Also before me is testimony from Brenda Joyce McGuire, M.D., who spoke in support of Dr. Holder's application. Dr. McGuire's association with Dr. Holder began in 2011, when she and Dr. Holder were volunteers at an organization that was at the time called the African and American Friendship Association for Cooperation and Development.[221] She testified that she holds Dr. Holder ''in high esteem,'' and that he has always ''shown a lot of caring for the people that he works with, that his medical knowledge is extremely good, and that he's always displayed, you know, good character, integrity, [and] compassion.'' [222] She added that ''Minnesota is becoming increasingly diverse, with large populations of immigrants and refugees. Dr. Holder, being of African descent, born in Africa and raised in this country, relates well culturally and even linguistically with a lot of the refugees . . . and immigrants that we have here.'' [223]

Dr. Holder also introduced the testimony of his mother, Wilhelmina Valerie Holder, M.D., a public health physician who currently serves as a community advocate who assists in decreasing ''health disparities'' and improving ''health equity.'' [224] Dr. Holder described her son's account of the 2008 crash, stating that he ''couldn't remember much, but he remembered when he was getting the seizure, and a police reached in the car and hit him on his nose a couple of times.'' [225] Given that this account was based on Dr. Wilhelmina Holder's recollection of what her son told her, and given the unreliable nature of Dr. Mark Holder's account of the circumstances attendant to the crash, I find I can give little weight to the testimony of Wilhelmina Holder's account of the crash or its aftermath.[226]

Also testifying on behalf of the Respondent was Cidijah Rodney-Somersall, M.D., a pediatrician with a practice in Atlanta, Georgia.[227] According to Dr. Somersall,

> Mark is a very enthusiastic person who was very passionate about, or he's very passionate about medicine and patient care. He's someone who is, has great bedside manner. He's very charming, he has a love for people, and he always appeared to provide excellent patient care.
>
> He was very good in terms of gathering a full history, just finding about the patient, not only their medical problems, but socially. And I mean, I was always impressed by him as a medical student, the kind of care that he provided. He was bright, and he was a great medical student, and seemed to be a very good healthcare professional.[228]

Also before me is the sworn statement of Jerome Potts, M.D., who is the Department Chief of Family and Community Medicine at the Whittier Clinic, Hennepin County (Minnesota) Medical Center.[229] Dr. Potts avers Dr. Holder's service as an employee at the clinic in June 2012 has been subject to close monitoring, including random toxicology screening.[230] Dr. Potts avers that he has personally closely supervised and monitored Dr. Holder, and states that Dr. Holder ''met all the conditions of his employment and at no point has he demonstrated a lapse in judgment or provided substandard care to patients.'' [231] According to Dr. Potts, Dr. Holder

> [I]s very diligent in documenting his charts and they are in compliance with all of our policies and procedures. His interaction with other staff and peers can be described as respectful, professional, and kind. I believe that his past issues have made him a more empathetic physician and colleague. He has earned my trust and that of his peers and patients. . . . I continue to trust Dr. Holder and am confident that he will continue to deliver quality medical care that is above reproach and meets all applicable standards.[232]

It is not clear the extent to which Dr. Potts is familiar with Dr. Holder's past, as his statement was received in lieu of live testimony, and as such the Government was not able to cross examine this witness.[233] Accordingly, while I give weight to Dr. Potts' description of Dr. Holder's current professional demeanor and performance, I cannot give weight to Dr. Potts' report that ''Dr. Holder shared details about the incident in Florida.'' [234] As a result, while I can and do receive Dr. Potts' statement averring Dr. Holder's successful employment at Whittier Clinic, those statements do not constitute evidence of any acknowledgement of past misconduct by Dr. Holder, nor do they serve as evidence of remediation for that past misconduct.

Dr. Holder presented live testimony of Laurie Kardon, M.D., who spoke in support of his application. Dr. Kardon worked with Dr. Holder at MD Now in 2007 and 2008, and said he had an excellent bedside manner when working there, and that ''[p]atients loved him'' for his ability to provide ''accurate diagnoses and treatment.'' [235] Dr. Kardon testified:

> I trust his medical knowledge, I trust his judgment, I trust his judgment in taking care of patients and his treatment, and his follow-up with patients. I would trust him with my life and with the life of my family.
>
> As a person I knew him mostly in a professional capacity prior to his, his accident, and I visited him several times in the hospital, and with him and also got to know his family after his accident, from the hospital on forward, and am just as equally impressed with the hard work that he's done since his accident to regain, first, his life. That he survived that at all is miraculous, and just equally impressed with the work, the hard work that he has done to regain his personal and professional life.[236]

Although testifying about Dr. Holder's good reputation, Dr. Kardon acknowledged that she was unaware that Dr. Holder admitted to having diverted controlled substances through other employees at MD Now.[237] Further, her opinion is given less weight after considering the response she made to the Government's inquiry during cross-examination. Government's counsel predicated a question by stating what

[218] Tr. at 472, 479.
[219] *Id.* at 146.
[220] *Id.* and Gov't Ex. 30 at 2–5.
[221] Tr. at 544.
[222] *Id.* at 546–47.
[223] *Id.* at 547.
[224] *Id.* at 552.
[225] *Id.* at 553.
[226] *Id.* at 553–54.
[227] *Id.* at 557.
[228] *Id.* at 559.
[229] Resp. Ex. T, admitted over Government objection, Tr. at 561–62.
[230] Resp. Ex. T at 1.
[231] *Id.* at 2.
[232] *Id.*
[233] *Id.* at 561–62.
[234] Resp. Ex. T at 1.
[235] Tr. at 566–67.
[236] *Id.* at 568.
[237] *Id.* at 570.

had been established at this point in the hearing:

> Mr. Lawson: I'm telling you that [Dr. Holder has] admitted to [having diverted controlled substances through other employees at MD Now] in court under oath, so you can assume it's true. . . . Does the fact that he's admitted to diverting and using controlled substances unlawfully through his employment at MD Now change your stated opinion as to how much you trust him and value his professional reputation?
>
> Dr. Kardon: It does not, because I don't think that's true.[238]

Testifying on his own behalf, Dr. Holder sought to relate his history of conflicts with law enforcement officials, including his being repeatedly being shocked by a Taser during his encounter with first responders after the crash in 2008, and raising the claim that he had been arrested for trespassing in Minnesota under conditions he felt indicated improper police conduct.[239] He also wanted to express how adversely he had been affected by the crash in 2008, fearing that he ''may never be able to function again'' but that, eschewing surgeries after the crash, he prayed, ''and I was delivered by all of them, step by step.'' [240]

Dr. Holder admitted to his past use of Adderall without a prescription, and to his past use of marijuana, but did so without providing specifics and without identifying a time period for this conduct.[241] When asked whether he took responsibility for what happened in Florida, Dr. Holder again equivocated with respect to diversion of controlled substances:

> I do take responsibility for the situation that happened in Florida. And there's a lot of things that I'm very unproud of, and the thing is, is I cannot remember diverting any medications with SS. I cannot remember and I honestly cannot remember how the medications got into the car, got into my car, but I do admit completely to using Adderall without prescriptions. And like I said, there's also a lot of my life that I'm not proud of, but I think that from there to now I've gone a long way, and I believe that I've displayed it through my actions.[242]

Dr. Holder also pointed to his completion of the requirements imposed by the Minnesota Medical Board, but offered no apologies for failing to complete the PRN monitoring program in Florida—other than to assert that ''I really could not support myself in Florida anymore because the restrictions I had on my license.'' [243]

Dr. Holder said one of the restrictions still in place at the clinic in Minnesota was imposed by his employer, in that his current employer has the right to drug test him for five years, adding that he has never failed a test since beginning at this place of employment.[244] The record is silent, however, with respect to the presence of any other monitoring requirements.

Dr. Holder stated that if he had his DEA certificate of registration, ''I'd be able to moonlight'' and would not have the financial problems he currently is facing.[245] When asked why I should recommend the DEA grant his application, Dr. Holder stated:

> For one, I think that it's clear to me, and I want to make it clear to the Court again, that I've done some wrong things in the past and I've made some errors in the past, and I'm taking responsibility for the errors I've done. And since I've made these errors, I've worked diligently to the point where I am right now, complying with the things that I needed to comply with to get to this point.
>
> And so I deserve my DEA registration. I put the work in school, I'm a Board-Certified Family Medicine physician, and I've worked towards these things to this point.
>
> Number two, I think that the community actually needs me. I think that there's a need for family physicians and not only family physicians, but people that care for people, and I fall into that category where I care for people and I'll do the best job that I can to help people.
>
> And number three, partly because of this situation as well, I am at no risk of diverting medicines, and I will be clear to say that I would never, in no circumstance would I divert medications to anybody else or myself.[246]

Analysis

Four material factual premises compel the ultimate finding required in this case. First, the record now before the Administrator demonstrates that Dr. Holder has a history of noncompliance with laws regulating controlled substances renders restoring to him a DEA Certificate of Registration inconsistent with the public interest. Second, Dr. Holder's history of false representation to professional boards and law enforcement authorities calls into question whether he can be entrusted with the authority to prescribe controlled substances. Third, there is substantial evidence that Dr. Holder made a material misstatement when applying for his DEA Certificate of Registration in 2012. And fourth, while there is some evidence of Dr. Holder's efforts at remediation, that evidence does not, by at least preponderance, overcome the Government's demonstration that granting a Certificate of Registration would be inconsistent with the public interest.

Much of what has been presented by the Administrator in the Order to Show Cause is uncontroverted. Dr. Holder acknowledged that there were no factual disputes regarding the facts appearing in paragraphs two through six of the Order.[247] Independent of Respondent's admissions, the Government presented preponderant evidence establishing that Dr. Holder improperly prescribed Percocet and Xanax to Patient S.S., then used Patient S.S. in order to illegally obtain sixty Adderall tablets, then, while under the influence of marijuana and amphetamines, caused an automobile crash that seriously injured himself and his passenger.

The Government further established a history of professional disciplinary action against Dr. Holder in Florida and Minnesota, throughout which Dr. Holder gave false and misleading information to the state investigators, and followed that by providing a materially false answer regarding that history when applying for a Certificate of Registration from the DEA. Throughout the proceedings before me, Dr. Holder has provided inconsistent and evasive responses to questions presented by the Government, calling into question whether even now the Administrator has a complete record of Dr. Holder's history of misconduct.

There is substantial evidence that Dr. Holder obtained the restoration of his unrestricted state medical license by providing incomplete and misleading evidence to the Minnesota Board of Medical Practice. There is also evidence that Dr. Holder unilaterally terminated his participation in a monitoring program required of him by the Florida Board of Medicine, without completing the five-year period of Board-ordered probation and without completing the steps required by that Board to ensure his rehabilitation prior to his return to practice in Florida. Similarly, evidence of rehabilitation in the program established in Minnesota is lacking, as that program was based on a less than forthright description of Dr. Holder's illegal and improper conduct in Florida.

Elements of a *Prima Facie* Case

This administrative action began when the DEA's Administrator, through her Deputy Administrator, issued an Order proposing to deny Dr. Holder's application for a DEA Certificate of

[238] *Id.* at 569–70.

[239] *Id.* at 574–75; *see also* Gov't Ex. 37 at 10–11.

[240] Tr. at 578.

[241] *Id.* at 579.

[242] *Id.* at 590–91.

[243] *Id.* at 581.

[244] *Id.* at 588–89.

[245] *Id.* at 591.

[246] *Id.* at 592–93.

[247] Respondent's Written Closing Statement at 11.

Registration.[248] The Order alleged that granting Dr. Holder's application would be inconsistent with the public interest, as that term is used in sections 823(f) of Chapter 21 of the United States Code.[249] Independent of this basis for denying the application, the Government also proposes to deny the application pursuant to sections 824(a)(1) and 824(a)(4) of Chapter 21 of the United States Code,[250] based on the material misrepresentation appearing in the March 7, 2012 application regarding whether Dr. Holder's professional license has ever been suspended or limited.[251] Thus, in order to deny Dr. Holder's application, the Government has the burden of establishing, by at least a preponderance of the evidence, that either (1) allowing Dr. Holder to issue prescriptions for controlled substances would be contrary to the public interest; or (2) Dr. Holder submitted an application for a Certificate of Registration that included a material misrepresentation of fact; or both.[252]

While the burden of establishing that granting a Certificate of Registration application would contravene the public interest never shifts from the Government, once the Government meets this burden, Dr. Holder has the opportunity to present evidence that he accepts responsibility for his misconduct, and has taken appropriate steps to prevent misconduct in the future.[253]

Regarding the first of these two bases for denying Respondent's application, under the registration requirements found in 21 U.S.C. 823(f), the Administrator is expected to consider five factors in determining the public interest when presented with the actions of a physician seeking to prescribe controlled substances These factors are:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.[254]

Any one of these factors may constitute a sufficient basis for denying an application for a Certificate of Registration.[255] Any one or a combination of factors may be relied upon, and when exercising authority as an impartial adjudicator, the Administrator may properly give each factor whatever weight she deems appropriate in determining whether an application should be rejected.[256] Moreover, although the Administrator is obliged to consider all five of the public interest factors, she is ''not required to make findings as to all of the factors.'' [257] The Administrator also is not required to discuss each factor in equal detail, or even every factor in any given level of detail.[258] The balancing of the public interest factors ''is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest.'' [259]

Factor One—Recommendations of the State Licensing Board

In its post-hearing brief, the Government argues that ''Factors One, Two, Four and Five militate against the issuance of a DEA Registration to Respondent.'' [260] It then modifies this argument slightly, asserting only that when considering the evidence under Factor One, ''the decisions of the Florida and Minnesota Medical Boards should be given nominal weight.'' [261]

I find the actions of state medical regulators in Minnesota and Florida, although not cast as ''recommendation[s],'' establish a basis for finding that Dr. Holder's application should be denied. Factor One considers ''[t]he recommendation of the appropriate State licensing board or professional disciplinary authority.'' [262] Although the recommendation of the applicable state medical board is probative of Factor One, the Administrator possesses ''a separate oversight responsibility with respect to the handling of controlled substances'' and therefore must make an ''independent determination as to whether the granting [or revocation] of [a registration] would be in the public interest.'' [263] In the exercise of that ''separate oversight responsibility,'' the Administrator may regard as probative of the public interest an applicant's experience before state medical boards.

I note the legal premise, presented by the Government in its post-hearing brief, that the decisions of state medical boards regarding a licensee's ability to practice medicine in the jurisdiction of those boards ''are not in any sense an official recommendation regarding this proceeding's outcome.'' [264] I agree. There is in this record no express recommendation directed to the DEA by any medical board, either in support of or in opposition to, granting Respondent a DEA Certificate of Registration.

Instead, the parties have acknowledged by stipulation that the Florida Department of Health issued an Emergency Suspension of Respondent's license to practice medicine on January 26, 2009 and filed an Administrative Complaint against Respondent on February 13, 2009.[265] The Florida Board of Medicine issued a final Order indefinitely suspending Respondent's medical license on June 19, 2009.[266] The parties further stipulated that Respondent filed for reinstatement of his Florida medical license on November 8, 2010, and the Florida Board of Medicine reinstated Respondent's medical license pursuant to numerous restrictions, terms and conditions on December 16, 2010, but that thereafter, Respondent voluntarily

[248] A.L.J. Ex. One.

[249] 21 U.S.C. 823.

[250] 21 U.S.C. 824 Denial, revocation, or suspension of registration (a) Grounds—a registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance or a list I chemical may be suspended or revoked by the Attorney General upon a finding that the registrant—(1) has materially falsified any application filed pursuant to or required by this subchapter or subchapter II of this chapter; . . . [or] (4) has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest.

[251] A.L.J. Ex. One at 1.

[252] 21 U.S.C. 823(f); 21 CFR 1301.44(d)–(e); *see also Steadman* v. *SEC*, 450 U.S. 91, 100–01 (1981).

[253] *Marc G. Medinnus, D.D.S.,* 78 FR 62683–01, 62691–93 (DEA October 22, 2013).

[254] 21 U.S.C. 823(f).

[255] *Robert A. Leslie, M.D.*, 68 FR 15227–01, 15230 (DEA March 28, 2003).

[256] *Morall* v. *DEA*, 412 F.3d 165, 173–74 (D.C. Cir. 2005); *JLB, Inc., d/b/a Boyd Drugs*, 53 FR 43945–02, 43947 (DEA October 31, 1988); *see also David E. Trawick, D.D.S.*, 53 FR 5326–01, 5327 (DEA February 23, 1988); *see also David E. Trawick, D.D.S.*, 53 FR 5326–01, 5327 (DEA February 23, 1988).

[257] *Hoxie* v. *DEA*, 419 F.3d 477, 482 (6th Cir. 2005); *see also Morall* v. *DEA*, 412 F.3d at 173–74 (D.C. Cir. 2005).

[258] *Trawick* v. *DEA*, 861 F.2d 72, 76 (4th Cir. 1988).

[259] *Jayam Krishna-Iyer, M.D.,* 74 FR 459–01, 462 (DEA January 6, 2009).

[260] Government's Proposed Findings of Fact and Conclusions of Law at 29.

[261] *Id.* at 34.

[262] 21 U.S.C. 823(f).

[263] *Mortimer B. Levin, D.O.*, 55 FR 8209–01, 8210 (DEA March 7, 1990).

[264] Government's Proposed Findings of Fact and Conclusions of Law at 30 (quoting *Gregory D. Owens, D.D.S.*, 74 FR 36751–01, 36755 (DEA July 24, 2009)).

[265] A.L.J. Ex. 31 at 2.

[266] *Id.*

surrendered his Florida medical license on March 3, 2011.[267]

Also before me is the parties' stipulation that on March 25, 2011, Respondent applied for a medical license from the Minnesota Board of Medical Practice (BMP); that by letter dated June 21, 2011, Respondent was informed that the BMP's Licensure committee intended to recommend denial of Respondent's application.[268] By letter dated August 9, 2011, Respondent's then-counsel requested reconsideration before the BMP.[269] This letter included an affidavit from respondent as well as several enclosures.[270] By letter dated September 26, 2011, the Minnesota BMP requested Respondent's personal appearance before the Licensure Committee to discuss his application to practice medicine, and after Respondent appeared before the Licensure Committee and discussed his use of controlled substances that had not been prescribed for him, on November 12, 2011, Respondent was granted a restricted, conditional license to practice in Minnesota, and one year later Respondent was granted an unrestricted license to practice medicine in Minnesota.[271]

My concern with respect to evidence relating to the licensure actions taken by the medical boards in Florida and Minnesota rests not so much with their ultimate decisions, but with the process that led to those decisions being made. The Government is correct, in my view, in proposing that Respondent's misrepresentations to these boards call into question whether the actions taken by these regulators would be the same had they been told the same things Dr. Holder reported as true during this administrative process.

The Government's identification of the nature of these misrepresentations accurately reflects the many ways in which the two state medical boards were acting with less than a complete and accurate record due to Dr. Holder's duplicity.[272] Those misrepresentations regarding Dr. Holder's ability to recall what happened immediately preceding the June 2008 crash, his description of his history of abusing marijuana and Adderall, and his description of the nature of his injuries and those of his passenger, all threaten the integrity of the administrative process by which the Florida and Minnesota boards performed their assessments of Dr. Holder's fitness to practice medicine in those states. Accordingly, nothing in our record supports a finding that the elements of Factor One warrant a conclusion that granting Respondent's application would be consistent with the public interest.

Factor Two—Dispensing Experience

With respect to Factors Two and Four, the Government in its post-hearing brief addresses both factors together.[273] I think the better practice is to examine Factors Two and Four separately. Under 21 U.S.C. 823(f)(2) (Factor Two), the Administrator is required to consider ''experience in dispensing, or conducting research with respect to controlled substances.'' [274]

This provision calls for an examination of a prescription writer's familiarity with the complexities associated with dispensing controlled substances under the Controlled Substances Act. Where, from the evidence, it appears a prescribing source's conduct, training, or credentials (*i.e.*, his or her experience) creates in the Administrator's mind a substantial concern regarding the source's prescription practice, Factor Two requires the Administrator to examine such conduct, training and credentials. The purpose of such an examination is not limited to only those instances where the source violated a provision of controlled substance law. Were that the purpose of 21 U.S.C. 823(f)(2), Factors Two and Four would be duplicative, and Factor Two would have no meaning distinct from that of Factor Four.

By Factor Two's plain language, Congress called for more than a mere consideration of violations of controlled substance laws when the Administrator engages in a review under Factor Two. In my view, evidence of deficiencies in an applicant's conduct, training, or credentials could support a finding that the public interest would not be well-served by permitting the applicant to prescribe controlled substances, even if there was no showing that the conduct amounted to a violation of laws relating to the distribution of controlled substances. Accordingly, in the analysis that follows, evidence pertaining to Factors Two and Four will be addressed separately.

The record before me includes very little evidence regarding Dr. Holder's experience dispensing controlled substances. By training, he noted experience in clinical settings here and abroad that suggest a deep understanding of the medical needs of the poor. As Dr. Kardon noted in her correspondence with the Minnesota Board of Medical Practice, Dr. Holder ''is committed to the humanitarian goal of improving healthcare for the poor and underserved.'' [275]

Most of his reported experience to date, however, appears to have had little to do with prescribing controlled substances. After successfully completing his residency, Dr. Holder continued to gain experience in a clinical practice in fields not generally associated with dispensing controlled substances, including service as the program coordinator for African and American Friendship Association for Cooperation and Development, which involved planning and implementing curriculum for the Foreign Trained Health Care Professional—Medical English program; service as the founder of Land Pilot, Inc. in Crozierville, Liberia, developing ''a conglomerate of various enterprises recognized for superior quality of services and products in Liberia'' in 2009; service as founder of M.B.H. Wellness Report, which developed ''a holistic approach to increase both the quantity and quality of life in a nontraditional medical setting'' in 2009; service as founder of Liberian Initiative for Enrichment in Monrovia, Liberia, where he developed an institution that ''conducts clinical research specifically for African American pollution globally''; service from 2009 to 2010 as chairman of the board of Bentol Development Association, ''assisting in the economic, medical, and social planning for the development'' of his mother's hometown in Liberia; and service from 2006 to 2008 as founder and president of Mperial Health PA in Miami, Florida, ''operating healthcare consultation and providing medical services through emergency home visits, urgent care centers, and wellness training.''[276]

From this record, the most significant post-graduate prescribing experience attributed to Dr. Holder is that which he obtained while working at MD Now for seven months [277] and while serving in

[267] *Id.*

[268] *Id.*

[269] *Id.* at 3.

[270] *Id.*

[271] *Id.*

[272] *See* Government's Proposed Findings of Fact and Conclusions of Law at 31–33 and citations to the record therein.

[273] *Id.* at 34–35.

[274] In this context, ''dispensing'' is defined as ''deliver[ing] a controlled substance to an ultimate user or research subject by, or pursuant to the lawful order of, a practitioner, including the prescribing and administering of a controlled substance and the packaging, labeling or compounding necessary to prepare the substance for such delivery. The term 'dispenser' means a practitioner who so delivers a controlled substance to an ultimate user or research subject.'' 21 U.S.C.A. § 802(10).

[275] Gov't Ex. 37 at 5.

[276] *Id.* at 29.

[277] Tr. at 120.

his family medicine residency at the University of Miami from 2004 to 2007. Even here, however, while this experience includes training in critical care and emergency medicine (both of which may emphasize the use of controlled substances), the residency reflects a curriculum that was not concentrated in a practice requiring the dispensation of controlled substances, including emphases in infectious diseases, pediatrics, ''wards'' medicine, and women's health. Thus, while Dr. Holder's experiences as an independent contractor at MD Now and parts of his residence do suggest experience in dispensing controlled substances, the overall arc of his practice has not been one that would support a finding that his experience in dispensing controlled substances is substantial.

The record also establishes, through the testimony of Dr. Holder and Patient S.S., that Dr. Holder entered the world of drug dealers, using his experience and his association with Patient S.S. to acquire cocaine and marijuana on a regular basis. As a result of his association with Patient S.S., Dr. Holder is not only knowledgeable in the ways and means used to acquire illicit controlled substances; he is now personally experienced in those ways and means.

Coupling this character of experience with the negative features of his experience arising out of his improper prescription practice, discussed below in the analysis of Factor Four, I find the Government has presented under Factor Two preponderant evidence establishing that granting Respondent a DEA Certificate of Registration would be inconsistent with the public interest.

Factor Three—Conviction Record

Under Factor Three the Administrator is to consider an applicant's conviction record under federal or state laws relating to the manufacture, distribution, or dispensing of controlled substances.[278] Neither the Government nor Respondent has raised any claims pertaining to Factor Three, and there is no evidence that Dr. Holder has been convicted of any laws related to dispensing controlled substances. Accordingly, Factor Three does not serve as a basis for granting or denying Respondent's application for a DEA Certificate of Registration.

Factor Four—Compliance With Applicable Laws

Under Factor Four, the Administrator may consider evidence regarding ''[c]ompliance with applicable state, federal, or local laws relating to controlled substances.'' [279] ''A prescription for a controlled substance is unlawful unless it has been issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.'' [280] Departing from the usual course of professional practice can have profound negative consequences. Here, by acknowledging the truth of those facts appearing in paragraphs two through six in the Order to Show Cause, Dr. Holder has acknowledged in his post-hearing brief that the record establishes by preponderant evidence that he failed to comply with applicable law relating to controlled substances.[281] Upon such evidence the Government has demonstrated that granting Respondent's application would not be in the public interest, and has therefore established a legally sufficient basis for the Administrator to deny this application under Factor Four.

Factor Five—Other Conduct

In its post-hearing brief, the Government urges that the Administrator make an adverse finding under Factor Five, based on Dr. Holder's ''complete and utter lack of candor'' to the DEA and to state regulators.[282] Factor Five calls for the Administrator to consider the public interest in the context of ''[s]uch other conduct which may threaten the public health and safety.'' [283] A history of substance abuse, coupled with a pattern of obstructing and misleading governmental officials when the abuse created significant problems for Dr. Holder, is evidence of conduct that may threaten the public health and safety.

In discussing Factor Five, I exclude for the moment my assessment of the evidence pertaining to the DEA application filed by Dr. Holder. Making a material misrepresentation in a DEA application is conduct that falls within the scope of 21 U.S.C. 824(a)(1), and as such it is beyond the scope of Factor Five and will be addressed below.

The Factor Five concerns that are raised in this record arise when we examine Dr. Holder's conduct before the state medical boards, his behavior during the DEA investigation into his application, and his conduct before me during the evidentiary hearing. If I accept as true Dr. Holder's claim that because of his injuries he recalled none of the details of the 2008 automobile crash, I can only conclude Dr. Holder intentionally misled the Minnesota Medical Board when he stated, under oath, that neither he nor his passenger ''was seriously hurt from the accident.'' [284] Nothing from the records pertaining to that crash, including the police report and records created in N.P.'s lawsuit seeking damages for injuries she sustained in that crash, would have supported Dr. Holder's description of the consequences of the crash.

Similarly, his inconsistent testimony regarding his history of drug use, his professed inability to recall where he obtained illicit supplies of controlled substances, his use of deflection and non-responsive answers during the hearing, and his refusal to provide DEA Diversion Investigator McKenna complete copies of his treatment and monitoring at PRN and HPSP after repeated requests for the same, all constitute preponderant evidence of ''other behavior'' warranting a finding that registration would be inconsistent with the public interest under Factor Five.

Material Falsification of a DEA Registration Application

The record establishes that when he submitted his DEA application for registration on March 7, 2012, Dr. Holder falsely represented his medical licenses had never been suspended, denied, or restricted. ''Just as materially falsifying an application provides a basis for revoking an existing registration without proof of any other misconduct, *see* 21 U.S.C. 824(a)(1), it also provides an independent and adequate ground for denying an application.'' [285] Thus, I can and do recommend denying Dr. Holder's application based on the false information he provided in his March 7, 2012 application, irrespective of the Government's claim that his registration is not consistent with the public interest.

In his post-hearing brief, Dr. Holder argues that the misrepresentation was not ''material,'' and that as such there was no violation of 21 U.S.C. 824(a)(1).[286] In support, Dr. Holder asserts that the false answer ''was not capable of influencing the agency. Answering the liability questions in the negative does not grant an applicant a favorable response; it leads to

[278] 21 U.S.C. 823(f)(3).

[279] 21 U.S.C. 823(f)(4).

[280] *Sun & Lake Pharmacy, Inc., D.B.A. The Medicine Shoppe*, 76 FR 24523–02, 23530 (DEA May 2, 2011).

[281] Respondent's Written Closing Statement at 11.

[282] Government's Proposed Findings of Fact and Conclusions of Law at 37.

[283] 21 U.S.C. 823(f)(5).

[284] Gov't Ex. 37 at 10.

[285] *The Medicine Shoppe Pharmacy*, 74334–01, 74338 (DEA December 31, 2007).

[286] Respondent's Written Closing Statement at 6.

verification by a registration specialist. It is the findings of the registration specialist that has the capacity to influence the agency.'' [287]

The factual predicate for this argument is that when an application is filed with the DEA, a registration specialist employed by the DEA checks to see if the applicant's medical license has been subject to adverse action by any state medical licensing board. Dr. Holder correctly notes that in her testimony, Diversion Investigator McKenna explained that when her office receives an application for registration, a registration specialist working at the office queries the state boards to determine if there any board actions present online.[288] Because the office she works at covers Minnesota and North Dakota, the specialist used the Internet to check the records maintained by the medical boards of those two states.[289] When the specialist discovered board action in Minnesota, she was, by internal office policy, unable to proceed on her own, and instead had to forward the application to a Diversion Investigator to investigate.[290]

According to Investigator McKenna, when Dr. Holder's application was brought to her attention (after the specialist determined there was a disciplinary record regarding Dr. Holder in the records of the Minnesota Board), she too checked the Board's online records.[291] In this way, she not only found evidence of Board action in Minnesota, but those records referred to Board action in Florida, leading Investigator McKenna to learn about the Florida Board's suspension of Dr. Holder's license and his subsequent surrender of the same.[292]

In his argument, Dr. Holder correctly posits that the Government ''has to show that the applicant provided false information in his/her application and that the false information provided is material.'' [293] He also correctly posits that a false statement is '''material' if it has a natural tendency to influence or was capable of influencing the decision making body to which it is addressed.'' [294] I reject as without merit his conclusion, however, that because a registration specialist reviews these applications, it was only the specialist who has ''the capacity to influence the agency,'' [295] and that Dr. Holder's false response to Question Three was therefore not material.

As the Government sufficiently points out in its post-hearing brief, ''[a]nswers to the liability question[s] are always material because DEA relies on the answers to these questions to determine whether it is necessary to conduct an investigation prior to granting an application.'' [296] I find substantial evidence supports the factual premise presented by the Government, that Respondent's false answer to Question Three was ''designed to shield Respondent's DEA application from the same troubling scrutiny that his application for a Minnesota medical license was subject to.'' [297] Put differently, when Dr. Holder's former attorney, Mr. Harbison, asked Investigator McKenna the rhetorical question, ''why would [Dr. Holder] lie when he knew it was public record?'', the answer is that by doing so, Dr. Holder could hope to obtain a DEA Certificate of Registration, if no one at the DEA checked to confirm the truth of his answers.[298]

The evidence further establishes that Dr. Holder's decision to answer Question Three in the negative was intentional. When given the opportunity to explain his response to this question during Investigator McKenna's meeting with him, Dr. Holder reviewed the language in Question Three, and underlined the first word, ''surrendered'' to indicate he answered in the negative after reading just this part of the question.[299] There is, however, no evidence suggesting he was unaware of the rest of the words in the question, nor that he sought any guidance with respect to the meaning of the words used in the question. The question is not of such complexity that a person of ordinary intelligence would have difficulty understanding each of its terms; and the circumstances attendant to filling out such an application are not so alien as to suggest persons filling out the application would not know they needed to read the entire text of each question before answering the same. From the testimony presented and the documentary evidence now before me, I find substantial preponderant evidence establishing Dr. Holder submitted an application for registration that he knew contained materially false information.

I am mindful that denial of an application may be appropriate based on an unintentional falsification, as noted in Dr. Holder's post-hearing brief.[300] Thus, if the Administrator were persuaded that the record before her does not support a finding of intentional falsification, denial of the application would still be available, provided she recognize that ''intent to deceive is a relevant consideration in determining whether a registrant or applicant should possess a DEA registration.'' [301] I find this step to be superfluous, given that from the evidence before me I find Dr. Holder purposefully answered as he did, intending on obtaining his best chance at securing a DEA registration without disclosing his past disciplinary experiences.

Evidence of Remediation

Where the Government has established by at least a preponderance of the evidence that granting an application for a Certificate of Registration is not in the public interest, the applicant has the ability to present evidence of remediation. Mitigating evidence relevant to these proceedings generally includes two elements: An acknowledgement of responsibility by the applicant, and evidence of corrective measures taken by the applicant.

From the evidence before me, however, I find insufficient evidence to establish the presence of remediation efforts that would mitigate adverse findings based on Factors One, Two, Four and Five. Dr. Holder testified that ''I've had to completely surrender my will and what I've found from this, is I have actually have reached a place of joy, advancement and completion.'' [302] I have no reason to doubt this claim, but neither can I use this claim to support a recommendation in Dr. Holder's favor.

The most probative evidence of Dr. Holder's efforts to address any drug abuse problems he may have had would have come from the reports by monitors in the Florida PRN program and Minnesota's HPSP program. Even as he insists he has and had no drug abuse problem, the evidence of drug abuse associated with the 2008 crash, his abuse of marijuana and cocaine prior to

[287] *Id.* at 7.

[288] Tr. at 444.

[289] *Id.*

[290] *Id.*

[291] *Id.* at 453.

[292] *Id.* at 453–54.

[293] Respondent's Written Closing Statement at 6.

[294] *Id.* (citing *The Medicine Shoppe Pharmacy*, 72 FR 74334–01, 74338 (DEA December 31 2007)).

[295] Respondent's Written Closing Statement at 6–7.

[296] Government's Proposed Findings of Fact and Conclusions of Law at 29–30 (emphasis added *sic*) (quoting *Theodore Neujahr, D.V.M.*, 65 FR 5680–01, 5681 (DEA February 4, 2000)).

[297] Government's Proposed Findings of Fact and Conclusions of Law at 30.

[298] Tr. at 463.

[299] *Id.* at 463–64.

[300] Respondent's Written Closing Statement at 6 (citing *Darryl J. Mohr, M.D.*, 77 FR 34998 (DEA June 12, 2012)).

[301] Respondent's Written Closing Statement at 6 (citing *Darryl J. Mohr, M.D.*, 77 FR 34998–01, [35013] (DEA June 12, 2012)) (quoting *Rosalind A. Cropper, M.D.*, 66 FR 41040–02, 41048 (DEA August 6, 2001)).

[302] Tr. at 187.

the crash, and his adamant determination to deflect and minimize the adverse impact of his drug use are all both abundant and troubling. Dr. Holder has thwarted a complete review of the steps he has taken (or has failed to take) by refusing Investigator McKenna's request for releases that would allow the DEA to see the PRN and HPSP reports. We have what appears to be only part of the report maintained by HPSP, and none of the report by PRN. In the absence of such evidence, I cannot find Respondent has established by at least preponderant evidence that he has accepted responsibility for his wrong-doing and has put in place effective corrective measures that would guard against future misconduct.

Findings of Fact

1. On March 7, 2012, Respondent, Mark William Andrew Holder, M.D., submitted an application for a DEA Certificate of Registration to handle controlled substances.

2. Respondent previously held DEA Certificate of Registration BH9956232, issued on November 21, 2007, with a registered address of 221 164th Street NE., Suite 329, North Miami Beach, Florida. This registration expired by its own terms on October 31, 2009.

3. On June 4, 2008, Respondent saw Patient S.S., a 25 year old male, at the MD Now Urgent Care Centers Royal Palm Beach facility. This was Patient S.S.'s initial encounter with Respondent in Respondent's professional capacity and Patient S.S.'s first visit of any kind to MD Now. Respondent prescribed Patient S.S. Percocet and Xanax, allegedly for back pain. The records of this visit indicate that Respondent failed to document a complete medical history and physical examination and that he failed to determine either the nature or the intensity of the patient's pain and the nature of the patient's current and past treatment for pain. Patient S.S. reported to Respondent that he was currently taking Percocet, Flexeril, and Xanax, yet the records contained no indication that Respondent inquired as to the identity of who previously treated and prescribed to the patient for his alleged back pain and anxiety issues. Respondent's brief treatment records indicate a diagnosis of ''disc degeneration'' despite the complete absence of any indication that Respondent reviewed any imaging studies or prior medical records to support this diagnosis.

4. Respondent's prescriptions for Percocet and Xanax issued on June 4, 2008 to Patient S.S. were issued outside the usual course of professional practice and for other than a legitimate medical purpose.

5. On June 11, 2008, Respondent issued a handwritten prescription to Patient S.S. for 60 tablets of 30 mg Adderall, a Schedule II controlled substance. The prescription indicates that Respondent issued the prescription from MD Now's Lake Worth, Florida facility, located at 4570 Lantana Road. MN Now has no medical records or any other documentation of Patient S.S.'s visit on June 11, 2008, nor is there any record of the issuance of this prescription. Respondent wrote the prescription without conducting an examination, without making a diagnosis for any condition necessitating the prescription, and without documenting the fact that Respondent had prescribed Adderall for this patient.

6. Respondent's prescription for Adderall issued on June 11, 2008 to Patient S.S. was issued outside the usual course of professional practice and for other than a legitimate medical purpose.

7. Respondent directed Patient S.S. to deliver the filled Adderall prescription back to him, for his own personal use. Patient S.S. complied with this direction, diverting the prescription to Respondent, who then exercised control over the filled prescription.

8. On June 13, 2008, at approximately 2:57 a.m., Respondent drove his Cadillac over a median, across three lanes of oncoming traffic into a street sign and concrete light pole, severely injuring himself and a passenger, N.P. The vial of Adderall Patient S.S. obtained from the prescription Respondent issued was located in Respondent's vehicle, with 41 of the 60 tablets remaining. Respondent's blood subsequently tested positive for amphetamines and marijuana, resulting in Respondent's arrest for driving under the influence of amphetamines and marijuana, driving on a suspended license, and obtaining amphetamines by fraud.

9. By an Order of Emergency Suspension dated January 26, 2009, the State of Florida Department of Health suspended Respondent's license to practice medicine in Florida. It did so after finding Respondent violated Section 458.331(1)(r), Florida Statutes, which prohibited Respondent from prescribing or administering controlled substances to himself. It also found Respondent violated Section 458.331(1)(q), Florida Statutes, which prohibited Respondent from prescribing Adderall to a patient without conducting an examination, without making a diagnosis for any condition necessitating the prescription, and without documenting that he had prescribed Adderall for the patient or providing a justification for the prescription. It also found Respondent violated Section 458.311(1)(cc), Florida Statutes, by prescribing Adderall for purposes other than those authorized by that Section, after determining that Respondent wrote an Adderall prescription for Patient S.S., who then filled the prescription and upon being reimbursed for the cost of the prescription delivered to Respondent the filled prescription for Respondent's own use.

10. By a Stipulation and Order dated November 12, 2011, the Minnesota Board of Medical Practice issued a restricted medical license to Respondent, upon its review of a report of chemical abuse and diversion of controlled substances for Respondent's own use. Under the terms of the Stipulation and Order, Respondent was authorized to practice medicine in Minnesota only upon agreeing to (1) participate in the Health Professionals Services Program for at least one year and complying with all of the requirements of that program; (2) submit to a minimum of six unannounced biological fluid screens per quarter; (3) execute a release authorizing the Program to release a copy of Respondent's monitoring plan to the Board; (4) practice only in a setting approved in advance by the Board; and (5) obtain a supervising physician who shall provide quarterly reports to the Board.

11. On March 7, 2012, Respondent submitted the application for a DEA Certificate of Registration to handle controlled substances under Schedules 2, 2N, 3, 3N, 4 and 5, identifying the business location as 2810 Nicollet Avenue South, Minneapolis, Minnesota 55408–3160. In this application, when asked ''Has the applicant ever surrendered (for cause) or had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?'' Respondent falsely answered ''No'' to this question.

12. In the course of investigating the circumstances surrounding state medical board action pertaining to Respondent's medical licenses in Florida and Minnesota, DEA Diversion Investigator Virginia McKenna met with or spoke with Respondent on several occasions between July 19, 2012 and August 23, 2013. Throughout this period, Investigator McKenna made repeated requests for Respondent to provide the DEA with copies of

monitoring and treatment records reflecting action by the medical boards in Florida and Minnesota. Initially, and for a period extending more than six months, Respondent deferred complying with these requests while assuring Investigator McKenna he would comply. By April 2013, when the records still had not been produced, Investigator McKenna presented Respondent with release forms that would authorize the DEA to receive copies of these reports. Respondent refused to sign the releases, and advised Investigator McKenna that he would not permit the DEA access to the PRN report from Florida, and gave her what appears to be an incomplete set of records reflecting the report from Minnesota.

13. In meetings and conversations conducted by DEA Diversion Investigators McKenna, Jack Henderson, and Joseph Cappello, Respondent gave evasive and conflicting answers to questions regarding his history of drug abuse, his use and abuse of marijuana and Adderall, the sources supplying him with controlled substances, his ability to recall the events immediately prior to and after the June 13, 2008 crash, the nature and severity of injuries he and his passenger sustained due to the crash, his use of controlled substances while working at MD Now, and his reasons for answering registration application Question Three in the negative. He provided similarly evasive and conflicting answers to questions presented to him by the medical boards in Florida and Minnesota, particularly minimizing the severity of injuries he and his passenger sustained in the June 13, 2008 crash. Respondent continued providing evasive, inconsistent, and deflecting responses during the evidentiary hearing he requested upon his receipt of the pending DEA Order to Show Cause.

14. Evidence of remediation in this record takes the form of Respondent's successful completion of a one-year period of monitoring under the auspices of the Minnesota Health Professional Services Program; letters expressing support by family members, professional colleagues and patients; and Respondent's testimony averring that he has changed his lifestyle, gotten married, produced a daughter, and learned from his experiences. Circumstances calling into question the weight that can be attributed to this evidence include the fact that the monitoring program established by the Minnesota Board was based on Respondent's material misrepresentation of the nature of the injuries he and his passenger sustained in the June 2008 crash, and his failure to disclose the extent and nature of his history of drug abuse. Further, the record establishes that upon its inquiry into Respondent's actions relating to the June 13, 2008 automobile crash, medical regulators in Florida ordered Respondent to participate in monitoring and a five-year period of probation, which Respondent failed to comply with, surrendering his medical license in that state in order to avoid these remedial requirements. There is thus insufficient evidence of remediation to overcome the Government's *prima facie* case.

Conclusions of Law

1. When it proposes to deny a new application for a DEA Certificate of Registration pursuant to U.S.C. 824(a)(1), the Government is required to establish by at least a preponderance of the evidence that Respondent materially falsified a DEA registration application.

2. Where preponderant evidence establishes, as is the case here, that Respondent denied having a license to practice medicine either suspended or restricted, knowing that this was a false answer, the Government has established sufficient proof of Respondent materially falsifying a DEA registration application to warrant denial of the application.

3. When it proposes to deny a new application for a DEA Certificate of Registration pursuant to U.S.C. 824(a)(4), the Government is required to establish by at least a preponderance of the evidence that the applicant's registration is inconsistent with the public interest.[303]

4. Pursuant to U.S.C. 823(f), five factors must be considered when determining the public interest in this case pursuant to U.S.C. 824(a)(4):

(1) The recommendation of the appropriate state licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under federal or state laws relating to the manufacture, distribution, or dispensing of controlled substances.

(3) Compliance with applicable state, federal, or local laws relating to controlled substances.

(4) Such other conduct which may threaten the public health and safety.[304]

5. Under 21 U.S.C. 823(f)(1) (Factor One), where the record establishes a history of Respondent's license being first suspended by the Florida Department of Health and then voluntarily surrendered for cause, based on Respondent's decision not to participate in further monitoring by the Florida Department of Health; and a history of Respondent's license being restricted by the Minnesota Medical Board and then restored based on Respondent's false and misleading statements of his history of drug abuse and the circumstances surrounding a motor vehicle crash that had precipitated the action of the Florida Department of Health, the circumstances attendant to the action of these boards constitute evidence tending to establish that Respondent's DEA registration would be inconsistent with the public interest under Factor One.

6. In order to establish a basis for denying an application for a Certificate of Registration based on the provisions of 21 U.S.C. 823(f)(2) (Factor Two), the Government must present preponderant evidence establishing that Respondent's experience in dispensing controlled substances is of such character and quality that his registration would be inconsistent with the public interest. While there is some evidence that through the course of his education, training, and employment Respondent has acquired sufficient experience to appropriately fulfill those responsibilities attendant to persons authorized to prescribe controlled substances, the preponderant evidence of Respondent's experience in procuring controlled substances creates material questions regarding the benefit Respondent obtained from his positive experiences, where those experiences should have instilled in Respondent a greater sense of responsibility when procuring and using highly addictive controlled substances. If granted the authority to prescribe often-diverted controlled substances, Respondent's experience as demonstrated in this record would, in the event of relapse, constitute a threat to the public interest, particularly where Respondent continues to deny having drug abuse problems notwithstanding a history of abuse. While this risk is attenuated during Respondent's sustained period of stable recovery, it is sufficiently present here, given the absence of any on-going monitoring or treatment, to warrant a finding that Respondent's experience in dispensing controlled substances contradicts a finding that granting this application is consistent with the public interest. Accordingly, the Government has met its burden of establishing that registration would be inconsistent with the public interest under Factor Two.

[303] 21 U.S.C. 823(f) and 824(a)(4); 21 CFR 1301.44(d).

[304] 21 U.S.C. 823(f).

7. In order to establish a basis for denying an application for a Certificate of Registration based on the provisions of 21 U.S.C. 823(f)(3) (Factor Three), the Government must present evidence of Respondent's conviction record under federal or state laws relating to the manufacture, distribution, or dispensing of controlled substances. As this Factor is neither alleged by the Government nor suggested by the evidence, this Factor may not be considered to support the denial of Respondent's application for a DEA Certificate of Registration.

8. Under 21 U.S.C. 823(f)(4) (Factor Four), the Administrator is to consider the Respondent's compliance with applicable state, federal, or local laws relating to controlled substances. Federal law relating to controlled substances includes the requirement that all prescriptions for controlled substances must be for a legitimate medical purpose and must be issued in the ordinary course of a professional medical practice.[305] Where the preponderant evidence establishes Respondent unlawfully prescribed Percocet and Xanax to Patient S.S. on June 4, 2008, and unlawfully obtained and self-administered Adderall on June 11, 2008, the Government has demonstrated a basis for finding that granting this application would be inconsistent with the public interest, under Factor Four.

9. Under 21 U.S.C. 823(f)(5) (Factor Five), the Administrator is to consider, ''[s]uch other conduct which may threaten the public health and safety.'' Respondent's actions or omissions that threaten the public interest may constitute a basis for denying an application for a DEA registration under Factor Five, where the conduct is not within the scope of Factors One through Four.[306] Where by at least a preponderance of the evidence the Government establishes, as is the case here, that Respondent refused without good cause shown to execute releases granting the DEA access to monitoring reports in Minnesota and Florida; provided misleading accounts of the circumstances surrounding the June 13, 2008 motor vehicle crash in reports tendered to medical boards in Florida and Minnesota and in his accounts of the same to DEA investigators; and provided inconsistent and misleading accounts of his history of drug use to the DEA and to medical boards in Florida and Minnesota, the Government has met its burden of demonstrating that granting Respondent's application for a DEA registration would be inconsistent with the public interest under Factor Five.

10. Upon such evidence, the Government has met its burden and has made a prima facie case in support of the proposed order denying Respondent's application for a DEA Certificate of Registration.

11. Where the Government has made out its *prima facie* case supporting the denial of an application, Respondent has the opportunity to demonstrate by preponderant evidence that through acknowledgement and remediation, granting Respondent's application for a DEA Certificate of Registration would be consistent with the public interest.

12. Because ''past performance is the best predictor of future performance,'' [307] where an applicant has committed acts inconsistent with the public interest, the applicant must accept responsibility for his or her actions and demonstrate that he or she will not engage in future misconduct.[308] Further, admitting fault is ''properly consider[ed]'' by DEA to be an ''important factor [ ]'' in the public interest determination.[309]

13. The record now before the Administrator establishes that Respondent has failed to timely provide the DEA with reports of his treatment or monitoring from the Florida Medical Board and PRN and from the Minnesota Board of Medical Practice and HPSP; failed to acknowledge the need to provide forthright, accurate, and complete responses to questions presented regarding his prescription practice and his history of drug abuse; and failed to account for his false statement in making this application for DEA registration. Upon such evidence, Respondent has not rebutted the Government's *prima facie* case. Accordingly, the Government has established cause to deny this application.

Recommendation

As the Government has pursuant to 21 U.S.C. 824(a)(1) established by preponderant evidence that Respondent has materially falsified an application filed pursuant to subchapters I or II of Chapter 13 of Title 21, United States Code; and as the Government has pursuant to 21 U.S.C. 824(a)(4) established by preponderant evidence that granting a DEA Certificate of Registration to Respondent would be inconsistent with the public interest, and as Respondent has failed to rebut the case presented by the Government, Respondent's application for a DEA Certificate of Registration should be DENIED.

Dated: October 9, 2014.

s/ CHRISTOPHER B. MCNEIL

Administrative Law Judge

[FR Doc. 2015–28928 Filed 11–13–15; 8:45 am]

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[305] *Sun & Lake Pharmacy*, 76 FR 24523–02, 24530 (DEA May 2, 2011) (quoting 21 CFR 1306.04(a)); *George C. Aycock, M.D.*, 74 FR 17529–01, 17541 (DEA April 15, 2009).

[306] 21 U.S.C. 823(f)(5).

[307] *Medicine Shoppe-Jonesborough*, 73 FR 364–01, 387 (DEA January 2, 2008) (quoting *ALRA Labs., Inc.*, v. *DEA*, 54 F.3d 450, 452 (7th Cir. 1995)).

[308] *Medicine Shoppe-Jonesborough*, 73 FR at 387 (citing *Samuel S. Jackson*, 72 FR 23848–01, 23853 (DEA May 1, 2007)); *John H. Kennedy*, 71 FR 35705–01, 35709 (DEA June 21, 2006); *Prince George Daniels*, 60 FR 62884–01, 62887 (DEA December 7, 1995).

[309] *Medicine Shoppe-Jonesborough*, *supra*, 73 FR at 387 (quoting *Hoxie* v. *DEA*, 419 F.3d 477, 483 (6th Cir. 2005)).



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Part V

Department of Commerce

National Oceanic and Atmospheric Administration

50 CFR Part 679

Fisheries of the Exclusive Economic Zone Off Alaska; Bering Sea and Aleutian Islands Management Area; American Fisheries Act; Amendment 111; Proposed Rule

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 150817730–5730–01]

RIN 0648–BF29

Fisheries of the Exclusive Economic Zone Off Alaska; Bering Sea and Aleutian Islands Management Area; American Fisheries Act; Amendment 111

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes regulations to implement Amendment 111 to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP). The proposed rule would reduce bycatch limits, also known as prohibited species catch (PSC) limits, for Pacific halibut in the Bering Sea and Aleutian Islands (BSAI) groundfish fisheries by specific amounts in four groundfish sectors: The Amendment 80 sector (non-pollock trawl catcher/processors); the BSAI trawl limited access sector (all non-Amendment 80 trawl fishery participants); the non-trawl sector (primarily hook-and-line catcher/processors); and the Western Alaska Community Development Quota Program (CDQ Program, also referred to as the CDQ sector). This action is necessary to minimize halibut bycatch in the BSAI groundfish fisheries to the extent practicable and to achieve, on a continuing basis, optimum yield from the BSAI groundfish fisheries. This action is intended to promote the goals and objectives of the Magnuson-Stevens Fishery Conservation and Management Act, the FMP, and other applicable laws.

DATES: Submit comments on or before December 16, 2015.

ADDRESSES: You may submit comments, identified by NOAA–NMFS–2015–0092, by any one of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2015-0092,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Address written comments to Glenn Merrill, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region NMFS, Attn: Ellen Sebastian. Mail comments to P.O. Box 21668, Juneau, AK 99802.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address), confidential business information, or otherwise sensitive information voluntarily submitted by the commenter will be publicly accessible. NMFS will accept anonymous comments (enter N/A in the required fields, if you wish to remain anonymous).

Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in this proposed rule may be submitted by mail to NMFS at the above address; emailed to *OIRA_submission@omb.eop.gov;* or faxed to 202–395–5806.

Electronic copies of Amendment 111 to the FMP and the Environmental Assessment/Regulatory Impact Review/Initial Regulatory Flexibility Analysis (Analysis) for this action may be obtained from *http://www.regulations.gov* or from the Alaska Region Web site at *http://alaskafisheries.noaa.gov.*

FOR FURTHER INFORMATION CONTACT: Mary Alice McKeen, 907–586–7228.

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I. Authority for Action

NMFS manages the groundfish fisheries in the Exclusive Economic Zone (EEZ) of the BSAI under the FMP. The North Pacific Fishery Management Council (Council) prepared, and the Secretary of Commerce approved, the FMP pursuant to the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) and other applicable laws. Regulations implementing the FMP appear at 50 CFR part 679. General regulations that pertain to U.S. fisheries appear at 50 CFR part 600.

The Council submitted Amendment 111 for review by the Secretary of Commerce. A notice of availability of Amendment 111 was published in the **Federal Register** on October 29, 2015, with comments invited through December 28, 2015. All relevant written comments received by that time, whether specifically directed to Amendment 111, or to the proposed rule, will be considered in the approval/disapproval decision on Amendment 111.

II. Background

Pacific halibut (*Hippoglossus stenolepis*) is fully utilized in Alaska as a target species in subsistence, personal use, recreational (sport), and commercial halibut fisheries. Halibut has significant social, cultural, and economic importance to fishery

participants and fishing communities throughout the geographical range of the resource. Halibut is also incidentally taken as bycatch in groundfish fisheries. The Magnuson-Stevens Act defines bycatch as ''fish which are harvested in a fishery, but which are not sold or kept for personal use, and includes economic discards and regulatory discards. The term does not include fish released alive under a recreational catch and release fishery management program.'' 16 U.S.C. 1802 3(2).

The International Pacific Halibut Commission (IPHC) and NMFS manage Pacific halibut fisheries through regulations established under the authority of the Northern Pacific Halibut Act of 1982 (Halibut Act) (16 U.S.C. 773–773k). The IPHC adopts regulations governing the target fishery for Pacific halibut under the Convention between the United States and Canada for the Preservation of the Halibut Fishery of the North Pacific Ocean and Bering Sea (Convention), signed at Ottawa, Ontario, on March 2, 1953, as amended by a Protocol Amending the Convention (signed at Washington, DC, on March 29, 1979). For the United States, regulations governing the fishery for Pacific halibut developed by the IPHC are subject to acceptance by the Secretary of State with concurrence from the Secretary of Commerce. After acceptance by the Secretary of State and the Secretary of Commerce, NMFS publishes the IPHC regulations in the **Federal Register** as annual management measures pursuant to 50 CFR 300.62. The final rule implementing IPHC regulations for 2015 published on March 17, 2015 (80 FR 13771).

Section 773c(c) of the Halibut Act also provides the Council with authority to develop regulations that are in addition to, and not in conflict with, approved IPHC regulations. The Council has exercised this authority in the development of Federal regulations for the halibut fishery such as (1) Subsistence halibut fishery management measures, codified at § 300.65; (2) the limited access program for charter vessels in the guided sport fishery, codified at § 300.67; and (3) the Individual Fishing Quota (IFQ) Program for the commercial halibut and sablefish fisheries, codified at 50 CFR part 679, under the authority of section 773 of the Halibut Act and section 303(b) of the Magnuson-Stevens Act.

In recent years, catch limits for the commercial halibut fishery in the BSAI have declined in response to changing halibut stock conditions while limits on the maximum amount of halibut bycatch allowed in the groundfish fisheries have remained constant. The proposed rule would reduce halibut bycatch limits, also referred to as halibut PSC limits, in the BSAI groundfish fisheries. This proposed reduction in halibut PSC limits is consistent with the requirements of the Magnuson-Stevens Act to minimize bycatch to the extent practicable while achieving, on a continuing basis, optimum yield from the groundfish fisheries. This section of the preamble provides background on the halibut resource, halibut management, the halibut fisheries, and halibut bycatch in the groundfish fisheries in the BSAI. The following two sections describe the rationale and impacts of Amendment 111 and the proposed rule.

This preamble cites the most recent available data consistent with the Analysis prepared to support this action. The most recent data available varies depending on the specific data source. The Analysis and this preamble use (1) data through 2015 for information on commercial halibut fishery catch limits, (2) data through 2014 for information on the halibut stock and halibut PSC use, and (3) data through 2013 for information on commercial halibut harvests and revenue and groundfish fisheries harvests and revenue.

The Analysis and this preamble describe the potential impacts on the halibut stock and commercial, personal use, sport, and subsistence halibut fisheries in terms of net pounds instead of metric tons. This is a long-standing practice by the IPHC because the IPHC measures biomass and directed fishery removals in terms of net weight in pounds (*i.e.,* halibut that is headed and gutted) and not metric tons. The calculation of net pounds used by the IPHC adjusts the total weight of removals in pounds by reducing the total weight by 25 percent to calculate net weight in pounds. The Analysis uses metric tons when describing groundfish catch, halibut PSC limits, and the amount of halibut bycatch (PSC) used in the groundfish fisheries. This is consistent with a long-standing practice by NMFS.

A. The Halibut Resource

1. Status of the Halibut Stock

The IPHC assesses the status of the Pacific halibut stock at a coastwide level from California to the Bering Sea. Each year, the IPHC estimates the amount of exploitable biomass. Exploitable biomass is composed of halibut that are 26 inches in length or greater (O26), the size of fish that are accessible to fishing gear used in the IPHC halibut stock survey and in the halibut fisheries. From 2000 through 2010, exploitable biomass declined primarily as a result of decreasing size at age and smaller recruitments than those observed through the 1980s and 1990s. Since 2011, the exploitable biomass has been increasing slightly from a recent low of approximately 175 million pounds in 2011 to approximately 180 million pounds in 2015 (see Table 3–1 in Section 3.1.1.1 of the Analysis).

Annually, the IPHC also assesses female spawning biomass, another important indicator of the status of the halibut stock. Female spawning biomass is composed of female halibut of reproductive size. Generally, this includes female halibut that are O26, but a small proportion of the female spawning biomass includes female halibut less than 26 inches in length (U26). Female spawning biomass is considered an important indicator of the long-term reproductive health of the halibut resource. Since 2013, the estimated female spawning biomass appears to have stabilized near 200 million pounds. The stock assessment models used by the IPHC in 2015 project a stable or slightly increasing female spawning biomass over the next 3 years assuming current removal rates from all sources (see Table 3–4 in Section 3.1.2.1 of the Analysis).

Collectively, the current status of exploitable biomass and female spawning biomass indicate that the halibut stock is stable or potentially increasing slightly in overall abundance. Section 3.1.1 of the Analysis provides additional detail on the current and projected status of halibut exploitable biomass and female spawning biomass.

It is important to note that halibut is not a groundfish species under the FMP and therefore is not subject to the provisions of the Magnuson-Stevens Act requiring the establishment of an annual overfishing limit (OFL), an acceptable biological catch (ABC), or a total allowable catch (TAC) limit. The OFL represents a level of removals that cannot be exceeded without jeopardizing the sustainability of the stock. The ABC represents the maximum permissible harvest and is less than the OFL. The TAC represents the actual permissible catch limit. The TAC may be set equal to or less than the ABC; the TAC cannot exceed the ABC. The OFL and ABC are biologically-based harvest limits that are not to be exceeded. After the OFLs and ABCs are established, the Council recommends and NMFS implements annual TACs (see Section 3.2.3 of the FMP for a description of the process for specifying OFLs, ABCs, and TACs for groundfish fisheries in the BSAI).

Although halibut is not managed under an OFL, ABC, or TAC, the IPHC has developed policy to control removals during conditions of declining or poor stock abundance. The IPHC harvest policy includes a harvest control rule that reduces commercial harvest rates linearly if the stock is estimated to have fallen below established thresholds for female spawning biomass. These harvest control rules would severely curtail removals during times of particularly poor stock conditions. These harvest control rules have not been triggered, even during the most recent years of relatively low exploitable biomass (see Section 3.1.1.1 and Section 3.1.2.1 of the Analysis).

The best available information from the most recent halibut stock assessment indicates that the halibut female spawning biomass (SB) is estimated to be 42 percent of the equilibrium condition in the absence of fishing ($SB_{42\%}$). A female spawning biomass of $SB_{42\%}$ represents a 1 out of 10 chance that the stock is below 42 percent of the equilibrium condition in the absence of fishing. Removals at this level of female spawning biomass are generally considered to represent a conservative and risk-averse level of removals in federally-managed groundfish fisheries in the BSAI off Alaska (see Section 3.1.1.1 of the Analysis). A level of $SB_{42\%,}$ is significantly above the IPHC's harvest control rule thresholds that trigger additional restrictions on the commercial halibut fishery during times of poor stock status. IPHC's harvest control rules trigger reductions in halibut harvest rates at thresholds of $SB_{30\%}$ and $SB_{20\%}$. The best available data indicate that at current levels of removals, the halibut biomass would be expected to be stable, and well above the thresholds established by the IPHC. Additional information on the anticipated impacts of the proposed rule on the status of halibut stock is provided in Sections 3.1.1.1 and 3.1.5.3 of the Analysis.

2. Halibut Removals

Total annual removals of halibut from all sources at the coastwide level have been low in recent years compared to historical total annual removals. Total annual halibut removals include harvests in the commercial, personal use, sport, and subsistence fisheries, as well as bycatch and wastage (*i.e.,* bycatch in the commercial halibut fishery). From 2000 through 2010, total halibut removals averaged 90 million pounds and were as high as almost 100 million pounds in 2004 and 2005. Total annual removals averaged 50 million pounds from 2011 through 2014. The relatively low levels of total removals in recent years (*i.e.,* from 2011 through 2014) of approximately 50 million pounds correspond with declining exploitable biomass, from the late 1990s to around 2010. See Section 3.1.3 and 3.1.4 in the Analysis for additional information on halibut removals.

The commercial fisheries for halibut are the largest source of coastwide removals, accounting for an average of 62 percent (31 million pounds) of total removals from 2011 through 2014. Removals from personal use, sport and subsistence fisheries are a much smaller component of total coastwide removals, collectively averaging 16 percent of total removals from 2011 through 2014. Overall, the total amount and proportion of commercial removals has varied with exploitable biomass, increasing as exploitable biomass increases and decreasing as exploitable biomass decreases. The total amount of personal use, sport, and subsistence removals has been relatively constant since 2011, but the proportion of personal use, sport and subsistence removals has increased as the exploitable biomass and commercial removals have decreased.

Bycatch is the second largest component of total coastwide removals and averaged 19 percent of total removals from 2011 through 2014. Bycatch of halibut in groundfish fisheries averaged 9.4 million pounds coastwide from 2011 through 2014. Although bycatch represents the second largest source of halibut removals, the total tonnage of bycatch removals in recent years (*i.e.,* 2011 through 2014) is at its lowest level since 1990 (see Figure 3–11 in Section 3.1.3 and Table 3–18 in Section 3.1.4 of the Analysis). From 2011 through 2014, halibut bycatch removals ranged from a high of 10.1 million pounds in 2012 to a low of 8.9 million pounds in 2013. The majority of halibut bycatch coastwide is taken in groundfish fisheries in the Alaska EEZ, mostly in the BSAI groundfish fisheries. From 2011 through 2014, halibut bycatch in the BSAI represented on average 58 percent of the total coastwide halibut bycatch, and 10 percent of the total coastwide removals of halibut (see Table 3–10 in Section 3.1.3.3 and Table 3–18 in Section 3.1.4 of the Analysis).

3. Allocation of Halibut Among Fisheries

Pacific halibut is allocated among fisheries by a combination of management actions taken by the IPHC, the Council, and NMFS. The IPHC annually completes a halibut stock assessment and makes recommendations for annual management measures for the halibut fishery within Convention waters. These annual management measures include specific regulations governing the commercial halibut fishery, including area-specific catch limits, authorized gear, and fishing season dates. In the United States, the IPHC recommendations are subject to acceptance by the Secretary of State and the Secretary of Commerce, as described above in the ''Authority for Action'' section of this preamble. See Section 3.1.2 of the Analysis and the 2015 annual management measures for additional information on the process for establishing commercial halibut fishery catch limits (80 FR 13771, March 17, 2015).

Although the halibut stock is assessed at a coastwide level, commercial catch limits are established for each IPHC regulatory area (Area). Area 2 is composed of Area 2A (Washington, Oregon, and California); Area 2B (British Columbia); and Area 2C (Southeast Alaska). Area 3 is composed of Area 3A (Central Gulf of Alaska); Area 3B (Western Gulf of Alaska); and Area 4 (BSAI) composed of Areas 4A, 4B, 4C, 4D and 4E. The IPHC combines Areas 4C, 4D, and 4E into Area 4CDE for purposes of establishing a commercial fishery catch limit. Areas 4A and 4C, 4D, and 4E roughly correspond to the Bering Sea Subarea defined in the FMP. Area 4B roughly corresponds to the Aleutian Islands Subarea in the FMP. Area 4CDE encompasses most of the Bering Sea Subarea in the FMP. See Figure 15 in Part 679 and Table 1–1 in Section 1.5 of the Analysis for Area maps and additional information on halibut and groundfish management areas in the BSAI.

The IPHC has developed a harvest policy and area apportionment model for determining commercial halibut fishery catch limits in all Areas. Under the harvest policy and area apportionment model, the total amount of allowable halibut harvest (called the Total Constant Exploitation Yield) is designated for each Area. The IPHC deducts all removals other than commercial fishery harvests (*i.e.,* bycatch, personal use, sport, subsistence, and wastage) that are greater than 26 inches in length (O26) from the Total Constant Exploitation Yield. The resulting amount of halibut is called the Fishery Constant Exploitation Yield. The Fishery Constant Exploitation Yield is more commonly known as the ''blue line catch limit.'' However, the IPHC is not required to select the blue line catch limit as the annual commercial catch limit for an Area. The IPHC has the

discretion on an annual basis to select a commercial catch limit that is greater than or less than the blue line catch limit (*i.e.,* the Fishery Constant Exploitation Yield).

The IPHC considers the blue line catch limit along with information on different levels of harvest above and below the blue line catch limit to accommodate greater flexibility when selecting commercial catch limits. The IPHC utilizes a decision table that estimates the consequences to halibut stock, fishery status, and trends from a range of commercial catch limits at, above, and below the blue line catch limit (see Table 3–4 in Section 3.1.2.2 of the Analysis). This decision table accommodates uncertainty in the stock status and allows the IPHC to weigh the risk and benefits of management choices as it sets the annual commercial catch limits. For example, the IPHC consistently considers the socioeconomic impacts of different commercial catch limits in an Area on fishery participants. In some instances, the IPHC has recommended an area-specific commercial catch limit that is greater than the blue line catch limit to prevent adverse economic impacts from reduced harvest levels for fishery participants and fishing communities dependent on the fishery.

The flexibility that the IPHC has in setting commercial catch limits is demonstrated in the difference between the commercial catch limits relative to the blue line catch limits derived from application of its harvest policy. From 2006 (the first year the IPHC adopted its harvest policy) through 2015, the IPHC coastwide commercial catch limit recommendation exceeded the combined blue line catch limits for all Areas in 7 of the 10 years; and Area-specific commercial catch limits have exceeded blue line catch limits in all Areas at least once, and for some Areas, in most years over the past 10 years (see Table 3–5 in Section 3.1.2.2 of the Analysis).

Although the IPHC has adopted commercial catch limits greater than the blue line catch limit in most years, the halibut stock has not fallen to levels that reach the harvest control rule thresholds described in the ''Status of the Halibut Stock'' section of this preamble. Although neither the blue line catch limit derived from the IPHC's harvest policy, nor any commercial catch limit adopted by the IPHC is the same as an OFL, ABC, or TAC used for management of groundfish fisheries in Alaska, Section 3.1.1.1 of the Analysis notes that ''in the last four years, there is no information to suggest that halibut is subject to 'overfishing' as that term is commonly applied to stocks managed under the Magnuson-Stevens Act.'' For a more complete description of the IPHC process for establishing commercial catch limits, see Section 3.1.2.2 of the Analysis.

Under IPHC harvest policy, the amount of bycatch (including wastage in the commercial fishery) in an Area can affect the amounts of halibut available for harvest in commercial, personal use, sport, and subsistence fisheries in future years. Bycatch includes O26 and U26 halibut. The proportion of bycatch comprised of O26 and U26 halibut varies by Area. Under the current IPHC harvest policy, halibut bycatch in an Area that is O26 is deducted from the amount of halibut available for the commercial fishery. Therefore, reductions in the amount of O26 bycatch could provide an opportunity to increase the commercial catch limits for that Area in the year following the reduction.

The amount of U26 bycatch in the groundfish fishery or U26 wastage in the commercial halibut fishery could impact future harvests in commercial halibut fisheries and in personal use, sport, and subsistence use fisheries in all Areas coastwide. This is due to the migration of U26 halibut among Areas. Although information on the migration of U26 halibut on a coastwide basis is limited, the best available information indicates that a portion of the U26 halibut in Area 4 migrate in a southward pattern through the Gulf of Alaska (Areas 3B and 3A), Southeast Alaska (Area 2C), British Columbia (Area 2B), and ultimately to the west coast of the United States (Area 2A). Therefore, reducing U26 halibut removed as bycatch in Area 4 would be expected to contribute to the exploitable biomass in various Areas as these halibut grow to a size where they can reproduce and become available for harvest in halibut fisheries in future years in Area 4 and elsewhere along the coast. Section 3.1.3.5 of the Analysis contains additional information on the proportions of halibut bycatch that are O26 and U26 by Area. Section 3.1.1.2 of the Analysis contains additional information on the distribution and migration of halibut among Areas.

B. Halibut Fisheries in the BSAI

IPHC and NMFS regulations authorize the harvest of halibut in commercial, personal use, sport and subsistence fisheries only by hook-and-line gear. In the BSAI (Area 4), halibut is harvested primarily in commercial fisheries and secondarily in personal use, subsistence, and sport fisheries. Based on recent harvest data from 2011 through 2014, the sport fishery operating out of ports in the BSAI harvests approximately 20,000 pounds in Area 4 compared to approximately 40,000 pounds of personal use and subsistence harvest from Area 4, and more than 3,000,000 pounds in the Area 4 commercial fishery. Given the limited sport harvest in Area 4 and that this action is not likely to impact the sport fishery, this preamble does not address the sport fishery in additional detail. See Sections 3.1.2 and 3.1.4 of the Analysis for additional detail on personal use, sport, subsistence, and commercial halibut harvests in Area 4.

Subsistence halibut is caught by a rural resident or a member of a federally-recognized Alaska Native tribe for direct personal or family consumption as food, sharing for personal or family consumption as food, or customary trade. Pursuant to section 773c(c) of the Halibut Act, the Council developed, and NMFS implemented, the Subsistence Halibut Program to manage subsistence harvests in Alaska. Persons fishing for subsistence halibut must obtain a Subsistence Halibut Registration Certificate. Special permits for community harvest, ceremonial, and educational purposes also are available to qualified Alaska communities and federally-recognized Alaska Native tribes. A complete description of the Subsistence Halibut Program is provided in the final rule to implement the program (68 FR 18145, April 15, 2003).

In addition to subsistence harvest, IPHC annual management measures allow halibut caught in the commercial halibut fishery that are less than the legal size limit of 32 inches to be retained for personal use in the Area 4D and 4E CDQ halibut fishery as long as the fish are not sold or bartered. The CDQ groups are required to report the amount of personal use halibut retained during the CDQ halibut fishery to the IPHC. Section 3.1.4.4 of the Analysis contains a description of the personal use fishery.

The commercial halibut fishery in the BSAI is managed under the IFQ and CDQ Programs that allocate exclusive harvest privileges. The IFQ Program was implemented in 1995 (58 FR 59375, November 9, 1993). The Council and NMFS designed the IFQ Program to end a wasteful and unsafe ''race for fish,'' and maintain the social and economic character of the fixed-gear fisheries and the coastal fishing communities where many of these fisheries are based. Access to the halibut and sablefish fisheries is limited to those persons holding quota share (QS). Quota shares equate to exclusive harvesting privileges

that are given effect on an annual basis through the issuance of IFQ permits. An annual IFQ permit authorizes the permit holder to harvest a specified amount of IFQ halibut or sablefish in a regulatory area.

The CDQ Program was established in 1992 and amended substantially in 2006 (57 FR 54936, November 23, 1992). Under Section 305(i)(1)(D) of the Magnuson-Stevens Act, a total of 65 villages are authorized to participate in the CDQ Program. Six CDQ groups represent these villages. CDQ groups manage and administer allocations of crab, groundfish, and halibut and use the revenue derived from the harvest of these CDQ allocations to fund economic development activities and provide employment opportunities on behalf of the villages they represent.

Section 305(i)(B) of the Magnuson-Stevens Act specifies the proportion of crab, groundfish, and halibut in the BSAI allocated to the CDQ Program. Section 305(i)(C) of the Magnuson-Stevens Act specifies the proportion of the overall CDQ Program allocations assigned to each CDQ group. Each year, NMFS publishes the specific annual allocations to each CDQ group on the Alaska Region Web site at: *http://www.alaskafisheries.noaa.gov/cdq/current_historical.htm.* The amount of halibut for commercial harvest allocated to the CDQ Program varies by halibut management area and ranges from 20 to 100 percent of the commercial catch limits assigned to Areas 4B, 4C, 4D, and 4E. See Section 3.1.4.1 and Section 4.4.6 of the Analysis for additional information on the CDQ Program.

The combined CDQ and IFQ halibut fisheries in Area 4 were harvested by, on average, approximately 330 vessels from 2008 through 2013 (see Table 4–93 in Section 4.5.2 of the Analysis). The majority of these 330 vessels participate in the CDQ halibut fishery. Most vessels participating in the CDQ halibut fishery use small vessels that make relatively small harvests of several hundred or several thousand pounds. Fewer vessels participate in the IFQ fishery, but approximately 80 percent of the overall halibut harvest in Area 4 comes from vessels participating in the IFQ fishery (see Section 4.5.1 of the Analysis for additional detail).

The CDQ and IFQ halibut fisheries provide revenue to vessel owners and crew members that harvest halibut. These fisheries also provide economic benefits to shorebased halibut processors and socioeconomic benefits to BSAI fishing communities that provide support services to the halibut harvesting and processing sectors. The Analysis estimates that halibut harvests in the Area 4 CDQ and IFQ fisheries averaged 6.8 million pounds and generated an average of $32 million in ex-vessel revenues annually from 2008 through 2013. Area 4 halibut harvests and ex-vessel revenues declined over this period, resulting in negative economic impacts for fishery participants and affected fishing communities.

Since 2008, the Area 4 catch limit has declined by 63 percent from the peak catch limit of 8.85 million pounds in 2008 to a low of 3.28 million pounds in 2014. The 2015 Area 4 commercial catch limit has increased slightly from the recent low in 2014 to 3.82 million pounds. In 2008, the Area 4 commercial ex-vessel value peaked at $38 million. In 2013, Area 4 commercial ex-vessel value was at its lowest at $18 million. The declines in commercial catch limits have been greatest in Area 4CDE. In Area 4CDE, the commercial halibut fishery catch limit declined by 67 percent from the peak catch limit of 3.89 million pounds in 2008 to a low of 1.285 million pounds in 2014 and 2015. During this period, the IPHC decided to provide additional harvest opportunity in Area 4CDE by adopting higher commercial catch limits than would have resulted if the IPHC's blue line harvest policy recommendations were actually implemented. See Section 3.1.4.1, Section 4.5, and Appendix C of the Analysis for a complete description of the Area 4 commercial halibut fishery and the fishery participants. Additional detail on the IPHC's harvest policy and catch limits is provided in Section 3.1.2.1 of the Analysis.

C. Comparing Commercial Halibut Catch and Halibut Bycatch (PSC) in the Groundfish Fisheries in the BSAI

In Area 4, the specific proportion of removals that are taken as bycatch in the groundfish fisheries or as catch in the commercial halibut fishery has shifted over time. From 1990 to 1996 (the period prior to the recent peak and decline in removals in the halibut fishery), the commercial halibut fisheries averaged 37 percent and bycatch averaged 60 percent of total halibut removals in Area 4. From 1997 to 2011 (the period of the greatest increase and subsequent decline in the total removals of halibut), the commercial halibut fishery removals increased as a portion of total removals; the commercial halibut fisheries averaged 57 percent and bycatch averaged 41 percent of total halibut removals. In more recent years, the proportion of halibut removals from the commercial halibut fishery has declined. From 2012 through 2014 (the period of recent stability in the halibut exploitable biomass), the commercial halibut fishery averaged 41 percent and bycatch averaged 55 percent of total removals. See Figure 3–12 and Section 3.1.3 of the Analysis for additional detail.

Area 4CDE comprises most of the Bering Sea subarea and historically is the portion of Area 4 where the greatest removals of halibut from commercial fisheries and bycatch occur (see Figure 3–14 in Section 3.1.3.3 of the Analysis). From 1990 to 1996, the commercial halibut fisheries averaged 23 percent and bycatch averaged 77 percent of total halibut removals in Area 4CDE. From 1997 to 2011, commercial halibut fishery removals in Area 4CDE increased as a portion of total removals; the commercial halibut fisheries averaged 44 percent and bycatch averaged 56 percent of total halibut removals in Area 4CDE. In recent years, proportion of halibut removals from the commercial halibut fishery has declined. From 2012 through 2014, the commercial halibut fishery averaged 31 percent and bycatch averaged 68 percent of removals in Area 4CDE. See Figure 3–12 in Section 3.1.3.3 of the Analysis.

D. Halibut Bycatch Management in the BSAI Groundfish Fisheries

The Magnuson-Stevens Act authorizes the Council and NMFS to manage groundfish fisheries in the Alaska EEZ that take halibut as bycatch. The groundfish fisheries cannot be prosecuted without some level of halibut bycatch because groundfish and halibut occur in the same areas at the same times and no fishing gear or technique has been developed that can avoid all halibut bycatch. However, the Council and NMFS have taken a number of management actions over the past several decades to minimize halibut bycatch in the BSAI groundfish fisheries.

Most importantly, the Council has designated Pacific halibut and several other species (herring, salmon and steelhead, king crab, and Tanner crab) as ''prohibited species'' (Section 3.6.1 of the FMP). By regulation, the operator of any vessel fishing for groundfish in the BSAI must minimize the catch of prohibited species (§ 679.21(b)(2)(i)).

Although halibut is taken as bycatch by vessels using all types of gear (trawl, hook-and-line, pot, and jig gear), halibut bycatch primarily occurs in the trawl and hook-and-line groundfish fisheries. NMFS manages halibut bycatch in the BSAI by (1) establishing halibut PSC limits for trawl and non-trawl fisheries; (2) apportioning those halibut PSC

limits to groundfish sectors, fishery categories, and seasons; and (3) managing groundfish fisheries to prevent PSC from exceeding the established limits. The following sections provide additional information on the process NMFS uses to establish, apportion, and manage halibut PSC limits in the BSAI.

Consistent with National Standard 1 and National Standard 9 of the Magnuson-Stevens Act, the Council and NMFS use halibut PSC limits in the BSAI groundfish fisheries to minimize bycatch to the extent practicable while achieving, on a continuing basis, optimum yield from the groundfish fisheries. Halibut PSC limits in the groundfish fisheries provide an additional constraint on halibut PSC mortality and promote conservation of the halibut resource. With one limited exception described later in this preamble, groundfish fishing is prohibited once a halibut PSC limit has been reached for a particular sector or season. Therefore, halibut PSC limits must be set to balance the needs of fishermen, fishing communities, and U.S. consumers that depend on both halibut and groundfish resources.

1. Annual Halibut Bycatch (PSC) Limits and Apportionments of PSC Limits

The total annual halibut PSC limit in the BSAI is 4,575 metric tons (mt) (10.1 million pounds). Of this amount, 3,675 mt is apportioned to trawl gear and 900 mt is apportioned to non-trawl gear as specified at § 679.21(e). Trawl gear in the BSAI groundfish fisheries includes pelagic (midwater) trawl gear and non-pelagic (bottom) trawl gear. Non-trawl gear in the BSAI groundfish fisheries includes pot, hook-and-line, and jig gear.

The halibut PSC limit for trawl gear of 3,675 mt has been unchanged since 2000 (65 FR 31105, May 16, 2000). Section 3.6.4 of the FMP and § 679.21(e) specify that the halibut PSC limit for trawl gear will be apportioned among three groundfish sectors: (1) The CDQ Program (also called the CDQ sector in the proposed rule preamble), (2) the Amendment 80 sector, and (3) the BSAI trawl limited access sector.

A portion of the BSAI halibut PSC limit for trawl gear is first apportioned for use by the CDQ sector. The CDQ sector comprises all trawl and non-trawl vessels that harvest groundfish under the CDQ Program. The CDQ sector receives its halibut PSC apportionment as a Prohibited Species Quota (PSQ) Reserve (§ 679.2). Section 3.7.4.6 of the FMP and regulations at § 679.21(e) allocate 393 mt of the BSAI halibut PSC limit to the groundfish CDQ sector as PSQ Reserve. NMFS further apportions the halibut PSQ Reserve to each CDQ group as PSQ (§ 679.2) in proportion to the percentages specified by NMFS (71 FR 51804, August 31, 2006). PSQ serves as a halibut PSC limit for BSAI groundfish harvests by each CDQ group.

Under § 679.21(e)(3)(i)(A) and (e)(4)(i)(A), the halibut PSQ Reserve of 393 mt is deducted from the PSC limits established for both the trawl sector and the non-trawl sector: 326 mt is deducted from the trawl gear halibut PSC limit of 3,675 mt and 67 mt is deducted from the non-trawl gear halibut PSC limit of 900 mt. Sections 679.21(e)(3)(i)(A) and (e)(4)(i)(A) specify that the PSQ reserve is not further apportioned by gear or fishery or season. Therefore, the CDQ groups may use their halibut PSQ in any trawl or non-trawl gear groundfish CDQ fishery, subject to other requirements in regulation.

Following the deduction of the halibut PSQ reserve, the BSAI halibut PSC limit for trawl gear is further divided between the Amendment 80 and BSAI trawl limited access sectors as specified in Table 35 to part 679. The Amendment 80 sector is apportioned 2,325 mt. This amount is further apportioned to Amendment 80 cooperatives and the Amendment 80 limited access fishery, if any vessels elect to participate in the limited access fishery for that year. The apportionment of halibut PSC to an Amendment 80 cooperative is for exclusive use by the vessels participating in that cooperative. The method for apportioning halibut PSC between Amendment 80 cooperatives and the Amendment 80 limited access fishery is described at § 679.91(d)(2) and (3). Beginning in 2011, all participants in the Amendment 80 sector have participated in Amendment 80 cooperatives. Therefore, this preamble describes the harvesting and apportionment of halibut PSC to Amendment 80 cooperatives in greater detail.

The BSAI trawl limited access sector is assigned 875 mt of halibut PSC. This amount is further apportioned into PSC allowances among fishery categories through the annual harvest specifications process for those fishery categories in which BSAI trawl limited access fishery vessels participate. These fishery categories are (1) pollock/Atka mackerel/''other species'' fishery, (2) Pacific cod fishery, (3) rockfish fishery, and the 4) yellowfin sole fishery (80 FR 11919, March 5, 2015)).

The Amendment 80 Program established provisions that do not make the full amount of the halibut PSC limit available to the trawl sector (see Table 35 to part 679). A portion of the PSC limit is left ''in the water'' and is not available for use as halibut PSC in the groundfish fisheries. Since 2013, the annual amount of halibut PSC limit left in the water has been 150 mt. Additional description of the impacts of implementation of the Amendment 80 Program on BSAI halibut PSC apportionment is provided in the following ''Overview of the BSAI Groundfish Sectors'' section of the preamble.

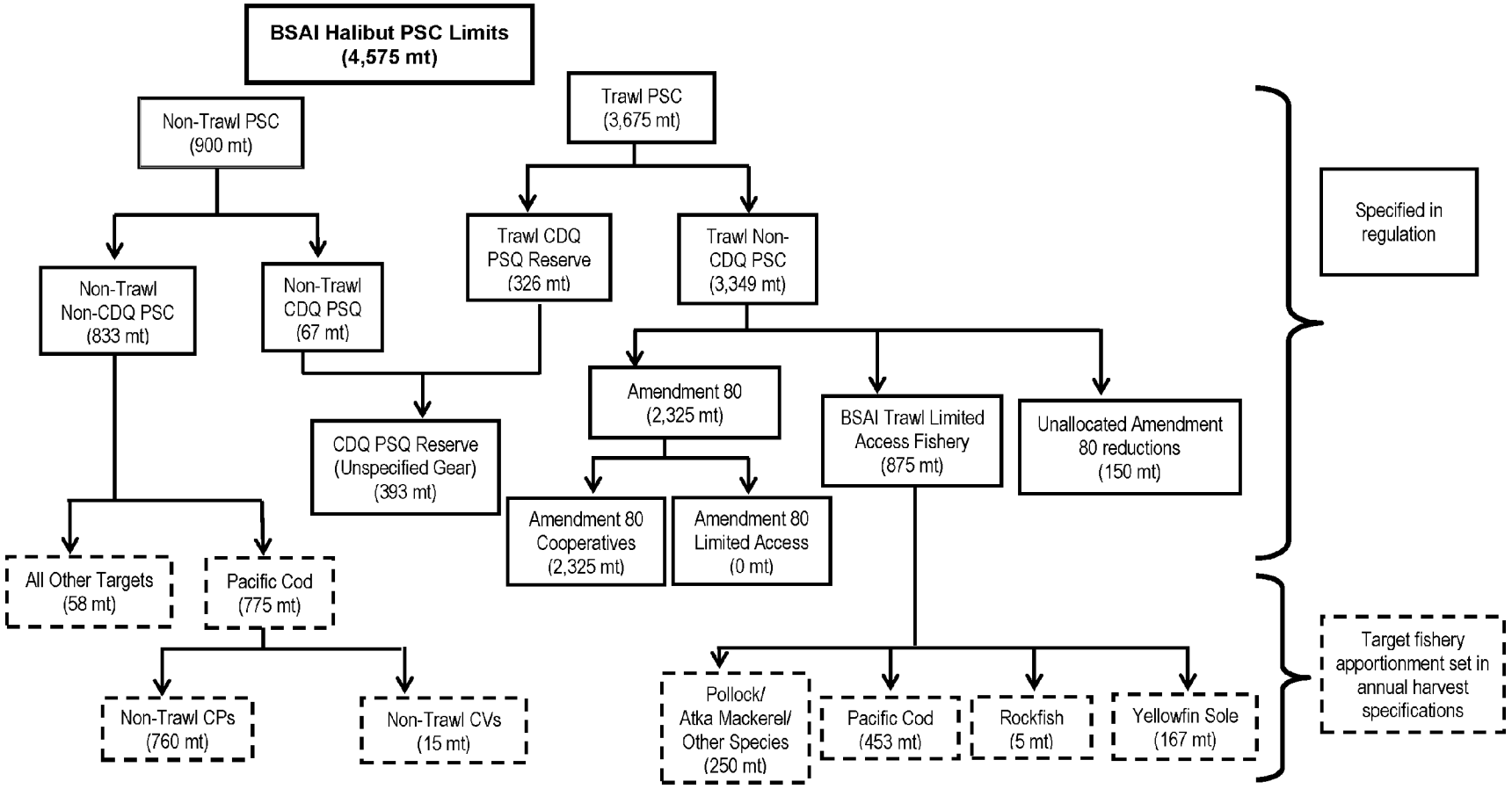
The BSAI halibut PSC limit for non-trawl gear of 900 mt has been in effect since 1993 (58 FR 14524, March 18, 1993). After assigning 67 mt for use by the CDQ sector as PSQ Reserve as described above, the remaining 833 mt of the non-trawl limit is further apportioned into PSC allowances among fishery categories through the annual harvest specifications process (80 FR 11919, March 5, 2015). These fishery categories are specified in § 679.21(e)(4)(ii) as: (1) Pacific cod hook-and-line catcher vessel fishery, (2) Pacific cod hook-and-line catcher/processor fishery, (3) sablefish hook-and-line fishery, (4) groundfish jig gear fishery, (5) groundfish pot gear fishery, and (6) other non-trawl fisheries.

Section 3.6 of the FMP authorizes the Council to exempt specific gear types from the non-trawl halibut PSC limits that are established through the annual harvest specifications process. In past annual consultations with the Council, NMFS has exempted pot gear, jig gear, and the sablefish IFQ hook-and-line gear fishery categories from the non-trawl halibut PSC limit. The Council and NMFS have exempted these gear types from halibut PSC limits, given the limited amount of halibut bycatch that is known to occur by pot and jig gear compared to the total halibut PSC use by other gear types. The sablefish IFQ hook-and-line fishery has not been included based on limited halibut PSC use, particularly in the BSAI. Additional rationale for exempting these gear types from halibut PSC limits is contained in the final 2015 and 2016 harvest specifications (80 FR 11919, March 5, 2015).

Figure 1 shows the process for establishing BSAI annual halibut PSC limits for each groundfish sector and the associated halibut PSC limits established for 2015 (see Section 2.1 of the Analysis for additional information).

BILLING CODE 3510–22–P

Figure 1. Flow Chart of the BSAI Halibut PSC Limit Apportionment Process and the Established Limits for 2015



BILLING CODE 3510–22–C

2. Overview of the BSAI Groundfish Sectors

a. Amendment 80 Sector

The Amendment 80 sector comprises trawl catcher/processors in the BSAI active in groundfish fisheries other than Bering Sea pollock (*i.e.,* the head-and-gut fleet or Amendment 80 vessels). The Amendment 80 species are the following six species: BSAI Atka mackerel, Aleutian Islands Pacific ocean perch, BSAI flathead sole, BSAI Pacific cod, BSAI rock sole, and BSAI yellowfin sole (§ 679.2). The Amendment 80 Program allocates a portion of the TACs of the Amendment 80 species between the Amendment 80 Program and other trawl fishery participants (72 FR 52668, September 14, 2007). The Amendment 80 Program also allocates crab and halibut PSC limits to constrain bycatch of these species while Amendment 80 vessels harvest groundfish. Fishing under the Amendment 80 Program began in 2008.

The Amendment 80 Program allocated QS for Amendment 80 species based on the historical catch of these species by Amendment 80 vessels. The Amendment 80 Program allows and facilitates the formation of Amendment 80 cooperatives among QS holders who receive an exclusive harvest privilege. This exclusive harvest privilege allows Amendment 80 cooperative participants to collaboratively manage their fishing operations and more efficiently harvest groundfish and PSC allocations.

The Amendment 80 sector can be divided between vessels that focus primarily on flatfish (*i.e.,* Alaska plaice, arrowtooth flounder, flathead sole, rock sole, and yellowfin sole) and those vessels that focus on Atka mackerel. In 2013, eleven Amendment 80 vessels focused on flatfish targets. Eight vessels focused on targeting Atka mackerel. The flatfish-focused vessels have higher rates of halibut bycatch than the Atka mackerel vessels. Section 4.4.2 of the Analysis provides detailed information on Amendment 80 sector participants, harvests, and revenues in the BSAI groundfish fisheries.

Annually, each Amendment 80 QS holder elects to participate either in a cooperative or the limited access fishery. Participants in the limited access fishery do not receive an exclusive harvest privilege for a portion of the TACs allocated to the Amendment 80 Program. Beginning in 2011, all QS holders have participated in one of two Amendment 80 cooperatives. For additional detail see Amendment 80 Cooperative Reports available on the NMFS Alaska Region Web site, *http://alaskafisheries.noaa.gov/sustainablefisheries/amds/80/default.htm.*

As specified in Section 3.7.5.2.1 of the FMP and at § 679.91, NMFS annually establishes a halibut PSC limit of 2,325 mt for the Amendment 80 sector. This halibut PSC limit is apportioned between Amendment 80 cooperatives and the limited access fishery according to § 679.91. Amendment 80 cooperatives are responsible for coordinating fishing activities to ensure the cooperative halibut PSC allocation is not exceeded. Section 679.91(h)(3)(xvi) prohibit each Amendment 80 cooperative from using halibut PSC in excess of the amount specified on its annual Amendment 80 Cooperative Quota permit. The regulations further specify that each member of the Amendment 80 cooperative is jointly and severally liable for any violations of the Amendment 80 Program regulations while fishing under the authority of an Amendment 80 Cooperative Quota permit.

In a year when there are vessels participating in the Amendment 80 limited access fishery, NMFS apportions the halibut PSC limit for the Amendment 80 limited access fishery into PSC allowances for the following six trawl fishery categories in which the vessels could participate: (1) Yellowfin sole fishery, (2) rock sole/flathead sole/''other flatfish'' fishery, (3) Greenland turbot/arrowtooth flounder/Kamchatka flounder/sablefish fishery, (4) rockfish fishery, (5) Pacific cod fishery, and (6) pollock/Atka mackerel/''other species'' fishery, which includes the midwater pollock fishery (see § 679.21(e)(3)(i)(B), (e)(3)(ii)(C), and (e)(3)(iv)).

NMFS manages the Amendment 80 limited access fishery halibut PSC allowances because participants in the Amendment 80 limited access fishery do not have exclusive privileges to use a specific amount of halibut PSC. To manage halibut PSC, NMFS monitors participation and PSC use in the Amendment 80 limited access fishery categories. Except for the pollock/Atka mackerel/''other species'' fishery, NMFS has the authority to close a trawl fishery category in the Amendment 80 limited access fishery if NMFS concludes that the fishery category will, or has, exceeded its halibut PSC allowance. A halibut PSC allowance is enforced through the prohibition against conducting any fishing contrary to notification of inseason action, closure, or adjustment (§ 679.7(a)(2)). The regulations establishing the exception for the pollock/Atka mackerel/''other species'' fishery are explained below in the section ''BSAI Trawl Limited Access Sector.''

Section 2.2.1 of the Analysis and the final rule implementing the Amendment 80 Program provide more detailed information on the process NMFS uses to assign Amendment 80 species and halibut PSC to each Amendment 80 cooperative and the Amendment 80 limited access fishery (72 FR 52668, September 14, 2007). The allocations of Amendment 80 species TACs and apportionments of halibut PSC to each of the Amendment 80 cooperatives are provided in the final 2014 and 2015 harvest specifications for the BSAI groundfish fisheries (80 FR 11919, March 05, 2015).

The Amendment 80 groundfish fisheries provide revenue to Amendment 80 vessel owners and crew members that harvest and process groundfish. In addition, the fisheries provide socioeconomic benefits to fishing communities that provide support services for Amendment 80 vessel operations. Amendment 80 groundfish harvests in the BSAI averaged 328,000 mt and generated $325 million in wholesale revenues annually from 2008 through 2013. Three groundfish species provided over three-quarters of the wholesale revenue for the Amendment 80 fleet from 2008 through 2013: yellowfin sole (38 percent of total revenue), Atka mackerel (20 percent), and rock sole (19 percent).

b. BSAI Trawl Limited Access Sector

The BSAI trawl limited access sector comprises all the trawl vessels in the BSAI except Amendment 80 catcher/processors. From 2008 to 2013, 141 vessels participated in the BSAI trawl limited access sector: 99 American Fisheries Act (AFA) catcher vessels that primarily target pollock and also fish for Pacific cod; 17 AFA catcher/processors that primarily target pollock and also fish for yellowfin sole and Pacific cod; and 25 non-AFA catcher vessels that primarily target Pacific cod and yellowfin sole, with some also targeting Atka mackerel and Pacific ocean perch (see Section 4.4.3 of the Analysis for additional detail).

The AFA is a limited access program for Bering Sea pollock implemented by statute in 1998 (Public Law 105–277, 16 U.S.C.A. statutory note). The AFA specified eligible vessels, established sector allocations of pollock, and allowed vessels to form cooperatives. All AFA catcher vessels and catcher/processors participate in the pollock fishery through cooperatives. The pollock fishery accounts for 64 percent of all groundfish harvests in the BSAI but takes a relatively small proportion of

halibut bycatch, averaging only 8 percent of total halibut bycatch in the BSAI from 2008 through 2013.

The BSAI trawl limited access sector is a limited access sector because vessels must have a License Limitation Program (LLP) groundfish license to conduct directed fishing for any groundfish in BSAI (see § 679.4(k)(1)). The LLP is a limited access program because a limited number of licenses are issued and a person only received an LLP license if that person met specific eligibility requirements. However, the LLP does not allocate exclusive harvest privileges for a specific portion of a fishery TAC like the Amendment 80 Program does for the six Amendment 80 species or like the AFA does for Bering Sea pollock. Thus, for all species but pollock, vessels in the BSAI trawl limited access sector are in competition with other participants to maximize their harvest of target species before they reach either their halibut PSC limits, or in the case of Bering Sea pollock, Chinook salmon PSC limits.

As specified in Section 3.7.5.2.1 of the FMP and at § 679.91, NMFS annually establishes a halibut PSC limit of 875 mt for the BSAI trawl limited access sector. This halibut PSC limit of 875 mt is apportioned to fishery categories through the annual harvest specification process. NMFS apportions this sector's PSC limit into PSC allowances among the following trawl fishery categories: (1) Yellowfin sole fishery, (2) rock sole/flathead sole/''other flatfish'' fishery, (3) Greenland turbot/arrowtooth flounder/Kamchatka flounder/sablefish fishery, (4) rockfish fishery, (5) Pacific cod fishery, and (6) pollock/Atka mackerel/''other species'' fishery, which includes the midwater pollock fishery. For additional detail see Table 16 in the 2015 and 2015 final harvest specifications (80 FR 11919, March 5, 2015) and § 679.21(e)(3)(i)(B), (e)(3)(ii)(C), and (e)(3)(iv)).

After NMFS establishes PSC allowances for these trawl fishery categories, NMFS may, through the annual harvest specification process, further apportion the allowances by season, according to criteria specified in regulation (§ 679.21(e)(5)). NMFS apportions some halibut PSC allowances in specific groundfish fisheries by season to ensure that a portion of the halibut PSC allowance for that fishery is available for use earlier in the year and a portion of the halibut PSC allowance remains to support groundfish fishing in that fishery that occurs later in the year. The limits assigned to each season for a groundfish fishery reflect halibut PSC likely to be taken during that season in that fishery.

In general, the PSC regulations state that if NMFS determines that any of these trawl fisheries will reach the PSC allowance for that fishery (or a seasonal apportionment of an allowance), NMFS closes that trawl fishery in the BSAI for the rest of the year, or, if applicable, for the rest of the season (§ 679.21(e)(7)(v)). NMFS has authority under current regulations to close the following trawl fisheries if they will reach their halibut PSC allowance: (1) Yellowfin sole fishery, (2) rock sole/flathead sole/''other flatfish'' fishery, (3) Greenland turbot/arrowtooth flounder/Kamchatka flounder/sablefish fishery, (4) rockfish fishery, and (5) Pacific cod fishery (§ 679.21(e)(7)(v)). For example, in May 2014, NMFS closed the yellowfin sole fishery throughout the BSAI to prevent that fishery from exceeding its halibut PSC allowance (79 FR 29136, May 21, 2014). The Pacific cod and yellowfin sole fisheries are the primary fisheries that can be constrained by halibut PSC limits in the BSAI trawl limited access sector.

The regulations include an exception for the pollock/Atka mackerel/''other species'' fishery category. If the pollock/Atka mackerel/''other species'' fishery category will reach its halibut PSC allowance, NMFS does not have the authority to close the pollock/Atka mackerel/''other species'' fishery category. This is the result of the interaction of several regulations. As noted previously, NMFS must count all halibut PSC in the midwater pollock fishery category against the PSC allowance for the pollock/Atka mackerel/''other species'' fishery category (§ 679.21(e)(3)(ii)(C)). By a regulation adopted in 1992, if the PSC allowance for the pollock/Atka mackerel/''other species'' category will be reached, NMFS only has authority to close directed fishing for pollock to trawl vessels using nonpelagic trawl gear (57 FR 43926, 43935, September 23, 1992; § 679.21(e)(7)(i)). However, in 2000, NMFS prohibited directed fishing for pollock in the BSAI with nonpelagic trawl gear at all times and extended that prohibition to CDQ sector vessels in 2006 (65 FR 31105, May 16, 2000; 71 FR 36694, June 28, 2006; § 679.24(b)(4)). Thus, if the halibut PSC allowance for the trawl fishery category of pollock/Atka mackerel/''other species'' will be reached, NMFS does not have authority to take additional action. The Council did not recommend, and NMFS did not propose, changes in the management of the pollock/Atka mackerel/''other species'' fishery.

Even though NMFS does not have authority to close this fishery, halibut PSC use in the pollock/Atka mackerel/''other species'' fishery category recently (*i.e.,* 2013 and 2014) was below the amount the PSC allowance for this fishery category. Based on recent halibut PSC use, NMFS anticipates that halibut PSC in this trawl fishery category would not exceed the PSC allowance that would be established for this fishery category under this proposed rule in future years. However, if this fishery did exceed its PSC allowance, NMFS considers recent halibut PSC use each year when it establishes PSC allowances and could increase the PSC allowance for this fishery category. But because the regulation establishes an overall halibut PSC limit for the BSAI trawl limited access sector of 710 mt, an increase in the halibut PSC allowance for one fishery category in this sector would be matched by a corresponding decrease in the halibut PSC allowance for other fishery category or categories in this sector.

The BSAI trawl limited access fisheries provide revenue to vessel owners and crew members that harvest and process groundfish. In addition, the fisheries provide socioeconomic benefits to fishing communities that provide support services for BSAI trawl limited access vessel operations. Groundfish harvests in the BSAI trawl limited access fisheries averaged 1 million mt and generated $1.3 billion in wholesale revenues from 2008 through 2013. During this period, the pollock fishery was 93 percent of the groundfish harvest and wholesale revenue for the BSAI trawl limited access sector. The Pacific cod fishery was 4 percent and the yellowfin sole fishery was 2 percent of the groundfish harvest and wholesale revenue for the BSAI trawl limited access sector. Section 4.4.3 of the Analysis provides detailed information on participants, harvests, and revenues in the BSAI trawl limited access sector fisheries.

c. BSAI Non-trawl Sector

The BSAI non-trawl sector comprises all the non-trawl vessels in the BSAI except vessels fishing for groundfish in the CDQ sector. Non-trawl vessels participating in the CDQ sector are addressed in the following section of the preamble. As described in the ''Annual Halibut Bycatch (PSC) Limits and Apportionments of PSC Limits'' section of the preamble above, the Council and NMFS have exempted pot gear, jig gear, and the sablefish IFQ hook-and-line gear fishery categories from halibut PSC limits. Because these three fishery categories are currently exempted from halibut PSC limits, this section of the preamble does not address these fishery categories (see Section 3.1.3.1 of the

Analysis for additional detail on the pot gear, jig gear, and the sablefish IFQ hook-and-line gear fishery categories).

From 2008 to 2013, an average of 47 vessels participated in the portion of the BSAI non-trawl sector subject to halibut PSC limits: 35 hook-and-line catcher/processor vessels that primarily targeted Pacific cod and to a lesser extent Greenland turbot; and 12 hook-and-line catcher vessels that targeted only Pacific cod.

Hook-and-line catcher/processor vessels that target Pacific cod comprise the greatest number of vessels and amount of harvests in the non-trawl sector. The Analysis shows that from 2008 through 2013, hook-and-line catcher/processors harvested more than 98 percent of all of the fish harvested by the non-trawl sector. Most of this harvest was from the BSAI Pacific cod fishery. The BSAI hook-and-line catcher/processors harvested 99 percent of the total amount of Pacific cod harvested in the BSAI by non-trawl vessels. The BSAI Pacific cod fishery comprised 98 percent of total harvests for the hook-and-line catcher/processors from 2008 through 2013 (see Sections 4.4.4 and 4.4.5 of the Analysis). All but one hook-and-line catcher/processor fishing in the BSAI participates in a voluntary cooperative, the Freezer Longline Conservation Cooperative (FLCC). The FLCC has allowed hook-and-line catcher/processors to fish as a coordinated group and has allowed less efficient vessels to decrease fishing or stop entirely. Additional details about the FLCC are provided in Section 4.4.4.8 of the Analysis.

The BSAI non-trawl sector also includes hook-and-line catcher vessels that exclusively target Pacific cod. Data from 2008 through 2013 show that harvests of BSAI Pacific cod comprised 100 percent of the total harvests and total revenue for these vessels. The BSAI hook-and-line catcher vessels targeting Pacific cod harvested 1 percent of the total amount of Pacific cod harvested in the BSAI by non-trawl vessels from 2008 through 2013. During this period, 42 unique vessels participated in the hook-and-line catcher vessel fishery, although the number of vessels participating in this fishery has declined from 20 in 2008 to 11 in 2013 (see Section 4.4.5.1 of the Analysis).

Some non-trawl vessels also harvest groundfish other than Pacific cod, but harvests of these other species are limited. Over the past decade, only hook-and-line catcher/processors have participated in the other non-trawl fisheries, specifically targeting Greenland turbot. Hook-and-line catcher/processor harvested approximately 40 percent of the total amount of Greenland turbot harvested in the BSAI from 2008 through 2013 (see Table 4–10 in Section 4.4.1.6 and Table 4–50 in Section 4.4.4.2 of the Analysis). During this time period, 20 unique vessels participated in the hook-and-line catcher/processor fishery for Greenland turbot, although the number of vessels participating in recent years (from 2010 through 2013) has ranged between 13 and 7 each year (see Section 4.4.4.1 of the Analysis).

Under current regulations, the non-trawl sector's PSC limit of 833 mt is apportioned under the annual harvest specification process. Section 679.21(e)(4)(i)(C) specifies that NMFS will apportion the BSAI non-trawl sector's PSC limit into PSC allowances ''based on each category's proportional share of the anticipated bycatch mortality of halibut during a fishing year and the need to optimize the amount of total groundfish harvested under the non-trawl halibut PSC limit.'' As explained above in ''Annual Halibut Bycatch (PSC) limits and Apportionment of PSC limits,'' NMFS has apportioned the PSC limit for the BSAI non-trawl sector among three non-trawl fishery categories: (1) Pacific cod hook-and-line catcher vessel fishery, (2) Pacific cod hook-and-line catcher/processor fishery, and (3) other non-trawl fisheries. NMFS has the same authority to apportion, by season, the halibut PSC allowances among the non-trawl fisheries as it has for the trawl fisheries (§ 679.21(e)(5)).

As with trawl fisheries, NMFS manages the halibut PSC allowances for the non-trawl fisheries through fishery closures. Section 679.21(e)(8) specifies that if NMFS concludes that a non-trawl fishery will reach its halibut PSC allowance (or a seasonal apportionment of an allowance), it will close that non-trawl fishery in the entire BSAI for the rest of the year (or the rest of the season).

The non-trawl fisheries provide revenue to vessel owners and crew members that harvest and process groundfish on catcher vessels and catcher/processors. In addition, the fisheries provide economic benefits to shorebased processors that receive landings of Pacific cod from catcher vessels and to fishing communities that provide support services for BSAI non-trawl vessel operations. Groundfish harvests in the BSAI non-trawl fisheries averaged 116,000 mt and generated $160 million in wholesale revenues annually from 2008 through 2013. Sections 4.4.4 and 4.4.5 of the Analysis provides detailed information on participants, harvests, and revenues in the BSAI trawl limited access groundfish fisheries.

d. CDQ Sector

The CDQ sector includes all trawl and non-trawl vessels that harvest groundfish under the CDQ Program. CDQ vessels primarily target pollock using trawl gear and target Pacific cod using hook-and-line gear. Other species such as yellowfin sole, several flatfish species, Atka mackerel and Pacific ocean perch allocated to the CDQ sector are targeted by vessels using trawl gear.

From 2008 to 2013, 56 vessels participated in the CDQ sector using trawl and non-trawl gear to harvest BSAI groundfish, with nearly 60 percent of the vessels operating in the pollock and Pacific cod target fisheries. The pollock fishery accounted for 73 percent of the total groundfish harvest in the CDQ sector from 2008 through 2013. Vessels participating in the CDQ sector fully harvest the sector's pollock and Pacific cod allocations. Vessels participating in the CDQ sector have not fully harvested other allocations of groundfish species due to a variety of operational factors and choices described in Section 4.4.6 of the Analysis.

As specified in Section 3.7.4.6 of the FMP and at § 679.21(e), NMFS annually establishes a halibut PSC limit of 393 mt for the CDQ sector. The halibut PSC limit is divided among the six CDQ groups by established percentages (71 FR 51804 (August 31, 2006). Each CDQ group receives an apportionment of this halibut PSC limit as halibut prohibited species quota (PSQ), which is a specific amount of halibut that vessels fishing for that CDQ group may use in a year. The apportionment of halibut PSQ to each CDQ group is similar to the apportionment of halibut PSC Cooperative Quota to an Amendment 80 cooperative. The CDQ group manages the use of its halibut PSQ apportionment. The CDQ group has the responsibility to ensure that the vessels fishing its CDQ groundfish allocation do not use halibut PSQ in excess of the amount of the CDQ group's halibut PSQ. This limit is enforced at § 679.7(d)(3), which prohibits a CDQ group from exceeding its apportionment of halibut PSQ.

The CDQ groundfish fisheries provide revenue to CDQ groups that receive royalties from leasing their groundfish allocations for harvest by vessels that participate in non-CDQ groundfish fisheries. In addition, CDQ groundfish harvests provide revenue to vessel owners and crew members that harvest and process groundfish on catcher

vessels and catcher/processors, to shorebased processors that receive landings of CDQ groundfish, and to fishing communities that provide support services for vessels fishing in CDQ groundfish fisheries. By species, the CDQ groundfish allocations that generate revenue for the CDQ groups are as follows: 75 percent of wholesale revenue from pollock; 15 percent from Pacific cod; 6 percent from yellowfin sole; and 4 percent from all other species. Section 4.4.6.1 of the Analysis describes the vessels that participate in harvesting the CDQ allocations of groundfish.

From 2008 through 2013, the CDQ sector has consistently harvested almost 100 percent of its pollock allocations. The average annual pollock harvests from 2008 through 2014 are 112,000 mt resulting in $150 million in wholesale revenues. From 2008 through 2013, the CDQ sector harvested an average of 60 percent of its non-pollock species allocations. During this period, vessels in the CDQ sector averaged annual non-pollock groundfish harvests of 42,000 mt and $50 million in wholesale revenues. Section 4.4.6 of the Analysis provides detailed information on participants, harvests, and revenues in the CDQ groundfish fisheries.

As described in the ''Halibut Fisheries in the BSAI'' section of the preamble above, CDQ groups also receive an annual allocation of the commercial halibut fishery catch limit recommended by the IPHC. CDQ halibut allocations provide revenue to vessel owners and crew members that harvest and process halibut, to shorebased processors that receive landings of CDQ halibut, and to fishing communities that provide support services for vessels fishing in CDQ halibut fisheries. Sections 4.5.1 and 4.5.2 of the Analysis provide detailed information on participants, harvests, and revenues in the CDQ halibut fisheries.

3. Halibut Bycatch (PSC) Use in the BSAI Groundfish Sectors

The annual halibut PSC limit established for each BSAI groundfish sector is an upper limit on halibut PSC in that sector for that year. However, the amount of halibut PSC used by a BSAI groundfish sector is almost always less than its halibut PSC limit. Halibut PSC use is less than the halibut PSC limit due to a wide range of operational factors such as the need to avoid a closure or an enforcement action if a PSC allocation or allowance is reached. Table 1 shows the halibut PSC limit and average halibut PSC use for the Amendment 80, BSAI trawl limited access, BSAI non-trawl, and CDQ sectors from 2008 through 2014.

TABLE 1—CURRENT BSAI HALIBUT PSC LIMITS AND USE BY BSAI GROUNDFISH SECTOR FROM 2008 THROUGH 2014

BSAI Groundfish sector	Current annual BSAI halibut PSC limit (mt)	Current annual BSAI halibut PSC limit as a % of the total annual BSAI halibut PSC limit	Average annual BSAI halibut PSC use from 2008–2014 (mt)	Average annual BSAI halibut PSC use from 2008–2014 as a % of total annual BSAI halibut PSC use	Average annual BSAI halibut PSC use from 2008–2014 as % of the sector's BSAI halibut PSC limit
Amendment 80 sector	2,325	53	2,047	59	88
BSAI trawl limited access sector	875	20	710	20	81
BSAI non-trawl sector	833	19	505	15	61
CDQ sector	393	9	215	6	55
Total for all sectors	4,426	100	3,477	100	79

Table 1 shows that the Amendment 80 sector used the largest portion of halibut PSC in recent years. The Amendment 80 sector used, on average, approximately 60 percent of the total amount of halibut PSC used by all BSAI groundfish sectors from 2008 through 2014. The BSAI trawl limited access sector used 20 percent, the BSAI non-trawl sector used 15 percent, and the CDQ sector used 6 percent of the total amount of halibut PSC.

Table 3–14 in Section 3.1.3.3 of the Analysis shows halibut PSC annually for each sector from 2008 through 2014. The Amendment 80 sector used, on average, 88 percent of its annual halibut PSC limit from 2008 through 2014. Halibut PSC use in the Amendment 80 sector varies annually, and the sector's use as a percentage of the limit from 2008 through 2014 ranged from 78 percent in 2011 to 97 percent in 2010.

The BSAI trawl limited access sector used, on average, 81 percent of its annual halibut PSC limit from 2008 through 2014, varying from 55 percent of the sector limit in 2010 to 110 percent of the sector limit in 2012.

The BSAI non-trawl sector used, on average, 61 percent of its annual halibut PSC limit from 2008 through 2014. Like the trawl sectors, halibut PSC use in the non-trawl sector varied substantially on an annual basis. Almost all of the halibut PSC in the non-trawl sector is used by hook-and-line catcher/processors targeting Pacific cod. These vessels averaged 98 percent of the total non-trawl halibut PSC use from 2008 through 2014. Halibut PSC use in the Pacific cod hook-and-line catcher/processor sector has declined since 2010 following formation of the FLCC. From 2008 through 2014, halibut PSC use by the non-trawl sector ranged from 52 percent of the sector limit in 2014 to 74 percent of the sector limit in 2008.

The CDQ sector used, on average, 55 percent of its annual halibut PSC limit from 2008 through 2014, varying from 38 percent of the sector limit in 2009 to 67 percent of the sector limit in 2013. Halibut PSC use in the CDQ sector has typically been much lower than the PSC limit due to a variety of operational choices to limit catch of some groundfish species, and the methods used by CDQ groups to assign halibut PSC when fishing jointly for CDQ and non-CDQ species. Section 4.4.6.2 of the Analysis describes these factors in greater detail.

For all sectors, Section 3.1.3.3 of the Analysis describes the annual variations in halibut PSC use resulting from changes in groundfish TACs and changes in weather, environmental conditions, and other factors. Historical halibut PSC use information shows that each sector's PSC use has varied annually in response to these changing conditions. NMFS anticipates that these annual variations in halibut PSC use would continue under the proposed rule.

III. Rationale and Impacts of Amendment 111 and the Proposed Rule

Amendment 111 and the proposed rule would reduce the current halibut PSC limits for the BSAI groundfish fisheries. Amendment 111 and the proposed rule are necessary to minimize halibut bycatch to the extent practicable in the BSAI groundfish fisheries, while at the same time providing for the long-term sustainable optimum yield from the groundfish fisheries. By reducing halibut PSC in the groundfish fisheries from current levels, the proposed rule may provide additional harvest opportunities in halibut fisheries in the BSAI and, ultimately, in other Areas (Areas 2 and 3). This section describes the rationale for and the anticipated impacts of the halibut PSC limit reductions that would be implemented by the proposed rule.

In recommending the proposed rule, the Council considered the fact that the halibut resource is fully allocated. Recent declines in halibut exploitable biomass, particularly in Area 4 in the BSAI, underscore the need to minimize bycatch of halibut in the groundfish fisheries to the extent practicable. Since the existing BSAI halibut PSC limits were established in 2000, the exploitable biomass has declined and the commercial halibut sector has experienced decreased catch limits as a result (see Section 2.4 of the Analysis).

Since 2008, the commercial halibut fishery catch limit in the BSAI in Area 4 has declined, although the 2015 commercial catch limit in Area 4 has increased slightly from the recent low in 2014. The Council determined that the proposed rule is necessary because catch limits for the commercial halibut fisheries in the BSAI have declined in recent years and because the halibut PSC used in the BSAI groundfish fisheries has increased as a proportion of total halibut removals.

In recommending the proposed rule, the Council and NMFS considered alternatives that ranged from a 10 percent to a 50 percent reduction in halibut PSC limits for each of the four BSAI groundfish sectors: the Amendment 80, the BSAI trawl limited access, the non-trawl, and the CDQ sectors. The Council and NMFS determined that it was appropriate to recommend a PSC limit reduction for each sector to recognize differences among the sectors in halibut PSC use and management as well as differences in fishery participation, gear and operation type, and available tools to further reduce halibut PSC use.

In making its recommendation, the Council and NMFS also considered the national standards in section 301(a) of the Magnuson-Stevens Act. This preamble has already described the consideration of National Standard 1 (prevent overfishing while ensuring, on a continuing basis, optimum yield from the fisheries), and National Standard 9 (minimize bycatch, to the extent practicable, and where bycatch cannot be avoided, minimize bycatch mortality). Two other national standards were particularly relevant to the Council and NMFS in developing Amendment 111 and the proposed rule: National Standard 8 (provide for the sustained participation of fishing communities and to the extent practicable, minimize adverse economic impacts on such communities) and National Standard 4 (allocation of fishing privileges shall be fair and equitable). Section 6.1 of the Analysis provides additional detail on the consideration of the national standards. The Council believes, and NMFS agrees, that the proposed PSC limit reductions are consistent with the national standards.

The Council and NMFS considered the impacts of alternative ranges of halibut PSC limit reductions on (1) the halibut stock, (2) the halibut fishery participants and fishing communities that are engaged in directed halibut fisheries in the BSAI and in other Areas, and (3) the BSAI groundfish fishery participants and fishing communities that are engaged in the BSAI groundfish fisheries. The Analysis provides detailed information that the Council and NMFS considered for the proposed rule.

After considering these factors, the Council recommended, and NMFS proposes, to reduce halibut PSC limits by 25 percent in the Amendment 80 sector, 15 percent in the BSAI trawl limited access sector, 15 percent in the non-trawl sector, and 20 percent in the CDQ sector. The resulting halibut PSC limits from this proposed reduction would be 1,745 mt for the Amendment 80 sector; 745 mt for the BSAI trawl limited access sector; 710 mt for the BSAI non-trawl sector; and 315 mt for the CDQ sector. The following sections of the preamble describe the rationale for and impacts of the proposed rule on the halibut stock, the directed halibut fishery and fishing communities, and the BSAI groundfish fishery participants and fishing communities.

A. Methods for Analysis of Impacts

In order to analyze the impact of the proposed rule and other alternatives considered, the Analysis made two broad assumptions. First, the Analysis assumed the IPHC would (1) differentiate halibut that are over 26 inches in length (O26) from halibut that are under 26 inches in length (U26) for purposes of the annual stock assessment and for establishing commercial fishery catch limits, and (2) establish the blue line catch limit as the commercial fishery catch limit for all IPHC areas. The Analysis assumes application of the IPHC harvest policy because it represents the stated policies of the IPHC and because possible changes in this policy, or the specific commercial catch limits that will actually be adopted by the IPHC, cannot be known or predicted. As described above in the ''Allocation of Halibut Among Fisheries'' section above, the IPHC is not required to apply its harvest policy and frequently has deviated from it when adopting annual catch limits. However, for purposes of this analysis, assuming application of the IPHC harvest policy is the best available method for analyzing the effects of Amendment 111 and the proposed rule.

Second, based on this assumption, the Analysis provides a prospective evaluation of the economic impacts of halibut PSC limit reductions on halibut fisheries and the groundfish fisheries for ten years (2014 through 2023) under two scenarios with different assumptions about the ability of fishery participants to coordinate harvesting activities to minimize halibut PSC. The ''low impact'' scenario assumes that fishery participants are able to coordinate harvesting activities to achieve almost optimal efficiency in the use of PSC across all sectors. In other words, the impact of halibut PSC reductions can be mitigated to the maximum extent practicable through well-coordinated sector-wide efforts. The ''high impact'' scenario assumes significantly less coordination across the sector and models each company operating individually to optimize its PSC use. In other words, each company within a sector will attempt to mitigate the impact of halibut PSC reductions on their operations, but with less well-coordinated sector-wide efforts. Section 4.6 of the Analysis details the methods used. Based on the Analysis and information provided to the Council in public testimony, NMFS determined that the BSAI groundfish sectors have varying abilities to optimize efficient use of halibut PSC, and it is likely that the actual economic impacts of the proposed rule will fall within the range between the low impact and high impact scenarios presented in the Analysis.

B. Impacts on the Halibut Stock

The Council determined, and NMFS agrees, that the proposed rule would

reduce halibut PSC relative to current halibut PSC use. This reduction in halibut PSC use is expected to increase the total amount of halibut exploitable biomass, and potentially the female spawning biomass. Reductions in halibut PSC would be expected to provide additional harvest opportunities to commercial, personal use, sport, and subsistence halibut fisheries in the BSAI and in other Areas.

Overall, the Council's recommendation is expected to result in a decrease of approximately 361 mt in halibut PSC relative to current levels of halibut PSC use (see Section 4.13 of the Analysis). A decrease of 361 mt represents approximately a 10 percent decrease in total halibut PSC relative to current use. This estimate is based on the assumption that the Amendment 80 sector, which is the sector most constrained by the proposed halibut PSC limit, would fully use its halibut PSC limit of 1,745 mt in each year. As Table 1 of this preamble and Section 3.1.3.3 of the Analysis show, the BSAI groundfish sectors have consistently used less than their halibut PSC allocations due to regulatory and operational limits. Therefore, the actual PSC reduction would likely be higher than this estimate.

The best available information estimates that approximately 64 percent of the halibut PSC mortality in the BSAI is O26 halibut (see Table 4–219 in Section 4.14.1.4 of the Analysis). Assuming that the IPHC were to apply its current harvest policy when adopting annual catch limits and the proportion of O26 and U26 bycatch remains constant, the halibut ''savings'' from reductions in halibut PSC use under the proposed rule would be expected to provide an additional commercial harvest opportunity in the year following the halibut PSC reduction. Therefore, the primary impact of the proposed rule would be to provide additional harvest opportunity to the Area 4 commercial fishery because most (64 percent) of the bycatch is O26. This result would be expected under all of the alternatives to reduce halibut PSC limits (from 10 to 50 percent) considered by the Council and NMFS.

The best available information estimates that approximately 36 percent of halibut PSC mortality in the BSAI is U26 halibut (see Table 4–219 in Section 4.14.1.4 of the Analysis). The proposed reductions in halibut PSC use would decrease mortality of U26 halibut, which could benefit the halibut stock by contributing to the long-term abundance of the halibut resource. Ultimately, reductions in U26 bycatch could result in additional halibut that can grow and reproduce and then ultimately be harvested in the commercial, personal use, sport and subsistence fisheries on a coastwide basis. The extent to which a decrease in U26 halibut PSC may affect the coastwide female spawning biomass is not well-known based on the best available information (see Section 3.1.1.2 of the Analysis for additional detail).

While the impacts of a decrease in U26 halibut mortality on the coastwide halibut stock are not well-known, the best available information suggests that reductions in U26 halibut PSC under the proposed rule are unlikely to impact the long-term abundance of the halibut stock. The Analysis estimates that even under the most conservative halibut PSC reductions considered by the Council, a 50 percent reduction of the PSC limits in all four BSAI groundfish sectors, the reduction in the amount of U26 halibut PSC would likely range from 690,000 pounds to 740,000 pounds. Therefore, even under the greatest PSC limit reduction alternatives considered, this reduction would represent less than 1 percent of the 2015 coastwide female spawning halibut biomass (see Table 3–1 in Section 3.1.1 of the Analysis).

The Council determined, and NMFS agrees, that under the reduction in U26 halibut mortality estimated from the proposed rule, a reduction estimated to range from 188,000 to 210,000 pounds, the proposed rule could result in some conservation benefit compared to the status quo. The conservation benefit would be limited because it comprises a small proportion of the total female spawning biomass (less than 1 percent of the total female spawning biomass). The specific long-term impacts of reduced U26 bycatch on potential long-term commercial, personal use, sport, or subsistence harvests in a specific Area cannot be predicted with certainty given the available information. Some of the factors affecting the ability to determine impacts are the variable time required for U26 bycatch to grow, reproduce, and become available for harvest; changes in halibut stock abundance on a coastwide basis; and changes in the distribution of harvestable biomass by area in the future. Section 4.14.1.2 of the Analysis reviewed the potential long-term halibut stock impacts of halibut bycatch reduction measures throughout all Areas under a range of assumptions and concluded that the overall impact of these reductions was limited on an annual and 10-year basis. Therefore, under the proposed rule, overall halibut mortality would not be expected to change significantly.

C. Impacts on Halibut Fishery Participants and Fishing Communities

In recommending the proposed rule, the Council and NMFS considered the impacts of reducing halibut PSC limits on fishermen and fishing communities that depend on the halibut resources in the BSAI and in other Areas in Alaska, British Columbia, and the U.S. West Coast, including the commercial, personal use, sport, and subsistence fisheries (see Section 4.13.3 and 4.14.1 of the Analysis).

Specifically, the Analysis estimates the potential increases in halibut fishery harvests and revenues in Area 4 and in other Areas from reduced halibut PSC limits. The proposed reduction in halibut PSC limits could benefit participants in the commercial halibut fisheries if it results in increased levels of harvestable halibut and increased catch limits. Catch limits are not established for the personal use, sport, and subsistence halibut fisheries in Area 4, and the proposed reduction in halibut PSC limits is not expected to impact halibut harvests in those fisheries in the near term, because harvests in personal use, sport, and subsistence fisheries are deducted before commercial catch limits are established.

The Analysis estimates that the proposed rule could result in increased commercial fishery harvests in Area 4 ranging from 315,000 pounds to 353,000 pounds each year compared to current levels of harvests over the 10-year period used for the Analysis. This increased harvest is estimated to provide additional commercial halibut fishery revenues ranging from $3.4 million to $3.5 million each year, which would total $34 million to $38 million over the 10-year period (see Table 4–210 in Section 4.14 of the Analysis). This increased revenue is due to the increased availability of O26 and U26 to the commercial halibut fishery from the halibut PSC reductions.

The Analysis estimates that the proposed rule could reduce U26 bycatch that may provide an additional 64,000 pounds to 72,000 pounds of directed halibut harvest annually in Areas outside of Area 4 (*i.e.,* Areas 2 and 3). These savings are estimated to provide additional halibut revenues to fishery participants ranging from $2.7 million to $3 million annually over a 10-year period once the proposed rule is implemented. The Analysis notes that these potential benefits would not accrue until the halibut have reached a size where they could be harvested. The Analysis assumes this will occur from 6 through 10 years after the halibut PSC

savings occur (see Table 4–211 in Section 4.14 of the Analysis).

The Analysis describes the potential impacts of the proposed rule on BSAI coastal fishing communities that participate in the halibut fishery, especially in Area 4CDE. Section 4.14.1.3 of the Analysis states that the proposed action is likely to provide the greatest benefit to fishing communities in the BSAI that are highly dependent on halibut as a primary source of revenue for local vessels that participate in the commercial fishery. Appendix C to the Analysis includes a detailed description of the fishing communities most dependent on the halibut resource in the BSAI. Relative to the status quo, the proposed rule may provide additional opportunities for fishing community residents to harvest halibut by reducing the maximum amount of halibut PSC that can be taken in the groundfish fisheries. Although additional reductions in halibut PSC limits may provide additional harvest opportunities to residents participating in the commercial halibut fishery, the benefit to any one community would be limited by the distribution of harvest privileges among participants in the IFQ and CDQ Programs (see Section 4.14.1.4 of the Analysis for additional detail).

D. Impacts on BSAI Groundfish Fishery Participants and Fishing Communities

The Council and NMFS considered the impacts of reduced halibut PSC limits on BSAI groundfish sector participants. As discussed in Section 4.14.2.2 of the Analysis, the Council and NMFS considered a number of factors in making the proposed reductions to halibut PSC limits for each BSAI groundfish sector. First, the Council and NMFS considered the relative amount of halibut PSC in each of the BSAI groundfish sectors. Second, the Council and NMFS considered whether a groundfish sector had been able to harvest groundfish TACs with lower amounts of halibut PSC use than the sector's current limit. Third, the Council and NMFS considered the ''tools'' (*i.e.,* changes in fishery operations) available to each groundfish sector to adapt to halibut PSC limit reductions. Fourth, the Council and NMFS considered the potential socioeconomic impacts of reduced halibut PSC limits. As part of this last consideration, the Council and NMFS considered both the adverse socioeconomic impacts of halibut PSC limit reductions from reduced groundfish harvests on BSAI groundfish harvesters and fishing communities that participate in groundfish fisheries, as well as the potential benefits to the halibut harvesters and fishing communities that participate in the halibut fishery. The Analysis provides detailed information for each of these factors.

1. Amendment 80 Sector Halibut Bycatch (PSC) Limit Reduction

The Council recommended, and NMFS proposes, a minimum 25 percent reduction in the halibut PSC limit for the Amendment 80 sector. The reduction in the halibut PSC limit for the Amendment 80 sector from 2,325 mt to 1,745 mt is a reduction of 580 mt. The proposed halibut PSC limit of 1,745 mt would be a 15 percent reduction from the amount of halibut PSC used, on average, by the Amendment 80 sector from 2008 through 2014. The proposed halibut PSC limit would be a 17 percent reduction from Amendment 80 sector halibut PSC use in 2014 (see Section 3.1.3.3 of the Analysis). This is the largest reduction for any of the four groundfish sectors subject to the proposed rule.

This 1,745 halibut PSC limit would apply to all Amendment 80 vessels participating in an Amendment 80 cooperative. The Council also considered a more restrictive halibut PSC limit that would apply to any participants in the Amendment 80 limited access fishery. Because all Amendment 80 vessels are assigned to Amendment 80 cooperatives currently, and are likely to continue to participate in Amendment 80 cooperatives in the future, the Council and NMFS anticipate that the 1,745 mt halibut PSC limit will apply to the entire Amendment 80 sector. The halibut PSC limit that would apply to participants in the Amendment 80 limited access fishery is described later in this preamble.

The Amendment 80 sector uses the largest portion of halibut PSC in the BSAI groundfish fisheries: 59 percent from 2008 through 2014 as shown in Table 1 in this preamble and in Section 3.1.3.3 of the Analysis. Therefore, the proposed halibut PSC limit would be expected to have the greatest impact on the Amendment 80 sector relative to the other BSAI groundfish sectors.

The Council and NMFS considered the use of halibut PSC by the Amendment 80 sector. On average, the Amendment 80 sector has not used the full amount of its halibut PSC allocation as shown above in Table 1 in this preamble and in Table 3–14 in Section 3.1.3.3 of the Analysis. The Analysis shows that total groundfish harvests by the Amendment 80 sector in the years of lowest and highest halibut PSC use were not substantially different from the average total amount of groundfish harvested by the Amendment 80 sector from 2008 through 2014. The Amendment 80 sector averaged 324,000 mt of groundfish harvest from 2008 through 2014. The Amendment 80 sector harvested 325,000 mt of groundfish in 2011, the year of lowest PSC use, and 337,000 mt in 2010, the year of highest PSC use (see Table 4–1 in Section 4.4.1.1 of the Analysis). The Council determined, and NMFS agrees, that the best available information indicates that the proposed halibut PSC limit for the Amendment 80 sector would be below its lowest use of halibut PSC in any year.

The Council and NMFS recognize that some of the patterns of halibut PSC use observed in the Amendment 80 sector are due to a range of biological, oceanographic, and operational factors, but the Analysis indicates that halibut PSC rates could be reduced through additional changes in fishery operations (*i.e.,* the expanded use of tools). Although the Analysis does not specifically quantify how easily or how much improvement can be made with limited impact on groundfish harvests, the Analysis indicates that limiting harvests or modifying fishery operations could reduce PSC use considerably. Although the Analysis indicates that the Amendment 80 sector could lower its use of halibut PSC through changes in fishery operations, the Council and NMFS agree that the proposed rule would likely result in reduced groundfish harvests for the Amendment 80 sector.

The Council and NMFS considered the tools available to the Amendment 80 sector to reduce halibut PSC under the proposed rule. First, the Council and NMFS considered recently implemented regulatory provisions that could aid the Amendment 80 sector's ability to adapt to reduced halibut PSC limits. Section 3.1.3.6 and Appendices A and B of the Analysis describe that implementation of the flatfish flexibility program in 2014 allows the sector to increase or decrease harvests of yellowfin sole, rock sole, or flathead sole throughout the season to respond to changing bycatch and market conditions (79 FR 56671, September 23, 2014). Additional Atka mackerel opportunities became available to the Amendment 80 fleet with the implementation of revised Steller sea lion protection measures in 2015 (79 FR 70286, November 25, 2014). Although Atka mackerel is not evenly allocated among all Amendment 80 vessels, it provides additional harvest opportunity for a high value groundfish species with a low rate of halibut PSC that could offset other halibut PSC use

in a cooperative and that could reduce overall halibut PSC use for the sector.

Second, the Council and NMFS considered the tools that have, in whole or in part, been voluntarily adopted by the Amendment 80 sector. Public testimony from representatives of the Amendment 80 sector indicated that some of these tools have not been fully used by all fishery participants in recent years. This indicates additional reductions in halibut PSC through the expanded use of these tools are achievable and practicable.

These tools are described in detail in Section 3.1.3.6 and Appendix B of the Analysis and are summarized here:

- Expanding the use of gear modifications known as excluders to reduce the bycatch of halibut;
- Improving communication on the fishing grounds within and between Amendment 80 cooperatives;
- Using modified pelagic trawl gear to harvest groundfish instead of non-pelagic gear. Generally, pelagic trawl gear has a lower incidental rate of halibut bycatch and it has shown promise in the Central Gulf of Alaska rockfish fisheries, and other fisheries nationally in harvesting a number of groundfish species;
- Using test hauls to gauge halibut rates and considering the use of night-time hauls that tend to have lower halibut PSC rates;
- Modifying the timing of fishing to reduce halibut PSC rates toward the end of the year;
- Defining a threshold halibut PSC rate (*e.g.,* when the halibut PSC rate is greater than 80 percent of the average halibut PSC rate) that would lead to fishery management actions such as stopping fishing in an area or moving fishing operations. Requiring vessels to react to these rates through Amendment 80 cooperative contracts could significantly reduce halibut PSC limits;
- Shifting the composition of species that are harvested to focus on species that appear to have a lower intrinsic rate of halibut PSC than other species (*e.g.,* shifting away from arrowtooth flounder to yellowfin sole); and
- Establishing measures to shift fishing effort away from specific geographic locations with higher halibut PSC rates relative to other areas.

Although the proposed rule would establish a halibut PSC limit of 1,745 mt, NMFS believes it is likely that the Amendment 80 sector, specifically participants in the Amendment 80 cooperatives, would use less halibut PSC than the proposed limit. Testimony before the Council indicated that Amendment 80 participants typically manage their halibut PSC allocations with a 5 percent buffer, meaning that an Amendment 80 cooperative would plan to use at least 5 percent less halibut PSC than the Cooperative Quota allocation it receives. NMFS believes that Amendment 80 vessels are likely to establish a buffer as described in public testimony to the Council because the consequences of a cooperative exceeding its halibut PSC allocation can be significant: Financial penalties by the cooperative against the vessel or vessels that resulted in the cooperative exceeding its allocation of halibut PSC; an enforcement action against the cooperative pursuant to § § 679.91(h)(3)(xvi); and a prohibition against fishing for all Amendment 80 species pursuant to § 679.7(o)(4)(v).

The Council and NMFS considered the socioeconomic impact of the proposed rule on the Amendment 80 sector and fishing communities participating in the Amendment 80 fisheries. Table 4–187 in Section 4.13.1 of the Analysis estimates that the proposed rule would result in BSAI groundfish harvest reductions in the Amendment 80 sector between 9,500 mt to 25,700 mt each year during the 10-year analytical period, for a total of 95,000 mt to 257,000 mt for the full 10-year period. The Analysis estimates that the reduction in Amendment 80 groundfish harvests would reduce wholesale revenues for fishery participants from $6.2 million to $18.7 million for each year during the 10-year analytical period. The total wholesale revenue reduction is estimated to range from $62 million to $187 million for the full 10-year period. The Analysis describes that reduced groundfish harvests and revenues would also negatively impact fishing communities that are engaged in the BSAI groundfish fisheries (see Section 4.14.2 and Appendix C of the Analysis). Section 4.4.2.5 describes that the economic value of the use of halibut as PSC in the Amendment 80 sector is substantial as measured by average groundfish wholesale revenue generated per mt of halibut used as PSC to support the Amendment 80 sector.

The Council and NMFS considered a range of alternatives that would have resulted in halibut PSC reductions to Amendment 80 cooperatives ranging from a 10 percent to a 50 percent reduction relative to the current limit. As shown in Table 1 of this preamble, the average halibut PSC used in the Amendment 80 sector from 2008 through 2014 was 2,047 mt, which is less than the 10 percent reduction alternative (*i.e.,* 2,093 mt). The Amendment 80 sector has demonstrated that it can maintain a high level of groundfish harvests in some years and use an amount of halibut PSC that is equivalent to a 20 percent reduction in its halibut PSC limit. At the upper end, alternatives that would have reduced the halibut PSC limit by 50, 45, 40, 35, or 30 percent would have come at significant economic cost to the Amendment 80 sector and fishing communities participating in the Amendment 80 sector fisheries. The best available information suggests it is not clear that additional changes in fishery operations could accommodate these high levels of reductions other than foregoing substantial harvest and revenue.

Overall, alternatives that would have imposed a 50, 45, 40, 35, or 30 percent reduction would have been expected to reduce net benefits to the Nation because the socioeconomic benefits from the potential increase in harvest opportunities would be less than the negative socioeconomic impacts from foregone BSAI groundfish harvests. Section 4.8.1 of the Analysis describes the relative impacts of alternatives that would have further reduced halibut PSC limits for Amendment 80 cooperatives. The proposed rule would implement a halibut PSC reduction that balances the need to minimize bycatch to the extent practicable while considering the net benefits to the Nation, the impacts to fishing communities, and the long-term objective of providing for a sustained groundfish harvest by Amendment 80 cooperatives.

Ultimately, the Council determined, and NMFS agrees, that the proposed rule would minimize halibut bycatch to the extent practicable in the Amendment 80 sector after considering information on the sector's use of halibut PSC in recent years, the availability of a number of tools for Amendment 80 cooperatives and vessels to reduce halibut PSC use, the likely impact on net benefits to the Nation, and potential additional harvest opportunities to halibut fishery participants in Area 4 and elsewhere.

Under the status quo and the proposed rule, if all Amendment 80 vessels participate in a cooperative, the Amendment 80 cooperatives will be allocated the total proposed Amendment 80 sector halibut PSC limit of 1,745 mt. If any Amendment 80 vessels elect to participate in the limited access fishery, the proposed rule would reduce the halibut PSC limit for that fishery by 40 percent from the status quo. This reduction of 40 percent of the halibut PSC limit would only apply to the proportional amount of Amendment 80 QS assigned to the Amendment 80 limited access fishery. For example, if

100 percent of the Amendment 80 QS (*i.e.,* 100 percent of the Amendment 80 vessels) are assigned to the Amendment 80 limited access fishery in a particular year, and none is assigned to Amendment 80 cooperatives, the Amendment 80 limited access fishery would collectively be assigned a PSC limit of 1,395 mt, an amount that is 40 percent less than the current Amendment 80 sector halibut PSC limit of 2,325 mt.

If only a portion of the Amendment 80 QS and vessels are assigned to the Amendment 80 limited access fishery, NMFS would use the process described in Section 2.2.1 of the Analysis to allocate PSC limits between the Amendment 80 cooperatives and vessels in the limited access fishery. A brief summary of that process is provided here. NMFS would first determine the amount of halibut PSC that would be assigned to the Amendment 80 cooperatives. For example, if 80 percent of the Amendment 80 QS were assigned to cooperatives, NMFS would allocate 1,396 mt of halibut PSC (80 percent of the proposed Amendment 80 sector halibut PSC limit of 1,745 mt) to the cooperative (1,745 mt * 0.8 = 1,396). To calculate the amount of halibut PSC assigned for use in the Amendment 80 limited access fishery, NMFS would subtract the amount of halibut PSC allocated to Amendment 80 cooperatives from the total Amendment 80 sector PSC limit. In this example, this amount would be 349 mt (1,745 mt − 1,396 mt = 349 mt). NMFS would apply an additional 20 percent reduction by multiplying the remaining amount of halibut PSC remaining by 0.8 or 80 percent (349 mt * 0.8 = 279 mt). Therefore, this assignment of 279 mt would represent a 40 percent reduction compared to the status quo assignment to the Amendment 80 limited access fishery.

Under the proposed rule, some halibut PSC available to the Amendment 80 sector will be left unallocated and remain in the water if a portion of the Amendment 80 sector participates in the Amendment 80 limited access fishery. Using the example above, 1,396 mt is allocated to the Amendment 80 cooperatives, and 279 mt is assigned to the Amendment 80 limited access fishery. This adds up to 1,675 mt, an amount that is 70 mt less than the amount of halibut PSC (1,745 mt) that could have been allocated if all Amendment 80 sector participants were members of a cooperative.

The Council and NMFS considered the same factors for the halibut PSC limit applicable to the Amendment 80 cooperatives for the Amendment 80 limited access fishery. However, the Council recommended, and NMFS proposes, the more restrictive halibut PSC limit for the Amendment 80 limited access fishery to encourage cooperative management. Cooperative management is likely to provide a sustainable long-term approach to bycatch management. A fast-paced Amendment 80 limited access fishery could result in PSC that exceeds its halibut PSC limit. Therefore, a larger PSC limit reduction is appropriate to recognize management uncertainty and encourage cooperative formation as described in Section 4.8.2 of the Analysis.

The Council recommended and NMFS proposes a halibut PSC limit reduction of 40 percent for the Amendment 80 limited access fishery after considering the fact that although it is likely that all participants in the Amendment 80 sector will continue to fish in cooperatives, there are a range of factors that could create conditions that result in a participant ending up in the Amendment 80 limited access fishery. These factors include specific cooperative structure and participation requirements, and an individual's operating conditions. Therefore, the Council determined, and NMFS agrees, that a halibut PSC limit more restrictive than a 40 percent reduction would not be consistent with the purpose and need for this action because it could create incentives for members of a cooperative to purposefully exclude a specific Amendment 80 QS holder from cooperative membership. This exclusion could force that QS holder to participate in the limited access fishery and diminish their competitiveness within the sector to the potential benefit of other Amendment 80 QS holders. Similarly, a halibut PSC limit less restrictive than 40 percent may not provide sufficient incentives to encourage and maintain cooperative formation. A less restrictive halibut PSC limit could result in a PSC limit for the Amendment 80 limited access fishery that would encourage entry in the fishery and result in a difficult to manage ''race for fish'' that could result in halibut PSC limits being exceeded. See Section 2.2.1 of the Analysis for additional details on the proposed reduction to the Amendment 80 sector halibut PSC limit.

2. BSAI Trawl Limited Access Sector Halibut Bycatch (PSC) Limit Reduction

The proposed rule would establish a 15 percent reduction in the halibut PSC limit for the BSAI trawl limited access sector. The reduction in the PSC limit for the BSAI trawl limited access sector from 875 mt to 745 mt is a reduction of 130 mt. The BSAI trawl limited access sector used the second largest portion of halibut PSC in the BSAI groundfish fisheries from 2008 through 2014 (20 percent, as shown in Table 1 in this preamble and in Section 3.1.3.3 of the Analysis).

The Council and NMFS considered halibut PSC use in the BSAI trawl limited access sector. The BSAI trawl limited access sector, on average, has not used the full amount of halibut PSC assigned to the sector. As shown in Table 1 in this preamble and in Table 3–14 in Section 3.1.3.3 of the Analysis, on average the BSAI trawl limited access sector used 81 percent of the BSAI trawl limited access sector halibut PSC limit from 2008 through 2014.

As described in the ''Overview of the BSAI Groundfish Sectors'' section above, the Pacific cod and yellowfin sole fisheries are the primary fisheries that would be constrained by the proposed halibut PSC limits in the BSAI trawl limited access sector. Overall PSC used in the Pacific cod and yellowfin sole fisheries from 2008 through 2014 averaged 64 percent of the sector's annual apportionments (see Tables 4–38 and 4–39 in Section 4.4.3.4 of the Analysis).

From 2008 through 2014, the BSAI trawl limited access sector did not exceed the PSC apportioned to the Pacific cod fishery, used only 36 percent of its apportionment in one year (2009), and has used less than 60 percent of its apportionment in 3 years (2008, 2010, and 2011) (see Tables 4–38 and 4–39 in Section 4.4.3.4 of the Analysis for more detail). From 2008 through 2014, the BSAI trawl limited access sector exceeded the PSC apportioned to the yellowfin sole fishery in one year (2013), but has used only 16 percent of its apportionment in one year (2010), and has used less than 50 percent of its apportionment in 2 years (2009 and 2011) [see Tables 4–38 and 4–39 in Section 4.4.3.4 of the Analysis for more detail]. The Analysis and public testimony indicate that there are a variety of factors that contributed to lower PSC use in these years including changing oceanographic conditions, the amount of TAC available for harvests, and operational choices by vessel operators to fish in different areas or fisheries. However, the best available data on halibut PSC use indicate that in most years it is reasonable to expect that both Pacific cod and yellowfin sole can be harvested under the halibut PSC limits established by the proposed rule.

The Council and NMFS considered the tools that could be adopted by the BSAI trawl limited access sector. The Analysis describes a number of tools

that are currently available to the BSAI trawl limited sector to achieve overall bycatch levels similar to those in 2009, 2010, and 2011. First, the pollock fishery could undertake, and has undertaken measures to minimize bycatch, even though it would not be directly limited by this proposed action. Those measures are important because the pollock fishery comprises roughly 41 percent of the PSC use in the BSAI trawl limited access sector (see Figure 4–28 in Section 4.4.3.4 of the Analysis). The pollock fleet is fully managed under a catch share program, the AFA, and has demonstrated a well-established ability to constrain and reduce bycatch below established limits. Section 4.6.3 of the Analysis describes that the AFA sector has demonstrated an ability to consistently maintain bycatch of Chinook salmon below the PSC limits established in Amendment 91 to the FMP (75 FR 53026, August 30, 2010). The best available information indicates that the recent lower amount of halibut PSC use in the pollock fishery is not likely to increase given increased scrutiny by the AFA sector on halibut PSC. Second, additional opportunities, though limited, are available to harvest Pacific cod and pollock in the Aleutian Islands and later in the year under revised Steller sea lion protection measures that were implemented in 2015 (79 FR 70286, November 25, 2014). The opportunity to harvest Pacific cod and pollock later in the year and in the Aleutian Islands provides additional flexibility for vessels in the BSAI trawl limited access sector to fish when and where halibut PSC rates may be lower.

Section 4.9 of the Analysis notes that a ''race for fish'' exists in the BSAI trawl limited access sector, specifically in the Pacific cod and yellowfin sole fisheries. Appendix B of the Analysis examined the operations of catcher/processors in the yellowfin sole fishery and notes that several changes in fishery behavior could be undertaken by this fleet to minimize halibut PSC. Because the yellowfin sole fishery is not managed under a catch share program, there may be some limitations on the ability of participants to coordinate efforts to establish threshold PSC rates and adopt measures to react to those rates by shifting geographic locations, but some level of coordination seems practicable among the participants in this fishery.

The Council and NMFS considered the socioeconomic impact of the proposed rule on the BSAI trawl limited access sector and fishing communities that participate in the fisheries. Reductions in halibut PSC limits greater than actual halibut PSC use could be expected to impose a substantial socioeconomic cost on some BSAI trawl limited access sector participants. Under the two economic scenarios considered, and summarized in Table 4–210 in Section 4.14 of the Analysis, reduced revenue to the BSAI trawl limited access sector from the proposed halibut PSC limit reduction ranges from $14 million to $31 million dollars over a 10-year period, or $1.4 million to $3.2 million dollars annually, of the first wholesale value to the BSAI trawl limited access sector for non-pollock harvests. Section 4.4.3.5 of the Analysis describes that the economic value of the use of halibut as PSC in the BSAI trawl limited access sector is substantial as measured by the average groundfish wholesale revenue generated per metric ton of halibut used as PSC to support BSAI trawl limited access sector.

The proposed rule establishes a halibut PSC limit reduction that recognizes there are more limited tools for the BSAI trawl limited access sector than the Amendment 80 sector, but that the BSAI trawl limited sector has demonstrated an ability, on average, to maintain existing harvests at the level of the proposed reduction. Under the proposed rule, the BSAI trawl limited access sector would have to reduce its halibut PSC use relative to several recent years of halibut PSC use. As described in Appendix B of the Analysis, the BSAI trawl limited access sector has some tools available to reduce halibut PSC use. Reducing groundfish fishing or changing behavior during time periods with higher halibut rates may result in some mitigation of the impacts of a reduction in halibut PSC limits. Fishing earlier in the year would appear to result in lower halibut PSC rates. The proposed rule would result in halibut PSC limits that could be restrictive in some years relative to current management. However, the halibut PSC reduction implemented by the proposed rule would be expected to result in limited reductions in groundfish harvests in most years.

The Council and NMFS considered a range of alternative halibut PSC reductions for the BSAI trawl limited access sector. Less restrictive halibut PSC limit reductions (*i.e.,* a 10 percent reduction) would not be expected to have an impact on current or likely future halibut PSC use because the BSAI trawl limited access sector has demonstrated an ability to maintain halibut PSC limits below this level. The Council and NMFS also considered more restrictive halibut PSC limits. Ultimately, the Council recommended, and NMFS proposes the 15 percent reduction after considering the relatively limited impact of the BSAI trawl limited access sector on halibut PSC use, the more limited tools available to the sector to practicably reduce its halibut PSC use, and the overall socioeconomic cost to the sector, communities participating in the sector, and the Nation resulting from more restrictive halibut PSC limits. The Council and NMFS also considered the limited benefits that further reductions in halibut PSC limits may provide to halibut fishery users and communities participating in the halibut fishery. The Council and NMFS determined that the proposed halibut PSC limit is likely to provide incentives for the BSAI trawl limited access sector to more fully develop and use tools that improve on the reduced halibut PSC use achieved in 2010 and 2011.

3. BSAI Non-Trawl Sector Halibut Bycatch (PSC) Limit Reduction

The BSAI non-trawl sector has the third greatest amount of halibut PSC use among the BSAI groundfish fishery sectors. As Table 1 in this preamble and Table 4–209 in Section 4.14 of the Analysis show, the non-trawl sector is assigned 833 mt, or approximately 19 percent of the current halibut PSC limit in the BSAI, and used approximately 15 percent of the average amount of halibut PSC used in the BSAI from 2008 through 2014.

The Council and NMFS considered halibut PSC use in the non-trawl sector. The non-trawl sector has clearly used far less than its current PSC apportionment, particularly in recent years. Table 1 in this preamble shows that from 2008 through 2014, the combined non-trawl sectors have used an average of 61 percent of the total non-trawl halibut PSC apportionment. Pacific cod hook-and-line catcher/processors have used 99.4 percent of the non-trawl halibut PSC on average from 2008 through 2014. Because of the overwhelming use of halibut PSC by Pacific cod hook-and-line catcher/processors relative to other non-trawl fishery participants, this section is focused primarily on the impacts of the proposed action on Pacific cod hook-and-line catcher/processors.

The Council and NMFS also considered the tools that could be adopted by the non-trawl sector. The Analysis and public testimony have described the efforts by hook-and-line catcher/processors to minimize their halibut PSC use in recent years. Appendix B of the Analysis describes a range of performance metrics for this fleet. The data in Appendix B show a consistent trend of lower halibut PSC rates year-over-year, particularly beginning in 2011 (see Table 7 in

Appendix B of the Analysis). Appendix B does not show a clear signal of increasing halibut PSC use by Pacific cod hook-and-line catcher/processors toward the end of the year as shown for the Amendment 80 and BSAI trawl limited access sectors (see Figure 11 in Appendix B of the Analysis). This suggests that the Pacific cod hook-and-line catcher/processors are likely employing some operational tools that have led to lower halibut PSC use in recent years (see Tables 4 and 5 in Appendix B of the Analysis).

Table 4–210 in Section 4.14 of the Analysis shows that reductions in halibut PSC would not be expected to limit groundfish harvest in the non-trawl sector until reductions reach a level 30 percent lower than the current halibut PSC limit. Therefore, the proposed reduction in the current halibut PSC limit by 15 percent would not be expected to result in reduced groundfish harvests and revenues. Based on the best available information, the proposed action would not likely have a negative economic impact on the non-trawl sector because all harvests could be accommodated under the reduced limit.

The Council and NMFS considered the socioeconomic impact of the proposed rule on the non-trawl sector and communities participating in the non-trawl fisheries. Reductions in halibut PSC limits would have to be greater than actual halibut PSC use to impose a substantial socioeconomic cost on the non-trawl sector participants. Under the two economic scenarios considered, and summarized in Table 4–210 in Section 4.14 of the Analysis, the impacts of reduced halibut PSC limits to the non-trawl sector would not be expected to have an economic cost from reduced groundfish revenues until the halibut PSC limit is reduced by at least 30 percent. Section 4.4.4.5 describes that the economic value of the use of halibut as PSC is substantial in the non-trawl fishery, as measured by the average wholesale groundfish revenue generated per mt of halibut used as PSC to support the non-trawl sector.

The Council and NMFS considered more restrictive halibut PSC reductions for the non-trawl sector. The Analysis shows that halibut PSC limit reductions would need to be extremely high relative to the current halibut PSC limit to yield actual reductions from current use. For example, a 50 percent reduction in the PSC limit for the non-trawl sector to a PSC limit of 380 mt would yield only 96 mt of savings compared to the 2008 through 2014 average, or only 10 mt relative to 2014 use (See Table 1 of this preamble and Table 4–209 in Section 4.14 of the Analysis). The Council did not recommend, and NMFS does not propose, more restrictive halibut PSC limits for the non-trawl sector given the relatively limited use of halibut PSC by the non-trawl sector, the consistent trend of halibut PSC use that is well below current halibut PSC limits, and the limited benefit that additional reductions would be likely to provide to the halibut fishery and communities participating in the halibut fishery relative to the negative socioeconomic impacts to participants in the non-trawl sector. Given these factors, the Council and NMFS determined that the proposed reduction is consistent with the purpose and need for this action and additional reductions in the non-trawl halibut PSC limit would not be practicable.

4. CDQ Sector Halibut Bycatch (PSC) Limit Reduction

The CDQ sector has the fourth greatest impact on PSC of the BSAI groundfish sectors. As Table 1 in this preamble and Table 4–209 in Section 4.14 of the Analysis show, the CDQ sector is assigned approximately 9 percent of the current halibut PSC limit in the BSAI, and uses approximately 6 percent of the average amount of halibut PSC in the BSAI from 2008 through 2014.

The Council and NMFS considered halibut PSC use in the CDQ sector. The CDQ sector has consistently used far less halibut PSC than its current PSC limit, particularly in recent years. Table 1 of this preamble shows that from 2008 through 2014, the sector has used an average of 55 percent of its halibut PSC limit. PSC use has not exceeded 70 percent of the CDQ sector halibut PSC limit, and no CDQ group has exceeded its halibut PSC limit during this time.

The Council and NMFS also considered the tools that could be adopted by the CDQ sector. The CDQ sector clearly has, and uses, many of the tools that are available to the Amendment 80, AFA, and Pacific cod hook-and-line catcher/processor sectors because CDQ groups harvest their allocations in conjunction with vessels operating in those fisheries (Section 3.1.3.6 of the Analysis). The data on the use of halibut PSC indicates that these tools are being effectively used to minimize halibut PSC use in the CDQ sector.

The Council and NMFS considered the socioeconomic impact of the proposed rule on the CDQ sector and communities participating in the CDQ fisheries. The proposed rule would not be expected to have an adverse economic impact on the CDQ groups and would not be expected to constrain groundfish harvests. Table 4–210 in Section 4.14 of the Analysis shows that until halibut PSC reductions reach a level of 35 percent, there does not appear to be an economic impact on the CDQ sector from reduced groundfish harvests and revenues. Section 4.4.6 of the Analysis contains additional information on the economic impacts of the proposed rule for the CDQ sector.

As Table 4–210 in Section 4.14 of the Analysis shows, the proposed halibut PSC reduction of 20 percent relative to current limits would not materially impact the CDQ participants, but would prevent the potential increase of halibut PSC use in future years. It is clear that the level of halibut PSC reduction proposed in this rule is practicable because in all years analyzed, halibut PSC use by the CDQ sector has been less than this limit.

The Council and NMFS considered whether additional halibut PSC limit reductions would be appropriate given the substantial gap between actual halibut PSC use and the current halibut PSC limit in the CDQ sector. The Analysis shows that halibut PSC limit reductions would need to be extremely high relative to the current halibut PSC limit to yield actual deductions. For example, a 50 percent reduction in the CDQ sector halibut PSC limit to 197 mt would yield only 18 mt of savings compared to the average use from 2008 through 2014 average, or only 47 mt relative to 2014 use. Neither the Analysis nor public testimony indicated that it is reasonable to expect that halibut PSC use in the CDQ sector will increase relative to current use. Therefore, the Council and NMFS determined that it is impracticable to establish a reduction that would be expected to substantially constrain the CDQ sector given the limited amount of halibut PSC used by the sector and the limited potential harvest opportunity to the commercial halibut fishery that a more restrictive halibut PSC limit would provide.

E. Summary of Impacts

During public testimony to the Council, some participants in halibut fisheries and members of the public recommended greater reductions of halibut PSC limits than the proposed rule would implement. However, halibut bycatch cannot be avoided completely, unless groundfish fishing is completely stopped. The Council and NMFS believe that more stringent PSC limit reductions are not practicable for the groundfish sectors.

As described above, the Council and NMFS considered impacts on the halibut stock and concluded that under all the alternatives considered, the impact on exploitable biomass and the halibut female spawning biomass was not likely to be significant. The Council and NMFS considered the impact on the halibut fishery and fishing communities participating in the halibut fishery and concluded that larger halibut PSC reductions in some sectors, particularly the Amendment 80 and BSAI trawl limited access sectors, would be expected to provide greater harvest opportunities in the halibut fisheries than would be realized under the proposed reductions. However, the Council and NMFS considered that larger halibut PSC reductions in these two sectors would be expected to have an adverse impact from foregone groundfish harvests and revenues. The adverse socioeconomic impact on fishing communities participating in the groundfish fisheries would be greater with larger halibut PSC reductions.

Based on the best available information, the Council and NMFS anticipate that participants in the Amendment 80 and BSAI trawl limited access sectors will need to modify their fishing behavior in response to lower halibut PSC limits. Based on the Analysis and public testimony received from groundfish industry participants on the extent to which individual vessels are able to change their fishing behavior to reduce PSC use, the Council and NMFS believe that the proposed halibut PSC reductions would minimize halibut bycatch to the extent practicable.

IV. The Proposed Rule

The proposed rule would implement Amendment 111 to the FMP primarily by revising § 679.21 to reduce BSAI halibut PSC limits for the Amendment 80 sector, BSAI trawl limited access sector, BSAI non-trawl sector, and the CDQ Program. The proposed rule would also make minor changes in terminology, reorganize regulatory text, and make other technical changes.

A. Reduction in Halibut PSC Limits

The proposed rule would establish the following halibut PSC limits at § 679.21(b): 1,745 mt for the Amendment 80 sector; 745 mt for the BSAI trawl limited access sector; 710 mt for the BSAI non-trawl sector; and 315 mt for the CDQ Program. These limits result in an overall BSAI halibut PSC limit of 3,515 mt.

1. Amendment 80 Sector

The proposed rule would establish at § 679.21(b)(1)(i) a maximum halibut PSC limit of 1,745 mt for the Amendment 80 sector. If no vessels participate in the Amendment 80 limited access fishery in a year, NMFS will allocate the entire Amendment 80 halibut PSC limit of 1,745 mt among the Amendment 80 cooperatives that submitted a timely application for an Amendment 80 cooperative permit for that year.

If any Amendment 80 vessels chose to fish in the Amendment 80 limited access fishery, the proposed rule would establish the amount of PSC assigned to the Amendment 80 limited access fishery. The proposed rule would revise § 679.91(d)(1) and (d)(3), so that the Amendment 80 limited access fishery would be assigned only 80 percent of the halibut PSC that is remaining after halibut PSC has been assigned to Amendment 80 cooperatives. This regulatory change would result in an overall reduction of the halibut PSC limit to the Amendment 80 limited access sector of 40 percent compared to existing regulations. With these proposed regulatory changes, it is important to note that the combined halibut PSC limit for Amendment 80 cooperatives and the Amendment 80 limited access fishery would not sum to 1,745 mt. As described earlier in this preamble, the Amendment 80 limited access fishery would be assigned an amount of PSC that is 20 percent less than what the vessels in the Amendment 80 limited access fishery would receive if they had participated in a cooperative for that year.

2. BSAI Trawl Limited Access Sector

The proposed rule would establish at § 679.21(b)(1)(ii) a halibut PSC limit of 745 mt for the BSAI trawl limited access sector. The proposed rule would make no change in the annual harvest specification process whereby NMFS apportions the overall sector PSC limit of the BSAI trawl limited access sector into PSC allowances for these trawl fishery categories. The proposed rule would make no change in the process whereby NMFS may make seasonal apportionments of the trawl PSC allowances.

3. BSAI Non-Trawl Sector

The proposed rule would establish at § 679.21(b)(1)(iii) a halibut PSC limit of 710 mt for the BSAI non-trawl sector. The proposed rule would make no change in the annual harvest specification process whereby NMFS has authority to apportion the overall sector PSC limit into non-trawl fishery categories. The proposed rule would make no change in the annual harvest specification process whereby NMFS has authority to make seasonal apportions of the non-trawl PSC allowances. NMFS will continue annual consultations with the Council to determine whether the pot gear, jig gear, and the sablefish IFQ hook-and-line gear fisheries will be exempt from the non-trawl halibut PSC limit as described in the ''Annual Halibut Bycatch (PSC) Limits and Apportionments of PSC Limits'' section of this preamble.

4. CDQ Sector

The proposed rule would establish at § 679.21(b)(1)(iv) a halibut PSC limit of 315 mt for the CDQ Program (*i.e.,* CDQ sector). This amount would not be deducted from the trawl PSC limit or the non-trawl PSC limit. The proposed rule would not modify the designation of this PSC limit as a PSQ Reserve.

The proposed rule would remove provisions at § 679.21(e)(3)(i)(A)(2)(*ii*) and § 679.21(e)(4)(i)(A) that allocate a portion of the halibut PSQ reserve from the trawl sector and a portion from the non-trawl sector. These regulatory provisions are no longer necessary with the establishment of a separate halibut PSC limit for the CDQ Program at § 679.21(b)(1)(iv).

The proposed rule would make no other changes in the process for the establishment and use of the halibut PSQ Reserve under the CDQ Program.

B. Minor Change in Terminology

The proposed rule would make a minor change in terminology and use ''halibut PSC allowances'' rather than ''halibut bycatch allowances'' to describe the apportionment of a halibut PSC sector limit into fishery categories. Section 679.21(e) currently uses ''bycatch allowances'' to describe the subdivision of a halibut PSC sector limit into fishery categories. NMFS believes that the term ''PSC allowance'' is more accurate than ''bycatch allowance'' because bycatch is broader than PSC. NMFS acknowledges that bycatch is often, or even typically, used to refer to the unintended catch of halibut by the groundfish fisheries. However, NMFS concluded that the regulatory text should use the accurate term, PSC, in regulations governing the catch of halibut by the BSAI groundfish fisheries.

The proposed rule also changes the term ''incidental catch'' to ''PSC'' at § 679.21(e)(3)(ii)(C). The current regulations at § 679.21(e)(3)(ii)(C) direct NMFS to count incidental catch of all halibut taken by the midwater pollock fishery against the bycatch allowance

for the pollock/Atka mackerel/''other species'' category. The definition of ''incidental catch'' in § 679.2 excludes fish that are discarded and returned to the sea. The proposed rule uses the correct term, halibut PSC, in § 679.21(b)(1)(ii)(C) to describe halibut caught by the midwater pollock fishery.

C. Reorganization and Other Technical Changes

The proposed rule would reorganize § 679.21 by creating a new § 679.21(b) that will contain all the provisions that are specific to BSAI halibut PSC limits. In the current regulations, § 679.21(a) is reserved, § 679.21(b) contains general provisions regarding PSC management, and § 679.21(e) contains provisions for BSAI PSC limits for all prohibited species: halibut, salmon, crab, and herring. The proposed rule would move the general provisions from § 679.21(b) to § 679.21(a). The proposed rule would place all provisions in § 679.21(e) that are specific to BSAI halibut PSC limits into § 679.21(b). The proposed rule would specify the BSAI halibut PSC limits for each of the four groundfish sectors in § 679.21(b) and would note that the total of all the BSAI halibut PSC limits is 3,515 mt. This consolidation of BSAI halibut PSC regulations into § 679.21(b) would clarify the regulations for the public.

The proposed reorganization of halibut PSC regulations at § 679.21(b) would have four sections. Section 679.21(b)(1) would establish the halibut PSC limits for the four groundfish sectors: the Amendment 80 sector; the BSAI trawl limited access sector; the BSAI non-trawl sector; and the CDQ Program. Section 679.21(b)(2) would maintain NMFS's authority to make seasonal apportionments of PSC allowances, which is currently at § 679.21(e)(5). Section 679.21(b)(3) would maintain the provisions regarding notification of PSC allowances, which is currently at § 679.21(e)(6). Section 679.21(b)(4) would maintain the management of BSAI halibut PSC allowances through directed fishery closures, which is currently at § 679.21(e)(7)(i) and (v).

The proposed rule would also revise Table 35 to part 679. Table 35 currently specifies the BSAI halibut PSC limits for the Amendment 80 sector and BSAI trawl limited access sector. The proposed rule would change Table 35 to include the revised halibut PSC limits.

Because halibut PSC regulations at § 679.21(e) are cross-referenced in other regulations, the proposed rule would change all cross-references to the halibut-specific provisions in § 679.21(e) throughout part 679 to the new halibut-specific regulations at § 679.21(b). The proposed rule would also change all cross-references in current regulations to the general PSC provisions that are now in § 679.21(b) to the new location for the general provisions in § 679.21(a). For each revised paragraph, this proposed rule includes the revised cross-references in the regulatory text and repeats the text that is not otherwise modified. Table 2 lists the location of regulations with cross-references that would be revised by the proposed rule.

TABLE 2—LIST OF PROPOSED CHANGES IN CROSS-REFERENCES

Location of revised cross-references
§ 679.2, definitions of definitions of ''Directed fishing'', ''Herring Savings Area'', ''PSQ reserve'', and ''Sablefish''.
§ 679.7(a)(12), § 679.7(k)(1)(v), and § 679.7(k)(4)(iii).
§ 679.20(d)(2).
§ 679.23(f), and § 679.23(g)(3).
§ 679.24(c)(2)(ii)(A), § 679.24(c)(2)(ii)(B), § 679.24(c)(3), § 679.24(c)(4), and § 679.24(a)(2)(ii)(A).
§ 679.26(d)(2).
§ 679.31(a)(4).
§ 679.64(a)(3).

V. Classification

Pursuant to Section 304(b)(1)(A) and 305(d) of the Magnuson-Stevens Act, the NMFS Assistant Administrator has determined that the proposed rule is consistent with the FMP, other provisions of the Magnuson-Stevens Act, and other applicable law, subject to further consideration of comments received during the public comment period.

The proposed rule has been determined to be not significant for purposes of Executive Order 12866.

A. Initial Regulatory Flexibility Analysis

An Initial Regulatory Flexibility Analysis (IRFA) was prepared for this action, as required by Section 603 of the Regulatory Flexibility Act (RFA). The IRFA describes the economic impact the proposed rule, if adopted, would have on small entities. The IRFA describes the reasons why this action is being proposed; the objectives and legal basis for the proposed rule; the number and description of small entities directly regulated by the proposed action; any projected reporting, recordkeeping, or other compliance requirements of the proposed rule; any overlapping, duplicative, or conflicting Federal rules; impacts of the action on small entities; and any significant alternatives to the proposed rule that would accomplish the stated objectives of the Magnuson-Stevens Act, and any other applicable statutes, and would minimize any significant adverse impacts of the proposed rule on small entities. Descriptions of the proposed action, its purpose, and the legal basis are contained earlier in this preamble and are not repeated here. A summary of the IRFA follows. A copy of the IRFA is available from NMFS (see **ADDRESSES**).

1. Number and Description of Small Entities Directly Regulated by the Proposed Action

The proposed action would directly regulate those entities that participate in harvesting groundfish from the Federal or parallel groundfish fisheries of the BSAI subject to a halibut PSC limit. The RFA recognizes and defines three kinds of small entities that could be regulated by this proposed action: (1) Small businesses, (2) small non-profit organizations, and (3) small government jurisdictions. This proposed action would directly regulate small businesses that participate in the harvesting of groundfish, and small non-profit organizations.

The IFRA estimates the number of directly regulated small entities based on size criteria established for industry sectors defined by the Small Business Administration (SBA). According to the SBA criteria, the groundfish fishery is defined as a finfish harvesting sector. An entity primarily involved in finfish harvesting is a small entity if it is independently owned and operated and not dominant in its field of operation (including its affiliates), and if it has combined annual gross receipts not in

excess of $20.5 million for all its affiliated operations worldwide. Based on the best available and most recent data from 2014, the IRFA estimates that a maximum of up to 178 vessels could be directly regulated by this action. The IRFA assumes that each vessel is a unique entity. The IRFA states that this likely overestimates the total number of directly regulated entities because some vessels are likely affiliated through common ownership. However, these potential affiliations are not known with the best available data and cannot be predicted.

Only 19 of these directly regulated entities are estimated to be small entities based on the best available data on the gross receipts from these entities and their known affiliates. Seventeen of these small entities are hook-and-line catcher vessels that participate in the non-trawl sector, and two are trawl catcher vessels that participate in the BSAI trawl limited access sector, specifically the Pacific cod target fishery.

The IRFA states that all six of the CDQ groups would be directly regulated by this proposed action. The six CDQ groups are: The Aleutian Pribilof Island Community Development Association, the Bristol Bay Economic Development Corporation, the Central Bering Sea Fishermen's Association, the Coastal Villages Region Fund, the Norton Sound Economic Development Corporation, and the Yukon Delta Fisheries Development Association. Each of the six CDQ groups receives an exclusive allocation of halibut PSC that would be reduced (*i.e.,* regulated) under this proposed action. The six CDQ groups are non-profit organizations and none is dominant in its field; consequently each is defined as a small entity under the RFA.

2. Federal Rules That May Duplicate, Overlap, or Conflict With the Proposed Action

NMFS has not identified any duplication, overlap, or conflict between this proposed action and existing Federal rules.

3. Impacts of the Action on Small Entities

The proposed action is intended to reduce halibut PSC mortality by decreasing halibut PSC limits available for use in the BSAI groundfish fisheries. Any reductions in harvest by groundfish harvesters would impact revenue generated from the BSAI groundfish fisheries. The 17 hook-and-line catcher vessels that participate in the non-trawl sector are not likely to be affected by the proposed reduction in the halibut PSC limit for the non-trawl sector because current and anticipated halibut PSC use in this sector is substantially less than the proposed halibut PSC limit that would be established. The 2 trawl catcher vessels that participate in the BSAI trawl limited access sector may be limited by the proposed reduction in the halibut PSC limit for the BSAI trawl limited access sector (15 percent) in some years because halibut PSC use by the BSAI trawl limited access sector has exceeded the halibut PSC limit that would be established by the proposed action.

The six CDQ groups are not likely to be affected by the proposed reduction in the halibut PSC limit for the CDQ sector (20 percent) because current and anticipated halibut PSC use in the CDQ sector is substantially less than the proposed halibut PSC limit that would be established. However, some CDQ groups will experience an adverse impact from PSC reductions in the Amendment 80 and BSAI trawl limited access sectors, to the extent that they have ownership interests in vessels operating in those sectors, and the proposed halibut PSC limits constrain harvest and resulting revenue. The CDQ groups' ownership interests are described in Section 4.12 of the Analysis.

4. Description of Significant Alternatives Considered

The Council considered an extensive series of alternatives, options, and suboptions to reduce halibut PSC limits in the BSAI, including the ''no action'' alternative. The RIR presents the complete set of alternatives (see **ADDRESSES**). Alternative 1 is Status Quo/No Action alternative, which would retain the current BSAI halibut PSC limits in the FMP and in regulations. Alternative 2 would amend the FMP and regulations to reduce BSAI halibut PSC limits for six groundfish sectors. Alternative 2 includes six options. Each of the options under Alternative 2 contained seven suboptions analyzing halibut PSC limit reductions ranging from 10 percent to 50 percent for each sector. Option 1 would reduce halibut PSC limits for the Amendment 80 sector. The reductions would range from 232 mt to 1,162 mt. Option 2 would reduce halibut PSC limits for the BSAI trawl limited access sector. The reductions would range from 87 mt to 437 mt. Option 3 would reduce halibut PSC limits for the Pacific cod hook-and-line catcher/processor sector. The reductions would range from 76 mt to 380 mt. Option 4 would reduce halibut PSC limits for hook-and-line vessels participating in target fisheries other than Pacific cod or sablefish. The reductions would range from 6 mt to 29 mt. Option 5 would reduce halibut PSC limits for the Pacific cod hook-and-line catcher vessel sector. The reductions would range from 1 mt to 7 mt. Option 6 would reduce halibut PSC limits for the CDQ sector. The reductions would range from 39 mt to 196 mt.

Section 2.5 of the Analysis describes other significant alternatives to the proposed rule that the Council considered but did not advance for further analysis: (1) Apportioning the halibut PSC limit for the BSAI trawl limited access sector between AFA trawl catcher vessels and non-AFA trawl catch vessels based on the halibut PSC by these vessel categories from 2009 through 2013; (2) implementing permanent measures in the Amendment 80 sector for deck sorting of halibut; (3) establishing a seasonal apportionment of the halibut PSC limit for the BSAI trawl limited access sector. Each of these alternatives would have changed the current management structure for regulating halibut PSC limits in BSAI. The Council's preferred alternative is a straightforward reduction in halibut PSC limits by sector. The Council's preferred alternative leaves the current management structure intact and most expeditiously achieves the Council's objective of reducing halibut PSC limit to the extent practicable in accord with National Standard 9.

Based on the best available scientific data and information, none of the alternatives except the preferred alternative appear to have the potential to accomplish the stated objectives of the Magnuson-Stevens Act and other applicable statutes (as reflected in the proposed action), while minimizing any significant adverse economic impact on small entities beyond those achieved under the proposed action. The proposed action would minimize bycatch to the extent practicable with existing management tools. Thus, the proposed action would minimize the impacts on small entities in the BSAI groundfish fisheries and promote more efficient use of the available halibut PSC limits.

5. Recordkeeping and Reporting Requirements

This action does not modify recordkeeping or reporting requirements.

B. Tribal Consultation

Executive Order (E.O.) 13175 of November 6, 2000 (25 U.S.C. 450 note), the Executive Memorandum of April 29, 1994 (25 U.S.C. 450 note), the American Indian and Alaska Native Policy of the

U.S. Department of Commerce (March 30, 1995), and the Department of Commerce Tribal Consultation and Coordination policy (78 FR 33331, June 4, 2013) outline the responsibilities of NMFS for Federal policies that have tribal implications. Section 161 of Public Law 108–199 (188 Stat. 452), as amended by section 518 of Public Law 109–447 (118 Stat. 3267), extends the consultation requirements of E.O. 13175 to Alaska Native corporations. Under the E.O. and agency policies, NMFS must ensure meaningful and timely input by tribal officials and representatives of Alaska Native corporations in the development of regulatory policies that have tribal implications. NMFS will provide a copy of this proposed rule to all federally recognized tribal governments and Alaska Native corporations to notify them of the opportunity to comment or request a consultation on this proposed action.

Section 5(b)(2)(B) of E.O. 13175 requires NMFS to prepare a ''tribal summary impact statement'' for any regulation that has tribal implications, that imposes substantial direct compliance costs on Indian tribal governments, and is not required by statute. The tribal summary impact statement must contain (1) a description of the extent of the agency's prior consultation with tribal officials, (2) a summary of the nature of their concerns, (3) the agency's position supporting the need to issue the regulation, and (4) a statement of the extent to which the concerns of tribal officials have been met. If the Secretary of Commerce approves this proposed action, a tribal impact summary statement that addresses the four questions above will be included in the final rule.

List of Subjects in 50 CFR Part 679

Alaska, Fisheries, Reporting and recordkeeping requirements.

Dated: November 9, 2015.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR part 679 is proposed to be amended as follows:

PART 679—FISHERIES OF THE EXCLUSIVE ECONOMIC ZONE OFF ALASKA

■ 1. The authority citation for 50 CFR part 679 continues to read as follows:

Authority: 16 U.S.C. 773 *et seq.;* 1801 *et seq.;* 3631 *et seq.;* Pub. L. 108–447; Pub. L. 111–281.

■ 2. In § 679.2, revise the definitions for paragraph (5) of ''Directed fishing'', ''Herring Savings Area'', ''PSQ reserve'', and ''Sablefish (black cod)'' to read as follows:

§ 679.2 Definitions.

* * * * *

Directed fishing means:

* * * * *

(5) *With respect to the harvest of flatfish in the Bering Sea subarea,* for purposes of nonpelagic trawl restrictions under § 679.22(a) and modified nonpelagic trawl gear requirements under §§ 679.7(c)(5) and 679.24(f), fishing with nonpelagic trawl gear during any fishing trip that results in a retained aggregate amount of yellowfin sole, rock sole, Greenland turbot, arrowtooth flounder, flathead sole, Alaska plaice, and other flatfish that is greater than the retained amount of any other fishery category defined under § 679.21(b)(1)(ii) or of sablefish.

* * * * *

Herring Savings Area means any of three areas in the BSAI presented in Figure 4 to this part (see also § 679.21(b)(4) for additional closure information).

* * * * *

PSQ reserve means the amount of a prohibited species catch limit established under § 679.21 that has been allocated to the CDQ Program under § 679.21.

* * * * *

Sablefish (black cod) means *Anoplopoma fimbria.* (See also *IFQ sablefish; sablefish as a prohibited species* at § 679.21(a)(5); and *sablefish as a prohibited species* at § 679.24(c)(2)(ii)).

* * * * *

■ 3. In § 679.7, revise paragraphs (a)(12), (k)(1)(v), and (k)(4)(iii) to read as follows:

§ 679.7 Prohibitions.

* * * * *

(a) * * *

(12) *Prohibited species donation program.* Retain or possess prohibited species, defined at § 679.21(a)(1), except as permitted to do so under the PSD program as provided by § 679.26, or as authorized by other applicable law.

* * * * *

(k) * * *

(1) * * *

(v) *Directed fishing after a sideboard closure.* Use a listed AFA catcher/processor or a catcher/processor designated on a listed AFA catcher/processor permit to engage in directed fishing for a groundfish species or species group in the BSAI after the Regional Administrator has issued an AFA catcher/processor sideboard directed fishing closure for that groundfish species or species group under §§ 679.20(d)(1)(iv), 679.21(b)(4)(iii), or 679.21(e)(3)(v).

* * * * *

(4) * * *

(iii) *Groundfish sideboard closures.* Use an AFA catcher vessel to engage in directed fishing for a groundfish species or species group in the BSAI or GOA after the Regional Administrator has issued an AFA catcher vessel sideboard directed fishing closure for that groundfish species or species group under § 679.20(d)(1)(iv), 679.21(b)(4)(iii), or 679.21(e)(3)(iv), if the vessel's AFA permit does not contain a sideboard exemption for that groundfish species or species group.

* * * * *

■ 4. In § 679.21,

■ a. Redesignate paragraph (b) as paragraph (a);

■ b. Revise newly redesignated paragraph (a)(4);

■ c. Add a new paragraph (b);

■ d. Revise paragraph (e) heading;

■ e. Remove and reserve paragraphs (e)(1)(iv), (e)(2), and (e)(3)(i)(A)(*2*);

■ f. Revise paragraph (e)(3)(ii) heading, paragraphs (e)(3)(ii)(A) and (C), (e)(3)(iv), paragraph (e)(3)(iv)(B)(*2*) heading, (e)(3)(v), and (e)(3)(vi)(A) and (B);

■ g. Remove and reserve paragraph (e)(4);

■ h. Remove paragraph (e)(5)(iv);

■ i. Revise paragraphs (e)(6)(i) and (ii), and (e)(7)(i);

■ j. Remove and reserve paragraph (e)(7)(v); and

■ k. Remove paragraph (e)(8).

The revisions and additions read as follows:

§ 679.21 Prohibited species by catch management.

(a) * * *

(4) *Prohibited species taken seaward of the EEZ off Alaska.* No vessel fishing for groundfish in the GOA or BSAI may have on board any species listed in this paragraph (a) that was taken in waters seaward of these management areas, regardless of whether retention of such species was authorized by other applicable laws.

* * * * *

(b) *BSAI halibut PSC limits*—(1) *Establishment of BSAI halibut PSC limits.* Subject to the provisions in paragraphs (b)(1)(i) through (iv) of this section, the following four BSAI halibut PSC limits are established, which total 3,515 mt: Amendment 80 sector—1,745 mt; BSAI trawl limited access sector—

745 mt; BSAI non-trawl sector—710 mt; and CDQ Program—315 mt (established as a PSQ reserve).

(i) *Amendment 80 sector.* The PSC limit of halibut caught while conducting any fishery in the Amendment 80 sector is an amount of halibut equivalent to 1,745 mt of halibut mortality. Halibut PSC limits within the Amendment 80 sector will be established for Amendment 80 cooperatives and the Amendment 80 limited access fishery according to the procedure and formulae in § 679.91(d) and (f). If halibut PSC is assigned to the Amendment 80 limited access fishery, it will be apportioned into PSC allowances for trawl fishery categories according to the procedure in paragraphs (b)(1)(ii)(A)(*2*) and (*3*) of this section.

(ii) *BSAI trawl limited access sector*—(A) *General.* (*1*) The PSC limit of halibut caught while conducting any fishery in the BSAI trawl limited access sector is an amount of halibut equivalent to 745 mt of halibut mortality.

(*2*) NMFS, after consultation with the Council, will apportion the PSC limit set forth under paragraph (b)(1)(ii)(A)(*1*) of this section into PSC allowances for the trawl fishery categories defined in paragraphs (b)(1)(ii)(B)(*1*) through (*6*) of this section.

(*3*) Apportionment of the trawl halibut PSC limit set forth under paragraph (b)(1)(ii)(A)(*1*) of this section among the trawl fishery categories will be based on each category's proportional share of the anticipated halibut PSC during a fishing year and the need to optimize the amount of total groundfish harvested under the halibut PSC limit for this sector.

(*4*) The sum of all PSC allowances for this sector will equal the PSC limit set forth under paragraph (b)(1)(ii)(A)(*1*) of this section.

(B) *Trawl fishery categories.* For purposes of apportioning the trawl PSC limit set forth under paragraph (b)(1)(ii)(A)(*1*) of this section among trawl fisheries, the following fishery categories are specified and defined in terms of round-weight equivalents of those groundfish species or species groups for which a TAC has been specified under § 679.20.

(*1*) *Midwater pollock fishery.* Fishing with trawl gear during any weekly reporting period that results in a catch of pollock that is 95 percent or more of the total amount of groundfish caught during the week.

(*2*) *Flatfish fishery.* Fishing with trawl gear during any weekly reporting period that results in a retained aggregate amount of rock sole, ''other flatfish,'' and yellowfin sole that is greater than the retained amount of any other fishery category defined under this paragraph (b)(1)(ii)(B).

(*i*) *Yellowfin sole fishery.* Fishing with trawl gear during any weekly reporting period that is defined as a flatfish fishery under this paragraph (b)(1)(ii)(B)(*2*) and results in a retained amount of yellowfin sole that is 70 percent or more of the retained aggregate amount of rock sole, ''other flatfish,'' and yellowfin sole.

(*ii*) *Rock sole/flathead sole/Alaska plaice/''other flatfish'' fishery.* Fishing with trawl gear during any weekly reporting period that is defined as a flatfish fishery under this paragraph (b)(1)(ii)(B)(*2*) and is not a yellowfin sole fishery as defined under paragraph (b)(1)(ii)(B)(*2*)(*i*) of this section.

(*3*) *Greenland turbot/arrowtooth flounder/Kamchatka flounder/sablefish fishery.* Fishing with trawl gear during any weekly reporting period that results in a retained aggregate amount of Greenland turbot, arrowtooth flounder, Kamchatka flounder, and sablefish that is greater than the retained amount of any other fishery category defined under this paragraph (b)(1)(ii)(B).

(*4*) *Rockfish fishery.* Fishing with trawl gear during any weekly reporting period that results in a retained aggregate amount of rockfish species that is greater than the retained amount of any other fishery category defined under this paragraph (b)(1)(ii)(B).

(*5*) *Pacific cod fishery.* Fishing with trawl gear during any weekly reporting period that results in a retained aggregate amount of Pacific cod that is greater than the retained amount of any other groundfish fishery category defined under this paragraph (b)(1)(ii)(B).

(*6*) *Pollock/Atka mackerel/''other species.''* Fishing with trawl gear during any weekly reporting period that results in a retained aggregate amount of pollock other than pollock harvested in the midwater pollock fishery defined under paragraph (b)(1)(ii)(B)(*1*) of this section, Atka mackerel, and ''other species'' that is greater than the retained amount of any other fishery category defined under this paragraph (b)(1)(ii)(B).

(C) *Halibut PSC in midwater pollock fishery.* Any amount of halibut that is incidentally taken in the midwater pollock fishery, as defined in paragraph (b)(1)(ii)(B)(*1*) of this section, will be counted against the halibut PSC allowance specified for the pollock/Atka mackerel/''other species'' category, as defined in paragraph (b)(1)(ii)(B)(*6*) of this section.

(iii) *BSAI Non-trawl Sector*—(A) *General.* (*1*) The PSC limit of halibut caught while conducting any fishery in the BSAI non-trawl sector is an amount of halibut equivalent to 710 mt of halibut mortality.

(*2*) NMFS, after consultation with the Council, will apportion the PSC limit set forth under paragraph (b)(1)(iii)(A)(*1*) into PSC allowances for the non-trawl fishery categories defined under paragraph (b)(1)(iii)(B) of this section.

(*3*) Apportionment of the non-trawl halibut PSC limit of 710 mt among the non-trawl fishery categories will be based on each category's proportional share of the anticipated halibut PSC during a fishing year and the need to optimize the amount of total groundfish harvested under the halibut PSC limit for this sector.

(*4*) The sum of all PSC allowances for this sector will equal the PSC limit set forth under paragraph (b)(1)(iii)(A)(*1*) of this section.

(B) *Non-trawl fishery categories.* For purposes of apportioning the non-trawl halibut PSC limit among fisheries, the following fishery categories are specified and defined in terms of round-weight equivalents of those BSAI groundfish species for which a TAC has been specified under § 679.20.

(*1*) *Pacific cod hook-and-line catcher vessel fishery.* Catcher vessels fishing with hook-and-line gear during any weekly reporting period that results in a retained catch of Pacific cod that is greater than the retained amount of any other groundfish species.

(*2*) *Pacific cod hook-and-line catcher/processor fishery.* Catcher/processors fishing with hook-and-line gear during any weekly reporting period that results in a retained catch of Pacific cod that is greater than the retained amount of any other groundfish species.

(*3*) *Sablefish hook-and-line fishery.* Fishing with hook-and-line gear during any weekly reporting period that results in a retained catch of sablefish that is greater than the retained amount of any other groundfish species.

(*4*) *Groundfish jig gear fishery.* Fishing with jig gear during any weekly reporting period that results in a retained catch of groundfish.

(*5*) *Groundfish pot gear fishery.* Fishing with pot gear under restrictions set forth in § 679.24(b) during any weekly reporting period that results in a retained catch of groundfish.

(*6*) *Other non-trawl fisheries.* Fishing for groundfish with non-trawl gear during any weekly reporting period that results in a retained catch of groundfish and does not qualify as a Pacific cod hook-and-line catcher vessel fishery, a Pacific cod hook-and-line catcher/processor fishery, a sablefish hook-and-

line fishery, a jig gear fishery, or a groundfish pot gear fishery as defined under paragraphs (b)(1)(iii)(B)(*1*) through (*5*) of this section.

(iv) *CDQ Program.* The PSC limit of halibut caught while conducting any fishery in the CDQ Program is an amount of halibut equivalent to 315 mt of halibut mortality. The PSC limit to the CDQ Program will be treated as a Prohibited Species Quota (PSQ) reserve to the CDQ Program for all purposes under 50 CFR part 679 including §§ 679.31 and 679.7(d)(3). The PSQ limit is not apportioned by gear, fishery, or season.

(2) *Seasonal apportionments of BSAI halibut PSC allowances*—(i) *General.* NMFS, after consultation with the Council, may apportion a halibut PSC allowance on a seasonal basis.

(ii) *Factors to be considered.* NMFS will base any seasonal apportionment of a PSC allowance on the following types of information:

(A) Seasonal distribution of prohibited species;

(B) Seasonal distribution of target groundfish species relative to prohibited species distribution;

(C) Expected PSC needs on a seasonal basis relevant to change in prohibited species biomass and expected catches of target groundfish species;

(D) Expected variations in PSC rates throughout the fishing year;

(E) Expected changes in directed groundfish fishing seasons;

(F) Expected start of fishing effort; or

(G) Economic effects of establishing seasonal prohibited species apportionments on segments of the target groundfish industry.

(iii) *Seasonal trawl fishery PSC allowances*—(A) *Unused seasonal apportionments.* Unused seasonal apportionments of trawl fishery PSC allowances made under paragraph (b)(2) of this section will be added to its respective fishery PSC allowance for the next season during a current fishing year.

(B) *Seasonal apportionment exceeded.* If a seasonal apportionment of a trawl fishery PSC allowance made under paragraph (b)(2) of this section is exceeded, the amount by which the seasonal apportionment is exceeded will be deducted from its respective apportionment for the next season during a current fishing year.

(iv) *Seasonal non-trawl fishery PSC allowances*—(A) *Unused seasonal apportionments.* Any unused portion of a seasonal non-trawl fishery PSC allowance made under paragraph (b)(2) of this section will be reapportioned to the fishery's remaining seasonal PSC allowances during a current fishing year in a manner determined by NMFS, after consultation with the Council, based on the types of information listed under paragraph (b)(2)(ii) of this section.

(B) *Seasonal apportionment exceeded.* If a seasonal apportionment of a non-trawl fishery PSC allowance made under paragraph (b)(2) of this section is exceeded, the amount by which the seasonal apportionment is exceeded will be deducted from the fishery's remaining seasonal PSC allowances during a current fishing year in a manner determined by NMFS, after consultation with the Council, based on the types of information listed under paragraph (b)(2)(ii) of this section.

(3) *Notification of allowances*—(i) *General.* NMFS will publish in the **Federal Register,** for up to two fishing years, the proposed and final BSAI halibut PSC allowances, the seasonal apportionments thereof, and the manner in which seasonal apportionments of non-trawl fishery PSC allowances will be managed.

(ii) *Public comment.* Public comment will be accepted by NMFS on the proposed PSC allowances seasonal apportionments thereof, and the manner in which seasonal apportionments of non-trawl fishery PSC allowances will be managed, for a period specified in the notice of proposed specifications published in the **Federal Register**.

(4) *Management of BSAI halibut PSC allowances*—(i) *Trawl sector—Amendment 80 limited access fishery and BSAI trawl limited access sector: Closures*—(A) *Exception.* When a PSC allowance, or seasonal apportionment thereof, specified for the pollock/Atka mackerel/''other species'' fishery category, as defined in § 679.21(b)(1)(ii)(B)(*6*) is reached, only directed fishing for pollock is closed to trawl vessels using nonpelagic trawl gear.

(B) *Closures.* Except as provided in paragraph (b)(4)(i)(A) of this section, if, during the fishing year, the Regional Administrator determines that U.S. fishing vessels participating in any of the trawl fishery categories listed in paragraphs (b)(1)(ii)(B)(*2*) through (*6*) of this section will catch the halibut PSC allowance, or seasonal apportionment thereof, specified for that fishery category under paragraph (b)(1)(i) or (b)(1)(ii) of this section, NMFS will publish in the **Federal Register** the closure of the entire BSAI to directed fishing for each species and/or species group in that fishery category for the remainder of the year or for the remainder of the season.

(ii) *BSAI non-trawl sector: Closures.* If, during the fishing year, the Regional Administrator determines that U.S. fishing vessels participating in any of the non-trawl fishery categories listed under paragraph (b)(1)(iii) of this section will catch the halibut PSC allowance, or seasonal apportionment thereof, specified for that fishery category under paragraph (b)(1)(iii) of this section, NMFS will publish in the **Federal Register** the closure of the entire BSAI to directed fishing with the relevant gear type for each species and/or species group in that fishery category.

(iii) *AFA PSC sideboard limits.* Halibut PSC limits for the AFA catcher/processor sector and the AFA trawl catcher vessel sector will be established pursuant to § 679.64(a) and (b) and managed through directed fishing closures for the AFA catcher/processor sector and the AFA trawl catcher vessel sector in the groundfish fisheries for which the PSC limit applies.

* * * * *

(e) *BSAI PSC limits for crab, salmon, herring*—

* * * * *

(3) * * *

(ii) *Red king crab, C. bairdi, and C. opilio*—(A) *General.* For vessels engaged in directed fishing for groundfish in the BSAI, other than vessels fishing under a CQ permit assigned to an Amendment 80 cooperative, the PSC limits for red king crab, *C. bairdi,* and *C. opilio* will be apportioned to the trawl fishery categories defined in paragraphs (e)(3)(iv)(B) through (F) of this section.

* * * * *

(C) *Incidental catch in midwater pollock fishery.* Any amount of red king crab, *C. bairdi,* or *C. opilio* that is incidentally taken in the midwater pollock fishery as defined in paragraph (e)(3)(iv)(A) of this section will be counted against the bycatch allowances specified for the pollock/Atka mackerel/''other species'' category defined in paragraph (e)(3)(iv)(F) of this section.

* * * * *

(iv) *Trawl fishery categories.* For purposes of apportioning trawl PSC limits for crab and herring among fisheries, other than crab PSC CQ assigned to an Amendment 80 cooperative, the following fishery categories are specified and defined in terms of round-weight equivalents of those groundfish species or species groups for which a TAC has been specified under § 679.20.

(B) * * *

(*2*) *Rock sole/flathead sole/Alaska plaice/''other flatfish'' fishery.* * * *

* * * * *

(v) *AFA prohibited species catch limitations.* Crab PSC limits for the AFA catcher/processor sector and the AFA trawl catcher vessel sector will be

established according to the procedures and formulas set out in § 679.64(a) and (b) and managed through directed fishing closures for the AFA catcher/processor sector and the AFA trawl catcher vessel sector in the groundfish fisheries for which the PSC limit applies.

(vi) * * *

(A) Crab PSC limits for the Amendment 80 sector in the BSAI will be established according to the procedure and formulae set out in § 679.91(d) through (f); and

(B) Crab PSC assigned to the Amendment 80 limited access fishery will be managed through directed fishing closures for Amendment 80 vessels to which the crab bycatch limits apply.

* * * * *

(6) * * *

(i) *General.* NMFS will publish in the **Federal Register**, for up to two fishing years, the annual red king crab PSC limit, and, if applicable, the amount of this PSC limit specified for the RKCSS, the annual *C. bairdi* PSC limit, the annual *C. opilio* PSC limit, the proposed and final PSQ reserve amounts, the proposed and final bycatch allowances, and the seasonal apportionments thereof, as required by paragraph (e) of this section.

(ii) *Public comment.* Public comment will be accepted by NMFS on the proposed annual red king crab PSC limit and, if applicable, the amount of this PSC limit specified for the RKCSS, the annual *C. bairdi* PSC limit, the annual *C. opilio* PSC limit, the proposed and final bycatch allowances, seasonal apportionments thereof, and the manner in which seasonal apportionments of non-trawl fishery bycatch allowances will be managed, for a period specified in the notice of proposed specifications published in the **Federal Register**.

(7) * * *

(i) *Exception.* When a bycatch allowance, or seasonal apportionment thereof, specified for the pollock/Atka mackerel/''other species'' fishery category is reached, only directed fishing for pollock is closed to trawl vessels using nonpelagic trawl gear.

* * * * *

■ 5. In § 679.31, revise paragraph (a)(4) to read as follows:

§ 679.31 CDQ and PSQ reserves, allocations, and transfers.

(a) * * *

(4) *PSQ reserve.* (See §§ 679.21(e)(3)(i)(A) and 679.21(b)(1)(iv))

* * * * *

■ 6. In § 679.64, revise paragraph (a)(3) to read as follows:

§ 679.64 Harvesting sideboard limits in other fisheries.

(a) * * *

(3) *How will AFA catcher/processor sideboard limits be managed?* The Regional Administrator will manage groundfish harvest limits and PSC bycatch limits for AFA catcher/processors through directed fishing closures in fisheries established under paragraph (a)(1) of this section in accordance with the procedures set out in §§ 679.20(d)(1)(iv) and 679.21(b)(4)(iii).

* * * * *

■ 7. In § 679.91, revise paragraphs (d)(1) and (3) to read as follows:

§ 679.91 Amendment 80 Program annual harvester privileges.

* * * * *

(d) * * *

(1) *Amount of Amendment 80 halibut PSC for the Amendment 80 sector.* The amount of halibut PSC limit for the Amendment 80 sector for each calendar year is specified in Table 35 to this part. That halibut PSC is then assigned to Amendment 80 cooperatives and the Amendment 80 limited access fishery pursuant to paragraphs (d)(2) and (3) of this section. If one or more Amendment 80 vessels participate in the Amendment 80 limited access fishery, the halibut PSC limit assigned to the Amendment 80 sector will be reduced pursuant to paragraph (d)(3) of this section.

* * * * *

(3) *Amount of Amendment 80 halibut PSC assigned to the Amendment 80 limited access fishery.* The amount of Amendment 80 halibut PSC assigned to the Amendment 80 limited access fishery is equal to the amount of halibut PSC assigned to the Amendment 80 sector, as specified in Table 35 to this part, subtracting the amount of Amendment 80 halibut PSC assigned as CQ to all Amendment 80 cooperatives as determined in paragraph (d)(2)(iv) of this section, multiplied by 80 percent.

* * * * *

§§ 679.20, 679.23, 679.24, and 679.26 [Amended]

■ 8. At each of the locations shown in the ''Location'' column, remove the phrase indicated in the ''Remove'' column and replace it with the phrase indicated in the ''Add'' column for the number of times indicated in the ''Frequency'' column.

Location	Remove	Add	Frequency
§ 679.20(d)(2)	§ 679.21(b)	§ 679.21(a)	1
§ 679.23(f)	§ 679.21(b)	§ 679.21(a)	1
§ 679.23(g)(3)	§ 679.21(b)	§ 679.21(a)	1
§ 679.24(c)(2)(ii)(A)	§ 679.21(b)	§ 679.21(a)	1
§ 679.24(c)(2)(ii)(B)	§ 679.21(b)	§ 679.21(a)	1
§ 679.24(c)(3)	§ 679.21(b)	§ 679.21(a)	1
§ 679.24(c)(4)	§ 679.21(b)	§ 679.21(a)	1
§ 679.25(a)(2)(ii)(A)	§ 679.21(b)	§ 679.21(a)	1
§ 679.26(d)(2)	§ 679.21(b)	§ 679.21(a)	1

■ 9. Revise table 35 to part 679 to read as follows:

TABLE 35 TO PART 679—APPORTIONMENT OF CRAB PSC AND HALIBUT PSC BETWEEN THE AMENDMENT 80 AND BSAI TRAWL LIMITED ACCESS SECTORS

Fishery	Halibut PSC limit in the BSAI	Zone 1 Red king crab PSC limit . . .	*C. opilio* crab PSC limit (COBLZ) . . .	Zone 1 *C. bairdi* crab PSC limit . . .	Zone 2 *C. bairdi* crab PSC limit . . .
.....		as a percentage of the total BSAI trawl PSC limit after allocation as PSQ			
Amendment 80 sector	1,745mt	49.98	49.15	42.11	23.67
BSAI trawl limited access	745 mt	30.58	32.14	46.99	46.81

■ 10. Revise table 40 to part 679 to read as follows:

TABLE 40 TO PART 679—BSAI HALIBUT PSC SIDEBOARD LIMITS FOR AFA CATCHER/PROCESSORS AND AFA CATCHER VESSELS

In the following target species categories as defined in § 679.21(b)(1)(iii) and (e)(3)(iv) . . .	The AFA catcher/processor halibut PSC sideboard limit in metric tons is . . .	The AFA catcher vessel halibut PSC sideboard limit in metric tons is . . .
All target species categories	286	N/A
Pacific cod trawl	N/A	887
Pacific cod hook-and-line or pot	N/A	2
Yellowfin sole	N/A	101
Rock sole/flathead sole/"other flatfish" [1]	N/A	228
Turbot/Arrowtooth/Sablefish	N/A	0
Rockfish [2]	N/A	2
Pollock/Atka mackerel/"other species"	N/A	5

[1] "Other flatfish" for PSC monitoring includes all flatfish species, except for halibut (a prohibited species), Greenland turbot, rock sole, flathead sole, yellowfin sole, and arrowtooth flounder.
[2] Applicable from July 1 through December 31.

[FR Doc. 2015–28889 Filed 11–13–15; 8:45 am]

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Part VI

The President

Executive Order 13710—Termination of Emergency With Respect to the Actions and Policies of Former Liberian President Charles Taylor

Federal Register
Vol. 80, No. 220
Monday, November 16, 2015

Presidential Documents

Title 3—

The President

Executive Order 13710 of November 12, 2015

Termination of Emergency With Respect to the Actions and Policies of Former Liberian President Charles Taylor

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) (IEEPA), the National Emergencies Act (50 U.S.C. 1601 *et seq.*) (NEA), section 5 of the United Nations Participation Act, as amended (22 U.S.C. 287c) (UNPA), and section 301 of title 3, United States Code,

I, BARACK OBAMA, President of the United States of America, find that the situation that gave rise to the declaration of a national emergency in Executive Order 13348 of July 22, 2004, with respect to the actions and policies of former Liberian President Charles Taylor and other persons, in particular their unlawful depletion of Liberian resources and their removal from Liberia and secreting of Liberian funds and property, has been significantly altered by Liberia's significant advances to promote democracy and the orderly development of its political, administrative, and economic institutions, including presidential elections in 2005 and 2011, which were internationally recognized as freely held; the 2012 conviction of, and 50-year prison sentence for, former Liberian President Charles Taylor and the affirmation on appeal of that conviction and sentence; and the diminished ability of those connected to former Liberian President Charles Taylor to undermine Liberia's progress. Accordingly, I hereby terminate the national emergency declared in Executive Order 13348, revoke that order, and further order:

Section 1. Pursuant to section 202(a) of the NEA (50 U.S.C. 1622(a)), termination of the national emergency declared in Executive Order 13348 shall not affect any action taken or proceeding pending not finally concluded or determined as of the effective date of this order, any action or proceeding based on any act committed prior to the effective date, or any rights or duties that matured or penalties that were incurred prior to the effective date of this order.

Sec. 2. This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

Sec. 3. (a) This order is effective at 2:00 p.m. eastern standard time on November 12, 2015.

(b) This order shall be transmitted to the Congress and published in the *Federal Register.*



THE WHITE HOUSE,
November 12, 2015.

[FR Doc. 2015–29403
Filed 11–13–15; 11:15 am]
Billing code 3295–F6–P

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